

**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, 2007

or

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

For the transition period from _____ to _____

Commission File Number 001-33092

LEMAITRE VASCULAR, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)
63 Second Avenue, Burlington, Massachusetts
(Address of principal executive offices)

04-2825458

(I.R.S. Employer Identification No.)
01803
(Zip Code)

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

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

Title of each class	Name of each exchange on which registered
Common Stock, \$0.01 par value per share	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 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 equity held by non-affiliates of the registrant, based on the last sale price for such stock on June 29, 2007: \$48,022,776. At March 27, 2008, the Registrant had 15,526,185 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
2007 FORM 10-K ANNUAL REPORT
TABLE OF CONTENTS

[PART I](#)

Item 1.	Business	2
Item 1A.	Risk Factors	23
Item 1B.	Unresolved Staff Comments	48
Item 2.	Properties	48
Item 3.	Legal Proceedings	48
Item 4.	Submission Of Matters to a Vote of Security Holders	48

[PART II](#)

Item 5.	Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	49
Item 6.	Selected Financial Data	52
Item 7.	Management’s Discussion and Analysis of Financial Condition and Results of Operations	53
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	71
Item 8.	Financial Statements and Supplementary Data	72
Item 9.	Changes In and Disagreements With Accountants on Accounting and Financial Disclosure	72
Item 9A.	Controls and Procedures	72
Item 9B.	Other Information	73

[PART III](#)

Item 10.	Directors, Executive Officers and Corporate Governance	74
Item 11.	Executive Compensation	74
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	74
Item 13.	Certain Relationships and Related Transactions, and Director Independence	74
Item 14.	Principal Accounting Fees and Services	74

[PART IV](#)

Item 15.	Exhibits, Financial Statements Schedules and Reports on Form 8-K	75
----------	--	----

[SIGNATURES](#)

EX-10.35	SUPPLY AND DISTRIBUTION AGREEMENT	77
EX-21.1	SUBSIDIARIES OF THE REGISTRANT	
EX-23.1	CONSENT OF ERNST & YOUNG LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM	
EX-31.1	SECTION 302 CERTIFICATION OF THE C.E.O.	
EX-31.2	SECTION 302 CERTIFICATION OF THE C.F.O.	
EX-32.1	SECTION 906 CERTIFICATION OF THE C.E.O.	
EX-32.2	SECTION 906 CERTIFICATION OF THE C.F.O.	

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,” “projects,” “will,” “would,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We have based these forward-looking statements on our current expectations and projections about future events. Although we believe that the expectations underlying any of our forward-looking statements are reasonable, these expectations may prove to be incorrect, and all of these statements are subject to risks and uncertainties. Should one or more of these risks and uncertainties materialize, or should underlying assumptions, projections, or expectations prove incorrect, actual results, performance, or financial condition may vary materially and adversely from those anticipated, estimated, or expected. We have identified below some important factors that could cause our forward-looking statements to differ materially from actual results, performance, or financial conditions:

- the unpredictability of our quarterly net sales and results of operations;
- our ability to keep pace with a rapidly evolving marketplace and to develop or acquire and then successfully market new and enhanced products;
- a highly competitive market for medical devices;
- the effect of a disaster at any of our manufacturing facilities;
- the loss of any significant suppliers, especially sole-source suppliers;
- the loss of any distributor or any significant customer, especially in regard to any product that has a limited distributor or customer base;
- our ability to adequately grow our operations and attain sufficient operating scale;
- our ability to identify, acquire, and successfully integrate new products, businesses, and technologies;
- our ability to obtain adequate profit margins;
- our ability to effectively protect our intellectual property and not infringe on the intellectual property of others;
- possible product liability lawsuits and product recalls;
- inadequate levels of third-party reimbursement to healthcare providers;
- our ability to initiate, complete, or achieve favorable results from clinical studies of our products;
- our ability to obtain and maintain U.S. and foreign regulatory clearance for our products and our manufacturing operations;
- our ability to raise sufficient capital when necessary or at satisfactory valuations;
- loss of key personnel; and
- other factors discussed elsewhere in this Annual Report on Form 10-K.

We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the section entitled “Risk Factors,” that we believe could cause actual results or events to differ materially from the

[Table of Contents](#)

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.

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, AnastoClip, EndoFit, Expandable LeMaitre Valvulotome, Flexcel, Glow ‘N Tell, Grice, Inahara-Pruitt, InvisiGrip, MollRing Cutter, NovaSil, OptiLock, Periscope, Pruitt, Pruitt-Inahara, Reddick, VascuTape, VCS, and the LeMaitre Vascular logo are registered trademarks of LeMaitre Vascular, and Albograft, aSpire, Biomateriali, EndoHelix, EndoRE, F3, LeverEdge, Martin, TT, and UniFit 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 Valvulotome, the Pruitt-Inahara Carotid Shunt, and VascuTape Radiopaque Tape.

We have grown our business by using a three-pronged strategy: building a worldwide direct sales force, acquiring complementary vascular devices, and developing and enhancing our in-house manufacturing competencies. Since 1998 we have completed ten acquisitions and consolidated most of our manufacturing operations into our Burlington, Massachusetts, headquarters.

We have sought to take advantage of the trend towards endovascular techniques that utilize more complex, higher-priced devices by acquiring new product lines. For example, in 2005 we acquired our EndoFit and UniFit Aortic Stent Grafts, which are endovascular implants used to treat aortic aneurysms and dissections, and in 2007 we acquired our EndoRE line of products, which are primarily used in the minimally invasive treatment of blockages in the major arteries of the leg. 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 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 14 current product lines approaches \$1 billion. In addition, we distribute an additional product line of a third party that addresses a market that we estimate approximates \$50 million in the territories where we have distribution rights. The increasing incidence and diagnosis of peripheral vascular disease is driving the growth of the market for peripheral vascular devices, which we estimate is growing at 8% per year. We believe that our strong brands, growing sales force, expanding suite of peripheral vascular devices, and broad network of vascular surgeon customers uniquely position us to capture an increasing share of this large and growing market.

We sell our products primarily through a direct sales force. Our sales force was comprised of 57 field sales representatives in North America, the European Union, and Japan as of December 31, 2007. We also sell our products through a network of distributors in various countries outside of the United States and Canada. For the year ended December 31, 2007, approximately 90% of our net sales were generated through direct sales, and no customer accounted for more than approximately 4% of our net sales.

[Table of Contents](#)

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 (ir.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 or Form 10-K or any of our other securities filings unless specifically incorporated herein or therein by reference. In addition, our filings with the Securities and Exchange Commission may be accessed through the Securities and Exchange Commission's Electronic Data Gathering, Analysis and Retrieval (EDGAR) system at www.sec.gov. You may also 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 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.

Industry Background

We estimate that peripheral vascular disease affects more than 20 million people worldwide, including 12 million people in the United States and 7 million people in Europe. 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.

The Vascular Device Market and the Role of the Vascular Surgeon

We estimate that the worldwide market for peripheral vascular devices is approximately \$3 billion. We believe that this market is growing due to the increase in the incidence and diagnosis of peripheral vascular disease, the shift to higher priced endovascular devices, and the adoption of western healthcare standards by the developing world.

Vascular surgeons primarily treat peripheral vascular disease, but 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 performed vascular procedures in the United States, and that there are more than 3,000 vascular surgeons in Europe and Japan. 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 patients with a wider range of treatment options. The ability to perform conventional surgery also allows vascular surgeons to convert to an open vascular approach should the need arise during an interventional procedure.

[Table of Contents](#)

Conventional vascular surgery involves opening the body, cutting vessels, and suturing, and includes procedures such as lower extremity bypass surgery, carotid endarterectomy, and open abdominal aneurysm repair. Vascular surgery is often invasive and requires extended hospital stays. In contrast, endovascular procedures typically are minimally invasive and involve repairing vessels from within. Catheter-based devices are inserted through a small incision and are directed with the assistance of real-time imaging technologies. Typical endovascular procedures include angioplasty, stenting, stent-grafting, and atherectomy.

Vascular surgeons are increasingly adopting new endovascular techniques. According to the Healthcare Cost and Utilization Project, of the 1.1 million surgical procedures for peripheral vascular disease performed in the United States in 2003, over 38% were endovascular procedures, as compared to 25% in 1997. Due in part to the reduced hospital stays that they enable, endovascular devices typically command significantly higher prices than vascular surgery devices.

We believe that the purchasing volume of the vascular surgeon will continue to increase as a result of these trends. Given our long-term focus on the vascular surgeon, we believe we are well-positioned to address the needs of this attractive target customer.

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 Valvulotome. We sold this device exclusively during the 1980s, and in 1992 we generated annual net sales of \$0.8 million. We accomplished this with four employees, sharing space with Dr. LeMaitre's private surgical practice in Andover, Massachusetts.

In 1992, George W. LeMaitre, our Chairman and Chief Executive Officer, and Dr. LeMaitre's son, joined LeMaitre Vascular with a vision of creating a company focused on serving the broader needs of the vascular surgeon. Throughout most of the 1990s, we used cash generated from operations and a nominal amount of bank debt to fund the further development of the valvulotome and to establish our brand. In 1997, we generated annual net sales of \$3.0 million with 15 employees.

Beginning in 1998, we initiated a strategic plan to accelerate our growth through the execution of three key initiatives:

- build a worldwide direct sales force;
- acquire complementary vascular devices; and
- develop in-house manufacturing and assembly capabilities.

In order to execute on these three initiatives, we raised \$16.4 million of equity capital through a series of private financing rounds from 1998 to 2005. From 1998 to 2005, we completed six acquisitions for an aggregate consideration of \$14.9 million in cash, assumed debt and stock. Seven of our 14 product lines were acquired via these acquisitions. We have completed the integration of each of these product lines and businesses, consolidating virtually all of the associated manufacturing operations into our Burlington, Massachusetts, headquarters.

In October 2006, we completed our initial public offering, raising net proceeds of approximately \$36 million before expenses. From our initial public offering through December 31, 2007, we have continued to execute on our primary business strategies by increasing the number of our field sales representatives from 36 to 57; hiring our first direct sales personnel in Austria, France, Ireland, Italy, and Sweden; increasing the number of research and development engineers from three to seven; launching four new products; and completing the following strategic acquisitions:

- In April 2007, we acquired our LeverEdge Contrast Injector, a hand-powered injection system used in obtaining accurate radiographic images of the vasculature, from Cardiovascular Innovations, LLC.

[Table of Contents](#)

- In September 2007, we acquired our EndoRE line of remote endarterectomy products, which are used in a hybrid open/endovascular procedure for the minimally invasive removal of plaque from the major arteries of the leg, as part of the business of Vascular Architects.
- In December 2007, we acquired a number of patent applications and associated intellectual property, all relating to a novel endovascular device, from Arizona Heart Innovative Technologies, LLC.
- In December 2007, we acquired Biomateriali, S.r.l., a privately held Italian manufacturer of polyester prosthetic grafts for vessel replacement in the peripherals, abdomen, and thorax.

Due in part to these efforts, we generated net sales of \$41.4 million for the year ended December 31, 2007, and we currently offer 14 product lines across three product categories, excluding the Powerlink System—an abdominal stent graft manufactured by Endologix, Inc. that we distribute in several European countries.

Our Business Strategies

Our goal is to be the leading global provider of medical devices to vascular surgeons and interventionalists.

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

- **Further Expand Our Direct Sales Force.** We sell our products primarily through a direct sales force comprised as of December 31, 2007, of 57 field sales representatives in North America, the European Union, and Japan. At the time of our October 2006 initial public offering we had 36 sales representatives. Having expanded our sales force by over 50% in the last fifteen months, in the near term we intend to focus on integrating our recently acquired products to our representatives' product offerings, seek efficiencies in our sales efforts, and fully develop cross-selling opportunities. While continuing to expand our sales force as need dictates and opportunities allow, we may also convert select countries from distributor to direct sales, as we did in Ireland and Sweden in 2007. We believe that direct-to-hospital sales engender closer customer relationships, allow for higher selling prices and gross margins, and are not subject to the risk of customer churn resulting from distributor turnover.
- **Add Complementary Products through Acquisitions.** We believe our significant experience in acquiring and integrating product lines and businesses is one of our competitive advantages. Since 1998, we have completed ten acquisitions. We actively track industry developments and plan to acquire additional product lines and businesses as a means of further accessing the approximately \$3 billion peripheral vascular device market. We intend to pursue acquisitions in a disciplined manner to expand and diversify our product offerings and add new technology platforms.
- **Extend Our Market Reach through Research and Development and Additional Regulatory Approvals.** By refining our current product lines and developing new applications for our existing technologies, we plan to extend our reach into the peripheral vascular device market. Our current research and development efforts include improvements and additions to the products in our endovascular and dialysis access product category. We also intend to obtain regulatory approvals for our devices in new markets. For example, we currently market our aortic stent graft devices in the European Union and have focused our near-term efforts on obtaining regulatory approval for these products in the United States. We also intend to seek approval for the sale of our Albograft product line in the United States.

[Table of Contents](#)

Our Products

The following table describes the primary use and regulatory status of each of our 14 product lines:

<u>Product Category</u>	<u>Product Line</u>	<u>Primary Use</u>	<u>Available for Sale in</u>			
			<u>United States</u>	<u>European Union</u>	<u>Japan</u>	
Endovascular & Dialysis Access	EndoFit Thoracic Stent Graft	Endovascular repair of thoracic aortic aneurysm and dissection		✓		
	UniFit Abdominal Stent Graft	Endovascular repair of abdominal aortic aneurysm	In clinical studies(1)	✓		
	aSpire Covered Stent	Holding open major leg arteries that have had blockages removed(2)	✓	✓		
	LeverEdge Contrast Injector	Injection of media to monitor blood flow and determine vessel location	✓	✓		
	VascuTape Radiopaque Tape	Improvement in precision and accuracy of endovascular procedures	✓	✓	✓	
	AnastoClip Vessel Closure System	Attachment of blood vessels, primarily for dialysis access	✓	✓	✓	
	Albograft Vascular Graft	Synthetic vessels for use in bypass and replacement procedures		✓		
	EndoRE Remote Endarterectomy Devices	Removal of blockages in the major arteries of the leg	✓	✓		
	InvisiGrip Vein Stripper	Single-incision removal of varicose veins	✓	✓	Application submitted(3)	
	Expandable LeMaitre Valvulotome	Destruction of vein valves to create vein bypass graft	✓	✓	✓	
Vascular	Pruitt-Inahara, Pruitt F3, and Flexcel Carotid Shunts	Facilitation of blood flow to brain during carotid plaque removal	✓	✓(4)	✓(4)	
	LeMaitre Balloon Catheters	Removal of blood clots; occlusion, and facilitation of blood flow	✓	✓	✓	
	General Surgery	OptiLock Implantable Port	Central venous infusion of drugs and nutrients	✓	✓	
		Reddick Cholangiogram Catheter	Introduction of dye into the cystic duct	✓	✓	Application submitted(3)

(1) We are conducting a clinical study in the United States on the UniFit Abdominal Stent Graft. See “—Clinical Studies” for a description of this clinical study.

[Table of Contents](#)

- (2) This is the approved use for the aSpire Covered Stent in the European Union., where it is often used in conjunction with our EndoRE line of remote endarterectomy devices. In the U.S., the device is approved for use in lung airways that have been narrowed by disease.
- (3) We have submitted an application for Shonin registration with the Japan Ministry of Health, Labor and Welfare.
- (4) The Pruitt F3 and Flexcel Carotid Shunts were launched in 2007 and are only available for sale in the United States.

Effective January 1, 2007, we became the exclusive distributor for the Powerlink System—an abdominal stent graft manufactured by Endologix, Inc.—in several European countries, including Germany, France, and the United Kingdom. We believe that this product complements our EndoFit Thoracic Stent Graft and UniFit Abdominal Stent Graft product lines, allowing our growing European sales force to offer a complete range of stent grafts for the entire aorta.

In addition to the sale of our own products and the distribution of the Powerlink System, we engage in a limited amount of private label manufacture for another medical device company, Sorin Biomedica SpA.

Endovascular & Dialysis Access Products

Endovascular

Our endovascular products are used by vascular surgeons and interventionalists in minimally invasive endovascular procedures, such as angioplasty, stenting, stent-grafting, and atherectomy.

EndoFit Thoracic Stent Graft

The EndoFit Thoracic Stent Graft is a line of endovascular grafts used to treat an aortic aneurysm, a weakening and ballooning of the aorta, or an aortic dissection, a separation of the layers of the aortic wall that often leads to rupture and death, in each case in the upper part of the aorta, known as the thoracic aorta. EndoFit's flexible, encapsulated design, in contrast to devices currently available commercially, uses expanded polytetrafluoroethylene (ePTFE), which is designed to prevent stent scaffolding from contacting either the blood stream or the vessel wall. This design also allows us to offer a wide range of stent graft sizes, including tapered grafts, which fit a wider range of patient anatomies than many of our competitors' products. Our design also allows us to rapidly build the device to fulfill custom orders; for the year ended December 31, 2007, approximately 49% of our EndoFit and UniFit stent grafts were custom-made. In 2007 we introduced our TT Tortuous Tracker Delivery System, which replaces a third-party product that we previously used to deploy the EndoFit device, as well as the next-generation version of our EndoFit stent graft, which features a uniform top stent design. We acquired our EndoFit product line through our acquisition of Endomed in February 2005.

Our EndoFit Thoracic Stent Graft product line is currently sold in the European Union and a small number of foreign jurisdictions.

UniFit Abdominal Stent Graft

The UniFit Abdominal Stent Graft is a line of non-bifurcated endovascular grafts used to treat aneurysms in the lower part of the aorta, known as the abdominal aorta, and the iliac arteries. The UniFit device is similar in design to the EndoFit device, with a flexible, encapsulated design and similar manufacturing advantages that allows us to offer a wide range of stent graft sizes and custom-built devices. We acquired our UniFit product line through our acquisition of Endomed in February 2005.

[Table of Contents](#)

This product line is currently sold in the European Union and a small number of foreign jurisdictions. We are currently conducting a pivotal study in the United States for the UniFit device.

aSpire Covered Stent

The aSpire Covered Stent is a spiral-shaped nitinol stent covered entirely by ePTFE that is used to keep blood vessels and lung airways open after blockages have been removed. Due to its spiral shape, the aSpire Covered Graft is highly flexible, conforms to varying airway and vessel diameters, and, unlike tube-shaped covered stents, does not cut off supply to side branches, which could cause tissue damage. We acquired the aSpire Covered Graft product line and related operations through our acquisition of the business of Vascular Architects in September 2007.

Our aSpire Covered Stent is currently sold in the European Union, where it is approved for use in the major arteries of the leg, and in the United States, where it is approved for use in the lungs and trachea for narrowings caused by disease.

LeverEdge Contrast Injector

The LeverEdge Contrast Injector is a manually operated device used to inject contrast media—solutions that are highly visible in x-ray and fluoroscopic images—into the circulatory system. These solutions enable interventionalists to evaluate blood flow and locate vessels, blockages, and leaks. Less expensive than electronic injection systems, the LeverEdge device is sold sterile and allows interventionalists direct control in contrast delivery, permitting high-quality imaging with a reduced amount of contrast, which reduces patient discomfort and hospital costs. Compared to other manual systems, including conventional syringes, the LeverEdge Contrast Injector is able to deliver contrast at much higher pressures, allowing for the use of smaller and less invasive catheters. We acquired the LeverEdge product line and related operations from Cardiovascular Innovations, LLC in April 2007.

Our LeverEdge Contrast Injector is currently sold in the United States and Europe.

VascuTape Radiopaque Tape

VascuTape Radiopaque Tape is a flexible, medical-grade tape with centimeter or millimeter markings printed in our proprietary radiopaque ink that is visible both to the eye and to an x-ray machine or fluoroscope. VascuTape Radiopaque Tape is applied to the skin and provides interventionalists with a simple way to cross-reference precisely between the inside and the outside of a patient's body, allowing them to accurately size or locate tributaries or lesions beneath the skin. VascuTape Radiopaque Tape enables smaller skin incisions, more accurate lesion location, more precise stent and catheter sizing, and reduced contrast injections. VascuTape Radiopaque Tape was invented by our founder, George D. LeMaitre, M.D., and received 510(k) clearance from the United States Food and Drug Administration (the FDA) in 1993.

Our VascuTape product line is currently sold in the United States, the European Union, Japan, and many other foreign jurisdictions.

AnastoClip Vessel Closure System

The AnastoClip Vessel Closure System is a titanium clip implanted by vascular surgeons to attach vessels, native and prosthetic, to each other. The AnastoClip Vessel Closure System creates an interrupted anastomosis, or a vessel attachment that expands and contracts as the vessel pulses, which we believe improves the durability of the anastomosis. The AnastoClip Vessel Closure System has the further advantage that it does not puncture the vessel wall and disrupt blood flow. A retrospective 1,110-patient clinical study published in the August 2003 *Journal of Vascular Surgery* found that the AnastoClip Vessel Closure System improved 24-month patency

[Table of Contents](#)

versus traditional continuous sutures from approximately 34% to 54% in arterio-venous fistulae, which are surgical attachments of arteries and veins, and from approximately 17% to 36% in prosthetic grafts attachments. Patency data was collected from a total of 1,385 vascular access anastomoses. We acquired the AnastoClip Vessel Closure System product line and related operations from Tyco Healthcare in February 2004.

Our AnastoClip Vessel Closure System product line is currently sold in the United States, the European Union, Japan, and many other foreign jurisdictions.

Powerlink System

The Powerlink System is a one-piece, self-expanding bifurcated stent graft. The Powerlink System's unique delivery mechanism requires only a surgical incision in one leg, whereas other bifurcated stent grafts typically need surgical exposure of the femoral artery in both legs to introduce multiple components.

The Powerlink System is manufactured by Endologix, Inc. and distributed by us in select European markets, including Germany, France, the United Kingdom, and several other countries.

Vascular Products

Our vascular products are used primarily in open vascular surgery for the treatment of peripheral vascular disease.

Albograft Vascular Graft

The Albograft Vascular Graft is a collagen-coated polyester graft used to bypass or replace diseased arteries. Available in both straight tube and bifurcated versions, the Albograft Vascular Graft offers superior feel and ease of manipulation to our surgeon customers, while the collagen coating provides immediate, impermeable sealing of suture holes. These knitted and woven vascular grafts are an essential part of the vascular surgeon's toolkit and complement LeMaitre Vascular's other product lines. The Albograft Vascular Graft is the most recent addition to our product lines, introduced with the acquisition of Biomateriali S.r.l. in December 2007.

Our Albograft Vascular Graft is currently sold in the European Union and many other foreign jurisdictions through an exclusive distribution relationship with Edwards Lifesciences AG.

EndoRE Remote Endarterectomy Devices

The 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 only a single incision in the groin. Our EndoRE devices are used to separate the blockage from the vessel, cut the far end of the blockage to free it for removal, and withdraw the blockage from the vessel. A retrospective 133-patient clinical study published in the February 2006 *Journal of Vascular Surgery* found that, compared to bypass procedures, this minimally invasive procedure leads to less trauma to the patient and reduced hospital stays. It also postpones the use of the patient's own veins for bypass, preserving them for later use, and opens up formerly blocked side vessels to help restore circulation to a larger area. We acquired the EndoRE product line through our acquisition of the business of Vascular Architects in September 2007.

Our EndoRE Remote Endarterectomy Devices are currently sold in the United States and Europe.

InvisiGrip Vein Stripper

The InvisiGrip Vein Stripper is a single-incision, inversion vein stripper designed to provide a less traumatic alternative to standard vein strippers for the removal of the saphenous vein. Our InvisiGrip device enables the

[Table of Contents](#)

surgeon to complete the procedure in a minimally invasive fashion with just one incision versus a traditional two-incision procedure. We developed this device internally based on a patent we licensed from Robertus Welten, M.D., a vascular surgeon.

Our InvisiGrip product line is currently sold in the United States, the European Union, and many other foreign jurisdictions.

Expandable LeMaitre Valvulotome

The Expandable LeMaitre Valvulotome cuts valves in the saphenous vein, a vein that runs from the ankle to the groin, so that it can function as a bypass vessel to carry blood past diseased arteries to the lower leg or the foot. The Expandable LeMaitre Valvulotome is the only self-sizing, self-centering valvulotome available. We believe that the Expandable LeMaitre Valvulotome reduces costs for hospitals by enabling less invasive bypass surgery to be performed with several one-inch 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 fixed-diameter valvulotome developed by our founder, George D. LeMaitre, M.D.

Our Expandable LeMaitre Valvulotome product line is currently sold in the United States, the European Union, Japan, and many other foreign jurisdictions.

Pruitt-Inahara, Pruitt F3, and Flexcel Carotid Shunts

The Pruitt-Inahara, Pruitt F3, 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-Inahara and Pruitt F3 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 the traditional method of externally placed clamps. We acquired the Pruitt-Inahara Carotid Shunt product line and related operations from Horizon Medical in March 2001. We introduced the Pruitt F3, our next-generation model of the Pruitt-Inahara Carotid Shunt, in January 2007 and our Flexcel Carotid Shunt in August 2007.

Our Pruitt-Inahara Carotid Shunts are currently sold in the United States, the European Union, Japan, and many other foreign jurisdictions. Our Pruitt F3 and Flexcel Carotid Shunts are currently sold only in the United States.

LeMaitre Embolectomy Catheters and Pruitt Occlusion and Perfusion Catheters

Embolectomy catheters are used to remove blood clots from arteries or veins. We manufacture single-lumen latex and latex-free embolectomy catheters as well as dual-lumen latex embolectomy catheters. The dual-lumen embolectomy catheter allows clot removal and simultaneous irrigation or guide-wire trackability. We acquired our LeMaitre Embolectomy Catheter product line and related operations in part from Vermed in June 1999 and in part from Horizon Medical in March 2001.

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 Occlusion and Perfusion Catheters reduce vessel trauma by using internal balloon fixation rather than traditional external clamp fixation. We acquired our Pruitt Occlusion and Perfusion Catheter product lines and related operations from Horizon Medical in March 2001.

Our embolectomy, occlusion, and perfusion catheters are currently sold in the United States, the European Union, Japan, and many other foreign jurisdictions.

General Surgery Products

OptiLock Implantable Port

Vascular access ports are implanted into the body and used for central venous administration of chemotherapy, fluids, nutrients, and other therapies as well as for blood sampling for diagnostic purposes. Our OptiLock Implantable Port is a plastic port with a differentiated connection system design that allows physicians to securely connect the catheter to the port. We acquired the OptiLock Implantable Port product line and related operations from Vermed in June 1999.

Our OptiLock Implantable Port product line is currently sold in the United States, the European Union, and many other foreign jurisdictions.

Reddick Cholangiogram Catheter and Laparoscopic Accessories

The Reddick Cholangiogram Catheter is used to inject dye into the cystic duct during a laparoscopic cholecystectomy. In this procedure, the gall bladder is dissected and removed through small punctures in the abdomen. We also offer two laparoscopic accessories used in laparoscopic gall bladder removal—the Reddick-Saye Screw and the Grice Suture Needle—which we license from third parties. We acquired the Reddick Cholangiogram Catheter and laparoscopic accessory product lines and related operations from Horizon Medical in March 2001.

Our Reddick Cholangiogram Catheter and laparoscopic accessory product lines are currently sold in the United States, the European Union, and many other foreign jurisdictions.

Clinical Studies

We conduct clinical studies in order to obtain regulatory approval and provide marketing data for our product lines. The goal of a clinical study is to evaluate the safety and/or clinical effectiveness of a device or the substantial equivalence to another device. During 2007, we had two active clinical studies:

- ***UniFit Abdominal Stent Graft (U.S. Clinical Study).*** In October 2002, the previous owner of our UniFit product line commenced a feasibility study in the United States to support a possible PMA application for the UniFit Abdominal Stent Graft. (See “—Government Regulation” for more on the PMA process.) We took over this study at the time of our acquisition of Endomed, Inc. in February 2005. In this study, we are seeking to demonstrate successful aneurysm exclusion without perioperative death, myocardial infarction, stroke, limb loss, or surgical conversion. We completed enrollment in November 2006 and are currently monitoring follow-up visits for the duration of this study. A feasibility study is a preliminary study and is not a pivotal trial, which would be the principal basis for PMA approval. In May 2006, we submitted an investigational device exemption (IDE) supplemental application to the FDA to begin a pivotal clinical trial to evaluate the safety and effectiveness of the UniFit Abdominal Stent Graft in the treatment of aorto, aorto-iliac, and/or iliac aneurysms. In May 2007, we received final approval from the FDA to commence the pivotal trial, which we refer to as the UNITE study, and as of December 31, 2007, we had enrolled seven patients in the trial. We plan to enroll 90 patients at up to 14 institutions. The primary effectiveness endpoint of the study is based on aneurysm exclusion as evaluated through one-year follow-up.
- ***EndoFit Thoracic Stent Graft (Chinese Clinical Study).*** In August 2005, we commenced a clinical study to obtain approval from the SFDA of our EndoFit Thoracic Stent Graft. In this study, we were seeking to demonstrate successful aneurysm exclusion without perioperative death, myocardial infarction, stroke, limb loss, or surgical conversion. We completed this study in May 2007 and submitted our application for approval to the SFDA in December 2007.

We are also sponsoring a multi-center, non-randomized pilot registry in the European Union, which we refer to as the DEDICATED registry, to evaluate the use of the EndoFit Thoracic Stent Graft in treating type B aortic

[Table of Contents](#)

dissections. Certain configurations of our EndoFit Thoracic Stent Graft are already indicated for use in the treatment of type B dissections. The registry is intended to support an enhanced marketing claim and provide the medical community with safety and efficacy data specific to this particular pathology. We plan to enroll 100 patients and have enrolled 27 patients at nine sites as of December 31, 2007. There are one-, three-, and six-month follow-up periods after the procedure.

Clinical studies are subject to a number of factors that can influence results, making it difficult to draw general conclusions. Peripheral vascular studies have historically involved very few patients, with even fewer patients available for long-term follow up and analysis. Among a small number of treated patients, these factors can influence the significance of clinical study results. Consequently, findings from one study should not be used to predict limitations or benefits of a particular means of treatment. We continually evaluate the potential financial benefits and costs of our clinical studies and the products being evaluated in them. If we determine that the costs associated with obtaining regulatory approval of a product exceed the potential financial benefits of that product or if the projected development timeline is inconsistent with our investment horizon, we may choose to stop a clinical study and/or the development of a product. See “Risk Factors—Our UniFit products are in, and our EndoFit products have recently completed, clinical studies.” If these clinical studies are unsuccessful, or if the FDA or other regulatory agencies do not accept or approve the results of such studies, these products may not successfully come to market and our business prospects may suffer.

In January 2008, the FDA audited the conduct of the feasibility study and pivotal clinical trial of our UniFit Abdominal Stent Graft. As a result of this audit, the FDA issued a formal notification, or Form FDA-483, listing nine observations. Specifically, the FDA observed that we had not adequately supervised participating sites, made all required reports to those sites and the FDA, or adequately maintained all records required by FDA regulations. We have revised our clinical trial procedures to address the FDA’s findings and have submitted a response letter to the FDA detailing the steps being taken.

Sales and Marketing

As of December 31, 2007, we employed 57 field sales representatives. 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. Having in the near term increased the size of our sales force by over 50% since our initial public offering in October 2006, we intend to focus on integrating our recently acquired product lines into our representatives’ product offerings, seek efficiencies in our sales efforts, and more fully develop cross-selling opportunities. We will continue to expand our sales force as need dictates and opportunities allow. Outside our direct markets, we generally sell our products through a network of country-specific distributors. We typically sign exclusive distribution agreements with terms of up to five years specifying minimum annual sales volumes and pricing. These agreements are only renewable by mutual agreement. As exceptions to our direct sales and country-specific distribution models, we sell our Albograft Vascular Graft products under an exclusive distribution agreement with Edwards Lifesciences AG, and we sell unbranded polyester vascular graft components to Sorin Biomedica SpA under a private label manufacturing program. We assumed each of these arrangements in connection with our acquisition of Biomateriali in December 2007.

We believe that our direct marketing efforts are critical to our brand development and continued success. Until 1998, we had no direct sales force and instead relied on direct marketing to generate brand awareness and product loyalty. We believe that this direct marketing approach continues to serve us well, allowing 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 and introducing manufacturing efficiency changes. We remain dedicated to improving

[Table of Contents](#)

manufacturing efficiencies and increasing automation. Our current product development efforts are largely focused on the endovascular space, including improvements to our EndoFit and UniFit Stent Grafts and improvements to our recently launched TT Delivery System, which is used to deliver those stent grafts. In addition, we are engaging in the research and development of new products, line extensions, and next-generation devices in our endovascular and dialysis access and traditional vascular surgery product categories.

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 use testing 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, safety, and effectiveness before commencing full-scale marketing of any product.

For fiscal 2005, 2006, and 2007, our research and development expenditures, including clinical study expenditures, were \$3.0 million, \$3.3 million and \$4.6 million, respectively, and represented between 10% and 11% of net sales. As of December 31, 2007, our research and development staff consisted of 13 full-time engineers and technicians.

Manufacturing

For most of 2007, our manufacturing facilities were located solely in Burlington, Massachusetts and included a 5,556 square foot ISO 14644-1 Class 8 clean room and a 2,100 square foot ISO 14644-1 Class 7 clean room. In December 2007, we acquired Biomateriali S.r.l., which produces our Albograft Vascular Graft product line in a 7,535 square foot ISO 14644-1 Class 8 clean room in Brindisi, Italy.

As a result of the six acquisitions we executed between 1998 and 2005, we have operated factories in a variety of locations including France; the United Kingdom; St. Petersburg, Florida; Lawrence, Massachusetts; and Phoenix, Arizona. All of these manufacturing operations have been relocated to our Burlington, Massachusetts, headquarters in an effort to reduce costs and bring manufacturing closer to our research and development personnel. In keeping with this approach, we moved certain production steps of the LeverEdge Contrast Injector to our Burlington facilities following our acquisition of the device in April 2007. In December 2007, our acquisition of Biomateriali provided us with an additional manufacturing facility in Brindisi, Italy. Although consolidation of our Italian manufacturing operations into our Burlington facility is not contemplated for the foreseeable future, we are evaluating the potential of moving some of our domestic manufacturing operations that may have synergies with our graft manufacturing to Brindisi in order to achieve cost savings.

With our acquisition of the business of Vascular Architects in September 2007, we inherited certain third-party manufacturing relationships relating to the production of the aSpire Covered Stent and each of the EndoRE Remote Endarterectomy Devices.

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 possible, 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.

Nearly all of our products are built to stock. The only exceptions are the EndoFit and UniFit Aortic Stent Grafts that we custom build for specific anatomies as requested by physicians. For the year ended December 31, 2007, about 49% of our EndoFit and UniFit Aortic Stent Grafts were custom made. We believe that our custom manufacturing of stent grafts is a competitive advantage that engenders surgeon loyalty and brand awareness.

[Table of Contents](#)

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 have implemented a variety of manufacturing strategies and techniques with the goal of improving our gross margin and increasing product quality. By instituting lean manufacturing techniques, also known as Kaizen, we have been able to reduce time, space, and materials from several of our production lines, while simultaneously improving quality.

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 been able to obtain adequate supplies of all product and components in a timely manner from existing sources.

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 or, in the case of the European Union, satisfactorily completed an alternate approval route that did not rely on compliance with quality system standards. Our manufacturing facilities are subject to periodic inspections by regulatory authorities and our Notified Body to ensure compliance with domestic and non-U.S. regulatory requirements. See “—Government Regulation.”

Competition

The markets in which our 14 product lines compete are characterized by rapid change resulting from technological advances and scientific discoveries. No one company competes against us in all of our product lines. Rather, we compete with a range of companies, from large to small, including both publicly traded and privately held device companies. Notable competitors include Applied Medical Resources Corporation, Cook Group Incorporated, C.R. Bard, Inc., Datascope Corp., Edwards LifeSciences Corporation, Getinge AB, Medtronic, Inc., Terumo Medical Corporation, Uresil, LLC, VNUS Medical Technologies, Inc., and W. L. Gore & Associates.

Our products compete primarily on the basis of their unique technology, quality, reliability, ease of use, cost-effectiveness, physician familiarity, brand recognition, and service support. Several of our products are sold at higher prices than those of our competitors. We believe that our continued success will depend on our ability to broaden and optimize our direct sales channel, acquire or develop additional 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 may also have greater experience in developing 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 great 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.

As of December 31, 2007, we had 123 issued patents and 45 pending patent applications in the United States, Europe, Japan, Australia, Canada, and other countries throughout the world 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 2012 to 2020. We do not expect the near-term expiration of any of our issued U.S. patents to adversely affect our intellectual property position.

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, Japan, 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.

While most of the world relies on a first-to-file system, the U.S. gives patent rights to whomever was the first to invent an idea, even if the inventor filed the related patent application after another was filed covering the same idea. Because patent applications can be maintained in secrecy for at least 18 months after their earliest priority date, and publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first to invent the subject matter covered by each of our pending U.S. patent applications or that we were the first to file non-U.S. patent applications for such subject matter. 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. Specifically, they opposed our granted European patent number 1,202,682, or the 682 patent, related to an ePTFE intraluminal device such as certain of our EndoFit and UniFit stent grafts, and our granted European patent number 1,148,838, or the 838 patent, related to an ePTFE vascular prosthesis such as certain of our EndoFit and UniFit stent grafts. As a result of the opposition proceedings, the granted patent claims in the 682 patent were canceled while the 838 patent survived with certain amendments that did not materially alter the coverage provided by that patent. Although the cancellation of the patent claims in the 682 patent does not affect our ability to manufacture, distribute, or sell any of our products, it could affect our right to exclude others from selling products similar to our EndoFit and UniFit stent grafts in Europe.

Because the U.S. follows a first-to-invent system, if a third party files a patent application relating to an invention claimed in our patents or patent applications, we may be required to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine who was the first to invent the idea in question and therefore who should own the patent rights to that idea. Such a proceeding could involve substantial uncertainties and cost, even if the eventual outcome is favorable to us. There can be no assurance that our patents, if issued, would be upheld as valid in court.

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

[Table of Contents](#)

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.

Certain aspects of our products are covered by patents held by third parties. We manufacture, market, and sell these products pursuant to license agreements with these third parties. These arrangements require us to pay royalties, typically determined as a percentage of our net sales for the underlying product. If we fail to make these payments or otherwise fail to observe the terms of these agreements, we may lose our ability to sell these products. For example, we manufacture, market, and sell our EndoFit and UniFit stent grafts pursuant to a sublicense from Bard Peripheral Vascular, Inc., a subsidiary of C.R. Bard, Inc., to a U.S. patent covering aspects of ePTFE. Our arrangement with Bard may preclude us from assigning the sublicense to a third party, including in connection with the sale of more than 30% of our capital stock or all or substantially all of our assets, without the prior consent of Bard. The loss by us of our right to manufacture, market, and sell our EndoFit and UniFit products could adversely affect our business and results of operations, perhaps materially. We also manufacture, market, and sell our AnastoClip Vessel Closure System, aSpire Covered Stent, Fogarty EndoHelix, Grice Suture Needle, MollRing Cutter, Reddick-Saye Screw, and Schubart Periscope 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, Pruitt, EndoFit, VascuTape, Glow 'N Tell, and Reddick, each of which is registered in the United States and the European Union, and in certain cases in other foreign countries.

We rely on trade secret protection for certain unpatented aspects of other proprietary technology. There can be no assurance that others will not independently develop or otherwise acquire substantially equivalent proprietary information or techniques, that others will not 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. In addition, 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

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 preamendment 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 requires PMA approval. In most cases, a user fee is required for 510(k) submissions and PMA applications.

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 in safety and effectiveness to a “predicate device” (*i.e.*, a previously 510(k)-cleared class I or class II device or a preamendment 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. 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 in its intended use, 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, or 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

[Table of Contents](#)

FDA of an IDE application. Both significant risk and non-significant risk investigational devices require approval from institutional review boards, or 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 the study, the sponsor must comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting, record keeping, and prohibitions on the promotion of investigational devices. The investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with all reporting and record-keeping requirements. Required records and reports are subject to inspection by the FDA. Prior to granting PMA approval, the FDA typically inspects the records relating to the conduct of the study and the clinical data supporting the PMA application for compliance with IDE requirements.

In January 2008, the FDA audited the conduct of the feasibility study and pivotal clinical trial of our UniFit Abdominal Stent Graft. As a result of this audit, the FDA issued a formal notification, or Form FDA-483, listing nine observations. Specifically, the FDA observed that we had not adequately supervised participating sites, made all required reports to those sites and the FDA, or adequately maintained all records required by FDA regulations. While we have revised our clinical trial procedures to address the FDA's findings and have submitted a response letter to the FDA detailing the steps being taken, we cannot assure you that we will be successful in implementing these changes or that the FDA will agree that our implementation is adequate. If the FDA finds that we are not in substantial compliance with IDE requirements, the FDA may issue a public warning letter or take other enforcement action against us, and the conduct of our clinical trial could be interrupted or discontinued.

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. In contrast, the FDA is requiring that both our UniFit Abdominal Stent Graft and EndoFit Thoracic Stent Graft undergo the PMA process, and, although we do not expect it, it is possible that the FDA could require the same for our Albograft Vascular Graft if we were to pursue its introduction to the United States market.

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.

[Table of Contents](#)

We are subject to inspection and marketing surveillance by the FDA to determine our compliance with regulatory requirements. 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.

In March 2006, the FDA inspected our facilities in Burlington, Massachusetts. The inspection resulted in the issuance of a formal notification, or Form FDA-483, listing three observations. Specifically, the FDA observed that we did not adequately document corrective and preventive actions taken by us to address quality problems, we did not identify all actions needed to prevent the recurrence of nonconforming product and other quality problems, and we had an incomplete procedure for implementing and recording actions taken to correct and prevent identified quality problems. While we have revised our procedures and conducted additional training to address the FDA's findings, we cannot assure you that we have been successful in implementing these changes or that the FDA will agree that our implementation is adequate. If the FDA finds that we are not in substantial compliance with the QSR, the FDA may issue a public warning letter or take other enforcement action against us and our operations could be disrupted and our manufacturing delayed.

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

Other U.S. Regulations

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

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

Non-U.S. Regulation

Sales of medical devices are subject to regulatory requirements in many countries. The regulatory review process may vary greatly from country to country. For example, the European Union has adopted numerous directives and standards relating to medical devices regulating their design, manufacture, clinical trials, labeling, and adverse event reporting, including the Medical Devices Directive (93/42/EEC), which is applicable to our products. Devices that comply with the requirements of the Medical Devices Directive are entitled to bear a *Conformité Européenne*, or CE mark, indicating that the device conforms with the essential requirements of the

[Table of Contents](#)

applicable directive and can be commercially distributed in countries that are members of the European Union, as well as Iceland, Lichtenstein, Norway, and Switzerland. Each member state of the European Union has implemented the directives into its respective national law and has each established a “Competent Authority” to apply the directive in its territory.

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

A manufacturer of low-risk devices typically may demonstrate conformity to the essential requirements based on a self-declaration. The European Standardization Committees have adopted numerous harmonized standards for specific types of medical devices. Compliance with relevant standards establishes a presumption of conformity with the essential requirements. Manufacturers of higher-risk devices generally must use a “Notified Body”—an appointed independent third party to assess conformity. This third-party assessment may consist of an audit of the manufacturer’s quality system and specific testing of the manufacturer’s devices. An assessment by a Notified Body in one country within the European Union is generally required in order for a manufacturer to commercially distribute the product throughout the European Union. Most of our devices are considered higher-risk devices that require Notified Body assessment.

The European medical device laws also address the advertising and promotion of medical devices, clinical investigations, and requirements for handling adverse events. Post-market surveillance of medical devices in the European Union is generally conducted on a country-by-country basis; however, the Directive sets forth certain specific requirements for reporting adverse events. The Medical Device Vigilance system is the mechanism by which adverse event reporting is managed and monitored in the European Union.

In 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. Implementation and enforcement of the reforms are evolving, and compliance guidance from the MHLW is still in development. 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

[Table of Contents](#)

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 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.

Third-party payors are increasingly challenging the prices charged for medical products and procedures and, where a reimbursement model is used, introducing maximum reimbursement limits for the procedures they cover. We believe that the minimally invasive procedures in which most of our products are used are generally less costly than open surgery because they frequently result in shorter hospitalization times. However, there is no guarantee that these procedures will be reimbursed. Third-party payors may not consider these minimally invasive procedures to be cost-effective and therefore refuse to authorize coverage.

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. Reimbursement approval must be obtained

[Table of Contents](#)

individually in each country in which our products are marketed. Outside the United States, we generally rely on the distributors who sell our products to obtain reimbursement approval for those countries in which they will sell our products. There can be no assurance that reimbursement approval will be received.

Fraud and Abuse Laws

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

Employees

We had 251 full-time employees at December 31, 2007. Of these employees, 111 were in manufacturing and research and development, 91 were in sales and marketing, 24 were in clinical, regulatory, and quality assurance, and 25 were in general and administrative. At our facility in Brindisi, Italy, we have 29 employees who are covered by one or more collective bargaining agreements negotiated with a union-authorized employee representative (*Rappresentanza Sindacale Unitaria*) and the two unions (FEMCA-CISL and FILCEA-CGIL) that represent employees at this location. We have never had a work stoppage, and we believe that our employee relations are good.

Backlog

We have not typically maintained a significant backlog. As a result, we do not believe that our backlog at any particular date is necessarily an accurate predictor of revenue for any succeeding period.

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. We experience some seasonal reduction of our product sales in our third fiscal quarter due to the summer holiday schedule of physicians and their patients.

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.

Risks Related to Our Business

We do not expect to achieve profitability in the near term, especially as we expand and integrate our direct sales force, conduct clinical studies, and acquire and develop new product offerings, businesses, or technologies.

As of December 31, 2007, we had an accumulated deficit of approximately \$12.9 million. We reported a net loss for the year ended on December 31, 2007, and we expect losses to continue through 2008. We intend to continue to incur substantial operating expenses as we make substantial expenditures to expand and integrate our direct sales force, conduct clinical studies, and acquire and develop new product offerings, businesses, or technologies. As a result, we do not expect to be profitable in the near term, and we will need to generate significant net sales in future periods to achieve and maintain profitability. Our ability to achieve and maintain profitability will be influenced by many factors, including:

- the level and timing of future sales and expenditures;
- market acceptance of our new products;
- the productivity of our direct sales force and distributors;
- the cost of our clinical studies;
- our ability to successfully acquire and develop competitive products;
- our ability to successfully integrate acquired businesses, products, or technologies;
- the impact on our business of competing products, technologies, and procedures;
- our ability to obtain regulatory approvals for our products in new markets;
- market and regulatory developments; and
- the cost of intellectual property challenges, if any.

We cannot assure you that we will achieve significant net sales or achieve and maintain profitability.

In order to address our capital needs, we may elect to raise funds through public or private sales of equity or from borrowings or from strategic partners. Additional equity financing, if available, may be dilutive to our stockholders; debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate our business; and strategic partnerships, if available, may result in royalties or other terms that reduce our economic potential from products under development.

Our results of operations are substantially dependent on businesses and assets that we acquired from third parties, and if we experience difficulties in completing the integration of these acquisitions into our business, or if we do not realize the anticipated benefits of these acquisitions, then our financial condition and results of operations could be adversely affected.

Since 1998 we have completed ten acquisitions. Our operating results are largely dependent on these acquired product lines, and this dependence exposes us to risks and uncertainties.

For example, following our acquisition of Biomateriali S.r.l. in December 2007, we were informed by Sorin Biomedica SpA, that Sorin would be reducing its purchases under an existing private label manufacturing program with Biomateriali. We estimate that this change in purchase volume will result in a \$550,000 reduction,

[Table of Contents](#)

approximately, in annual net sales of Biomateriali compared to annual net sales for the year preceding the acquisition. We can provide no assurance that similar changes in purchasing volume will not occur in the future in regard to Sorin or any other private label customer of, or distributor for, a company that we acquire.

In March 2008, we provided notice of an indemnity claim under the Biomateriali purchase agreement to the sellers of Biomateriali, contending that the sellers breached certain representations and warranties in the purchase agreement by failing to adequately disclose material information regarding the Sorin customer relationship. We have demanded the payment of damages of approximately \$0.5 million (denominated in Euros) and have ceased making certain post-closing payments to the sellers pending resolution of this indemnity claim.

There are also a number of contingent liabilities that we may face relating to the Biomateriali acquisition. For example, if our distribution agreement with Edwards Lifesciences AG is terminated or expires, we may be obligated to make payments to the sellers of approximately \$1.1 million to \$2.2 million. Further, upon termination of the distribution agreement we are obligated to either buy back non-expired inventory from Edwards at the original sales price for that inventory or direct the sale of that inventory to third parties. Currently, we have no specific plan to terminate this agreement; however, we may elect to terminate or modify the agreement prior to its expiration, which could result in a payment to the sellers of less than the full \$2.2 million and possibly the repurchase of inventory. Further, if the distribution agreement is terminated by Biomateriali due to a change in control of Biomateriali, we are required to pay a cancellation fee to the distributor equal to the product orders for the twelve months immediately preceding the date on which the distributor is notified of the termination.

We also may experience other difficulties related to our acquisitions. For example, in connection with our acquisition of our EndoFit and UniFit Stent Graft product lines, we acquired an ongoing clinical study related to the UniFit Abdominal Stent Graft. See “Business—Clinical Studies.” Our experience in conducting clinical studies is limited and we have experienced and may further experience difficulties or delays in transitioning this study or future studies. Any difficulties or delays we experience in connection with this clinical study could negatively impact our ability to obtain regulatory approval to market the UniFit Abdominal Stent Graft in certain markets. In addition, the products that we have acquired may need to be improved in order to gain broader market acceptance or may not compete effectively with existing products. We have limited experience with certain technologies underlying the acquired products. There can be no assurance that we will be successful developing the desired product improvements in a timely manner, if at all.

In April 2003, we acquired the Expedial Vascular Access Graft product line from Credent Limited, a UK company. In May 2004, we commenced a clinical study in the United States to collect data to submit to the FDA in support of 510(k) clearance for this device. In July 2006, we received preliminary data from the clinical study, suggesting that the device might not compare favorably to ePTFE grafts. As a result of our review of the clinical study results and less-than-planned sales of the Expedial product in Europe, we decided to cease the production and sale of this device. In October 2006, we sold certain manufacturing equipment, inventory, and intellectual property related to our Expedial Vascular Access Graft product line to CardioTech International, Inc. for total consideration of \$350,000 plus a five-percent royalty on CardioTech’s net sales of its CardioPass brand coronary artery bypass graft for a period of five years following the first commercial sale of a CardioPass graft. Clinical trials on the CardioPass graft have only recently been initiated and there can be no assurance that it will ever be commercialized.

Any of these difficulties could negatively impact our ability to realize the intended and anticipated benefits that we currently expect from our acquisitions and could have a material adverse effect on our financial condition and results of operations.

[Table of Contents](#)

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 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. 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.

Our results of operations could be negatively affected if we are unable to complete and integrate suitable acquisitions.

In order to expand our product offerings, we have acquired nine businesses and an uncommercialized patent portfolio since 1998, 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 companies, personnel, and products into our existing business;
- difficulties in integrating manufacturing operations into our existing business or successfully replicating manufacturing processes at new manufacturing facilities;
- difficulties or delays in transitioning clinical studies or unfavorable results from such clinical studies;
- difficulties or delays in commercializing intellectual property that we acquire;
- 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;
- difficulties in retaining key employees of the acquired business who are necessary to manage these acquisitions;
- difficulties in acquiring the right to and protecting intellectual property; or
- difficulties if the acquired company is remote or inconvenient to our Burlington, Massachusetts, headquarters.

For any of these reasons or as a result of other factors we may not realize the anticipated benefits of acquisitions.

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

We intend to convert select countries from distributor sales to direct sales, which could result in disruptions in our sales. This transition 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

[Table of Contents](#)

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. Also, our distribution agreements are typically exclusive with terms of up to five years. These agreements may temporarily constrain our ability to convert certain countries 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, in October 2007 we entered into a letter agreement with Serom Medical Technologies S.r.l. that ended Serom's distribution of our products in Italy as of January 25, 2008. Among the payments due to Serom under this letter agreement are consulting and transition services fees and a fee for termination of Serom's distribution rights under a contract with the prior owner of the Vascular Architects business. None of these payments were required under an existing contract or Italian law. We estimate that these additional costs for termination of the distribution relationship with Serom to be approximately \$240,000. These amounts were paid in part 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. If we elect to cooperate with a distributor, that distributor may require us to repurchase inventory that we had previously sold to that distributor, in which event we may need to make a corresponding negative adjustment to net sales.

Following termination of a distribution relationship, we may encounter difficulties in transitioning to a direct-sales model in the country in question. It may take us longer than expected to find sufficient qualified sales personnel to establish an effective sales force, which could negatively impact projected sales. If a distributor sold our products through a network of sales agents, rather than exclusively through its own personnel, we may not be able to establish relationships with all members of that network, temporarily limiting our access to the existing market. Similarly, failure to maintain or quickly re-establish a distributor's close relationships with the physicians who use our products could cause a drop in sales. On the logistical side, if a distributor entered into an agreement with a customer relating to sales of our products or successfully completed a customer's internal approval process, it may be difficult or impossible to assign the distributor's rights under such agreements or approvals, and sales to that customer may be delayed until a new agreement is entered or a new 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 solely of the distributor.

As a result of the above risks, there can be no assurance that we will be successful in transitioning to a direct sales model in the countries that we select, and difficulties that we encounter in this transition could negatively affect our business.

Existing or future acquisitions of new products or businesses could negatively affect our results of operations if we do not discover previously undisclosed liabilities.

In a future acquisition we could discover deficiencies withheld from us due to fraud or otherwise not uncovered in our due diligence prior to the acquisition, including deficiencies in internal controls, data adequacy and integrity, product quality, and regulatory compliance, as well as undisclosed and product liabilities, any of which could result in us becoming subject to penalties or other liabilities. Any such undisclosed liabilities could have an adverse effect on our financial condition and results of operations.

Some of our devices have been recently introduced into the market and may not achieve market acceptance, which could adversely affect our business.

Some of our devices have been recently introduced into the market, and we cannot assure you that they 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 device. In other cases, our devices may be used in new procedures and techniques, and if physicians do not adopt these procedures and techniques, demand for these devices would fail to develop. For example, in 2004 we launched our InvisiGrip Vein Stripper, which has not

[Table of Contents](#)

achieved widespread market adoption because of competing products and techniques. If our products do not gain market acceptance, our business could be adversely affected.

If we are unable to manage the anticipated growth of our business, our financial condition and operating results could be adversely affected.

The growth that we have experienced, and may experience in the future, will continue to provide challenges to our organization. For example, since 1998 we have completed ten acquisitions, and we expect to pursue additional acquisitions in the future. As our operations expand, both in terms of scope and geographic coverage, we expect that we will need to manage additional relationships with various partners, suppliers, and other organizations. We also will need to manage the corresponding growth of our manufacturing operations. Our ability to manage our operations and growth requires us to continue to improve our operational, financial, and management controls and reporting systems and procedures, and may in the future require us to transition to new enterprise management software. Such growth could place a strain on our administrative and operational infrastructure. We may not be able to make improvements to our management information and control systems in an efficient or timely manner, and we may discover deficiencies in existing systems and controls. If we cannot scale and manage our business appropriately, our anticipated growth may be impaired and our financial results could suffer.

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, 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, we obtain from a third-party supplier all of the nitinol stents used in our EndoFit Thoracic Stent Graft and UniFit Abdominal Stent Graft. Similarly, the EndoRE remote endarterectomy product line we added as a result of the Vascular Architects acquisition 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. Most of these suppliers could discontinue 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 could have an adverse effect on our financial condition and results of operations.

Any disruption in our manufacturing facilities could adversely affect our business and results of operations.

Our principal worldwide executive, distribution, and manufacturing operations are located at a 27,098 square foot leased facility and a nearby 7,477 square foot leased facility located in Burlington, Massachusetts. We also manufacture our Albograft Vascular Graft product line in a 16,146 square foot leased facility in Brindisi, Italy. 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

[Table of Contents](#)

losses, including potential damage to our reputation, and may not continue to be available to us on acceptable terms, or at all. In addition, our growth may outpace our manufacturing capacity, in which event we would need to locate, obtain, and build-out additional space. New or alternative facilities may not be available to us on acceptable terms. Even if we are able to identify such new or alternative facilities, we may incur additional costs and we may experience a disruption in the supply of our products until those facilities are available. Our leases for our Burlington, Massachusetts, manufacturing facilities expire in 2009, and we may not be able to renew these leases on terms acceptable to us or at all. Any disruption in our manufacturing capacity could have an adverse impact on our ability to produce sufficient inventory to meet the demands of our customers, which could have an adverse effect on our financial condition and results of operations.

We depend on our senior management team and other key scientific, sales, and technical personnel, and if we are unable to retain them or recruit additional qualified personnel we may not be able to manage our operations and meet our strategic objectives, which could have an adverse effect on our financial condition and results of operations.

We depend on the continued services of our senior management team and other key scientific, sales, and technical personnel, as well as our ability to continue to attract and retain additional highly qualified personnel. Our ability to retain our skilled labor force and our success in attracting and hiring new skilled employees will be a critical factor in determining whether we will be successful in the future. Each of our key employees may terminate his or her employment with us at any time. The loss of any of our senior management team or key employees could harm our business. We compete for such personnel with other companies, academic institutions, government entities, and other organizations. We may not be able to meet our future hiring needs or retain existing personnel on acceptable terms. We could face significant challenges and risks in hiring, training, managing, and retaining engineering and sales employees. Any loss or interruption of the services of our other key personnel could also significantly reduce our ability to effectively manage our operations and meet our strategic objectives, because we cannot assure you that we would be able to find an appropriate replacement should the need arise. We maintain life insurance payable to us on our Chairman and Chief Executive Officer, George W. LeMaitre, but not on our other key personnel.

If we do not maintain our relationships with our physician customers, our growth may be limited and our business could be harmed.

Physicians typically influence the medical device purchasing decisions of the hospitals and other healthcare institutions in which they practice. Consequently, our relationships with our physician customers are critical to our continued growth. We believe that these relationships are based on our long-standing reputation and presence in the market for peripheral vascular devices, the quality of our product offerings and clinical outcomes, our marketing efforts and our presence at medical society meetings. Any actual or perceived diminution in our reputation or the quality of our products or our failure or inability to maintain these other efforts could damage our current relationships, or prevent us from forming new relationships, with physicians and cause our growth to be limited and our business to be harmed.

Our primary 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, who in addition to performing traditional open surgical procedures, 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 radiologists and interventional cardiologists perform a greater percentage of these new procedures than we expect, our net sales may decline and our business may be affected.

[Table of Contents](#)

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.

We face competition from other companies, technologies, and alternative medical procedures, all of which could adversely impact our business, net sales, and results of operations. Consolidation in the medical technology industry could exacerbate these risks.

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 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, in particular our endovascular and dialysis access products. Recent industry consolidation could make the competitive environment more difficult for smaller companies like ours. 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 and may offer lower prices than we could offer profitably. 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. Any of these competitive factors could adversely impact our business, net sales, and results of operations.

If there is a disruption in the supply of products from Endologix, Inc. that we distribute, or if our relationship with Endologix is impaired, our net sales and results of operations could be adversely impacted.

We have entered into a three-year agreement with Endologix, Inc., to distribute the Powerlink System in several European countries, including Germany, France, and the United Kingdom. Our success in marketing the Powerlink System is dependent on our sales personnel being proficient in the product line, building physician relationships, and executing sales orders. If we are unable to market the Powerlink System successfully, or if our agreement with Endologix is terminated, our net sales and results of operations could suffer. If we do not meet our performance requirements under the agreement, the agreement may be terminated by Endologix. In addition, even if we market the Powerlink System successfully, if Endologix is unable to produce enough of its products to meet our demands, we may not be able to meet our customers' demands, and our net sales and results of operations may suffer. This distribution relationship also exposes us to the risk that the distribution of the Powerlink System disproportionately absorbs company resources that would otherwise be dedicated to other projects and the risk that the European market does not rapidly adopt the Powerlink System, in either of which cases our net sales and results of operations may suffer.

Our lack of customer purchase contracts makes it difficult to predict sales and plan manufacturing requirements, which could lead to lower net sales, higher expenses, and reduced margins.

We generally do not have long-term purchase contracts with our hospital customers, who typically order products on an as-needed basis. As a result, it is difficult to accurately forecast our component and product

[Table of Contents](#)

requirements. Our manufacturing and operating expenses are largely based on anticipated sales volume, and a significant portion of these expenses is and will continue to be fixed. We must plan production and order product components and third-party manufactured products several months in advance of customer orders. In addition, lead times for product components and third-party manufactured products that we order vary significantly and depend on factors such as the specific supplier and demand for each component at any given time. These factors expose us to a number of risks, such as the following:

- if we overestimate our requirements, or experience shortages, we may be obligated to carry more inventory than we need;
- if we underestimate our requirements, we may have an insufficient product component inventory, which could disrupt manufacturing of our products and cause delays in shipments and net sales; and
- if we experience shortages of product components from time to time, which could delay the manufacturing and shipping of our products.

If any of the foregoing occurs, it could lead to lower net sales, higher expenses, and reduced margins.

Our business strategy relies on assumptions about the market for our products, which, if incorrect, could adversely affect our business prospects and profitability.

We are focused on the market for devices used to treat peripheral vascular disease. We believe that demographic trends point towards an increase in the need for our products. However, the projected demand for our products could materially differ from actual demand if our assumptions regarding these trends and acceptance of our products by the medical community prove to be incorrect or do not materialize or if drug therapies gain more widespread acceptance as a viable alternative treatment, which in each case could adversely affect our business prospects and profitability.

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

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. Not requiring training specific to the use of our devices may expose us to greater risk of product liability if injuries occur during a procedure involving our products. In addition, if demand for our products continues to grow, less skilled surgeons will likely use the devices, potentially leading to an increased incidence of patient injury and an increased risk of product liability. The off-label use of our products may result in an increased risk of serious injuries or death. The potential for off-label use is greater in the case of a product—such as our aSpire Covered Stent—that is approved for a particular use in one country and approved for a different use in another.

As is the case with other medical device companies, product liability claims could be brought against us. 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. 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](#)

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 and Canada. For the year ended December 31, 2007, 39% of our net sales were derived from our operations outside of the United States and Canada. Our international sales operations expose us and our representatives, agents, and distributors to risks inherent in operating in foreign jurisdictions. These risks include:

- 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.

Any operations that we conduct in China will expose us to the risk of adverse changes in political, legal, and economic policies of the Chinese government, which changes could reduce the demand for our products in China and materially and adversely affect our competitive position in China.

Although we currently do not market any of our products in China, we have recently applied to obtain approval from the Chinese State Food and Drug Administration to market our EndoFit Thoracic Stent Graft in China. If and when this product is approved for sale in China, we expect to initially market our device using one or more distributors. Conducting business in China, if we seek to enter that market, would expose us to a variety of risks and uncertainties that are unique to China. The Chinese economy differs from the economies of most developed countries in many respects, including:

- level of government involvement;

[Table of Contents](#)

- economic structure;
- allocation of resources;
- level of development;
- inflation rates;
- growth rate; and
- control of foreign exchange.

The economy of China has been transitioning from a planned economy to a more market-oriented economy. Although in recent years the Chinese government has implemented measures emphasizing the utilization of market forces for economic reform, the reduction of state ownership of productive assets and the establishment of sound corporate governance in business enterprises, a substantial portion of productive assets in China is still owned by the Chinese government. In addition, the Chinese government continues to play a significant role in regulating industrial development. It also exercises significant control over China's economic growth through the allocation of resources, controlling payment of foreign currency-denominated obligations, setting monetary policy, and providing preferential treatment to particular industries or companies. Efforts by the Chinese government to slow the pace of growth of the Chinese economy could result in decreased capital expenditure by hospitals, which in turn could reduce demand for our products. In addition, the Chinese legal system is a civil law system based on written statutes. Unlike common law systems, it is a system in which decided legal cases have little precedential value. In 1979, the Chinese government began to promulgate a comprehensive system of laws and regulations governing economic matters in general. Accordingly, we cannot predict the effect of future developments in the Chinese legal system, including the promulgation of new laws, changes to existing laws, or the interpretation or enforcement thereof, or the preemption of local regulations by national laws.

Fluctuations in foreign currency exchange rates could result in declines in our reported sales and earnings.

Because the majority of our sales outside of the United States are denominated in local currencies, our reported sales and earnings are subject to fluctuations in foreign exchange rates. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our sales and earnings. At present, we manufacture very few of our products outside the United States and we do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U.S. dollar.

We rely on our independent distributors to market and sell our products in select markets outside of the United States and Canada.

Sales of our products through independent distributors represented 10% of our net sales for the year ended December 31, 2007. Our success in these markets depends largely upon marketing arrangements with distributors, in particular their sales and service expertise and relationships with their respective customers in the marketplace. Although we intend to replace some of these distributors with a direct sales force, this will take time and we may keep a distribution model in some markets. We do not control our distributors and they may not be successful in implementing our marketing plans.

Many of our distributors initially obtain and maintain foreign regulatory approval for sale of our products in their respective countries. We do not have long-term contracts with many of our distributors, and our distributors may terminate their relationships with us on little or no notice. In addition, some of our distributors are not required to purchase any minimum amount of products from us, may sell products that compete with ours or devote more efforts to selling other products, and may stop selling our products at any time. If we lose any of our significant distributors, if we fail to recruit and retain additional skilled distributors in these locations, or if our distributors devote more effort to selling products other than ours, our operations could be adversely affected. We have experienced turnover with some of our distributors in the past that has adversely affected our short-term financial results while we transitioned to new distributors. Similar occurrences could happen in the future.

We may not achieve positive cash flow from operations and, as a result, we may require additional capital. Failure to attract additional capital on acceptable terms could impair our growth.

We may require additional capital to execute our strategies and further expand our business. If our cash reserves, together with cash available under our credit facility and cash generated internally, are insufficient to fund our operations or our capital requirements, we will require additional debt or equity financing. If we raise additional capital through the issuance of debt, this debt will be senior to our outstanding shares of capital stock upon our liquidation. Financing may not be available or, if available, may not be available on terms satisfactory to us and could result in significant stockholder dilution. In addition, covenants in debt financing arrangements may restrict our ability to operate our business or obtain additional debt financing. These covenants may also require us to attain certain levels of financial performance and we may not be able to do so; any such failure may result in the acceleration of such debt and the foreclosure by our creditors on the collateral we used to secure the debt. We may also elect to raise additional funds through collaboration, licensing, marketing, or similar arrangements, and these arrangements may require us to relinquish valuable rights to our products or proprietary technologies, or grant licenses that are not favorable to us. If we fail to obtain sufficient additional capital in the future, we could be forced to curtail our growth strategy by reducing or delaying capital expenditures and acquisitions, delaying or postponing our product development efforts (including clinical studies), selling assets, restructuring our operations, or refinancing our indebtedness.

We rely on our management information systems for inventory management, distribution, and other functions and to maintain our research and development and clinical data. If our information systems fail to adequately perform these functions, or if we experience an interruption in their operation, our business and results of operations could be adversely affected.

The efficient operation of our business is dependent on our management information systems. We rely on our management information systems to effectively manage accounting, financial, human resources, and sales and marketing functions; manage order entry, order fulfillment, and inventory replenishment processes; and maintain our research and development and clinical data. We do not maintain redundant management information systems. The failure of our management information systems to perform as we anticipate could disrupt our business and product development and could result in decreased sales, increased overhead costs, excess inventory, and product shortages, causing our business and results of operations to suffer. In addition, our management information systems are vulnerable to damage or interruption from:

- earthquake, fire, flood, and other natural disasters;
- terrorist attacks and attacks by computer viruses or hackers; and
- power loss or the failure of our network infrastructure, telecommunications network, or the internet.

Any interruption in the use of our management information systems could have an adverse effect on our financial condition and results of operations.

From time to time we may become subject to tax audits or similar proceedings, and as a result we may owe additional taxes, interest, and penalties in amounts that may be material.

We are subject to income taxes in many countries, jurisdictions, and provinces, including the United States. In determining our global provision for income taxes, we are required to exercise judgment. Regularly, we make estimates where the ultimate tax determination is uncertain. While we believe our estimates are reasonable, we cannot assure you that the final determination of any tax audit or tax-related litigation will not be materially different from that reflected in our historical income tax provisions and accruals.

In February 2006 we received an audit notification from the Internal Revenue Service (IRS) requesting materials relating to our 2004 and 2005 federal tax return. In April 2007 we paid the IRS \$0.4 million resulting from adjustments to our 2004 and 2005 tax returns, the provision for which have been previously made as of

[Table of Contents](#)

December 31, 2006. In July 2007 we received an audit notification from the German tax authorities of an audit relating to our 2004, 2005, and 2006 German tax filings. The German federal tax authority proposed and we agreed to a final adjustment to the previously reported returns resulting in an assessment of \$0.3 million in 2007, the provision for which had previously been made as of December 31, 2006.

In addition, we are subject to sales, use, and similar taxes in many countries, jurisdictions, and provinces, including those states in the United States where we maintain a physical presence or have a substantial nexus. These taxing regimes are complex. For example, in the United States, each state and local taxing authority has its own interpretation of what constitutes a sufficient physical presence or nexus to require the collection and remittance of these taxes. Similarly, each state and local taxing authority has its own rules regarding the applicability of sales tax by customer or product type.

We employ a variety of strategies from time to time with respect to our international operations. There can be no assurance that these strategies will be accepted by the relevant taxing authorities. For example, we recently reorganized the corporate form of our Japanese subsidiary, resulting in a U.S. tax deduction. There can be no assurance that the IRS will agree with our position. If we are unsuccessful in this matter, our net operating loss carryforward may be reduced and our future results negatively impacted.

As of December 31, 2007, the liability for unrecognized tax benefits was approximately \$28,000 in our financial statements in connection with uncertain tax positions. The assessment of additional taxes, interest, and penalties as a result of audits, litigation, or otherwise, could be materially adverse to our current and future results of operations and financial condition.

Ownership of our common stock by our vascular surgeon customers, including members of our scientific advisory board, could negatively impact our reputation and as a result, our business and results of operations could suffer.

The stockholders who own our common stock include members of our scientific advisory board and other vascular surgeons who may use our devices and may recommend our devices for purchase by the hospitals at which they perform surgical procedures. The fact that such professionals are also our stockholders could attract unfavorable attention of the public, regulatory authorities, and the media, especially if the surgeons have not disclosed their relationships with us. Such perceptions could harm our reputation and could cause our business and results of operations to suffer.

If we fail to continue to expand our sales force, we could lose market share to our competitors and our results of operations could suffer.

One of our long-term business strategies is to continue to expand our direct sales force, particularly in markets where we believe we are currently underrepresented. For example, there are several large cities in the United States where we do not have any direct sales coverage. Outside the United States we rely on a small direct sales force in certain markets while we sell our products through independent sales distributors in other markets. Accordingly, there are a number of large markets where we believe we could expand direct sales coverage, such as Japan, France, and Italy. We may not be able to find a sufficient number of qualified medical device sales personnel to adequately address these markets in a cost-effective manner. We compete for experienced medical device sales personnel with our competitors, many of which are larger and have greater resources than we do and some of which may offer more attractive economic incentives than we do. Even if we are able to attract sales personnel, we may not be able to effectively train and retain such personnel. There can be no assurance that we will succeed in expanding our sales force, and difficulties that we encounter could negatively affect our business.

Risks Related to the Regulatory Environment

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 and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. U.S. and foreign regulations applicable to medical devices are wide-ranging and govern, among other things, the testing, marketing, and premarket clearance or approval of new medical devices, in addition to regulating manufacturing practices, reporting, promotion and advertising, importing and exporting, labeling, and record-keeping procedures.

Our failure to comply with applicable regulatory requirements could result in governmental agencies or a court taking action, including any of the following:

- issuing public warning letters to us;
- imposing fines and penalties on us;
- issuing an injunction preventing us from manufacturing or selling our products;
- bringing civil or criminal charges against us;
- delaying the introduction of our new products into the market;
- ordering a recall of, or detaining or seizing, our products; or
- withdrawing or denying approvals or clearances for our products.

If any or all of the foregoing were to occur, our business, results of operations, and reputation could suffer.

If we are not successful in obtaining and maintaining clearances and approvals from governmental agencies, we will not be able to sell our products, and our future growth will be significantly hampered. In order to market some of our products, notably our EndoFit and UniFit product lines, we will need to obtain approval of premarket applications from the FDA, which will require data from clinical trials. We have limited experience with these matters, in particular with conducting clinical trials.

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, unless it is exempt, 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, also known as "premarket notification," is the process used for our currently marketed products in the United States. This process 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 all of our current products that require clearances, these clearances may be revoked by the FDA 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.

Our EndoFit and UniFit products must receive PMA approval before being commercially distributed in the United States. To successfully obtain PMA approval of our EndoFit and UniFit devices and other devices that we

[Table of Contents](#)

may develop or acquire that are not approved for sale in the United States, such as the Albograft Vascular Graft, we will need to develop greater regulatory and clinical study expertise than we currently possess. This task will require us to devote significant resources to the improvement of our regulatory compliance and clinical study processes, including filling clinical and regulatory positions with personnel who have the requisite abilities and/or experience. We may not be able to find such personnel or be able to devote the necessary resources. In addition, our inexperience in these areas may cause significant delays in or otherwise harm our ability to successfully complete the complex undertaking of obtaining regulatory approval for these devices. We cannot assure you that we will ever obtain PMA approval for our EndoFit or UniFit devices or any other devices that we attempt to bring to market in the United States.

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. The products for which we are currently conducting studies are already approved for sale outside of the United States. While our studies are ongoing, unfavorable data may arise in connection with usage of our products outside the United States, which could adversely impact approval of our products in the United States. Conversely, unfavorable data from clinical studies in the United States may adversely impact sales of our products outside the United States. For example, in July 2006, we received unfavorable preliminary data from our United States clinical study of our Expedial Vascular Access Graft. The clinical study was designed to establish substantial equivalence to grafts manufactured using ePTFE for effectiveness in maintaining blood flow through the graft. The preliminary data from the clinical study suggested that the device did not compare favorably to ePTFE grafts in this regard. As a result of our review of the clinical study results and less than planned Expedial sales in Europe, we decided to forego further enrollment in the clinical study and cease worldwide production and sale of this device.

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.

Modifications to our marketed devices may require new regulatory clearances or premarket approvals, or may require us to cease marketing or recall the modified devices until clearances or approvals are obtained.

Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or would constitute a major change in its intended use, requires the submission of another 510(k) or PMA application to address the change. The FDA requires every manufacturer to make its own determination as to whether a modification requires a new 510(k) clearance or PMA. Although in the first instance we may determine that a change does not rise to a level of significance that would require us to make a submission, the FDA may review and disagree with our determination and can require us to submit a 510(k) or a PMA for a significant technological change or major change or modification in intended use. If the FDA requires us to submit a 510(k) or a PMA for any modification to a previously cleared device, we may be required to cease marketing the device, recall it, and not resume marketing until we obtain clearance or approval from the FDA for the modified version of the device. Delays in our receipt of regulatory clearance or approval will cause delays in our ability to sell our products, which could have a negative effect on our business, results of operations, and prospects. Also, we may be subject to regulatory fines, penalties, and/or other sanctions authorized by the Federal Food, Drug, and Cosmetic Act.

Our UniFit products are in, and our EndoFit products have recently completed, clinical studies. If our ongoing clinical study is unsuccessful, if the FDA or other regulatory agencies do not accept or approve the results of such studies, or if the FDA or other regulatory agencies find reason to interrupt or discontinue our ongoing study, these products may not come to market on a timely basis or at all, and our business prospects may suffer.

We currently have an ongoing clinical study to support a possible PMA application for our UniFit Abdominal Stent Graft, and we recently completed a Chinese clinical study to support approval from the Chinese State Food and Drug Administration (the SFDA) of our EndoFit Thoracic Stent Graft for marketing in China. We

[Table of Contents](#)

cannot assure you that the ongoing UniFit study will be successful or that the FDA or SFDA or other relevant regulatory agencies will accept the results of the applicable study and approve or clear the devices for sale. Further, we continue to evaluate the potential financial benefits and costs of our clinical studies and the products being evaluated in them. If we determine that the costs associated with attaining regulatory approval of a product exceed the potential financial benefits of that product, or if the projected development timeline is inconsistent with our investment horizon, we may choose to stop a clinical study and/or the development of a product.

In May 2006, we submitted an investigational device exemption, or IDE, supplemental application to the FDA to begin a pivotal clinical trial to evaluate the safety and effectiveness of the UniFit Abdominal Stent Graft in the treatment of aorto, aorto-iliac, and/or iliac aneurysms. In May 2007, we received final approval from the FDA to commence the pivotal trial, which we refer to as the UNITE study, and as of December 31, 2007, we had enrolled seven patients in the trial. We plan to enroll 90 patients at up to 14 institutions. The primary effectiveness endpoint of the study is based on aneurysm exclusion as evaluated through one-year follow-up. If the institutions participating in any of our clinical studies or trials do not enroll a sufficient number of patients to provide the clinical data necessary to obtain regulatory approval of the device being evaluated, or do not enroll patients in a timely fashion, the approval or clearance of that device for sale may be prevented or delayed.

In January 2008, the FDA audited the conduct of the feasibility study and pivotal clinical trial of our UniFit Abdominal Stent Graft. As a result of this audit, the FDA issued a formal notification, or Form FDA-483, listing nine observations. Specifically, the FDA observed that we had not adequately supervised participating sites, made all required reports to those sites and the FDA, or adequately maintained all records required by FDA regulations. While we have revised our clinical trial procedures to address the FDA's findings and have submitted a response letter to the FDA detailing the steps being taken, we cannot assure you that we will be successful in implementing these changes or that the FDA will agree that our implementation is adequate. If the FDA finds that we are not in substantial compliance with IDE requirements, the FDA may issue a public warning letter or take other enforcement action against us, and the conduct of our clinical trial could be interrupted or discontinued.

If our UniFit clinical study is unsuccessful, if the FDA or other regulatory agencies do not accept or approve the results of our UniFit or EndoFit studies, or the FDA or other regulatory agencies find reason to interrupt or discontinue an ongoing study, these products will not come to market on a timely basis or at all, and our business prospects may suffer.

Recent corruption scandals within the Chinese State Food and Drug Administration may delay or defeat our efforts to obtain regulatory approval for our products in China.

Although we currently do not market any of our products in China, we recently conducted a clinical study to obtain approval from the Chinese State Food and Drug Administration (the SFDA) to market our EndoFit Thoracic Stent Graft in China. In July 2007, the former head of the SFDA was executed following his conviction by the Chinese government for accepting bribes. Other senior administration officials have been charged and convicted of similar crimes. We understand from our advisors that these scandals within the SFDA have resulted in a slower, less predictable and more uncertain product medical device approval process. Accordingly, we cannot assure that you that we will obtain SFDA approval for our EndoFit device or our other products in a timely manner or at all. If we do not obtain SFDA approval with respect to our products, we will not be able to sell our products and our future growth will be hampered.

If we or some of our suppliers fail to comply with the FDA's Quality System Regulation and other applicable postmarket 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.

[Table of Contents](#)

We and some of our suppliers must comply with the FDA's Quality System Regulation, which governs the methods used in, and the facilities and controls used for, the design, testing, manufacture, control, quality assurance, installation, servicing, labeling, packaging, storage, and shipping of medical devices. The FDA enforces the Quality System Regulation through unannounced inspections. We have been, and anticipate in the future being, subject to such inspections. 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.

In March 2006, the FDA inspected our facilities in Burlington, Massachusetts. The inspection resulted in the issuance of a formal notification, or a Form FDA-483, listing three observations. Specifically, the FDA observed that we did not adequately document corrective and preventive actions taken by us to address quality problems, we did not identify all actions needed to prevent the recurrence of nonconforming product and other quality problems, and we had an incomplete procedure for implementing and recording actions taken to correct and prevent identified quality problems. While we have revised our procedures and conducted additional training to address the FDA's findings, we cannot assure you that we have been successful in implementing these changes or that the FDA will agree that our implementation is adequate. If the FDA finds that we are not in substantial compliance with the Quality System Regulation, the FDA may issue a public warning letter or take other 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 receiving regulatory clearance or approval, our products may be subject to product recalls, which may harm our reputation and divert managerial and financial resources.

The FDA and similar governmental authorities in other countries have the authority to order mandatory recall of our products or order their removal from the market if the governmental entity finds that our products would cause serious adverse health consequences or death. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design defects, including labeling defects. For example, in 2005 we initiated three voluntary recalls. Two of these recalls related to packaging flaws that compromised the sterility of the products, and the third recall arose from a labeling error. In 2007, we initiated a voluntary recall relating to finished goods inventory that we had acquired in connection with our acquisition of the LeverEdge Contrast Injector in April 2007. The recall related to a packaging flaw that compromised the sterility of the product. Any future recall of our products may harm our reputation with customers and divert managerial and financial resources.

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

[Table of Contents](#)

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/EEC). 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 all of our products except the Pruitt F3 and Flexcel Carotid Shunts. 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 initiate a recall or removal of our product from the market in order to address product deficiencies or malfunctions. Any recall of our products may harm our reputation with customers and divert managerial and financial resources.

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

Our manufacturing facilities are subject to periodic inspection by European regulatory authorities and Notified Bodies, and we must demonstrate compliance with the Medical Devices Directive. 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. Our failure to comply may have a material adverse effect on our business, financial condition, and results of operations.

In Japan, the Ministry of Health, Labor and Welfare (the MHLW) regulates medical devices through the Pharmaceutical Affairs Law, which was reformed effective April 1, 2005. Implementation and enforcement of the reforms are evolving, and compliance guidance from the MHLW is still in development. 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.

If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations, and financial condition could be adversely affected.

While we do not control referrals of healthcare services, and we do not receive payments directly from Medicare, Medicaid, or other third-party payors, healthcare laws and regulations apply broadly and may apply to

[Table of Contents](#)

our business. We could be subject to healthcare fraud and patient privacy regulation by the federal government and the states and international jurisdictions in which we conduct our business. The regulations that may affect our ability to operate include:

- the federal healthcare programs Anti-Kickback Statute, which constrains, among other things, our marketing practices, educational programs, pricing and discounting policies, and relationships with healthcare providers by prohibiting persons from soliciting, receiving, or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing, recommending, furnishing, or arranging for an item or service, for which payment may be made under a federal healthcare program such as the Medicare or Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us, because we provide coding and billing advice to customers;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to health care matters and which also imposes regulatory and contractual requirements relating to the privacy, security, and transmission of individually identifiable health information;
- state laws analogous to each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by non-governmental third-party payors, including commercial insurers, and state laws governing the privacy of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;
- federal physician self-referral prohibitions, such as The Ethics in Patient Referral Act of 1989, commonly referred to as the federal physician self-referral law or the Stark law, which under certain circumstances prohibit physicians from referring patients for services paid for by Medicare or Medicaid to any entity in which the physician or an immediate family member has an ownership, compensation, or other financial interest, unless a specific statutory or regulatory exception applies; and
- international regulations similar in nature and scope to the above-referenced requirements, including the European Union directive on data privacy, which imposes restrictions on the collection, use, disclosure, and processing of personal data.

While we believe that our present and past operations are and have been compliant in all material respects with the laws and regulations described above, there can be no assurance that we will not be found to be, or found to have been, in violation of any of such laws or regulations and as a result we may be subject to penalties, including civil and criminal penalties, damages, fines, and the curtailment or restructuring of our operations. Any penalties, damages, fines, or curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws or regulations is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws or regulations, even if we successfully defend against them, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Compliance with environmental laws and regulations could be expensive. Failure to comply with environmental laws and regulations could subject us to significant liability.

Our manufacturing operations and our research and development programs involve the use of hazardous substances and are subject to a variety of federal, state, and local environmental laws and regulations relating to the storage, use, discharge, disposal, and remediation of, and human exposure to, hazardous substances. Our research and development and manufacturing operations produce biological waste materials, such as human and

[Table of Contents](#)

animal tissue, and waste solvents, such as isopropyl alcohol. Regulatory authorities permit these operations, and the resulting waste materials are disposed of in material compliance with environmental laws and regulations. Compliance with these laws and regulations is expensive, and non-compliance could result in substantial liabilities, which could exceed our insurance coverage. In addition, our manufacturing operations may result in the release, discharge, emission, or disposal of hazardous substances that could cause us to incur substantial liabilities, including costs for investigation and remediation.

We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure, or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and operating results.

Inadequate levels of reimbursement from governmental or other third-party payors for procedures using our products may cause our net sales to decline.

Sales of our products depend in part on the reimbursement by governmental and private healthcare payors to our hospital and physician customers or their patients for the purchase and use of our products. In the United States, healthcare providers that purchase our products generally rely on third-party payors, principally federal Medicare, state Medicaid, and private health insurance plans, to pay for all or a portion of the cost of procedures. Any delays in obtaining, or an inability to obtain, payor coverage and reimbursement for our products or the services in which our products are used could have a material adverse effect on our business. In addition, if the reimbursement policies of domestic or foreign governmental or private healthcare payors change, our customers would likely change their purchasing patterns or the frequency of their purchases of the affected products.

Changes in healthcare systems in the United States or elsewhere could adversely affect the demand for our products, as well as the way we conduct business. Third-party payors have adopted, and are continuing to adopt, a number of healthcare policies intended to curb rising healthcare costs. These policies include:

- controls on government-funded reimbursement for healthcare services and price controls on medical products and services providers;
- limitations on coverage and reimbursement for new medical technologies and procedures; and
- the introduction of managed care or prospective payment systems in which healthcare providers contract to provide comprehensive healthcare for a fixed reimbursement amount per person or per procedure.

We are unable to predict whether federal, state, or local healthcare reform legislation or regulations, or private payor policies, affecting our business may be proposed or enacted in the future, or what effect any such legislation, regulations, or policies would have on our business. Any such legislation, regulations, or policies that affect the coverage and reimbursement of our current or future products, or the procedures utilizing our current or future products, could cause our net sales to decline.

Outside of the United States, reimbursement systems vary significantly by country. Many foreign markets have government-managed healthcare systems that govern reimbursement for new devices and procedures. In most markets, there are private insurance systems as well as government-managed systems. Additionally, some foreign reimbursement systems provide for limited payments within a given period. These systems are subject to the same pressures to curb rising healthcare costs and control healthcare expenditures as those in the United States. If adequate levels of reimbursement from third-party payors outside of the United States are not obtained, sales of our products outside of the United States may decrease and we may fail to achieve or maintain significant non-U.S. sales.

Risks Related to Intellectual Property

If we fail to adequately protect our intellectual property rights, or prevent use of our intellectual property by third parties, we could lose a significant competitive advantage and our business may suffer.

Our success depends in part on obtaining, maintaining, and enforcing our patents, trademarks, and other proprietary rights, and our ability to avoid infringing on the proprietary rights of others. We take precautionary steps to protect our technological advantages and intellectual property. We rely upon patent, trade secret, copyright, know-how, and trademark laws, as well as license agreements and contractual provisions, to establish our intellectual property rights and protect our products. These measures may only afford limited protection and may not:

- prevent our competitors from duplicating our products;
- prevent our competitors from gaining access to our proprietary information and technology; or
- permit us to gain or maintain a competitive advantage.

The issuance of a patent is not conclusive as to its validity or enforceability. Any patents we have obtained or will obtain in the future might also be invalidated or circumvented by third parties. In addition, our pending patent applications may not issue as patents or, if issued, may not provide commercially meaningful protection, as competitors may be able to design around our patents to produce alternative, non-infringing designs. Should such challenges to our patents be successful, competitors might be able to market products and use manufacturing processes that are substantially similar to ours. 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. Prior to launching major new products in our key markets, we typically evaluate existing intellectual property rights. However, our competitors may also have filed for patent protection that is not as yet a matter of public knowledge or claim trademark rights that have not been revealed through our availability searches. 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;

[Table of Contents](#)

- harm our reputation;
- cause us to cease making or selling products that incorporate the challenged intellectual property;
- require us to redesign, reengineer, or rebrand our products, which may not be possible and could be costly and time consuming if it is possible to do so at all;
- require us to enter into royalty or licensing agreements in order to obtain the right to use a third party's intellectual property, which agreements may not be available on terms acceptable to us or at all;
- divert the attention of our management and key personnel from other tasks important to the success of our business; or
- result in our customers or potential customers deferring or limiting their purchase or use of the affected products until resolution of the litigation.

It is also possible that one of our competitors could claim that our manufacturing process violates an existing patent. If we were unsuccessful in defending such a claim, we may be forced to stop production at one or more of our manufacturing facilities.

In addition, new patents obtained by our competitors could threaten a product's continued life in the market even after it has already been introduced. If our business is successful, the possibility may increase that others will assert infringement claims against us.

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, Boston Scientific Corporation initiated opposition proceedings in the European Patent Office to oppose our granted European patent number 1,202,682, or the 682 patent, related to an ePTFE intraluminal device such as certain of our EndoFit and UniFit stent grafts, and to oppose our granted European patent number 1,148,838, or the 838 patent, related to an ePTFE vascular prosthesis such as certain of our EndoFit and UniFit stent grafts. As a result of the opposition proceedings, the granted patent claims in the 682 patent were cancelled while the 838 patent survived with certain amendments that did not materially alter the coverage provided by that patent. Although the cancellation of the patent claims in the 682 patent does not affect our ability to manufacture, distribute, or sell any of our products, it could affect our right to exclude others from selling products similar to our EndoFit and UniFit stent grafts in Europe.

We may become involved in lawsuits and administrative proceedings to protect, defend, or enforce our patents that would be expensive and time consuming.

In order to protect or enforce our patent rights, we may initiate patent litigation or interference or opposition proceedings against third parties in the United States or in foreign countries. The defense of intellectual property rights, including patent rights through lawsuits, interference, or opposition proceedings, and other legal and administrative proceedings can be costly and can divert our technical and management personnel from their normal responsibilities. Such costs increase our operating losses and reduce our resources available for development activities. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. For example, during the course of this kind of litigation and despite protective orders entered by the court, confidential information may be inadvertently disclosed in the form of documents or testimony in connection with discovery requests, depositions, or study testimony. This disclosure could materially adversely affect our business and financial results.

[Table of Contents](#)

If we fail to observe the terms of our agreements with third-party patent holders, we may lose the ability to manufacture, market, or sell some of our products.

Certain aspects of our products are the subject of patents held by third parties. We manufacture, market, and sell these products pursuant to license agreements with these third parties. These arrangements require us to pay royalties, typically determined as a percentage of our net sales for the underlying product. If we fail to make these payments or otherwise fail to observe the terms of these agreements, we may lose our ability to sell these products. For example, we manufacture, market, and sell our EndoFit and UniFit stent grafts pursuant to a sublicense from Bard Peripheral Vascular, Inc., a subsidiary of C.R. Bard, Inc., to a U.S. patent covering aspects of ePTFE. Our arrangement with Bard may preclude us from assigning the sublicense to a third party, including in connection with the sale of more than 30% of our capital stock or all or substantially all of our assets, without the prior consent of Bard. The loss by us of our right to manufacture, market, and sell our EndoFit and UniFit products could adversely affect our business and results of operations, perhaps materially.

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;
- the public's reaction to our press releases, our other public announcements, and our filings with the Securities and Exchange Commission;
- strategic actions by us or our competitors, such as acquisitions or restructurings;
- 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;
- 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;
- public concern as to the safety or efficacy of our products;
- changes in financial markets or general economic conditions, including those resulting from war, incidents of terrorism, and responses to such events;
- sales of common stock by us or our directors, officers, or principal stockholders; 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.

[Table of Contents](#)

We may experience significant fluctuations in our quarterly results, and in particular we project that we will not be profitable for 2008, which may cause our stock price to decline.

We reported a net loss for the year ended December 31, 2007, and we expect to report a loss in 2008. These losses, together with fluctuations in our quarterly and annual results of operations have resulted and will continue to result from numerous factors, including:

- changes in the mix of products we sell;
- changes in the demand for our products;
- seasonality in the sales of our products;
- increased product and price competition;
- the loss of any distributor or any significant customer, especially in regard to any product that has a limited distributor or customer base;
- effects of domestic and foreign economic conditions and exchange rates on our industry and/or customers;
- changes in our ability to obtain products and product components that are manufactured for us by third parties, especially the loss of sole-source suppliers, as well as variations in prices of these products and product components;
- our ability to attain and maintain production volumes and quality levels for our products and product components;
- the effect of a disaster at any of our manufacturing facilities;
- delays in the development or commercial introduction of new versions of our products or components we use in our products;
- failure to initiate, complete, or achieve favorable results from clinical studies of our products on a timely basis or at all;
- delays in obtaining regulatory clearance for new versions of our products or failure to maintain such clearance for our existing products and manufacturing operations;
- changes in the availability of third-party reimbursement for our products;
- possible product liability lawsuits and product recalls;
- loss of intellectual property protection or infringement on the intellectual property of others;
- strategic actions by us, such as acquisitions of additional businesses, products, or technologies;
- costs incurred in connection with the termination of contractual and other relationships, including distributorships;
- material changes in headcount; and
- the loss of key personnel.

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.

In addition, we anticipate that our operating expenses will increase substantially in the foreseeable future as we continue to expand our sales and marketing, manufacturing, and product development activities. We estimate

[Table of Contents](#)

that our continued expansion efforts, higher expenses, and the fees associated with distributor terminations will offset the effect of increased revenues and will lead to a net loss in 2008, which may result in a decline in the market price for our common stock.

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.

As of February 1, 2008, our directors, officers, and affiliated stockholders holding more than 5% of our common stock collectively control approximately 53.2% 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.

Future acquisitions that we make may be dilutive to our current stockholders.

We intend to pursue the acquisition of complementary products, technologies, or businesses, and in connection with these acquisitions we may use substantial portions of our available cash or make dilutive issuances of securities. In addition, an acquisition could impair our operating results by causing us to incur debt or requiring us to recognize acquisition expenses or amortize, depreciate, or impair acquired assets. This debt would be senior to our outstanding shares of capital stock upon our liquidation.

The requirements of being a public company may strain our resources and distract management.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the Exchange Act), the Sarbanes-Oxley Act of 2002, and other federal and state laws. These requirements may place a strain on our people, systems, and resources. The Exchange Act requires that we file annual, quarterly, and current reports with respect to our business and financial condition. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal controls over financial reporting. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal controls over financial reporting, significant resources and management oversight are required. This may divert management's attention from other business concerns, which could have a material adverse effect on our business, financial condition, results of operations, and cash flows.

We will be exposed to risks relating to evaluation of controls required by Section 404 of the Sarbanes-Oxley Act.

Changing laws, regulations, and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and related regulations implemented by the SEC and the NASDAQ Global Market, are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities more time-consuming. We have evaluated our internal controls systems to allow management to report on, and our independent auditors in 2008 to attest to, our internal controls. We have performed the system and process evaluation and testing (and any necessary remediation) required to comply with the management certification and auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. We cannot be certain as to the timing of completion of our remediation actions or the impact of the same on our operations, since there is presently no precedent available by which to measure compliance adequacy. If we are not able to implement the requirements of Section 404 in a timely manner or with adequate compliance, we may be subject to sanctions or investigation by regulatory authorities, including the SEC or the NASDAQ Global Market. This type of action could adversely affect our financial results or investors' confidence in our company and our ability to access capital markets, and could cause our stock price to decline. In addition, the controls and procedures that we are implementing may not comply with all of the relevant rules and regulations of the SEC and the NASDAQ Global Market. If we fail to implement and maintain effective controls and procedures, we may be unable to provide the required financial information in a timely and reliable manner.

[Table of Contents](#)

As part of our evaluation of internal controls, we recently conducted an assessment of the effectiveness of our internal control over financial reporting. In making this evaluation, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its *Internal Control-Integrated Framework*. Based upon this evaluation, we concluded that we did not maintain effective internal control over financial reporting as of December 31, 2007, as a result of a material weakness in controls regarding certain accruals and the related reconciliation and review process of the financial statement close process. A “material weakness in internal control over financial reporting” is one or more deficiencies in process that create a reasonable possibility that a material misstatement of a company’s annual or interim financial statements will not be prevented or detected on a timely basis. Deficiencies in our controls over our accruals and reconciliation process resulted in a reasonable possibility that a material misstatement of our annual and fourth quarter interim financial statements would not have been prevented or detected by us in the normal course of our financial statement close process. We have therefore instituted remedial action to ensure that this potential is not reasonably possible and the controls in the financial statement close process have been strengthened.

We also maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is processed, summarized, and reported within the time periods specified in the SEC’s rules and forms. As of December 31, 2007, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Due to the identification of a material weakness in internal control over financial reporting with respect to certain accruals and the related reconciliation and review process of the financial statement close process, as described below, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2007, our disclosure controls and procedures were not effective.

Despite the identification of a material weakness, our Chief Executive Officer and Chief Financial Officer have concluded that the financial statements included in this Form 10-K present fairly, in all material respects, our financial position, results of operations, and cash flows for the periods presented in conformity with generally accepted accounting principles. However, if we are not successful in effecting remedial action, our financial results could be reported inaccurately or in an untimely fashion, which could adversely affect investors’ confidence in our internal controls and our company and cause our stock price to decline.

If we fail to meet the listing requirements of The Nasdaq Stock Market and do not take such corrective action as the Nasdaq Listing Qualifications Department may require, trading in our securities may be halted and we may be delisted from the NASDAQ Global Market.

As an issuer listed on the NASDAQ Global Market, we must comply with the Marketplace Rules of The Nasdaq Stock Market in order to maintain that listing. Nasdaq-listed companies that do not maintain compliance with those Rules face having trading in their stock halted and, if they do not regain compliance as required by the Nasdaq Listing Qualifications Department, may be delisted. If a company is delisted, its listed stock would no longer be publicly tradable, and holders of that stock may face issues of liquidity and a decrease in the value of that stock.

Our corporate documents and Delaware law contain provisions that could discourage, delay, or prevent a change in control of our company.

Provisions in our restated certificate of incorporation and restated bylaws may discourage, delay, or prevent a merger or acquisition involving us that our stockholders may consider favorable. For example, our restated certificate of incorporation authorizes our board of directors to issue up to 5,000,000 shares of “blank check” preferred stock. Without stockholder approval, the board of directors has the authority to attach special rights,

[Table of Contents](#)

including voting and dividend rights, to this preferred stock. With these rights, preferred stockholders could make it more difficult for a third party to acquire us. In addition, our restated certificate of incorporation provides for a staggered board of directors, whereby directors serve for three-year terms, with approximately one third of the directors coming up for reelection each year. Having a staggered board makes it more difficult for a third party to obtain control of our board of directors through a proxy contest, which may be a necessary step in an acquisition of us that is not favored by our board of directors.

We are also subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law. Under these provisions, if anyone becomes an “interested stockholder,” we may not enter into a “business combination” with that person for three years without special approval, which could discourage a third party from making a takeover offer and could delay or prevent a change of control. For purposes of Section 203, “interested stockholder” means, generally, someone owning 15% or more of our outstanding voting stock or an affiliate of ours that owned 15% or more of our outstanding voting stock during the past three years, subject to certain exceptions as described in Section 203.

We do not expect to pay cash dividends in the foreseeable future.

We do not anticipate paying cash dividends in the foreseeable future. The payment of cash dividends will depend on our earnings, capital requirements, financial condition, prospects, and other factors our board of directors may deem relevant and may also be restricted by contractual agreements. If we do not pay dividends, our stock may be less valuable because a return on your investment will only occur if our stock price appreciates.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our principal worldwide executive, distribution, and manufacturing operations are located at a 27,098 square foot leased facility and a nearby 7,477 square foot leased facility, located in Burlington, Massachusetts. In addition, our international operations are headquartered at a 12,841 square foot leased facility located in Sulzbach, Germany, our Albograft manufacturing operations are located at a 16,146 square foot leased facility in Brindisi, Italy, our Italian sales offices are located at a 323 square foot leased facility located in Rome, Italy, and our Asian operations are located at a 2,140 square foot leased facility located in Tokyo, Japan. The leases for our two Burlington facilities expire in 2009 and the leases for our Sulzbach, Brindisi, and Tokyo facilities expire in 2010, 2016, and 2010, respectively. The lease for our offices in Rome is on a month-to-month basis. Based on our current operating plan, we believe our current facilities are adequate.

Item 3. Legal Proceedings

We are not party to any material pending or threatened litigation.

Item 4. Submission of Matters to a Vote of Security Holders

Not applicable.

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

Our common stock 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 closing prices of our common stock as reported on The NASDAQ National Market for the five quarters beginning October 19, 2006, and ending December 31, 2007:

	<u>High</u>	<u>Low</u>
<u>Year ended December 31, 2006:</u>		
Fourth quarter from October 19 to December 31, 2006	\$ 6.45	\$ 5.50
<u>Year ended December 31, 2007:</u>		
First quarter ended March 31, 2007	\$ 6.82	\$ 5.88
Second quarter ended June 30, 2007	\$ 6.66	\$ 5.70
Third quarter ended September 30, 2007	\$ 7.54	\$ 5.56
Fourth quarter ended December 31, 2007	\$ 7.65	\$ 5.90

Holders of Record

On March 27, 2008, the closing price per share of our common stock was \$3.31, as reported on The NASDAQ Global Market, and we had approximately 314 stockholders of record.

Dividend Policy

We have never paid a cash dividend and have no present intention to pay cash dividends in the foreseeable future. We intend to retain any future earnings for use in our business.

Securities Authorized for Issuance under Equity Compensation Plans

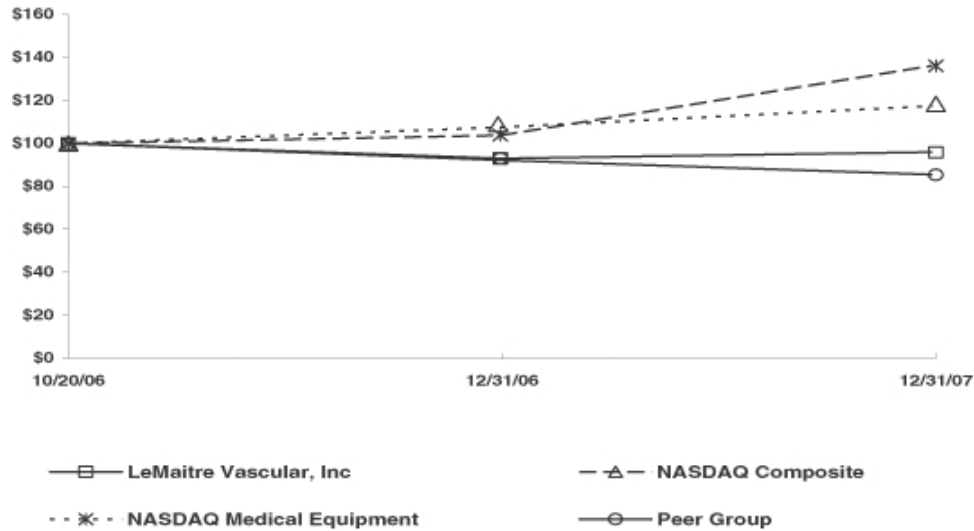
The following table sets forth information regarding our equity compensation plans in effect as of December 31, 2007. Each of our equity compensation plans is an "employee benefit plan" as defined by Rule 405 of Regulation C of the Securities Act of 1933.

<u>Plan category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights</u>	<u>Weighted-average exercise price of outstanding options, warrants and rights</u>	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))</u>
	(a)	(b)	(c)
Equity compensation plans approved by security holders	1,651,832	\$ 5.33	515,321
Equity compensation plans not approved by security holders	—	—	—
Total	<u>1,651,832</u>	<u>\$ 5.33</u>	<u>515,321</u>

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 LeMaitre’s initial public offering on October 19, 2006, through the end of LeMaitre’s fiscal year ended December 31, 2007. The graph assumes an investment of \$100.00 made at the opening of trading on October 20, 2006, 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.

COMPARISON OF 14 MONTH CUMULATIVE TOTAL RETURN*
Among LeMaitre Vascular, Inc, The NASDAQ Composite Index
And The NASDAQ Medical Equipment Index



* \$100 invested on 10/20/06 in stock or on 9/30/06 in index-including reinvestment of dividends. Fiscal year ending December 31.

	10/06	12/06	12/07
LeMaitre Vascular, Inc	100.00	93.02	96.12
NASDAQ Composite	100.00	107.55	117.50
NASDAQ Medical Equipment	100.00	103.72	136.26
Peer Group	100.00	92.24	85.71

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., Endologix, Inc., ev3 Inc., Foxhollow Technologies, Inc. (up to the date of acquisition by ev3 Inc.), Integra Lifesciences Holdings Corporation, Kensey Nash Corporation, and Vascular Solutions, Inc.

Recent Sales of Unregistered Securities

On October 19, 2006, we completed our initial public offering of 5,500,000 shares of our common stock at a price to the public of \$7.00 per share for an aggregate offering price of \$38.5 million. The offer and sale of all of the shares in the initial public offering were registered under the Securities Act of 1933, as amended, pursuant to a registration statement on Form S-1 (File No. 333-133532), which was declared effective by the Securities and Exchange Commission on October 18, 2006. Goldman, Sachs & Co., CIBC World Markets Corp., Cowen and Company, LLC and Thomas Weisel Partners LLC were the managing underwriters of the initial public offering. The offering commenced on October 19, 2006, and did not terminate until after the sale of all of the securities registered in the registration statement.

We received aggregate net proceeds of approximately \$35.8 million, after deducting underwriting discounts and commissions of \$2.7 million. We incurred approximately \$3.0 million of additional expenses associated with the initial public offering. None of the underwriting discounts and commissions or offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10 percent or more of our common stock or to any affiliates of ours. From the effective date of the registration statement through December 31, 2007, we have spent \$12.9 million, including \$3.9 million to pay down all outstanding indebtedness under two term loans and a revolving line of credit, \$1.2 million for payment of expenses related to our initial public offering, \$5.1 million for acquisitions, \$1.1 million for the early termination of our Italian distributor, \$0.3 million for the acquisition of licenses and technology, \$1.1 million for equipment, and \$0.2 million for working capital purposes. No payments for such expenses were made directly or indirectly to (i) any of our directors, officers or their associates, (ii) any person(s) owning 10% or more of any class of our equity securities or (iii) any of our affiliates. At December 31, 2007, we had approximately \$22.9 million of cash equivalents and marketable securities.

We expect to use the remaining proceeds from our initial public offering for general corporate purposes. Our management has broad discretion as to the use of the net proceeds. We may use a portion of the net proceeds for the acquisition of, or investment in, technologies or products that complement our business. As required by Securities and Exchange Commission regulations, we will provide further detail on our use of the net proceeds from our initial public offering in future periodic reports.

Issuer Purchases of Equity Securities

In the fourth quarter of 2007, we repurchased 12,784 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.

Issuer Purchases and other Acquisitions of Equity Securities				
Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Program	Approximate Dollar Value of Shares that May Yet be Purchased Under the Program
December 1, 2007 through December 31, 2007	12,784	\$ 6.37	N/A	N/A
Total	12,784(1)	—	—	—

(1) Represents shares withheld by us upon the vesting of restricted stock units to satisfy withholding taxes.

[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, 2005, 2006, and 2007, and the consolidated balance sheet data as of December 31, 2006 and 2007, 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, 2003 and 2004, and the consolidated balance sheet data as of December 31, 2003, 2004, and 2005 from our audited consolidated financial statements, which are not included in this Annual Report. Our historical results for any prior period are not necessarily indicative of results to be expected for any future period.

	Year ended December 31,				
	2003	2004	2005	2006	2007
(in thousands, except per share data)					
Consolidated Statements of Operations Data:					
Net sales	\$20,664	\$26,183	\$ 30,727	\$ 34,628	\$ 41,446
Cost of sales	6,208	7,780	8,927	9,367	10,739
Gross profit	14,456	18,403	21,800	25,261	30,707
Operating expenses:					
Sales and marketing	7,252	9,654	10,960	15,183	19,443
General and administrative	4,530	5,037	6,405	7,105	9,534
Research and development	2,265	2,120	3,015	3,301	4,591
Purchased research and development	—	—	—	—	373
Restructuring charges	733	435	998	257	1,042
Impairment charge	—	—	—	94	7
Total operating expenses	14,780	17,246	21,378	25,940	34,990
Income (loss) from operations:	(324)	1,157	422	(679)	(4,283)
Other income (expense):					
Interest income	3	9	4	299	1,299
Interest expense	(144)	(137)	(182)	(296)	(1)
Foreign currency gain (loss)	191	169	(217)	228	292
Other income (expense), net	(22)	(57)	551	(72)	(9)
Total other income (expense)	28	(16)	156	159	1,581
Income (loss) before income tax	(296)	1,141	578	(520)	(2,702)
Provision for (benefit from) income taxes	(74)	214	523	652	232
Net income (loss)	\$ (222)	\$ 927	\$ 55	\$ (1,172)	\$ (2,934)
Net income (loss) per share available for common shareholders:					
Basic	\$ (0.03)	\$ 0.10	\$ 0.01	\$ (0.15)	\$ (0.19)
Diluted	\$ (0.03)	\$ 0.10	\$ 0.01	\$ (0.15)	\$ (0.19)
Weighted-average shares outstanding:					
Basic	7,525	7,941	8,246	9,904	15,398
Diluted	7,525	8,354	8,701	9,904	15,398

[Table of Contents](#)

	December 31,				
	2003	2004	2005	2006	2007
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents	\$ 559	\$ 1,024	\$ 817	\$ 17,636	\$ 6,691
Marketable securities	—	—	—	13,182	16,198
Current assets	7,029	9,102	10,817	43,641	42,060
Total assets	16,894	20,501	25,068	56,963	61,151
Revolving line of credit and current portion of long-term debt	522	432	1,142	—	262
Current liabilities (excluding revolving line of credit and current portion of long-term debt)	2,977	3,374	3,953	5,378	10,077
Long-term liabilities	3,121	1,882	1,437	886	2,226
Total liabilities	6,620	5,688	6,532	6,264	12,565
Total stockholders' equity	10,274	14,813	18,536	50,699	48,586

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read this discussion together with our consolidated financial statements, the related notes to these financial statements, and other financial information included elsewhere in this Annual Report on Form 10-K. 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 addressed by our 14 current product lines exceeds \$1 billion and that the annual worldwide market for all peripheral vascular devices exceeds \$3 billion and is growing at 8 percent per year. 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. We currently manufacture all of our product lines in our Burlington, Massachusetts, headquarters with the exception of the LeverEdge Contrast Injector, that we acquired in April 2007 and the Vascular Architects products that we acquired in September 2007, for which the manufacturing is currently outsourced. In addition, our Albograft polyester graft product lines, which we acquired in December 2007, are manufactured at our facility in Brindisi, Italy.

Our products are used by vascular surgeons who treat peripheral vascular disease through both open surgical methods and more recently adopted 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 patients with a wider range of treatment options.

We believe that the purchasing volume of the vascular surgeon will increase and that the changing product needs of the vascular surgeon present us with attractive opportunities to sell new devices. As a result, we have sought out and acquired new products and businesses that address these needs, such as our acquisition of the contrast injector in April 2007, the remote endarterectomy suite of products in September 2007, our signing of a three-year distribution agreement as the exclusive distributor of the Endologix Powerlink System in 11 European countries, which commenced January 1, 2007, and the acquisition of a line of polyester vascular grafts in December 2007.

[Table of Contents](#)

In April 2007 we acquired the business, operations, and substantially all of the assets of Cardiovascular Innovations, LLC, which marketed a hand-powered contrast injector, called the LeverEdge Contrast Injector, for use in a variety of endovascular procedures. In September 2007, we acquired the business, operations and substantially all the of the assets of Vascular Architects, which marketed and sold devices for remote endarterectomy, a hybrid open/endovascular procedure for the minimally invasive removal of plaque, typically in the superficial femoral artery in the thigh. In December 2007 we acquired Biomateriali, S.r.l., a privately held Italian company that manufactures polyester prosthetic grafts for vessel replacement in the peripherals, abdomen, and thorax. Including these three acquisitions, we now offer 14 product lines across three product categories.

In October 2007 we reached an agreement to launch a direct sales force in Italy in January 2008. Prior to January 2008, we had sold our products in Italy through an exclusive distribution agreement with Serom Medical Technologies, Srl (Serom). We and Serom agreed in September 2007 to terminate Serom's exclusive rights as of January 25, 2008, in exchange for a termination fee of approximately \$1.1 million. Serom had previously held exclusive distribution rights in Italy from 1992 through the fourth quarter of 2007. This agreement is consistent with our strategy of going direct to the hospitals in our major markets.

In addition, effective January 1, 2007, we became the exclusive distributor for the Endologix Powerlink System, an abdominal stent graft, in 11 European countries, including Germany, France and the United Kingdom. We believe that this product complements our EndoFit Thoracic Stent Graft and UniFit Abdominal Stent Graft product lines, allowing our growing European sales force to offer a complete range of stent grafts for the entire aorta. Below is a listing of our product lines and product categories:

- Our **Endovascular & Dialysis Access** product category includes our EndoFit Thoracic Stent Graft, UniFit Abdominal Stent Graft, VascaTape Radiopaque Tape, AnastoClip Vessel Closure System, LeverEdge Contrast Injector, acquired in April 2007, and aSpire Covered Stent, acquired in September 2007. We also report the results of our distribution of the Endologix Powerlink System within this product category.
- Our **Vascular** product category includes our Expandable LeMaitre Valvulotome, Pruitt-Inahara and Pruitt F3 Carotid Shunts, InvisiGrip Vein Stripper, LeMaitre Balloon Catheters, and the five remote endarterectomy products acquired in September 2007, which include our Martin Dissector, Periscope, EndoHelix, MollRing Cutter, and Ring Dissector, and the Albograft line of polyester prosthetic grafts acquired in December 2007.
- Our **General Surgery** product category includes our Reddick Cholangiogram Catheter and OptiLock Implantable Port.

We evaluate the sales performance of our various product lines utilizing criteria that varies based upon the position of each product line in its expected life cycle. For established products, we typically review unit sales and selling prices. For faster growing products, we typically also focus upon new account generation and customer retention.

Our business opportunities include the following:

- the continued expansion of our sales force in North America, Europe and Japan;
- the addition of complementary products through further acquisitions;
- the updating of existing products and introduction of new products through research and development; and
- the introduction of our products in new markets upon obtainment of regulatory approvals in these markets.

We are currently pursuing each of these opportunities.

[Table of Contents](#)

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.

We sell our products primarily through a direct sales force. As of December 31, 2007, our sales force was comprised of 57 sales representatives in North America, the European Union and Japan; our sales force was comprised of 47 sales representatives as of December 31, 2006. We also sell our products through a network of distributors in various countries outside of the United States and Canada. Our worldwide headquarters are located in Burlington, Massachusetts. Our international operations are headquartered in Sulzbach, Germany. We also have sales offices located in Tokyo, Japan, and Rome, Italy, and a manufacturing facility in Brindisi, Italy. In 2007, approximately 90% of our net sales were generated through markets in which we employ direct sales representatives.

Approximately 39% of our net sales are denominated in currencies other than the U.S. dollar. Accordingly, our results of operations are influenced by changes in the currency exchange rates. Increases or decreases in the value of the U.S. dollar, as compared to other currencies in which our net sales are denominated, will directly affect our reported results as we translate those currencies into U.S. dollars for each fiscal period.

Further, our strategy for growing our business includes the acquisition of complementary product lines and companies and occasionally the discontinuance of products or activities that are no longer complementary. These actions may affect the comparability of our financial results from period to period and may cause substantial fluctuations period to period.

The following table indicates the impact of foreign currency fluctuations and changes to our business activities for each of our quarters during the three most recently completed fiscal years:

	2007				2006				2005			
	Dec	Sept	June	Mar	Dec	Sept	June	Mar	Dec	Sept	June	Mar
Total net sales	11,104	10,144	10,315	9,883	8,757	8,540	8,760	8,571	7,877	7,820	7,529	7,501
Impact of currency exchange rate fluctuations(1)	439	253	267	322	232	135	(1)	(287)	(266)	(3)	89	138
Net impact of acquisitions, distributed sales and discontinued products, excluding currency exchange rate fluctuations(2)	1,116	635	567	455	(252)	(383)	(107)	37	346	389	425	442

- (1) Represents the impact of the change in foreign exchange rates over the corresponding quarter of the prior year based on the weighted average exchange rate for each quarter.
- (2) Represents the impact of sales of products of acquired businesses and distributed sales of other manufacturers' products, net of sales related to discontinued products and other activities, measured based on 12 months' sales following the date of the event or transaction.

In January 2008 we were notified by one of our Biomateriali customers that they would no longer be purchasing a certain product line from us. This notification resulted in a write-down of the related inventory in the fourth quarter of 2007 of \$0.1 million. As a result of this development, we have determined that as of the date of the notification, related intangibles of \$0.4 million have been impaired and will be written off during the first quarter of 2008. In March 2008 we provided notice of an indemnity claim under the Biomateriali purchase agreement to the sellers of Biomateriali, contending that the sellers breached certain representations and

[Table of Contents](#)

warranties in the purchase agreement by failing to adequately disclose material information regarding a customer relationship. We have demanded the payment of damages of approximately \$0.5 million (denominated in Euros) and have ceased making certain post-closing payments to the sellers pending resolution of this indemnity claim. In addition, in January 2008 we initiated a plan to reorganize our worldwide operations and, as a result, incurred severance costs of \$0.4 million associated with the reduction of approximately 32 employees or 13% of our worldwide workforce.

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. 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 limited 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 selling and marketing expense consists primarily of salaries, commissions, travel and entertainment, attendance at medical society meetings, training programs, advertising and product promotions, direct mail, and other marketing costs.

General and administrative. General and administrative expense consists primarily of executive, finance and human resource expense, legal and accounting fees, information technology 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 and amortization of patents costs. It also includes costs associated with design and execution of clinical studies and regulatory submissions and costs to register, maintain, and defend our intellectual property.

Restructuring. Restructuring expense includes costs directly associated with closing plant facilities to consolidate our manufacturing operations and other moving expenses. These costs relate to distribution agreement termination expenses, lease termination expenses, severance, and retention costs for terminated employees, and other expenses associated with restructuring our operations.

Other income (expense). Other income (expense) primarily includes interest income and expense, foreign currency gains (losses), and other miscellaneous gains (losses).

Income tax expense. We are subject to federal and state income taxes for earnings generated in the U.S., which includes 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, and Japanese subsidiaries. Our consolidated tax expense is affected by the mix of our taxable income (loss) between the United States, Germany, France, Italy, 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, 2007, to the year ended December 31, 2006

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

	<u>2007</u>	<u>2006</u>	<u>Percent change</u>
		(\$ in thousands)	
Net sales	\$ 41,446	\$ 34,628	20%
Cost of sales	<u>10,739</u>	<u>9,367</u>	15%
Gross profit	30,707	25,261	22%
Operating expenses:			
Sales and marketing	19,443	15,183	28%
General and administrative	9,534	7,105	34%
Research and development	4,591	3,301	39%
Purchased research and development	373	—	100%
Restructuring charges	1,042	257	305%
Impairment charge	<u>7</u>	<u>94</u>	(93%)
Loss from operations	(4,283)	(679)	531%
Other income (expense):			
Interest income	1,299	299	334%
Interest expense	(1)	(296)	(100%)
Foreign currency gains	292	228	28%
Other income (expense), net	<u>(9)</u>	<u>(72)</u>	(88%)
Loss before income taxes	(2,702)	(520)	420%
Provision for income taxes	<u>232</u>	<u>652</u>	(64%)
Net loss	<u>\$ (2,934)</u>	<u>\$ (1,172)</u>	150%
Sales by product category:			
Endovascular & Dialysis	\$ 14,166	\$ 9,833	44%
Vascular	23,397	20,992	11%
General Surgery	<u>3,883</u>	<u>3,803</u>	2%
	<u>\$ 41,446</u>	<u>\$ 34,628</u>	20%
Sales by geography:			
United States and Canada	\$ 25,141	\$ 22,362	12%
Outside the United States and Canada	<u>16,305</u>	<u>12,266</u>	33%
	<u>\$ 41,446</u>	<u>\$ 34,628</u>	20%

Net sales. Net sales increased 20% to \$41.4 million in 2007 from \$34.6 million in 2006. Sales in our endovascular and dialysis access product category increased by 44%, while sales in our vascular and general surgery product categories grew by 11% and 2%, respectively, over the previous year. Increases were driven in part by higher average selling prices, the growth of our direct sales force, direct marketing efforts, the commencement of distribution of the Powerlink stent graft in Europe, the impact of foreign exchange fluctuations, and the acquisitions of the LeverEdge Contrast Injector, aSpire Stent, and EndoRE product lines.

Net sales by geography. Net sales in the United States and Canada increased 12% to \$25.1 million in 2007, as compared to \$22.4 million in 2006. The increase was driven primarily by increased average selling prices, the growth of our direct sales force, and the acquisitions of the LeverEdge Contrast Injector, aSpire Stent, and EndoRE product lines. Net sales outside of the United States and Canada increased 33% to \$16.3 million for

[Table of Contents](#)

2007 compared to \$12.3 million in 2006. The increase outside the United States and Canada was driven primarily by growth within our endovascular and dialysis access product category, which includes the Powerlink stent graft which we began selling in January 2007, and the impact of foreign currency fluctuations. Direct-to-hospital net sales represented 74% of the total net sales outside the United States and Canada in 2007, as compared to 64% in 2006.

Gross profit. Gross profit increased 22% to \$30.7 million in 2007 from \$25.3 million in 2006. This gross profit increase was driven primarily by greater net sales, higher average selling prices across several product categories, favorable foreign currency fluctuations, and cost savings resulting from improved operating efficiency in our Burlington, Massachusetts, facility. This improvement was partially offset by a \$0.1 million inventory charge in December 2007 related to the Biomateriali acquisition, as well as our distribution of the Powerlink stent graft, which we acquire at a cost that is greater as a percentage of average selling price than nearly all of our other product lines. Gross profit in 2006 was negatively impacted by a \$0.3 million inventory write-down related to our decision to cease the production and sale of our Expedial Vascular Access Graft product line. The total gross margin as a percentage of net sales was 74.1% in 2007, compared with 72.9% in 2006.

Sales and marketing. Sales and marketing expenses increased 28% to \$19.4 million in 2007, from \$15.2 million in 2006. This increase was driven primarily by the addition of sales professionals, their increased compensation, related taxes, benefits, and travel expenses. At the end of 2007, we employed 57 field sales representatives worldwide, as compared to 47 at the end of 2006.

General and administrative. General and administrative expense increased 34% to \$9.5 million in 2007 from \$7.1 million in 2006. The increase was primarily due to costs associated with being a public company including increased finance and legal staff, professional fees, and increased insurance expense.

Research and development. Research and development expense increased 39% to \$4.6 million in 2007 from \$3.3 million in 2006. This increase was primarily due to the hiring of research and development engineers and related product development expenses, focused largely on our endovascular and dialysis access product lines. We launched four new products in 2007, including the Pruitt F3 Carotid Shunt (January), the Flexcel Carotid Shunt (August), the TT Tortuous Tracker Delivery System (November), and the redesigned EndoFit Thoracic Stent Graft (December).

Restructuring. Restructuring expenses increased to approximately \$1.0 million in 2007 from approximately \$0.3 million in 2006. Expenses for 2007 include payments resulting from the termination of two former European distributors due to our decision to go direct in those countries. In addition, in February 2008 our former Italian distributor began providing us with market transition services, and we estimate that we will incur approximately \$0.6 million of related expense between February and July 2008. Expenses for 2006 include exit costs of \$0.2 million for our Phoenix, Arizona, facility, which closed in July 2006, and exit costs of \$31,000 for our Brymbo, Wales, facility, which closed in December 2005.

Purchased research and development. In conjunction with a technology acquisition in December 2007, we acquired in-process research and development with a fair value of \$0.4 million that was expensed on the date of acquisition, as the acquired technology had not yet reached technological feasibility and had no alternative future use to us at the date of acquisition. This treatment is consistent with the AICPA Practice Guide, *Assets Acquired in a Business Combination to be used in R&D Activities*.

Impairment charge. The impairment charge of \$0.1 million for 2006 resulted from the write-down of certain patents and production equipment in connection with our decision to cease production and sales of our Expedial Vascular Access Graft product line, net of the proceeds from the subsequent sale of those assets of \$0.4 million. We also wrote down \$0.3 million of related Expedial inventory, which has been included in cost of sales.

[Table of Contents](#)

Other income (expense). In 2007 interest income was \$1.3 million compared to \$0.3 million in 2006. The increase was due to a significant increase in cash on hand resulting from the proceeds of our initial public offering in October 2006. In 2007 interest expense decreased by \$0.3 million, as we used a portion of the proceeds from the initial public offering to pay down all outstanding indebtedness. Gain on foreign currency was due to a relative increase in the strength of the Euro as compared to the U.S. dollar. Other income (expense) for 2006 was primarily due to losses on the disposal of equipment in 2006.

Income tax expense

We recorded a provision for taxes in 2007 of \$0.2 million, despite losses before income taxes of \$2.7 million. This was the result of a number of factors, including taxes on profits of foreign subsidiaries, recovery of taxes paid by means of carry-back claims in excess of amounts previously recognized, deferred tax liabilities related to the amortization of goodwill for U.S. tax purposes, which cannot be used to reduce existing deferred tax assets, the tax effect of elimination of intercompany profit in inventory, and effects of changes in uncertain tax positions. We monitor the mix of profitability by tax jurisdiction and adjust our annual expected rate on a quarterly basis. While it is often difficult to predict the final outcome or the timing of resolution of any particular tax matter, we believe that the tax reserves reflect the probable outcome of known contingencies. Tax reserves established include transfer pricing, withholding taxes, and various state and foreign audit matters, some of which may be resolved in the near future resulting in an adjustment to the reserve, which includes the results of our foreign subsidiaries.

We provide a full valuation for net deferred tax assets, as we believe it is more likely than not that the future tax benefits from accumulated net operating losses and deferred taxes will not be realized. However, it is possible that the “more likely than not” criterion could be met at some time in the future, which could result in the reversal of a significant portion or all of the valuation allowance, which, at that time, would be recorded as a tax benefit in the consolidated statements of operations.

We adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—an Interpretation of FASB Statement No. 109*, (FIN 48) on January 1, 2007. This interpretation prescribes a comprehensive model for the financial statement recognition, measurement, presentation, and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. As a result of the implementation of FIN 48, we recognized no adjustment in the liability for unrecognized income tax benefits.

Results of Operations**Comparison of the year ended December 31, 2006, to the year ended December 31, 2005**

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

	<u>2006</u>	<u>2005</u>	<u>Percent change</u>
		(\$ in thousands)	
Net sales	\$ 34,628	\$ 30,727	13%
Cost of sales	9,367	8,927	5%
Gross profit	25,261	21,800	16%
Operating expenses:			
Sales and marketing	15,183	10,960	39%
General and administrative	7,105	6,405	11%
Research and development	3,301	3,015	9%
Restructuring charges	257	998	(74%)
Impairment charge	94	0	*
Income (loss) from operations	(679)	422	(261%)
Other income (expense):			
Interest income	299	4	*
Interest expense	(296)	(182)	63%
Foreign currency (loss) gain	228	(217)	(205%)
Other income (expense)	(72)	551	(113%)
Income (loss) before income taxes	(520)	578	(190%)
Provision for income taxes	652	523	25%
Net income (loss)	<u>\$ (1,172)</u>	<u>\$ 55</u>	<u>*</u>
Sales by product category:			
Endovascular & Dialysis	\$ 9,833	\$ 6,774	45%
Vascular	20,992	19,654	7%
General Surgery	3,803	3,600	6%
Branded Sales	34,628	30,028	15%
Private Label	0	699	*
	<u>\$ 34,628</u>	<u>\$ 30,727</u>	<u>13%</u>
Sales by geography:			
United States and Canada	\$ 22,362	\$ 20,056	11%
Outside the United States and Canada	12,266	10,671	15%
	<u>\$ 34,628</u>	<u>\$ 30,727</u>	<u>13%</u>

* Not a meaningful percentage relationship.

Net sales. Net sales increased 13% to \$34.6 million in 2006 from \$30.7 million in 2005. Sales in our endovascular and dialysis access product category increased by 45%, while sales in our vascular and general surgery product categories grew by 7% and 6%, respectively, over the same period in the previous year. Increases were driven by increased unit sales in the endovascular and dialysis access product category, the growth of our direct sales force, higher average selling prices across most product lines and an increase in direct marketing efforts. Sales in 2006 were reduced by the discontinuation of private label manufacturing activities and the Expedial Vascular Access Graft product line.

[Table of Contents](#)

Net sales by geography. Net sales in the United States and Canada increased 11% to \$22.4 million in 2006 compared to \$20.1 million in 2005. Net sales outside of the United States and Canada increased 15% to \$12.3 million for 2006 compared to \$10.7 million in 2005. Direct-to-hospital net sales represented 64% of the total net sales outside the United States and Canada in 2006, compared to 59% in 2005.

Gross profit. Gross profit increased 16% to \$25.3 million in 2006 from \$21.8 million in 2005. This gross profit increase was driven primarily by higher average selling prices across most product categories as well as cost savings resulting from the consolidation of manufacturing operations to our Burlington, Massachusetts, facility in 2005 and 2006. This gross profit increase was offset partially by a \$0.3 million inventory write-down related to our decision to cease the production and sale of our Expedial Vascular Access Graft product line in 2006.

Sales and marketing. Sales and marketing expenses increased 39% to \$15.2 million in 2006, from \$11.0 million in 2005. This increase was driven primarily by the addition of sales professionals in 2006, as well as an increase in marketing and advertising of our product lines primarily through direct mail, journal ads and trade shows. At the end of 2006, we employed 47 field sales representatives worldwide, as compared to 30 at the end of 2005.

General and administrative. General and administrative expense increased 11% to \$7.1 million in 2006 from \$6.4 million in 2005. The increase was driven primarily by the higher costs associated with being a public company, including increased finance and legal staff, professional fees and increased insurance expense. General and administrative expenses for 2005 included an accrual for sales tax exposure of \$0.2 million that did not occur in 2006, as well as \$0.2 million of general and administrative expenses related to our Phoenix, Arizona, and Brymbo, Wales, plants that were consolidated into the Burlington, Massachusetts, facility during 2005 and 2006.

Research and development. Research and development expense increased 9% to \$3.3 million in 2006 from \$3.0 million in 2005. This increase was mainly a result of higher regulatory costs related to the UniFit and EndoFit Aortic Stent Grafts, the hiring of product development engineers and the hiring of additional regulatory personnel.

Restructuring. Restructuring expenses decreased to approximately \$0.3 million in 2006 from approximately \$1.0 million in 2005. Expenses for 2006 included exit activity costs of \$0.2 million for our Phoenix, Arizona, facility that closed in July 2006 and exit costs of \$31,000 for our Brymbo, Wales, facility that closed in December 2005. Expenses for 2005 included exit costs for our St. Petersburg, Florida, Brymbo, Wales, and Neuilly-en-Thelle, France, facilities.

Impairment charge. Impairment charges amounted to \$0.1 million in 2006. We incurred no impairment charge in 2005. The impairment charge of \$0.1 million for 2006 resulted from the write-down of certain patents and production equipment in connection with our decision to cease production and sales of our Expedial Vascular Access Graft product line, net of the proceeds from the subsequent sale of those assets of \$0.4 million. We also wrote down \$0.3 million of related inventory, which has been included in cost of sales.

Other income (expense). For 2006 interest income was \$0.3 million compared to \$4,000 in 2005. The increase was due to a significant increase in cash on hand resulting from the proceeds of our initial public offering in October 2006. Interest expense in 2006 increased by \$0.1 million compared to 2005 due to an increase in our outstanding line of credit and term notes payable for the period prior to the initial public offering. Gain on foreign currency was due to a relative increase in the strength of the Euro as compared to the U.S. dollar. Other income (expense) for 2006 was primarily due to losses on the disposal of equipment in 2006, while 2005 amounts were largely due to the foreign exchange gain of \$0.6 million that we recognized as a result of the dissolution of our French subsidiary.

[Table of Contents](#)

Income tax expense. We are subject to income taxes in various jurisdictions. Significant judgment is required in determining our worldwide provision for income taxes. The 2007 tax provision was significantly different than that based on the federal statutory rate of 34% as a result of several factors, including taxes on profits of foreign subsidiaries, recovery of taxes paid by means of carry-back claims in excess of amounts previously recognized, deferred tax liabilities related to the amortization of goodwill for U.S. tax purposes, which cannot be used to reduce existing deferred tax assets, the tax effect of elimination of intercompany profit in inventory, and the effects of changes in uncertain tax positions. We monitor the mix of profitability by tax jurisdiction and adjust our annual expected rate on a quarterly basis. While it is often difficult to predict the final outcome or the timing of resolution of any particular tax matter, we believe that the tax reserves reflect the probable outcome of known contingencies. Tax reserves established include transfer pricing, withholding taxes, and various state and foreign audit matters, some of which may be resolved in the near future resulting in an adjustment to the reserve, which includes the results of our foreign subsidiaries. Our provision for income taxes in 2006 was \$0.7 million compared to \$0.5 million in 2005.

Liquidity and Capital Resources

At December 31, 2007, our cash and cash equivalents and marketable securities were \$22.9 million as compared to \$30.8 million at December 31, 2006. Our cash and cash equivalents are highly liquid investments with maturities of 90 days or less at the date of purchase and consist of time deposits and investments in money market funds with commercial banks and financial institutions and U.S. government obligations and are stated at cost, which approximates fair value. Our marketable securities are primarily marketable debt securities, commercial paper, corporate bonds, and U.S. government securities that we classify as available-for-sale and are carried at fair market value. We did not hold any auction-rated securities in our investment portfolio as of December 31, 2007.

The majority of our marketable securities have remaining maturities of two years or less. Our investment portfolio includes \$5.2 million of asset-backed securities collateralized by first-lien mortgages, credit card debt, and auto loans. In the event of a temporary decline in market value, we have the intent and ability to hold our debt investments for a sufficient period of time to allow for recovery of the principal amounts invested. We continually monitor the credit risk in our portfolio and attempt to mitigate our credit and interest rate exposures. We intend to continue to closely monitor future developments in the credit markets and make appropriate changes to our investment policy as necessary. Based on our ability to liquidate our investment portfolio, we do not anticipate any liquidity constraints as a result of the current credit environment.

We require cash to pay our operating expenses, make capital expenditures, and pay our long-term liabilities. Since our inception, we have funded our operations through private placements of equity securities, short-term borrowings, and funds generated from our operations. In October 2006 we completed our initial public offering of our common stock at a price to the public of \$7.00 per share. We sold 5,500,000 shares and received aggregate net proceeds of approximately \$35.8 million, after deducting underwriting discounts and commission of approximately \$2.7 million. We also incurred approximately \$3.0 million of additional expenses associated with our initial public offering of which we had paid approximately \$1.8 million prior to completing our initial public offering.

Of the \$35.8 million of net proceeds we received in our initial public offering, we have spent \$12.9 million, including \$3.9 million to pay down all outstanding indebtedness under two term loans and a revolving line of credit, \$1.2 million for payment of expenses related to our initial public offering, \$5.1 million for acquisitions, \$1.1 million for the early termination of our Italian distributor, and \$0.7 million for the acquisition and licensing of technology (of which \$0.4 million was expensed on the date of acquisition as in-process research and development). We expect our cash balances to decrease as we continue to use cash to fund our operations, make acquisitions, and make deferred payments related to prior acquisitions.

In August 2007 we amended our revolving line of credit with our bank. As a result of this amendment, our borrowing capacity increased to \$10 million and the maximum principal amount of any letters of credit issued as

[Table of Contents](#)

part of this facility increased to \$3 million. The maturity date for amounts borrowed was extended to August 2008. Loans made under this revolving line of credit bear interest rates at LIBOR plus 200 basis points or the bank's base rate, at our discretion. Borrowings under this line of credit are collateralized by substantially all of our assets. As of December 31, 2007, we had no borrowing outstanding under this line of credit. The loan agreement requires that we meet certain financial and operating covenants. As of December 31 2007, we were in compliance with these covenants.

Net cash used in operating activities. Net cash used in operating activities was \$1.8 million in 2007 and consisted of the \$2.9 million net loss adjusted for non-cash related items of \$3.1 million, including depreciation and amortization of \$1.4 million, stock-based compensation of \$0.6 million, deferred income taxes of \$0.6 million, provision for losses in accounts receivable of \$0.2 million, and inventory write-offs of \$0.5 million partially offset by accretion of discount on marketable securities of \$0.2 million, and net cash used from changes in operating assets and liabilities of \$2.0 million. The net cash used from changes in operating assets and liabilities was primarily a result of higher levels in inventory, accounts receivable, and prepaid expenses and other assets, partially offset by higher levels of accounts payable and other liabilities.

Net cash used in investing activities. Net cash used in investing activities was \$9.2 million in 2007. This was primarily due to the payment of \$5.1 million for the acquisitions that were completed in 2007: Biomateriali S.r.l., substantially all of the assets of The Wallace Enterprises, Inc., d/b/a Vascular Architects, and Cardiovascular Innovations, LLC, as well as \$0.5 million for the acquisition of technology from Arizona Heart Innovative Technologies, LLC., of which \$0.4 million was in-process research and development that was expensed on the date of acquisition. These acquisitions entail remaining non-contingent deferred purchase price obligations of approximately \$1.6 million.

Net cash provided by financing activities. Net cash provided by financing activities was \$10,000 in 2007. This was primarily due to proceeds from the issuance of common stock pursuant to the exercise of common stock options and the employee stock purchase plan, partially offset by expenses that we paid in 2007 associated with our 2006 initial public offering and the repurchase of our common stock.

We expect that our operating expenses will increase in absolute dollars in connection with the growth of our business and our operations as a public company, including consulting expenses associated with compliance with Section 404 of the Sarbanes-Oxley Act of 2002. We expect to fund these increased costs and expenditures from our cash flows from operations and our existing cash, cash equivalents, and marketable securities. However, our future capital requirements depend on numerous forward-looking factors. These factors include, but are not limited to, the following: the revenues generated by sales of our products; the costs associated with expanding our manufacturing, marketing, sales and distribution efforts; the rate of progress and cost of our research and development activities; patent litigation; the costs of obtaining and maintaining FDA and other regulatory clearances of our products and products in development; the effects of competing technological and market developments; the costs associated with being a public company, including consulting expenses associated with compliance with Section 404 of the Sarbanes-Oxley Act of 2002; and the number and timing of future acquisitions and other strategic transactions.

We believe that our current cash, cash equivalents, and marketable securities, the cash we expect to generate from operations as well as the available \$10 million line of credit with our bank, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months. However, we may require additional funds in order to make acquisitions. We may seek financing of future cash needs through the sale of equity securities and debt. We cannot assure you that additional financing will be available when needed or that, if available, such financing will be at terms favorable to us or our stockholders. Insufficient funds may require us to delay, scale back, or eliminate some or all of our business operations or may adversely affect our ability to operate as a going concern. If additional funds are obtained by issuing equity or debt securities, substantial dilution to existing stockholders may result.

Contractual obligations. Our principal contractual obligations consist of operating leases, termination costs to our former distributors, acquisition-related obligations, inventory purchase commitments, and income tax

[Table of Contents](#)

obligations under FIN 48 for unrecognized tax benefits. The following table summarizes our commitments to settle contractual obligations as of December 31, 2007:

<u>Contractual obligations</u>	<u>Total</u>	<u>Less than 1 year</u>	<u>1-3 years</u>	<u>3-5 years</u>
		(in thousands)		
Operating leases	\$ 1,717	\$ 964	\$ 724	\$ 29
Fees for termination of distributors	1,129	1,129	—	—
Purchase commitments for inventory	6,508	2,990	3,518	—
Acquisition-related obligations	3,765	873	684	2,208
FIN48 unrecognized tax benefits	28	28	—	—
Total contractual obligations	<u>\$13,147</u>	<u>\$5,984</u>	<u>\$4,926</u>	<u>\$2,237</u>

The commitments under our operating leases shown above consist primarily of lease payments for our Burlington, Massachusetts, corporate headquarters and manufacturing facility and a separate manufacturing and storage facility in Burlington, Massachusetts, each expiring in 2009; our Sulzbach, Germany office, expiring in 2010; and our Tokyo, Japan office, expiring in 2010.

In addition, there are potential contingent payments associated with the Biomateriali stock purchase agreement and product distribution agreement that could not be resolved beyond reasonable doubt as of December 31, 2007. These contingent payments could total up to \$2.2 million (based upon the exchange rates in effect on December 31, 2007). Due to the uncertainty of the future payouts, they have not been recorded as part of the purchase price for Biomateriali. When the contingencies are resolved, they may result in recognition of an additional cost and the purchase price will be adjusted at that time. The initial purchase price before including any contingent consideration is less than the sum of the fair value assigned to the assets acquired and the liabilities assumed (the excess). Therefore, in accordance with the guidance with SFAS No. 141, we have established a liability for the difference between the consideration recognized as of December 31, 2007, and the fair value of the net assets acquired. When the contingencies amounting to approximately \$2.2 million are resolved, any excess of the fair value of the contingent payments over the amount \$0.1 million that was recognized as if it were a liability will be recognized as an additional cost of the Biomateriali acquisition. If the amount initially recognized as if it were a liability exceeds the fair value of the contingent payments made, the excess will be allocated as a pro rata reduction of the amounts initially assigned to the identifiable intangible assets acquired in accordance with the guidance in SFAS No. 141.

Subsequent Events

In January 2008 we were notified by one of our Biomateriali customers that they would no longer be purchasing a certain product line from us. This notification resulted in a write-down of the related inventory in December 2007 of \$0.1 million. As a result of this development, we have determined that as of the date of the notification, related intangibles of \$0.4 million have been impaired and will be written off during the first quarter of 2008. In March 2008 we provided notice of an indemnity claim under the Biomateriali purchase agreement to the sellers of Biomateriali, contending that the sellers breached certain representations and warranties in the purchase agreement by failing to adequately disclose material information regarding a customer relationship. We have demanded the payment of damages of approximately \$0.5 million (denominated in Euros) and have ceased making certain post-closing payments to the sellers pending resolution of this indemnity claim.

In January 2008 we initiated a plan to reorganize our worldwide operations and, as a result, incurred severance costs of \$0.4 million associated with the reduction of approximately 32 employees or 13% of our worldwide workforce.

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, or U.S. GAAP. Our most significant accounting policies are

[Table of Contents](#)

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 U.S. 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, observance of trends in the industry, and information provided by physicians who use our products and information available from other outside sources, 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

We recognize revenue in accordance with SEC Staff Accounting Bulletin, or SAB, No. 104, *Revenue Recognition*. SAB No. 104 requires that four basic criteria must be met before revenue can be recognized: (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) collectibility is reasonably assured. We generally use customer purchase orders or contracts to determine the existence of an arrangement. Substantially all 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 probable, 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 in accordance with Statement of Financial Accounting Standards, or SFAS, No. 48, *Revenue Recognition When Right of Return Exists*, based on our historical return product history.

Accounts Receivable

Our accounts receivable are with customers based in the U.S. and internationally. Accounts receivable generally are due within 30 to 60 days of invoice and are stated at amounts due from customers, net of an allowance for doubtful accounts and sales returns. 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 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

[Table of Contents](#)

our existing accounts receivable. We review our allowance for doubtful accounts on a monthly basis and all past due balances are reviewed individually for collectibility. The provision for the allowance for doubtful accounts is recorded in general and administrative expenses.

Inventory

Inventory consists of finished products, work-in-process, and raw materials. We value inventory at the lower of cost or market value. Cost includes materials, labor, and manufacturing overhead and is determined using the first-in, first-out (FIFO) method. On a quarterly basis, we review inventory quantities on hand and analyze the provision for excess and obsolete inventory based primarily on product expiration dating and our estimated sales forecast, which is based on sales history and anticipated future demand. Our estimates of future product demand may not be accurate, and we may understate or overstate the provision required for excess and obsolete inventory. Accordingly, any significant unanticipated changes in demand could have a significant impact on the value of our inventory and results of operations.

Stock-based Compensation

Through December 31, 2005, we measured employee stock-based compensation expense using the intrinsic value-based method of accounting prescribed by Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, Financial Accounting Standards Board, or FASB, Interpretation No., or FIN, 44, *Accounting for Certain Transactions Involving Stock Compensation*, and related interpretations. For stock options granted to employees, no compensation expense was recognized unless the exercise price was less than the estimated fair value, for financial reporting purposes.

Until January 1, 2006, we complied with the disclosure requirements of SFAS No. 123, *Accounting for Stock-Based Compensation*, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure—an amendment of FASB Statement No. 123*, which required that we disclose our pro forma net income or loss and net income or loss per common share as if we had expensed the fair value of employee stock options. For purposes of this pro forma disclosure, we estimated the fair value of stock options issued to employees using the minimum value valuation option-pricing model. Our minimum value valuation option-pricing model required the input of highly subjective assumptions, including the expected life of these options and our expected stock price volatility. Therefore, the estimated fair value of our employee stock options could vary significantly as a result of changes in the assumptions used. Our use of the minimum value model was primarily due to our determination as to its appropriateness as well as its general acceptance as an option valuation technique for private companies. As described below, we no longer utilize the minimum value method subsequent to January 1, 2006, and the fair value of our options will be higher as a result.

Through December 31, 2007, we accounted for stock-based compensation expense for non-employees using the fair value method prescribed by SFAS No. 123, as continued by SFAS 123(R) and the Black-Scholes option-pricing model, and record the fair value, for financial reporting purposes, of non-employee stock options as an expense over either the vesting term of the option or the service period.

In December 2004, FASB issued SFAS No. 123(R), *Share-Based Payment*, which requires companies to expense the fair value of employee stock options and other forms of share-based compensation. Effective January 1, 2006, we adopted SFAS No. 123(R). SFAS No. 123(R) requires nonpublic companies that used the minimum value method in SFAS No. 123 for either recognition or pro forma disclosures to apply SFAS No. 123(R) using the prospective-transition method. As such, we will continue to apply APB 25 in future periods to equity awards outstanding at the date of SFAS No. 123(R)'s adoption that were measured using the minimum value method. In accordance with this standard, the prior period pro forma stock information has not been restated. In accordance with SFAS No. 123(R), we recognize the compensation cost of share-based awards on a straight-line basis over the vesting period of the award. For the year ended December 31, 2007, we recorded expense of approximately \$0.6 million in connection with share-based payment awards. The future expense of non-vested options of approximately \$1.8 million is to be recognized over a weighted-average period of 3.2 years.

[Table of Contents](#)

In 1997, we issued stock options to two of our executive officers for the purchase of an aggregate of 386,272 shares and to one of these executive officers an award of an additional 252,852 shares of our common stock. The options and award were subject to restricted stock agreements that provided us the right to purchase, and the executive officers with the right to cause us to purchase, these shares. The purchase right features of these agreements terminated upon the completion of our initial public offering in October 2006. We accounted for these options and award until 1998 using variable plan accounting since the exercise of the employee repurchase price was considered likely based on the lack of marketability of our common stock. After reviewing a variety of factors, we subsequently determined that the likelihood of either us or these executive officers exercising these purchase options was remote. Consequently, subsequent to 1998 we have accounted for these options and award using fixed plan accounting. See the notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Upon adoption of SFAS No. 123(R), based on the use of the prospective method of adoption, these options and this award will continue to be accounted for under APB No. 25 as fixed plan arrangements. Concurrently with the adoption of SFAS No. 123(R), we applied the guidance included in Accounting Series Release No. 268 and Emerging Issues Task Force No. D-98 with respect to the redemption feature related to these options and award. The effect of the adoption resulted in the classification of the intrinsic value of the redemption feature of \$6.5 million at January 1, 2006, from retained earnings to other than permanent equity. During 2006, the value of the redemption feature increased by \$0.3 million to \$6.8 million, which was charged against retained earnings. The repurchase and call right features terminated upon the completion of our public offering of our common stock resulting in a \$6.8 million credit to additional paid-in capital.

Prior to our initial public offering there was no public market for our common stock, and in connection with our issuance of stock options the fair value for our common stock was estimated by our board of directors, with input from management. Our board of directors exercised judgment in determining the estimated fair value of our common stock on the date of grant based on several factors, including transactions in our common stock, key milestones achieved in our business, and both historical and forecasted net sales. In the absence of a contemporaneous arms-length transaction, our board typically estimated the fair value of our common stock based upon an enterprise valuation determined by multiplying our trailing six months of net sales by two, and then multiplying that amount by four. We believed this to be a reasonable methodology based upon our internal peer company analyses and based on several arms-length transactions involving our common stock supportive of the results produced by this valuation methodology. We have not historically obtained contemporaneous valuations by an unrelated valuation specialist because, at the time of the issuances of stock options, we believed our estimates of the fair value of our common stock to be reasonable and consistent with our understanding of how similarly situated companies in our industry are valued.

As disclosed more fully in the notes of our financial statements, during 2007 we granted stock options at an exercise price of \$6.10 and restricted stock units with fair value prices ranging from \$5.74 to \$7.49.

In connection with the preparation of our financial statements for the year ended December 31, 2005, and in preparing for the initial public offering of our common stock, we reassessed the valuations of our common stock during the 12-month period ended March 31, 2006, in light of the AICPA's Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, which we refer to as the practice aid. In conducting this assessment we took into consideration the market and income approaches to valuation as set forth in the practice aid. We believe that the valuation methodologies that we used prior to this public offering are consistent with the practice aid. Based on the foregoing analysis, we concluded that for all options granted during the 12-month period ended March 31, 2006, in no case did the fair value of our common stock, for financial reporting purposes, exceed the exercise price for these options at the time of grant.

Valuation of Goodwill, Other Intangibles

When we acquire another company, the purchase price is allocated, as applicable, among acquired tangible net assets, identifiable intangible assets, and goodwill as required by U.S. GAAP. Goodwill represents the excess

[Table of Contents](#)

of the aggregate purchase price over the fair value of net assets of the acquired businesses. Goodwill is tested for impairment annually or more frequently if changes in circumstance or the occurrence of events suggest impairment exists. We evaluate the December 31 balance of the carrying value of goodwill based on a single reporting unit annually and more frequently if certain indicators are present or changes in circumstances suggest that impairment may exist. The first step of our goodwill impairment test, used to identify potential impairment, compares the fair value of our reporting unit with its carrying amount, including goodwill. If the fair value of our reporting unit exceeds its carrying amount, the goodwill of the reporting unit is considered not impaired, and thus the second step of the impairment test, used to measure the amount of the impairment loss, is unnecessary. If the carrying amount of our reporting unit exceeds its fair value, the second step of the goodwill impairment test is performed to measure the amount of impairment loss, if any. The second step of the goodwill impairment test, used to measure the amount of impairment loss, compares the implied fair value of the reporting unit goodwill as of the date of the impairment review with the carrying amount of that goodwill. The implied fair value of our goodwill is determined on the same basis as the amount of goodwill recognized in connection with a business combination. Specifically, we allocate the fair value of our reporting unit to all of the assets and liabilities of that unit (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 impairment charges were required during the year ended December 31, 2007. The test for impairment requires us to make several estimates about fair value, principally related to the determination that we operate as a single unit and therefore that fair value is based on the our market capitalization. Our estimates associated with the goodwill impairment tests are considered critical due to the amount of goodwill recorded on our combined consolidated balance sheets and the judgment required in determining fair value amounts. Goodwill was \$8.9 million as of December 31, 2006, and \$10.9 million as of December 31, 2007.

Other intangible assets consist primarily of purchased developed technology, patents, customer relationships, and trademarks and are amortized over their estimated useful lives, ranging from five to 17 years. We review these intangible assets for impairment as changes in circumstance or the occurrence of events suggest the remaining value may not be recoverable. Other intangible assets, net of accumulated amortization, were \$1.9 million as of December 31, 2006, and \$3.9 million as of December 31, 2007.

The evaluation of asset impairments related to other intangible assets requires us to make assumptions about future cash flows over the life of the asset being evaluated. These assumptions require significant judgment and actual results may differ from assumed or estimated amounts.

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 costs we anticipate incurring in connection with litigation and claims against us when we can reasonably estimate these costs. During the years ended December 31, 2005, 2006, and 2007, 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 shutdowns of specific sites. These restructuring charges, which reflect our commitment

[Table of Contents](#)

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.

Accounting for Income Taxes

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

We adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—an Interpretation of FASB Statement No. 109*, (FIN 48) on January 1, 2007. FIN 48 clarifies the accounting and reporting for uncertainties in income tax law. This interpretation prescribes a comprehensive model for the financial statement recognition, measurement, presentation, and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. As a result of the implementation of FIN 48, we recognized no adjustment in the liability for unrecognized income tax benefits.

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 \$2.5 million in 2007 and \$1.1 million in 2006.

Marketable Securities

We account for our investments in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. Our investments, primarily marketable debt securities, commercial paper, and U.S. government securities, are classified as available-for-sale and are carried at fair market value at December 31, 2007. The unrealized gains (losses) on available-for-sale securities are recorded in accumulated other comprehensive income (loss). We consider all highly liquid investments with original maturities of 90 days or less at the time of purchase to be cash equivalents, and investments with original maturities of greater than 90 days to be short-term investments.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of December 31, 2007. 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.

Recent Accounting Pronouncements

In September 2006 the FASB issued SFAS No. 157, *Fair Value Measurement*. SFAS No. 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors' requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 applied whenever other standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We are currently evaluating the effect that the adoption of SFAS No. 157 will have on our consolidated results and financial position.

In February 2007 the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities—Including an Amendment of FASB Statement No. 115*. SFAS No. 159 expands the use of fair value accounting but does not affect existing standards that require assets or liabilities to be carried at fair value. Under SFAS No. 159 a company may elect to use fair value to measure many financial instruments and certain other items at fair value. If the use of fair value is elected, any upfront costs and fees related to the item must be recognized in earnings and cannot be deferred, such as debt issuance costs. The fair value election is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to measure based on fair value. At the adoption date, unrealized gains and losses on existing items for which fair value has been elected are reported as a cumulative adjustment to beginning retained earnings. Subsequent to the adoption of SFAS No. 159, changes in fair value are recognized in earnings. Most of the provisions in SFAS No. 159 are elective; however, the amendment to SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, applies to all entities with available-for-sale and trading securities. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. We are currently evaluating the impact this adoption will have on our consolidated financial statements.

In June 2007 the FASB ratified the consensus reached on Emerging Issues Task Force (EITF) Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* (EITF 07-3). EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as expense as the goods are delivered or the related services are performed. EITF 07-3 will be effective on a prospective basis for fiscal years beginning after December 15, 2007, and will be adopted by us in the first quarter of 2008. We do not expect that the adoption of EITF 07-3 will have a material effect on our consolidated results of operations and financial condition.

In December 2007 the FASB issued SFAS No. 141 (revised 2007), *Business Combinations*, (SFAS No.141(R)). SFAS No. 141(R) establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired. SFAS No. 141(R) also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS No. 141(R) is effective for fiscal years beginning after December 15, 2008, and will be adopted by us in the first quarter of 2009. We are currently evaluating the potential impact, if any, of the adoption of SFAS No. 141(R) on our consolidated results of operations and financial condition.

In December 2007 the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements—an amendment of Accounting Research Bulletin No. 51*. SFAS 160 establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent's ownership interest, and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. SFAS 160 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS 160 is effective for fiscal years beginning after December 15, 2008, and will be adopted by us in the first quarter of 2009. We do not expect the adoption of SFAS 160 will have a material effect on our consolidated results of operations and financial condition.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to various market risks arising from adverse changes in market rates and prices, such as foreign exchange fluctuations and interest rates, which could impact our results of operations and financial position. We do not currently engage in any hedging or other market risk management tools, and we do not enter into derivatives or other financial instruments for trading or speculative purposes.

Foreign Currency Exchange Rate Risk. Fluctuations in the rate of exchange between the U.S. dollar and foreign currencies, primarily the Euro, could adversely affect our financial results. In addition, for the year ended December 31, 2007, approximately 41% of our sales were denominated in foreign currencies. Certain payments related to recent acquisitions are denominated in foreign currencies and certain of our products, namely the EndoRE devices, aSpire Covered Stent, and the Albograft Vascular Graft, are manufactured outside of the United States. We expect that foreign currencies will continue to represent a similarly significant percentage of our sales in the future. Selling, marketing, and administrative costs related to these sales are largely denominated in the same respective currencies, thereby mitigating our transaction risk exposure. Therefore, we believe that the risk of a significant impact on our operating income from foreign currency fluctuations is not substantial. However, for sales not denominated in U.S. dollars, 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 and if we price our products in the foreign currency, we will receive less in U.S. dollars than we did before the rate increase went into effect.

The majority of sales recorded in foreign currencies are denominated in the Euro. Our principal exchange rate risk therefore exists between the U.S. dollar and the Euro. Fluctuations from the beginning to the end of any given reporting period result in the re-measurement of our foreign currency-denominated receivables and payables, generating currency transaction gains or losses that impact our non-operating income/expense levels in the respective period and are reported in other (income) expense, net in our consolidated financial statements. We recorded a \$0.2 million foreign currency gain in 2006 and \$0.3 million foreign currency loss in 2007 related mainly to the re-measurement of our foreign currency-denominated receivables and payables. We do not currently hedge our exposure to foreign currency exchange rate fluctuations. We may, however, hedge such exposure to foreign currency exchange rate fluctuations in the future.

Interest Rate Risk. Our exposure to interest rate risk at December 31, 2007, is related primarily to our investment portfolio. Our investment portfolio includes fixed rate debt instruments of U.S. government and corporate issuers and is primarily short-term investments. The primary objective of our investments in debt instruments is to preserve principal while maximizing yields. A change in prevailing interest rates may cause the fair value of our investments to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing rate rises, the fair value of the principal amount of our investment will probably decline. To minimize this risk, investments are generally held to maturity. Due to the short-term nature of these investments, we believe we have no material exposure to interest rate risk arising from our investments.

Credit Risk. In addition, to a decline in interest rates, other economic variables, such as equity market fluctuations and changes in relative credit risk, could result in a higher decline in our investment portfolio. The majority of our marketable securities have remaining maturities of two years or less. Our investment portfolio includes \$5.1 million of asset-back securities collateralized by first-lien mortgages, credit card debt, and auto loans. We did not hold any auction-rated securities in our investment portfolio as of December 31, 2007. In the event of a temporary decline in market value, we have the intent and ability to hold our debt investments for a sufficient period of time to allow for recovery of the principal amounts invested. We continually monitor the credit risk in our portfolio and mitigate our credit and interest rate exposures in accordance with our policies. We intend to continue to closely monitor future developments in the credit markets and make appropriate changes to our investment policy as deemed necessary. Based on our ability to liquidate our investment portfolio we do not anticipate any liquidity constraints as a result of the current credit environment.

[Table of Contents](#)

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

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in reports we file or submit under the Securities and Exchange Act of 1934 is processed, summarized, and reported within the time periods specified in the SEC's rules and forms. As of December 31, 2007, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Due to the identification of a material weakness in internal control over financial reporting with respect to certain accruals and the related reconciliation and review process of the financial statement close process, as described below, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2007, our disclosure controls and procedures were not effective.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15(d)-15(f) under the Securities Exchange Act of 1934, as amended, as a process designed by, or under the supervision of our Chief Executive and Chief Financial Officers and effected by our board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and disposition of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

On December 20, 2007, we acquired all of the stock of Biomateriali S.r.l. (Biomateriali), a privately held Italian company that manufactures Dacron grafts for use in open abdominal aortic aneurysm and peripheral vascular procedures. Our consolidated financial statements include the operating results for Biomateriali from the date of acquisition. Upon consideration of the date of the acquisition, and the time constraints under which our management's evaluation would have to be made, our management determined that it would not be possible to conduct a sufficiently comprehensive evaluation of the acquired business' internal controls over financial reporting. Accordingly, these operations have been excluded from the scope of management's assessment of

[Table of Contents](#)

internal controls. Our consolidated sales for the year ended December 31, 2007, were \$41.4 million of which the results of Biomateriali were approximately \$1,000. Our consolidated total assets as of December 31, 2007, were \$61.2 million of which Biomateriali represented \$5.2 million, including \$1.2 million of identifiable intangible assets resulting from the acquisition.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2007. In conducting this evaluation, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), in *Internal Control—Integrated Framework*.

Based upon this evaluation, we concluded that we did not maintain effective internal control over financial reporting as of December 31, 2007, as a result of a material weakness in controls regarding the determination of certain accruals and related inadequate reconciliation and review procedures of the financial statement close process. This was principally due to inadequate oversight of the estimation and reconciliation process because of accounting staff turnover in December 2007. A material weakness in internal control over financial reporting is a significant deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected by employees on a timely basis in the normal course of their assigned functions. As a result of this material weakness, post-closing adjustments affecting accruals, cost of sales, research and development, and general and administrative expense were recorded. We have instituted, and are continuing to institute, remedial action to ensure that the controls in the financial statement close process regarding accruals and the related estimation, reconciliation, and review process have been strengthened such that a material misstatement of the Company's annual and interim consolidated financial statements is not reasonably possible. More specifically, we have hired, and are continuing to hire, new finance personnel and are providing additional training for our current finance personnel.

However, notwithstanding the material weakness discussed above, our Chief Executive Officer and Chief Financial Officer have concluded that the consolidated financial statements included in this Form 10-K present fairly, in all material respects, our financial position, results of operations, and cash flows for the periods presented in conformity with U.S. generally accepted accounting principles.

This Annual Report on Form 10-K does not include an attestation report of our registered independent public accounting firm regarding internal control over financial reporting pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only management's report on internal controls in this Annual Report on Form 10-K.

Pursuant to Item 308T 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

We have instituted and are continuing to institute remedial action to ensure the effectiveness of controls in the financial statement close process regarding accruals and the related estimation, reconciliation, and review process including hiring and providing additional training for our current finance personnel.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item concerning our directors and executive officers is incorporated by reference herein from the information to be contained in our 2008 definitive proxy statement (the "2008 Definitive Proxy Statement") for the 2008 annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days after the year ended December 31, 2007.

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 2008 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 required by this item concerning executive compensation is incorporated herein by reference from the information to be contained in the 2008 Definitive Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item concerning security ownership of certain beneficial owners and management is incorporated herein by reference from the information to be contained in the 2008 Definitive Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item concerning certain relationships and related transactions and director independence is incorporated herein by reference from the information to be contained in the 2008 Definitive Proxy Statement.

Item 14. Principal Accounting Fees and Services

The information required by this item concerning principal accounting fees and services is incorporated herein by reference from the information to be contained in the 2008 Definitive Proxy Statement.

PART IV

Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K

a) Documents filed as part of this Report.

- (1) The following consolidated financial statements are filed herewith in Item 8 of Part II above.
 - (i) Report of Independent Registered Public Accounting Firm
 - (ii) Consolidated Balance Sheets
 - (iii) Consolidated Statements of Operations
 - (iv) Consolidated Statements of Changes in Stockholders' Equity and Comprehensive Income (Loss)
 - (v) Consolidated Statements of Cash Flows
 - (vi) Notes to Consolidated Financial Statements

(2) Financial Statement Schedules

Schedule II—Valuation and Qualifying Accounts. Such schedule should be read in conjunction with the consolidated financial statements. All other supplemental schedules are omitted because of the absence of conditions under which they are required.

(3) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
3.1(1)	Amended and Restated By-laws of the Registrant
3.2(1)	Form of Amended and Restated Certificate of Incorporation of the Registrant
3.3(1)	Form of Second Amended and Restated Certificate of Incorporation of the Registrant
4.1(1)	Specimen Certificate evidencing shares of common stock
10.1(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
10.2(1)	Registration Rights Agreement dated June 17, 1998, by and between the Registrant and Housatonic Equity Investors, L.P.
10.3(1)	Patent Sublicense Agreement dated March 7, 2003, by and between IMPRA, Inc. and Endomed, Inc.
10.4(1)	Confirmation and Agreement dated February 2, 2005, by and between the Registrant and Bard Peripheral Vascular, Inc.
10.5(1)	License Agreement dated February 11, 1992, by and between United States Surgical Corporation and Spinnaker R&D Associates, as amended
10.6(1)	Side Letter Agreement dated January 30, 2004, by and between the Registrant and Spinnaker R&D Associates
10.7†(1)	Executive Retention and Severance Agreement dated October 10, 2005, by and between the Registrant and George W. LeMaitre
10.8†(1)	Executive Service Agreement dated September 17, 2003, by and between the Registrant and Peter Gebauer, as amended
10.9†(1)	Employment Agreement dated May 27, 2005, by and between the Registrant and Kevin Kelly
10.10†(1)	Employment Agreement dated April 20, 2006, by and between the Registrant and Joseph P. Pellegrino (corrected)

[Table of Contents](#)

<u>Exhibit Number</u>	<u>Description</u>
10.11†(1)	1997 Stock Option Plan and form of agreements thereunder
10.12†(1)	1998 Stock Option Plan and form of agreements thereunder
10.13†(1)	2000 Stock Option Plan and form of agreements thereunder
10.14†(1)	2004 Stock Option Plan and form of agreements thereunder
10.15†(1)	2006 Stock Option and Incentive Plan and form of agreements thereunder
10.16†(1)	2006 Employee Stock Purchase Plan
10.17(1)	Form of Indemnification Agreement between the Registrant and its directors and executive officers
10.22(1)	Guaranty of Vascutech Acquisition LLC in favor of Brown Brothers Harriman & Co. dated March 29, 2001, as amended
10.24†(1)	Employment Agreement dated June 20, 2006, by and between the Registrant and David Roberts
10.26(1)	Letter Agreement with Brown Brothers Harriman & Co. dated September 25, 2006
10.28(1)	Amendment to Guaranty of Vascutech Acquisition LLC in favor of Brown Brothers Harriman & Co. dated September 25, 2006
10.29(1)	Security Agreement of Vascutech Acquisition LLC in favor of Brown Brothers Harriman & Co. dated March 29, 2001, as amended
10.30†(2)	Form of Restricted Stock Unit Award Agreement under the Registrant's 2006 Stock Option and Incentive Plan
10.31†(3)	Management Incentive Compensation Plan (2007)
10.32(4)	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
10.33(5)	Fourth Amended and Restated Revolving Loan and Security Agreement dated August 23, 2007, between the Registrant and Brown Brothers Harriman & Co.
10.34(5)	Third Amended and Restated Promissory Note (Secured) in favor of Brown Brothers Harriman & Co. dated August 23, 2007
10.35#**	Supply and Distribution Agreement dated January 1, 2005, by and between Biomateriali Srl and Edwards Lifesciences AG, as amended
21.1**	List of Subsidiaries
23.2**	Consent of Ernst & Young LLP
31.1**	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2**	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
(1)	Previously filed as an exhibit to Registration Statement No. 333-133532 and incorporated herein by reference.
(2)	Previously filed as an exhibit to Form 8-K filed on December 26, 2006, and incorporated herein by reference.
(3)	Previously filed as an exhibit to Form 8-K filed April 27, 2007, and incorporated herein by reference.
(4)	Previously filed as an exhibit to Form 8-K filed June 15, 2007, and incorporated herein by reference.
(5)	Previously filed as an exhibit to Form 8-K filed August 29, 2007, and incorporated herein by reference.
†	Indicates a management contract or any compensatory plan, contract, or arrangement.
#	Confidential treatment requested for portions of this document.
**	Filed herewith

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 31, 2008.

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u> /s/ GEORGE W. LEMAITRE </u> George W. LeMaitre	Chief Executive Officer and Chairman of the Board Principal Executive Officer	March 31, 2008
<u> /s/ JOSEPH P. PELLEGRINO, JR. </u> Joseph P. Pellegrino, Jr.	Chief Financial Officer	March 31, 2008
<u> /s/ DUANE M. DESISTO </u> Duane M. DeSisto	Director	March 31, 2008
<u> /s/ DAVID N. GILL </u> David N. Gill	Director	March 31, 2008
<u> /s/ RUSSELL D. HAYS </u> Russell D. Hays	Director	March 31, 2008
<u> /s/ MICHAEL C. JACKSON </u> Michael C. Jackson	Director	March 31, 2008
<u> /s/ LAWRENCE J. JASINSKI </u> Lawrence J. Jasinski	Director	March 31, 2008
<u> /s/ CORNELIA W. LEMAITRE </u> Cornelia W. LeMaitre	Vice President, Human Resources and Director	March 31, 2008
<u> /s/ GEORGE D. LEMAITRE, M.D. </u> George D. LeMaitre, M.D.	Director	March 31, 2008
<u> /s/ DAVID B. ROBERTS </u> David B. Roberts	President and Director	March 31, 2008

INDEX TO FINANCIAL STATEMENTS

	<u>Page</u>
LeMaitre Vascular, Inc.	
<i>Consolidated Financial Statements</i>	
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2007 and 2006	F-3
Consolidated Statements of Operations for the Years Ended December 31, 2007, 2006, and 2005	F-4
Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss) for the Years Ended December 31, 2007, 2006, and 2005	F-5
Consolidated Statements of Cash Flows for the Years Ended December 31, 2007, 2006 and 2005	F-8
Notes to Consolidated Financial Statements	F-9

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, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity and comprehensive income (loss), and cash flows for each of the three years in the period ended December 31, 2007. Our audit also included the financial statement schedule listed at Item 15(a)2. These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule 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 consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of LeMaitre Vascular, Inc. at December 31, 2007 and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Note 1 to the consolidated financial statements, effective January 1, 2007, the Company adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—an Interpretation of FASB Statement No. 109*. As discussed in Note 1 to the consolidated financial statements, effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment*.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 27, 2008

LeMaitre Vascular, Inc.
Consolidated Balance Sheets

	December 31,	
	2007	2006
(in thousands, except share data)		
Assets		
Current assets:		
Cash and cash equivalents	\$ 6,691	\$ 17,626
Marketable securities	16,198	13,182
Accounts receivable, net of allowances of \$219 in 2007 and \$102 in 2006	7,020	5,060
Inventory	9,589	6,081
Prepaid expenses	2,562	1,296
Deferred tax asset	—	396
Total current assets	42,060	43,641
Property and equipment, net	2,891	2,389
Goodwill	10,942	8,853
Other intangibles, net	3,886	1,930
Other assets	1,372	150
Total assets	<u>\$ 61,151</u>	<u>\$ 56,963</u>
Liabilities and stockholders' equity		
Current liabilities:		
Revolving line of credit	\$ 262	\$ —
Accounts payable	2,565	818
Accrued expenses	6,661	4,528
Acquisition-related obligations	851	—
Current portion of capital lease obligations	—	32
Total current liabilities	10,339	5,378
Long-term debt	42	—
Deferred tax liabilities	996	833
Other long-term liabilities	1,188	53
Total liabilities	12,565	6,264
Stockholders' equity:		
Preferred stock, \$0.01 par value; 5,000,000 shares authorized, none outstanding	—	—
Common stock, \$0.01 par value; authorized 100,000,000 shares; issued 15,516,412 shares at December 31, 2007, and 15,322,526 shares at December 31, 2006	155	153
Additional paid-in capital	61,187	60,504
Accumulated deficit	(12,880)	(9,946)
Accumulated other comprehensive income	291	73
Treasury stock, at cost; 26,852 shares at December 31, 2007, and 14,068 at December 31, 2006	(167)	(85)
Total stockholders' equity	48,586	50,699
Total liabilities and stockholders' equity	<u>\$ 61,151</u>	<u>\$ 56,963</u>

See accompanying notes to consolidated financial statements.

LeMaitre Vascular, Inc.
Consolidated Statements of Operations

	Year ended December 31.		
	2007	2006	2005
	(in thousands, except per share data)		
Net sales	\$ 41,446	\$ 34,628	\$ 30,727
Cost of sales	10,739	9,367	8,927
Gross profit	30,707	25,261	21,800
Sales and marketing	19,443	15,183	10,960
General and administrative	9,534	7,105	6,405
Research and development	4,591	3,301	3,015
Purchased research and development	373	—	—
Restructuring charges	1,042	257	998
Impairment charge	7	94	—
Total operating expenses	34,990	25,940	21,378
Income (loss) from operations	(4,283)	(679)	422
Other income (expense):			
Interest income	1,299	299	4
Interest expense	(1)	(296)	(182)
Foreign currency gain (loss)	292	228	(217)
Other income (expense), net	(9)	(72)	(33)
Foreign currency translation adjustment due to dissolution of French subsidiary	—	—	584
Income (loss) before income taxes	(2,702)	(520)	578
Provision for income taxes	232	652	523
Net income (loss)	\$ (2,934)	\$ (1,172)	\$ 55
Net income (loss) available for common shareholders:			
Basic	\$ (0.19)	\$ (0.15)	\$ 0.01
Diluted	\$ (0.19)	\$ (0.15)	\$ 0.01
Weighted-average shares outstanding:			
Basic	15,398	9,904	8,246
Diluted	15,398	9,904	8,701

See accompanying notes to consolidated financial statements.

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

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Subscription Receivable	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders' Equity
	Shares	Amount	Shares	Amount						Amount	Shares	
Balance at December 31, 2004	63,731	\$2,191	8,040,298	\$ 81	\$ 14,031	\$ (48)	\$ (15)	\$ (2,060)	\$ 855	30,148	\$ (222)	\$ 14,813
Net income								55				55
Foreign currency translation adjustment from dissolution of French subsidiary									(584)			(584)
Foreign currency translation adjustment									(338)			(338)
Comprehensive net loss												(867)
Stock-based compensation					102		(102)					—
Collection of subscription receivable						48						48
Issuance of common stock			267,272	3	3,016							3,019
Common stock issued in connection with acquisition			223,863	2	1,998							2,000
Issuance of common stock for stock options exercised			28,800		96							96
Costs related to issuance of common stock					(45)							(45)
Amortization of deferred compensation							33					33
Sale of treasury stock										(2,212)	25	25
Purchase of treasury stock										50,039	(586)	(586)
Balance at December 31, 2005	63,731	\$2,191	8,560,233	\$ 86	\$19,198	\$ —	\$ (84)	\$ (2,005)	\$ (67)	77,975	\$ (783)	\$18,536

See accompanying notes to consolidated financial statements.

LeMaitre Vascular, Inc.
Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss)—(continued)
(in thousands, except share data)

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders' Equity
	Shares	Amount	Shares	Amount					Shares	Amount	
Balance at December 31, 2005	63,731	\$ 2,191	8,560,233	\$ 86	\$ 19,198	\$ (84)	\$ (2,005)	\$ (67)	77,975	\$ (783)	\$ 18,536
Effect of adoption of SFAS 123(R) for redemption feature of common stock awards							(6,474)				(6,474)
Net loss							(1,172)				(1,172)
Unrealized losses on available for-sale securities								(6)			(6)
Foreign currency translation adjustment								146			146
Comprehensive net loss											(1,032)
Issuance of common stock			41,907	—	262						262
Issuance of common stock from public offering, net of \$2,902 of issuance costs			5,500,000	55	32,848						32,903
Redemption of preferred stock to common stock	(63,731)	(2,191)	1,274,620	13	2,178						—
Increase in redemption feature of common stock awards							(295)				(295)
Cancellation of redemption feature of common stock awards					6,769						6,769
Issuance of common stock for stock options exercised			30,004	—	47						47
Stock-based compensation expense					142						142
Repurchase of common stock at cost									6,263	(74)	(74)
Repurchase of common stock at cost									14,068	(85)	(85)
Cancellation of treasury stock			(84,238)	(1)	(856)				(84,238)	857	—
Reclassification of deferred compensation upon adoption of SFAS No. 123(R)					(84)	84					
Balance at December 31, 2006	—	\$ —	15,322,526	\$ 153	\$ 60,504	\$ —	\$ (9,946)	\$ 73	14,068	\$ (85)	\$ 50,699

See accompanying notes to consolidated financial statements.

LeMaitre Vascular, Inc.

Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss)—(continued)

(in thousands, except share data)

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders' Equity
	Shares	Amount	Shares	Amount					Shares	Amount	
Balance at December 31, 2006	—	\$ —	15,322,526	\$ 153	\$ 60,504	\$ —	\$ (9,946)	\$ 73	14,068	\$ (85)	\$ 50,699
Net loss							(2,934)				(2,934)
Unrealized gains on available-for-sale securities								94			94
Foreign currency translation adjustment								124			124
Comprehensive net loss											(2,716)
Initial public offering costs					(121)						(121)
Issuance of common stock for stock options exercised and employee stock purchase plan			153,377	2	243						245
Vested restricted stock units			40,509								—
Stock-based compensation expense					561						561
Repurchase of common stock at cost									12,784	(82)	(82)
Balance at December 31, 2007	—	\$ —	15,516,412	\$ 155	\$ 61,187	\$ —	\$ (12,880)	\$ 291	26,852	\$ (167)	\$ 48,586

See accompanying notes to consolidated financial statements.

LeMaitre Vascular, Inc.
Consolidated Statements of Cash Flows

	Year ended December 31,		
	2007	2006	2005
	(in thousands)		
Operating activities			
Net income (loss)	\$ (2,934)	\$ (1,172)	\$ 55
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation and amortization	1,394	1,308	1,208
Stock-based compensation	561	404	33
Accretion of discount on marketable securities	(223)	(23)	-
Impairment charges	7	94	-
Provision for losses in accounts receivable	197	21	16
Provision for inventory write-downs	503	449	238
Provision for deferred income taxes	639	(6)	182
Foreign currency translation adjustment from dissolution of French subsidiary	—	—	(584)
Loss on disposal of property and equipment	6	83	45
Loss on sales of marketable securities	3	—	—
Changes in operating assets and liabilities, net of effect of business acquisitions:			
Accounts receivable	(1,679)	(710)	(404)
Inventory	(1,800)	(1,229)	(2,007)
Prepaid expenses and other assets	(920)	(1,031)	(97)
Accounts payable and other liabilities	2,420	1,263	113
Net cash used in operating activities	(1,826)	(549)	(1,202)
Investing activities			
Purchase of property and equipment	(1,120)	(969)	(1,013)
Cash paid for business acquisitions, net of cash acquired	(5,109)	—	(1,379)
Proceeds from sale of property and equipment	6	34	487
Proceeds from sale of impaired assets	—	323	—
Purchase of technology and licenses	(273)	—	—
Sales and maturities of marketable securities	9,402	295	300
Purchase of marketable securities	(12,094)	(13,431)	—
Other assets	—	76	223
Net cash used in investing activities	(9,188)	(13,672)	(1,382)
Financing activities			
Net proceeds from issuance of common stock	—	47	3,115
Proceeds from issuance of common stock pursuant to employee stock purchase plan	72	—	—
Proceeds from issuance of common stock pursuant to exercise of common stock options	173	—	—
Proceeds from initial public offering	—	35,805	—
Proceeds (repayment) under revolving line of credit	—	(710)	710
Proceeds from long-term debt	—	2,500	—
Principal payments on long-term debt	—	(3,580)	(432)
Principal payments on capital lease obligations	(32)	(87)	(347)
Collection of subscription receivable	-	-	48
Expenses associated with equity transactions	(121)	(2,644)	(45)
Purchase of treasury stock, net	(82)	(159)	(561)
Net cash provided by financing activities	10	31,172	2,488
Effect of exchange rate changes on cash and cash equivalents	69	(142)	189
Net (decrease) increase in cash and cash equivalents	(10,935)	16,809	93
Cash and cash equivalents at beginning of year	17,626	817	724
Cash and cash equivalents at end of year	<u>\$ 6,691</u>	<u>\$ 17,626</u>	<u>\$ 817</u>

See accompanying notes to consolidated financial statements.

LeMaitre Vascular, Inc.
Notes to Consolidated Financial Statements
December 31, 2007

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. LeMaitre Vascular develops, manufactures, and markets 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 thoracic stent grafts, abdominal stent grafts, anastomotic clips, radiopaque tape, valvulotomes, carotid shunts, remote endarterectomy devices, covered stents, contrast injectors, balloon catheters, vascular grafts, vein strippers, cholangiogram catheters and vascular access ports. We also distribute in 11 European countries an abdominal stent graft manufactured by a third party.

Consolidation

Our consolidated financial statements include the accounts of LeMaitre Vascular and the accounts of our wholly-owned subsidiaries, LeMaitre Vascular GmbH, LeMaitre Vascular GK (successor to LeMaitre Vascular KK, reorganized in June 2007), LeMaitre UK Acquisition LLC, Vascutech Acquisition LLC, LeMaitre Acquisition LLC, LeMaitre Vascular SAS (organized in 2007), Biomateriali S.r.l., (acquired in 2007), LeMaitre Vascular S.r.l. (organized in 2007), LeMaitre Vascular Limited (dissolved in 2006) and LeMaitre Vascular SARL (dissolved in 2005). All significant intercompany accounts and transactions have been eliminated in consolidation.

Certain prior year amounts have been reclassified in the consolidated financial statements and accompanying notes to conform to the current year presentation.

Foreign Currency Translation

In accordance Statement of Financial Accounting Standards (SFAS) No. 52, *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, amounted to \$0.3 million in 2007, \$0.2 million in 2006, and \$(0.2) million in 2005 and are included in other income (expense) in the accompanying consolidated statements of operations.

During 2004, we ceased our manufacturing operations in France and transferred production capacity to the United States. In connection therewith, in 2005 we legally dissolved our wholly owned subsidiary, LeMaitre Vascular SARL (SARL). In accordance with Financial Accounting Standards Board (FASB) Interpretation No. 37 (FIN 37), *Accounting for Translation Adjustments upon Sale of Part of an Investment in a Foreign Entity, an Interpretation of FASB Statement No. 52*, other comprehensive income of \$0.6 million related to the SARL dissolution has been reclassified from stockholders' equity to other income in our 2005 consolidated statement 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.

[Table of Contents](#)

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 enter into consigned inventory arrangements with either hospitals or distributors on a limited basis.

We recognize revenue in accordance with SEC Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition*. SAB 104 requires that four basic criteria must be met before revenue can be recognized: (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) collectibility is reasonably assured. We assess whether the fee is fixed or determinable based on the terms of the agreement associated with the transaction. Substantially all 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. The products we sell are primarily off the shelf (non-custom) disposable medical devices.

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. Our consigned transactions are immaterial. 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 probable, 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 account for product returns in accordance with SFAS No. 48, *Revenue Recognition When Right of Return Exists*, providing for returns 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, at which time title passes to customers. 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. These return policies apply to sales to both hospitals and distributors. Our products are subject to a limited warranty that our products have been manufactured with due care. 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 and supplies, are expensed as incurred.

Shipping and Handling Costs

Shipping and handling fees paid by customers are recorded as 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 selling, general, and administrative expenses in the accompanying Consolidated Statements of Operations. Advertising costs amounted to \$0.6 million in 2007, \$1.0 million in 2006, and \$0.3 million in 2005.

Cash and Cash Equivalents

We consider all highly liquid instruments purchased with maturity dates of three months or less to be cash equivalents. Cash and cash equivalents are primarily invested in money market investment accounts, commercial paper, and certificates of deposit. These amounts are stated at cost, which approximates fair value.

[Table of Contents](#)

Marketable Securities

We account for our investments in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. Our investments, primarily U.S. treasury obligations, federal agency obligations, marketable debt securities, and asset-backed securities, are classified as available-for-sale and are carried at fair market value at December 31, 2007. We consider all highly liquid investments with original maturities of greater than 90 days to be short-term marketable securities. We purchase and hold investments principally for selling them in the near term and classify all of our investments as short-term marketable securities. The unrealized gains (losses) on available-for-sale securities are recorded in accumulated other comprehensive income (loss).

Concentrations of Credit Risk

Our financial instruments that are exposed to concentrations of credit risk consist primarily of cash and cash equivalents, marketable securities, and accounts receivable. Cash equivalents represent highly liquid investments with maturities of three months 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.

Our accounts receivable are with customers based in the United States and internationally. Accounts receivable generally are due within 30 to 60 days of invoice and are stated at amounts due from customers, net of an allowance for doubtful accounts and sales returns. 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 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 collectibility. The provision for the allowance for doubtful accounts is recorded in general and administrative expenses.

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. The deferred payments associated with the Biomateriali S.r.l. acquisition are recorded at the present value using our incremental borrowing rate. The difference between the present value and the amount due will be amortized using the effective interest method over the period that each of liabilities is outstanding. The amortization will be recorded as interest expense.

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.

[Table of Contents](#)

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 and accelerated methods as follows:

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

Valuation of Business Combinations

We record intangible assets acquired in business combinations under the purchase method of accounting, in accordance with FAS No. 141, *Business Combinations*, and allocate the amounts paid for each acquisition to the assets acquired and liabilities assumed based on their fair values at the dates of the acquisition. The purchase price in excess of net tangible assets acquired is allocated to the identifiable intangible assets. The fair value of identifiable intangible assets is usually based upon detailed valuations performed by independent appraisers that use information and assumptions provided by management. We allocate any excess purchase price over the fair value of the net tangible and intangible assets acquired to goodwill.

Contingent Consideration

Certain of our business combinations involve the payment of contingent consideration. In accordance with SFAS No. 141, *Business Combinations*, we establish a contingent consideration liability at the acquisition date when the initial purchase price before including any contingent consideration is less than the sum of the fair value assigned to the assets acquired and the liabilities assumed (the excess). The liability established equals the lesser of the maximum amount of the potential contingent consideration or the excess. When the contingencies are resolved, any excess of the fair value of the contingent payments over the amount that was recognized as if it were a liability shall be recognized as an additional cost of the related acquisition. If the amount initially recognized as if it were a liability exceeds the fair value of the contingent payments made, the excess shall be allocated as a pro rata reduction of the amounts initially assigned to the identifiable intangible assets acquired.

Impairment of Long-lived Assets

We review the carrying value of our long-lived assets (primarily property and equipment and intangible assets) to assess the recoverability of these assets when indicators of impairment occur. 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 of December 31, 2006, we determined an impairment charge of \$0.4 million was required based upon the analysis of unfavorable preliminary data from our U.S. clinical study of the Expedial Vascular Access Graft. The preliminary clinical data suggested that the device may not compare favorably to ePTFE grafts. As a result of our review of the clinical study results, we decided to forego further enrollment in the clinical study and cease the production and sales of this device. During the second quarter of 2006, we determined that the future cash flows from the related patents and equipment were less than their carrying value. Fair value was determined by prices of similar products. Consequently, impairment charges to reduce the carrying value of these assets to fair value and related inventory to net realizable value totaled \$0.7 million, of which \$0.3 million related to the impairment of other intangible assets relating to the Expedial product line patents, approximately \$64,000 related to the write-down of related production equipment, and \$0.3 million related to inventory write-offs that were charged to cost of sales. During the fourth quarter of 2006, we sold certain manufacturing equipment, inventory, and intellectual property related to the Expedial Vascular Access Graft product line to CardioTech International,

[Table of Contents](#)

Inc., for total consideration of \$0.4 million plus a 5 percent royalty on CardioTech's net sales of its CardioPass brand coronary artery bypass graft for a period of five years following the first commercial sale of a CardioPass graft. The CardioPass graft is not yet in clinical trials, and there can be no assurance that it will ever be commercialized. As a result of the sale, we subsequently adjusted the initial impairment charge for \$0.3 million for the gain on the sale of the intellectual property and equipment, which is recorded as an adjustment to restructuring charges, and adjusted cost of sales for \$12,000 for the inventory sale.

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. In accordance with SFAS No. 142, *Goodwill and Other Intangible Assets*, goodwill is evaluated for impairment annually or more frequently if indicators of impairment are present or changes in circumstances suggest that impairment may exist. We evaluate the December 31 balance of the carrying value of goodwill based on a single reporting unit annually and more frequently if certain indicators are present or changes in circumstances suggest that impairment may exist. The first step of our goodwill impairment test, used to identify potential impairment, compares the fair value of our reporting unit with its carrying amount, including goodwill. If the fair value of our reporting unit exceeds its carrying amount, the goodwill of the reporting unit is considered not impaired; and the second step of the impairment test, used to measure the amount of the impairment loss, is unnecessary. If the carrying amount of our reporting unit exceeds its fair value, the second step of the goodwill impairment test is performed to measure the amount of impairment loss, if any. The second step of the goodwill impairment test, used to measure the amount of impairment loss, compares the implied fair value of the reporting unit goodwill as of the date of the impairment review with the carrying amount of that goodwill. 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 2007, 2006, or 2005.

Other Intangible Assets

Other intangible assets consist primarily of patents, trademarks, technology licenses, and customer relationships acquired in connection with business acquisitions and are amortized over their estimated useful lives, ranging from 5 to 17 years.

Stock-based Compensation

Effective January 1, 2006, we adopted SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS No. 123(R)). Under SFAS No. 123(R), we are required to recognize as expense the estimated fair value of all share-based payments to employees. In accordance with this standard, 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. We adopted SFAS No. 123(R) under the prospective-transition method, as required by the standard, using a Black-Scholes model to value stock options. Under this method, we recognized compensation cost for all share-based payments to employees based on the grant date estimate of fair value for those awards, beginning on January 1, 2006.

As a result of adopting SFAS 123(R) on January 1, 2006, our net loss for 2006, was \$0.1 million higher than if we had continued to account for share-based compensation under APB No. 25. Basic and diluted loss per share for 2006 would have been \$0.01 higher if we had continued to account for share-based compensation under APB No. 25.

[Table of Contents](#)

Prior to January 1, 2006, we elected to follow Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, FIN No. 44, *Accounting for Certain Transactions Involving Stock Compensation*, and related interpretations, in accounting for our stock-based compensation plans, rather than the alternative fair value accounting method provided for under SFAS No. 123, *Accounting for Stock-Based Compensation*, as this alternative requires the use of option valuation models that were not developed for use in valuing employee stock options. Under APB No. 25, when the number of options is fixed and the exercise price of options granted under these plans equals the market price of the underlying stock on the date of grant, no compensation expense recognition is required. Prior period pro forma stock option information disclosed was valued based on a Black-Scholes model using the minimum value method.

SFAS No. 123 requires that we disclose the pro forma effect of expensing the fair value of stock options issued to employees. Had we accounted for stock options issued to employees using the fair value model prescribed by SFAS No. 123, the pro forma effect would have been as follows:

	<u>2005</u>
	<u>(in thousands)</u>
Net income, as reported	\$ 55
Plus stock compensation cost as computed under APB No. 25	33
Less pro forma SFAS No. 123 option expense	<u>(374)</u>
Pro forma net loss	<u>\$ (286)</u>

In periods that we grant stock options, fair value assumptions are based on volatility, interest, and expected term over which the stock options will be outstanding. The computation of expected volatility is based on a study of historical volatility rates of comparable companies during a period comparable to the expected option term and our historical volatility. 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. The computation of expected option term is based on an average vesting term and the maximum contractual life of our stock options and restricted stock units (RSUs). Computation of expected forfeitures is based on historical forfeiture rates of our stock options. For both 2006 and 2007, we used an expected forfeiture rate of approximately 20 percent. Share-based compensation charges will be adjusted in future periods to reflect the results of actual forfeitures and vesting.

The components of share-based compensation expense included in net loss are as follows:

	<u>2007</u>	<u>2006</u>
	<u>(in thousands)</u>	<u>(in thousands)</u>
Stock option awards to employees under SFAS No. 123(R)	\$ 241	\$ 132
Common stock awards under SFAS No. 123(R)	303	262
Employee stock purchase plan	8	—
Stock option awards to non-employees under SFAS No. 123	9	10
Total stock-based compensation	<u>\$ 561</u>	<u>\$ 404</u>

We expect to record the unamortized portion of share-based compensation expense of \$1.8 million for existing stock options and RSUs outstanding at December 31, 2007, over a weighted-average period of 3.2 years.

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

[Table of Contents](#)

matters. We record charges for the costs we anticipate incurring in connection with litigation and claims against us when we can reasonably estimate these costs. During the years ended December 31, 2007, 2006, and 2005, we were not subject to any material litigation or claims and assessments.

Income Taxes

We adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—an Interpretation of FASB Statement No. 109*, (FIN 48) on January 1, 2007. FIN 48 clarifies the accounting and reporting for uncertainties in income tax law. This interpretation prescribes a comprehensive model for the financial statement recognition, measurement, presentation, and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. As a result of the implementation of FIN 48, we recognized no adjustment in the liability for unrecognized income tax benefits.

We operate in multiple taxing jurisdictions, both within the United States and outside of the United States and are or 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.

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 (Loss)

SFAS No. 130, *Reporting Comprehensive Income*, establishes standards for reporting and displaying comprehensive income (loss) and its components in the consolidated financial statements. Comprehensive income (loss) 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 (loss), comprehensive income (loss) 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 stockholders' equity and comprehensive income (loss). We present comprehensive income (loss) in our consolidated statements of stockholders' equity.

Accumulated other comprehensive income as of December 31, 2007, consisted of unrealized gains on available-for-sale securities of \$88,000 and foreign currency translation adjustments of \$203,000; and as of December 31, 2006, consisted of unrealized losses on available-for-sale securities of \$6,000 and foreign currency translation adjustments of \$79,000.

Restructuring

We record restructuring charges incurred in connection with consolidation or relocation of operations, exited business lines, or shutdowns of specific sites. These restructuring charges, which reflect our commitment to a termination or exit plan that will begin within 12 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.

Net Income (Loss) Per Share

Until January 1, 2007, we calculated net income (loss) per share in accordance with SFAS No. 128, *Earnings Per Share*, and Emerging Issues Task Force (EITF) 03-6, *Participating Securities and the Two-Class Method under FASB Statement No. 128, Earnings Per Share*. EITF 03-6 clarified the use of the "two-class" method of calculating earnings per share as originally prescribed in SFAS No. 128. Effective for periods beginning after March 31, 2004, EITF 03-6 provides guidance on how to determine whether a security should be considered a "participating security" for purposes of computing earnings per share and how earnings should be allocated to a participating security when using the two-class method for computing earnings per share.

[Table of Contents](#)

Under the two-class method, basic net income (loss) per share is computed by dividing the net income (loss) applicable to common stockholders by the weighted-average number of common shares outstanding for the fiscal period. Diluted net income (loss) per share is computed using the more dilutive of (a) the two-class method or (b) the if-converted method. Under EITF 03-6, we had determined that our Series A convertible preferred stock (Series A preferred stock) and, upon the adoption of SFAS 123(R), that certain options and shares of common stock (common stock awards) subject to a repurchase feature at other than fair value were participating securities. Our Series A preferred stock provided for a dividend in the event of liquidation or in the event a dividend was declared on the our common stock. Effective January 1, 2006, common stock awards subject to repurchase were allocated to net income based on the change in the repurchase value during each reporting period. The remaining income (loss) was then allocated to preferred and common stockholders, pro rata, based on ownership interests since the preferred stock participates in dividends on the same basis into which the preferred shares convert to common stock. Net losses were not allocated to participating securities. For all periods presented, the application of the two-class method was more dilutive than the if-converted method. Diluted net income (loss) per share gives effect to all potentially dilutive securities, including stock options using the treasury method, unless anti-dilutive.

In connection with the Company's initial public offering in October 2006, all outstanding shares of Series A preferred stock were automatically converted into shares of common stock and the repurchase feature of certain shares of common stock were terminated. Accordingly, effective January 1, 2007, the two class method no longer applies.

Net loss per share is based on the following:

	Year ended December 31,		
	2007	2006	2005
	(in thousands)		
Numerator:			
Net income (loss) as reported	\$ (2,934)	\$ (1,172)	\$ 55
Allocation of net income (loss):			
Basic:			
Redemption value of common stock awards	\$ —	\$ 295	\$ —
Undistributed net income allocated to participating stockholders:			
Preferred stock	—	—	7
Net income applicable to participating stockholders	—	295	7
Net income (loss) applicable to common stockholders	(2,934)	(1,467)	48
Net income (loss)	<u>\$ (2,934)</u>	<u>\$ (1,172)</u>	<u>\$ 55</u>
Diluted:			
Redemption value of common stock awards	\$ —	\$ 295	\$ —
Undistributed net income allocated to participating stockholders:			
Preferred stock	—	—	7
Net income applicable to participating stockholders	—	295	7
Net income (loss) applicable to common stockholders	(2,934)	(1,467)	48
Net income (loss)	<u>\$ (2,934)</u>	<u>\$ (1,172)</u>	<u>\$ 55</u>
Denominator:			
Weighted-average shares of common stock outstanding:			
Issued	15,398	9,904	8,240
Issuable in connection with acquisitions	—	—	6
	<u>15,398</u>	<u>9,904</u>	<u>8,246</u>
Common stock equivalents:			
Weighted-average shares of common stock issuable upon exercise of outstanding stock options	—	—	455
Shares used in computing diluted net income (loss) per common share, if dilutive	<u>15,398</u>	<u>9,904</u>	<u>8,701</u>

[Table of Contents](#)

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

	Year ended December 31,		
	2007	2006	2005
	(in thousands, except per share data)		
Basic:			
Net income (loss) available for common stockholders	\$ (2,934)	\$ (1,467)	\$ 48
Weighted average shares outstanding	15,398	9,904	8,246
Net income (loss) per share	\$ (0.19)	\$ (0.15)	\$ 0.01
Diluted:			
Net income (loss) available for common stockholders	\$ (2,934)	\$ (1,467)	\$ 48
Weighted-average shares of common stock	15,398	9,904	8,246
Common stock equivalents, if dilutive	—	—	455
Shares used in computing diluted net income (loss) per common share	15,398	9,904	8,701
Net income (loss) per share	\$ (0.19)	\$ (0.15)	\$ 0.01

The estimated number of shares issuable in future periods in connection with certain business acquisitions is based on the stated value of the common stock issuable and the fair value of the common stock at each reporting date.

For 2005 common stock equivalents represent the effect of options to purchase our common stock to the extent the fair value of the common stock exceeds the exercise price of the option. Due to the use of the two-class method, which is more dilutive than the if-converted method, common stock equivalents do not include the effect of the conversion of the our Series A Preferred Stock into 1,274,620 shares of common stock based on a 20-for-1 ratio. The two-class method assumes that a pro rata share of net income is allocated to preferred stockholders instead of assuming the preferred stock is converted to common stock.

For 2006 shares used in computing diluted net loss per common share exclude 791,934 weighted-average shares of common stock issuable upon exercise of outstanding stock options, as the effect of including those shares would be anti-dilutive. An additional 424,921 of common stock equivalents were excluded as a result of our net loss for the period. Due to the use of the two-class method, which is more dilutive than the if-converted method, common stock equivalents do not include the effect of the conversion of the our Series A Preferred Stock into 1,274,620 shares of common stock based on a 20-for-1 ratio. The two-class method assumes that a pro rata share of net income is allocated to preferred stockholders instead of assuming the preferred stock is converted to common stock.

For 2007 shares used in computing diluted net loss per common share excludes 737,053 weighted-average shares of common stock issuable upon exercise of outstanding stock options, as the effect of including those shares would be anti-dilutive. An additional 451,864 of common stock equivalents were excluded as a result of our net loss for the period.

We have never declared cash dividends and do not expect to do so in the foreseeable future.

Recent Accounting Pronouncements

In September 2006 the FASB issued SFAS No. 157, *Fair Value Measurement*. SFAS No. 157 establishes a framework for measuring fair value and requires expanded disclosures regarding fair value measurements. This accounting standard is effective for financial statements issued for fiscal years beginning after November 15, 2007. However, in January 2008, the FASB issued Staff Position FAS 157-b, *Effective Date of FASB Statement No. 157* (FSP FAS 157-b). This FSP permits entities to elect to defer the effective date of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis. The adoption of SFAS No. 157 will not have a material impact on our consolidated results of operations and financial position.

[Table of Contents](#)

In February 2007 the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities—Including an Amendment of FASB Statement No. 115*. SFAS No. 159 permits entities to choose, at specified election dates, to measure eligible items at fair value (the fair value option). A business entity shall report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting period. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. We are currently evaluating the impact this adoption will have on our consolidated financial statements.

In June 2007 the FASB ratified the consensus reached on Emerging Issues Task Force (EITF) Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* (EITF 07-3). EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as expense as the goods are delivered or the related services are performed. EITF 07-3 will be effective on a prospective basis for fiscal years beginning after December 15, 2007, and will be adopted by us in the first quarter of 2008. We do not expect that the adoption of EITF 07-3 will have a material effect on our consolidated results of operations and financial condition.

In December 2007 the FASB issued SFAS No. 141 (revised 2007), *Business Combinations*, (SFAS No. 141(R)). SFAS No. 141(R) replaces SFAS No. 141, *Business Combinations*, and requires the acquiring entity in a business combination to recognize the full fair value of assets acquired and liabilities assumed in the transaction; requires certain contingent assets and liabilities acquired to be recognized at their fair values on the acquisition date; requires contingent consideration to be recognized at its fair value on the acquisition date and changes in the fair value to be recognized in earnings until settled; requires the expensing of most transaction and restructuring costs; and generally requires the reversals of valuation allowances related to acquired deferred tax assets and changes to acquired income tax uncertainties to also be recognized in earnings. SFAS No. 141(R) is effective for financial statements issued for fiscal years beginning after December 15, 2008, and will be adopted by us in the first quarter of 2009. The adoption of SFAS No. 141(R) is expected to significantly affect the Company's accounting for business combinations entered into subsequent to December 31, 2008.

In December 2007 the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements—an amendment of Accounting Research Bulletin No. 51*. SFAS 160 establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent's ownership interest, and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. SFAS 160 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS 160 is effective for fiscal years beginning after December 15, 2008, and will be adopted by us in the first quarter of 2009. We do not expect the adoption of SFAS 160 will have a material effect on our consolidated results of operations and financial condition.

2. Marketable Securities

Marketable securities are primarily available-for-sale investments and consist of the following:

	As of December 31, 2007				As of December 31, 2006			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)							
Certificates of deposit	\$ —	\$ —	\$ —	\$ —	\$ 975	\$ —	\$ —	\$ 975
Commercial paper	—	—	—	—	882	—	—	882
U.S. treasury obligations	4,251	78	—	4,329	2,156	—	(8)	2,148
Federal agency obligations	4,001	15	—	4,016	—	—	—	—
Corporate bonds	2,720	1	(33)	2,688	2,671	—	—	2,671
Asset-backed securities	5,132	33	—	5,165	6,504	2	—	6,506
Total marketable securities	\$ 16,104	\$ 127	\$ (33)	\$ 16,198	\$ 13,188	\$ 2	\$ (8)	\$ 13,182

[Table of Contents](#)

In 2007 gross realized gains and losses on the sales of available-for-sale marketable securities were not material and have been included in Interest Income in the Consolidated Statements of Operations. In 2006 no realized gains or losses on the sales of available-for-sale marketable securities were recognized.

The amortized cost and estimated fair value of available-for-sale marketable securities as of December 31, 2007, by contractual maturity, were as follows:

	2007	
	Amortized Cost	Fair Value
(in thousands)		
Contractual maturities:		
Due in 1 year or less	\$ 5,891	\$ 5,912
Due in 1–2 years	3,580	3,607
Due in 2–5 years	4,895	4,930
Due after 5 years	1,738	1,749
Total	<u>\$ 16,104</u>	<u>\$ 16,198</u>

3. Acquisitions

Biomateriali

In December 2007 we acquired all of the stock of Biomateriali, Srl, (Biomateriali) a privately held Italian company. Biomateriali manufactures polyester grafts for use in open abdominal aortic aneurysm and peripheral vascular procedures. We believe the acquisition of Biomateriali provides us with access to the peripheral vascular graft market and leverages our sales network and complements our existing endovascular business. Our consolidated financial statements include the operating results for Biomateriali from the date of the acquisition. We believe that we can leverage our existing trade name and sales and marketing infrastructure to improve the revenue-generating potential of the business. Furthermore, we believe we can take advantage of our manufacturing, finance, and administration infrastructure to improve the financial results of the acquired business.

The aggregate purchase price was \$3.4 million and included: a \$1.9 million cash payment on the date of the acquisition; \$1.1 million deferred payment for the assumption of outstanding debt to their shareholders and their officers, of which \$0.5 million is payable in 2008 and \$0.6 million payable in 2009; \$0.2 million of direct acquisition costs; \$0.1 million for the deferred purchase price payment; and \$0.1 million of contingent consideration that will not be payable until the contingency is resolved. The current portion of the deferred payments has been included in Acquisition-related Obligations and the long-term portion has been included in Other Long-term Liabilities.

The initial purchase price before including any contingent consideration is less than the sum of the fair value assigned to the assets acquired and the liabilities assumed (the excess). There are two contingent obligations embedded in the Biomateriali purchase agreement. In accordance with the guidance with SFAS No. 141, we have established a liability of \$0.1 million for contingent obligations, which is the amount of the excess purchase price, in order to delay the recognition of the excess until the contingencies are resolved. When the contingencies are resolved, any excess of the fair value of the contingent payments over the amount \$0.1 million that was recognized as if it were a liability shall be recognized as an additional cost of the Biomateriali acquisition. If the amount initially recognized as if it were a liability exceeds the fair value of the contingent payments made, the excess shall be allocated as a pro rata reduction of the amounts initially assigned to the identifiable intangible assets acquired in accordance with the guidance in SFAS No. 141.

One contingent payment is to the seller in connection with the expiration or termination of one of Biomateriali's distributor agreements (Agreement). There are various potential outcomes to this contingency that have different amounts payable depending upon the outcome. In all but one of the possible outcomes, we are required to pay the seller a fee for either the early termination or the expiration of the Agreement. The fee ranges

[Table of Contents](#)

from \$1.1 million to \$2.2 million (denominated in Euro dollars), depending on the circumstances. If the Agreement remains in place for its full term and expires on December 31, 2011, we are required to pay \$2.2 million to the seller. Currently, we have no specific plan to terminate the Agreement; however, we may elect to terminate or modify the Agreement prior to its expiration, which could result in a payment to the sellers of less than the full \$2.2 million. Any payments made to the seller for this contingency will be recorded as an adjustment to goodwill in the period that the contingency is resolved.

The other contingent payment relates to the Biomateriali distributor mentioned above. If there is a change in control of Biomateriali, we have the right to terminate the Agreement, in which event we would be required to pay a cancellation fee to the distributor equal to the product orders for the 12 months immediately preceding the date on which we notify the distributor of the termination. Although Biomateriali experienced a change of control when we acquired it in December 2007, we have no specific plan to terminate the agreement. Any payment made to the distributor will be recorded in our consolidated statement of operations as a termination fee, not as an adjustment to the purchase price except to the extent the customer relationship information is acquired as part of the termination. In that event, the fair value of customer relationships will be capitalized and amortized over its useful life.

The deferred payments are denominated in Euro dollars and will be adjusted to reflect the current exchange rates at the end of each of the future reporting periods that any portion is outstanding. Any gains or losses realized will be recognized in our consolidated statement of operations. In addition, interest is being imputed on the deferred payment amounts; and the present value of the deferred payments was recorded as of the date of the acquisition using our incremental borrowing rate. The difference between the present value and the amount due will be amortized using the effective interest method over the period that each of these liabilities is outstanding. The amortization will be recorded as interest expense.

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

	<u>Allocated Fair Value</u> (in thousands)
Current assets	\$ 2,298
Property, plant, and equipment	456
Intangible assets	1,238
Other assets	1,186
Total assets acquired	<u>5,178</u>
Current liabilities	(1,391)
Other liabilities	(423)
Total liabilities assumed	<u>(1,814)</u>
	<u>\$ 3,364</u>

Of the \$1.2 million of acquired intangible assets, the following table reflects the allocation of the acquired intangible assets and related estimates of useful lives:

	<u>Allocated Fair Value</u>	<u>Weighted Average Useful Life</u>
	(in thousands)	
Customer and contract relationships	\$ 622	7.5 years
Patents	283	9.5 years
Trade names	283	9.5 years
Non-compete agreement	50	4.0 years
Total intangible assets	<u>\$ 1,238</u>	

[Table of Contents](#)

Vascular Architects

In September 2007 we acquired substantially all of the assets of Vascular Architects (VA), a privately held medical device company. VA marketed and sold devices for remote endarterectomy, a hybrid open/endovascular medical procedure. The purpose of the acquisition was to acquire products that will leverage our vascular surgery sales force. We believe that we can leverage our existing trade name and sales and marketing infrastructure to improve the revenue-generating potential of the business. Furthermore, we believe we can take advantage of our manufacturing, finance, and administration infrastructure to improve the financial results of the acquired business. These factors supported our belief that VA's value was higher as a business acquired by us rather than as an independent business and resulted in goodwill to be recognized in the transaction.

The aggregate purchase price was \$2.9 million. Under the terms of the purchase agreement, we acquired certain customer contracts, patents, and other intellectual property, in exchange for the assumption of certain liabilities. Approximately \$2.5 million was paid upon the execution of the purchase agreement and \$0.4 million is to be paid on the first anniversary of the signing.

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

	<u>Allocated Fair Value</u> (in thousands)
Current assets	\$ 580
Property, plant, and equipment	3
Intangible assets	658
Goodwill	1,783
Total assets acquired	3,024
Total current liabilities assumed	(114)
	<u>\$ 2,910</u>

Of the \$0.7 million of acquired intangible assets, the following table reflects the allocation of the acquired intangible assets and related estimates of useful lives:

	<u>Allocated Fair Value</u> (in thousands)	<u>Weighted Average Useful Life</u>
Customer relationships	\$ 375	7.5 years
Patents	141	8.0 years
Trade names	34	8.0 years
Non-compete agreement	108	5.0 years
Total intangible assets	<u>\$ 658</u>	

Cardiovascular Innovations, LLC

In April 2007 we acquired certain assets and assumed certain liabilities of Cardiovascular Innovations, LLC (CVI), a privately held medical device company for \$0.4 million. CVI had marketed a hand-powered contrast injector for use in a variety of endovascular procedures. The acquisition was determined to be a purchase of a business, and the results of the operations of CVI have been included in the consolidated financial statements from the date of acquisition.

The purpose of the acquisition was to acquire the patents, regulatory approvals, manufacturing know-how, and customer relationships to allow us to enter the hand-powered contrast injector market. We believe that we

[Table of Contents](#)

can leverage our existing trade name and sales and marketing infrastructure to improve the revenue-generating potential of the business. Furthermore, we believe we can take advantage of our manufacturing, finance, and administration infrastructure to improve the financial results of the acquired business.

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

	<u>Allocated Fair Value</u> (in thousands)
Current assets	\$ 80
Intangible assets	61
Goodwill	305
Total assets acquired	446
Current liabilities	(10)
	<u>\$ 436</u>

Intangible assets are attributable to patents and customer relationships and are being amortized over their estimated weighted-average useful life of 8.5 years.

Acquisitions of Technology

In December 2007 we purchased certain patents and in-process research and development, and entered into a non-compete agreement with Arizona Heart Innovative Technologies, LLC. Total consideration paid included \$0.5 million at the acquisition date and certain earn-out payments associated with the receipts of approvals to commercialize sales of the device in Europe and the U.S. Additionally, we are obligated to pay a milestone payment of \$100,000 upon the issuance of any U.S. patent that matures from any of the applications listed in the agreement including value ascribed to the in-process research and development. The fair value of the acquired in-process research and development cost of \$373,000 was expensed on the date of acquisition, as it had not yet reached technological feasibility and had no alternative future use at the date of acquisition. The fair value of this acquired in-process research and development is reported as purchased research and development costs in our 2007 consolidated statement of operations. The purchase price was allocated to the identifiable intangible assets based on their fair values at the date of the acquisition as determined by a valuation from an independent appraiser. We considered the \$100,000 milestone payment and earn-out payments associated with the receipts of approvals to commercialize the products in Europe and the United States to be contingent consideration that will be recorded as additional intangible assets in the period that the contingency is resolved.

In November 2007 we also acquired patents and patent applications in process for a total purchase price of \$62,500, and these have been capitalized as patents. In conjunction with this acquisition, we have entered into a consulting agreement with the former owner whereby he will provide consulting services to us as requested up to 10 days per year. We are also obligated to meet certain milestones. The first milestone requires the development of a first prototype of the product within 150 days after the agreement effective date; and if the milestone is missed, we are obligated to pay \$25,000. The second milestone requires CE mark approval within 17 months after the effective date; and if the milestone is missed, we are obligated to pay \$50,000. The third milestone requires us to make the first commercial sale of the product with 20 months after the effective date of the agreement. In the event that we fail to achieve any of these milestones, the seller can, within one year of the final milestone date, require that we grant the seller an exclusive, irrevocable license to the patent rights. In addition, we are contractually obligated to make royalty payments on any sales from the technology purchased.

Acquisition of Endomed

In February 2005 we acquired certain business assets and operations and assumed liabilities of Endomed, Inc. (Endomed), a medical device company located in Phoenix, Arizona, for \$4.1 million. The consideration

[Table of Contents](#)

consisted of \$2.2 million in cash, of which \$1.4 million was paid at the closing (\$0.8 million to creditors and \$0.6 million to Endomed); \$0.3 million was withheld as repayment for principal and interest due from Endomed for an advance; and \$0.5 million was payable to creditors. Additionally, 191,387 shares of common stock at a per share value of \$10.45 totaling \$2.0 million were issued to certain stockholders of Endomed to extinguish amounts owed by Endomed to its principal owners. The common stock was priced at the then-current share price of \$10.45 as determined by our board of directors.

The acquisition was determined to be a purchase of a business based upon the provisions of EITF Consensus, 98-3, *Determining Whether a Non Monetary Transaction Involves Receipt of Productive Assets or of a Business*, and the results of operations from the acquired business have been included in the consolidated financial statements from the date of acquisition.

The purpose of the acquisition was to acquire the patents (which include manufacturing techniques), customer relationships, trademarks, the manufacturing facility, equipment and the employee base to allow us to enter the endovascular stent graft market. We believed that we would be able to leverage our existing trade name, sales, and marketing functions to improve the revenue generating potential of the business. Furthermore, we believed we could leverage our manufacturing, finance, and administrative infrastructure to improve the financial results of the acquired business after the transaction. These factors supported our belief that Endomed's value was higher as a business acquired by us rather than as an independent business and resulted in goodwill to be recognized in the transaction.

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

	<u>Allocated Fair Value</u> (in thousands)
Current assets	\$ 887
Property, plant, and equipment	369
Intangible assets	959
Other assets	45
Goodwill	<u>2,170</u>
Total assets acquired	4,430
Current liabilities	<u>(352)</u>
	<u>\$ 4,078</u>

Intangible assets attributable to certain patents, customer relationships and trademarks amounted to \$1.0 million, and are being amortized over their estimated useful lives between 5.0 and 13.8 years, as shown below:

	<u>Allocated Fair Value</u> (in thousands)	<u>Weighted Average Useful Life</u>
Customer and contract relationships	\$ 213	7.5 years
Patents	696	13.8 years
Trademarks	<u>50</u>	5.0 years
Total intangible assets	<u>\$ 959</u>	

[Table of Contents](#)

4. Inventory

Inventory consists of the following:

	As of December 31,	
	2007	2006
	(in thousands)	
Raw materials	\$ 2,374	\$ 2,098
Work-in-process	1,540	501
Finished products	5,675	3,482
Total inventory	<u>\$9,589</u>	<u>\$6,081</u>

5. Property and Equipment

Property and equipment consists of the following:

	As of December 31,	
	2007	2006
	(in thousands)	
Computer hardware	\$ 1,943	\$ 1,558
Machinery and equipment	4,325	2,846
Leasehold improvements	1,251	1,482
Gross property and equipment	7,519	5,886
Less accumulated depreciation	4,628	3,497
Property and equipment, net	<u>\$2,891</u>	<u>\$ 2,389</u>

Depreciation expense amounted to approximately \$1.1 million in 2007, 2006, and 2005.

6. Goodwill and Other Intangibles

Goodwill consists of the following:

	As of December 31,	
	2007	2006
	(in thousands)	
Balance at beginning of year	\$ 8,853	\$ 8,853
Additions for acquisitions	2,089	—
Balance at end of year	<u>\$10,942</u>	<u>\$8,853</u>

Other intangibles consist of the following:

	2007			2006		
	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	\$ 2,184	\$ 532	\$ 1,652	\$ 1,534	\$ 520	\$ 1,014
Trademarks and technology licenses	1,265	356	909	898	141	757
Customer relationships	1,233	92	1,141	213	54	159
Other intangible assets	190	6	184	—	—	—
Total identifiable intangible assets	<u>\$ 4,872</u>	<u>\$ 986</u>	<u>\$ 3,886</u>	<u>\$2,645</u>	<u>\$ 715</u>	<u>\$1,930</u>

[Table of Contents](#)

These assets are being amortized over useful lives ranging from 5 to 17 years. The weighted-average amortization period for these intangibles as of December 31, 2007, is 9.56 years. Amortization expense amounted to \$0.3 million in 2007 and \$0.2 million in 2006 and 2005 and is included in general and administrative expense.

Estimated amortization expense for each of the five succeeding fiscal years, based upon the intangible assets at December 31, 2007, is as follows:

	<u>(in thousands)</u>
2008	\$ 539
2009	505
2010	492
2011	468
2012	427

7. Financing Arrangements

In February 2005 in connection with our acquisition of certain assets and operations of Endomed, we amended our existing revolving line of credit with our bank to allow borrowings in an amount not to exceed \$3.5 million for a 12-month period, and thereafter \$2.25 million. Borrowings under the line of credit accrued interest at the bank's prime rate and were due upon demand as of December 31, 2005. In May 2006 we amended and restated our revolving line of credit to commit the facility and allow borrowing in an amount not to exceed \$5.5 million.

In September 2006 we entered into an additional \$2.5 million term loan with our bank. This term loan included customary financial covenants and interest at a rate of 10% per annum. The term loan had an expiration date of September 2008, without penalty, and was required to be repaid if and to the extent that we received net proceeds from any sale of our equity in excess of \$2.5 million. In October 2006 we used \$3.9 million of the net proceeds from the public offering to pay down all outstanding indebtedness with the bank.

In August 2007 we amended our revolving line of credit with the bank to increase our borrowing capacity to \$10 million and increase the maximum principal amount of any letters of credit issued as part of this facility to \$3 million. The maturity date for amounts borrowed has been extended to August 2008. Loans made under this revolving line of credit bear interest rates at LIBOR plus 200 basis points or the bank's base rate, at our discretion. As of December 31, 2007, we had no borrowings outstanding under this revolving line of credit. Borrowings under this line of credit are collateralized by substantially all of our assets. The loan agreement requires that we meet certain financial and operating covenants. As of December 31, 2007, we were in compliance with these covenants.

Biomateriali had two existing revolving lines of credit with their bank for a total of approximately \$0.7 million to be used in connection with the financing of sales to certain customers at the date we acquired them. Loans made under these lines bear interest at 20% per annum. As of December 31, 2007, we had \$0.3 million of borrowings outstanding under one of these revolving lines of credit. The lines were paid in full in January 2008.

As part of the purchase of Biomateriali, we also assumed a loan from the Italian government under a program that provides funding to certain businesses in Italy through a combination of grants and loans if certain requirements are met. The loans are not required to be repaid until one year after project completion and are payable in ten annual payments of principal and interest at an interest rate of 0.74 percent. The present value of the loan was recorded as of the date of the acquisition using our incremental borrowing rate. Interest is being imputed on the loan, and the difference between the present value and the amount due will be amortized using the effective interest method over the period that the loan is outstanding. The amortization will be recorded as interest expense. The amount of the loan as of December 31, 2007, was approximately \$42,000 and has been included in our balance sheet in other long-term liabilities.

[Table of Contents](#)

8. Accrued Expenses

Accrued expenses consist of the following:

	As of December 31,	
	2007	2006
	(in thousands)	
Compensation and related taxes	\$ 3,146	\$ 2,270
Restructuring	1,129	46
Income and other taxes	673	852
Professional fees	811	439
Other	902	921
Total	<u>\$6,661</u>	<u>\$4,528</u>

9. 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. Rent expense was \$1.2 million in 2007, 2006, and 2005. In addition, we lease automobiles and capital equipment under both operating and capital leases. There were assets held under capital leases at December 31, 2007. Assets held under capital leases amounted to \$0.3 million at December 31, 2006, with accumulated amortization of \$0.2 million in 2006. Capital lease asset amortization is included in depreciation and amortization.

In connection with past operations in France, we had occupied the building under a sale-leaseback arrangement. Upon dissolution of the French operations, the building was sold to a third party in 2005 resulting in a gain of approximately \$66,000, which is included in other income in the 2005 consolidated statement of operations.

At December 31, 2007, 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:

	Operating Leases
	(in thousands)
2008	\$ 964
2009	518
2010	206
2011	16
2012	13
Total	<u>\$ 1,717</u>

Purchase Commitments

We have purchase commitments to purchase \$3.0 million of inventory in 2008 and \$3.5 million in 2009.

Other Commitments

In September 2007 we entered into termination agreements with two former European distributors. The terms of these agreements call for payments, which we estimate to be approximately \$1.1 million in the aggregate (based on the exchange rates in effect on December 31, 2007). These payments are subject to adjustment by us based on actual data, with payments to begin between December 2007 and April 2008. In addition, we have agreed to exercise a non-compete agreement and also entered into a consulting agreement for a six-month period beginning in February 2008. We estimate these costs to be approximately \$0.6 million, and these amounts will be expensed over the periods in which the services are provided or benefits are realized.

[Table of Contents](#)

10. Income Taxes

Income (loss) before income taxes is as follows:

	Year ended December 31,		
	2007	2006	2005
	(in thousands)		
United States	(\$1,235)	(\$460)	\$ 822
Foreign	(1,467)	(60)	(244)
Total	<u>(\$2,702)</u>	<u>(\$520)</u>	<u>\$ 578</u>

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,		
	2007	2006	2005
	(in thousands)		
Current:			
Federal	(\$564)	\$ 455	\$ 208
State	(35)	84	10
Foreign	192	119	123
	<u>(407)</u>	<u>658</u>	<u>341</u>
Deferred:			
Federal	663	(43)	150
State	3	(11)	32
Foreign	(27)	48	—
	<u>639</u>	<u>(6)</u>	<u>182</u>
	<u>\$ 232</u>	<u>\$ 652</u>	<u>\$ 523</u>

As of December 31, 2007, the liability for unrecognized tax benefits was \$28,000 relating to state tax nexus issues (discussed below), which had been recognized as of December 31, 2006. 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, 2008, except with respect to matters that may be identified under audit (discussed below) that we cannot reasonably estimate. We remain subject to examination until the statute of limitations expires for each respective tax jurisdiction. A reconciliation of beginning and ending amount of our unrecognized tax benefits is as follows:

	2007
	(in thousands)
Unrecognized tax benefits at the beginning of year	\$ 311
Increases in unrecognized tax benefits as a result of tax positions taken during the period	—
Decreases in unrecognized tax benefits as a result of tax positions taken during the period	—
Amount of decreases in the unrecognized tax benefits relating to settlements with taxing authorities	(283)
Reductions to unrecognized tax benefits as a result of a lapse of the applicable statutes of limitations	—
Unrecognized tax benefits at the end of the year	<u>\$ 28</u>

[Table of Contents](#)

Deferred taxes are attributable to the following temporary differences:

	As of December 31,	
	2007	2006
	(in thousands)	
Deferred tax assets:		
Inventory	\$ 631	\$ 359
Net operating loss carryovers	1,186	694
Tax credit carryovers	435	98
Reserves and accruals	461	171
Other intangibles	(92)	300
Property and equipment	142	(135)
Other	(28)	16
Gross deferred tax assets	2,735	1,503
Valuation allowance	(2,756)	(1,107)
Deferred tax (liabilities) assets	(21)	396
Deferred tax liabilities:		
Goodwill	(1,055)	(833)
Net deferred tax liability	(1,076)	(437)
Short-term deferred tax liability (asset)	80	(396)
Non-current deferred tax liabilities	(\$ 996)	(\$ 833)

As of December 31, 2007, we have a net operating loss carryforward in the United States of \$2.8 million that expires in 2027. We also have state net operating loss carryforwards of \$2.3 million that expire at various times through 2027. In addition, we have net operating loss carryforwards in France of \$0.6 million that do not expire and Japan of \$0.1 million that expire in 2014. We also have federal research and development tax credit carryforwards of approximately \$0.3 million and state tax credit carryforwards of approximately \$0.2 million that are available to reduce future tax liabilities, which expire at various dates through 2022. Included in the net operating loss carryforwards are stock option deductions of approximately \$0.1 million. The benefit of these tax deductions will be credited to additional paid-in capital upon being realized.

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

	2007	2006	2005
Federal statutory rate	34.0%	34.0%	34.0%
State tax, net of federal benefit	0.2%	(9.8%)	1.6%
Effect of foreign taxes	4.7%	(83.6%)	33.1%
Valuation allowance	(40.1%)	(2.9%)	8.2%
Research credits	0.0%	0.0%	(7.8%)
Permanent differences	(2.4%)	(20.7%)	9.1%
Uncertain tax provisions	1.7%	(49.4%)	0.0%
Other	(6.7%)	7.1%	12.3%
Effective tax rate	(8.6%)	(125.3%)	90.5%

We have also made an evaluation of the potential impact of state taxes being assessed by jurisdictions in which we do not believe that nexus exists. However, we believe that it is more likely than not that taxing jurisdictions may adopt a position adverse to us and, accordingly, have recorded a liability of approximately \$28,000 as of December 31, 2007.

We were examined by the Internal Revenue Service (IRS) for our 2004 and 2005 income tax returns. In 2007 the IRS proposed and we agreed to a final adjustment to the previously reported returns resulting in a payment of \$0.4 million in April 2007, which amount was included in accrued expenses as of December 31, 2006. We were

[Table of Contents](#)

examined by the German federal tax authority in 2007, for our 2004, 2005, and 2006 tax returns. The German federal tax authority proposed and we agreed to a final adjustment to the previously reported returns resulting in an assessment of \$0.3 million in 2007, which provision had been previously made as of December 31, 2006.

As of January 1, 2008, a summary of the tax years that remain subject to examination in our most significant tax jurisdictions are:

United States—Federal	2006 and forward
Germany	2007
Japan	2004 and forward

11. Stockholders' Equity

Series A Convertible Preferred Stock

In June 1998 we sold 63,731 shares of our designated Series A Convertible Preferred Stock to Housatonic Equity Investors, L.P., in a private placement for \$2.35 per share in exchange for \$3.0 million. In connection with our public offering, 63,731 shares of Series A Convertible Preferred Stock were automatically converted into 1,274,620 shares of common stock on a 20-for-1 basis. As of December 31, 2007 and 2006, there were no shares of preferred stock issued or outstanding.

Stock Award Plans

Under our 1997, 1998, 2000, and 2004 stock option plans, we allowed for the granting of options in the form of incentive stock options or nonqualified 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 an exercise price not less than the fair market value of the stock on the date of grant 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.

In connection with preparation for our initial public offering of our common stock, we reassessed the valuations of our common stock issued prior to the effective date of the initial public offering based on the provisions of the AICPA's Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* (TPA). In conducting this assessment, we took into consideration the market and income approaches to valuation as set forth in the TPA. We believe that the valuation methodologies that we used prior to this public offering are consistent with the TPA. Based on the foregoing analysis, we concluded that for all options granted prior to October 19, 2006, in no case did the fair value of common stock exceed the exercise price for these options at the time of grant.

Options to purchase 386,272 shares of common stock and an award for the purchase of 252,852 shares of our common stock were issued to two key executives in 1997. The options and award were subject to restricted stock agreements which provided the employee with a repurchase right and us with a call right at a formula-based price in the event of death, disability, and voluntary and involuntary termination, as defined. We accounted for these options and award until 1998 using variable plan accounting since the exercise of the employee repurchase price was considered likely based on the lack of marketability of our common stock. Subsequent to the sale of \$0.8 million of our common stock in 1998 to individual, non-institutional investors, we determined that the likelihood of the exercise of the repurchase feature was remote based upon the value of the formula-based price compared to the value of the common sold to the individual investors. In addition, due to bank

[Table of Contents](#)

covenant restrictions, we determined our ability to exercise the call right, which was terminated by us in December 2003, was also remote. Since 1998, the value of our common stock has always exceeded the formula-based price. Consequently, subsequent to 1998 we have accounted for these options and award using fixed plan accounting.

Upon adoption of SFAS No. 123(R), based on the use of the prospective method of adoption, we continued to account for these options and this award under APB No. 25 as fixed plan arrangements. Concurrently with the adoption of SFAS No. 123(R), we applied the guidance included in Accounting Series Release No. 268 and EITF No. D-98 with respect to the redemption feature related to these options and award. The effect of the adoption resulted in the classification of the intrinsic value of the redemption feature of \$6.5 million at January 1, 2006, from retained earnings to other than permanent equity. During 2006, the value of the redemption feature increased by \$0.3 million to \$6.8 million, which amount was charged against retained earnings. The repurchase and call right features terminated upon the completion of our initial public offering of our common stock completed on October 19, 2006, resulting in a \$6.8 million credit to additional paid-in capital and no further accounting for the redemption feature.

In May 2006 we approved a 2006 Stock Option and Incentive Plan (the 2006 Plan), which became effective upon the initial public offering. The plan allows for granting of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock units, unrestricted stock awards, and deferred stock awards to our officers, employees, directors, and consultants. We have reserved for issuance of an aggregate of 750,000 shares of common stock under the 2006 Plan. In connection with the adoption of the 2006 Plan, no further option grants are permitted under the 1997, 1988, 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 authorized for plans is 2,438,702, of which approximately 515,000 remain available for grant as of December 31, 2007. Approximately 539,000 shares of common stock are reserved for future issuance under our stock option plans as of December 31, 2007.

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

	<u>2007</u>	<u>2006</u>	<u>2005</u>
Dividend yield	0.0%	0.0%	0.0%
Volatility	65.0%	65.0%	0.0%
Risk-free interest rate	4.9%	4.7%	4.2%
Weighted average expected option term (in years)	5.0	5.0	6.5
Weighted average fair value per share of options granted	\$3.59	\$ 5.43	\$2.57

Changes in outstanding stock options for 2007 were as follows:

	<u>Number of shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term (in years)</u>	<u>Aggregate intrinsic value (1)</u>
Balance outstanding at December 31, 2006	1,601,254	\$ 6.07	4.70	\$ 3,364,535
Granted	30,000	\$ 6.10		\$ 3,000
Exercised	(140,020)	\$ 1.22		\$ 735,173
Forfeited	(89,010)	\$ 10.26		\$ 3,062
Balance outstanding at December 31, 2007	<u>1,402,224</u>	\$ 6.28	8.18	<u>\$2,667,066</u>
Vested at December 31, 2007	1,029,906	\$ 4.97	8.71	\$2,649,661
Expected to vest at December 31, 2007 (2)	295,651	\$ 9.92	6.71	13,814
Total	<u>1,325,557</u>			<u>\$ 2,663,475</u>

- (1) The amounts represent the difference between the exercise price and \$6.20, the closing price of our stock on December 31, 2007, for all in-the-money options outstanding.
- (2) Options outstanding that are expected to vest are net of estimated future option forfeitures in accordance with the provisions of SFAS No. 123(R).

[Table of Contents](#)

Information about stock options outstanding and exercisable as of December 31, 2007, is as follows:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Outstanding as of December 31, 2007	Weighted average Remaining Contractual Life	Weighted average exercise price	Shares	Weighted average exercise price
\$ 0.00 – \$ 1.24	297,678	19.42	\$ 0.10	297,678	\$ 0.10
\$ 1.24 – \$ 2.47	134,440	0.64	\$ 2.15	134,440	\$ 2.15
\$ 2.47 – \$ 3.70	78,060	1.92	\$ 3.50	78,060	\$ 3.50
\$ 3.71 – \$ 4.95	39,250	3.18	\$ 4.29	39,250	\$ 4.29
\$ 4.95 – \$ 6.19	115,998	5.87	\$ 6.01	28,380	\$ 6.02
\$ 6.19 – \$ 7.42	31,500	4.38	\$ 7.03	31,500	\$ 7.03
\$ 7.42 – \$ 8.66	257,264	5.23	\$ 7.89	229,449	\$ 7.84
\$ 8.66 – \$ 9.90	10,819	6.16	\$ 8.73	6,491	\$ 8.73
\$ 9.90 – \$11.13	150,160	7.04	\$ 10.53	64,370	\$ 10.52
\$11.13 – \$12.37	287,055	7.09	\$ 11.93	120,288	\$ 11.89
	<u>1,402,224</u>	8.18	\$ 6.28	<u>1,029,906</u>	\$ 4.97

The fair value of the options that vested during 2007 was \$0.8 million. The total intrinsic value of options exercised in 2007 was approximately \$735,000; in 2006, \$251,000; and 2005, \$195,000. The amount of cash received from the exercise of stock options for 2007 was approximately \$171,000 and for 2006 was \$47,000. As a result of the exercise of the stock options in 2007, we are entitled to a future tax deduction of \$37,000 which has been fully reserved as of December 31, 2007.

We account for stock options issued to non-employees using the fair value method prescribed by SFAS No. 123. We compute the fair value of non-employee stock options using the Black-Scholes option-pricing model using an appropriate volatility factor and record the fair value of non-employee stock options as expense over either the vesting term of the option or the service period with the following assumptions:

	2007	2006	2005
Dividend yield	0.0%	0.0%	0.0%
Volatility	65.0%	65.0%	65.0%
Risk-free interest rate	4.7%	4.7%	4.2%
Weighted average expected option term (in years)	3.5	4.3	5.0

We recorded approximately \$9,000 during 2007, \$10,000 during 2006, and \$41,000 during 2005 of compensation expense related to stock options granted to non-employees.

Restricted Stock Units

Beginning in 2006, we also issue 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. Unvested RSUs are forfeited and canceled as of the date that employment terminates. RSUs are settled in shares of our common stock upon vesting. We may withhold common stock upon our employees' vesting in RSUs in order to provide proceeds to cover minimum tax withholding liability as a result of the RSUs having vested. During the year ended December 31, 2007, we repurchased 12,784 of our \$0.01 par value common stock at a per share price of \$6.37 and an aggregate purchase price of \$0.1 million. The value of the shares represented the amount required to satisfy the employees' minimum obligations with respect to withholding taxes in connection with the vesting of shares of restricted stock.

[Table of Contents](#)

A summary of our RSU activity, which is subject to the fair value accounting requirements of SFAS 123(R), is as follows:

	<u>Shares</u>	<u>Weighted Average Grant Date Fair Value</u>
Balance outstanding at December 31, 2006	133,000	
Granted	175,016	\$ 6.31
Vested(1)	(40,509)	\$ 6.07
Canceled	(17,899)	\$ 6.06
Balance outstanding at December 31, 2007	249,608	

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

The fair value of the RSUs that vested during 2007 was \$0.3 million.

Employee Stock Purchase Plan

In May 2006 the Board of Directors and stockholders approved the 2006 Employee Stock Purchase Plan (ESPP), which is qualified under Section 423 of the Internal Revenue Code. ESPP is available to all eligible employees who may purchase shares during six-month offering periods commencing on February 1 and August 1 of each year at a price per share of 90 percent of the fair market value on the last date of each six-month offering period. Participating employees may elect to have up to 10 percent of their base pay withheld and applied toward the purchase of such shares. The rights of participating employees under ESPP terminate upon voluntary withdrawal from the plan at any time or upon termination of employment. As of December 31, 2007, 13,357 shares have been purchased under ESPP at a purchase price of \$5.41 per share and 236,643 shares remain available for purchase.

12. 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 matching contributions to the Plan in an amount determined by our Board of Directors. Company contributions vest ratably with six years of employment and amounted to approximately \$0.3 million for 2007, \$0.2 million for 2006, and \$0.1 million for 2005.

13. Restructuring Charges

We initiated a plan to close our Florida manufacturing operations in 2005 and as a result, incurred severance, lease termination, and other costs. These costs amounted to \$0.8 million in 2005. No further costs were incurred with respect to this exit-activity cost.

We initiated a plan to close our UK manufacturing operations in 2005 and as a result, incurred severance, lease termination, and other costs. These costs amounted to \$31,000 in 2006 and \$0.1 million in 2005. No further costs were incurred with respect to this exit-activity cost.

We initiated a plan to close our Arizona manufacturing operations in 2006 and as a result, incurred severance and other costs. These costs amounted to \$5,000 in 2007 and \$0.2 million in 2006. No further costs are expected to be incurred with respect to this exit-activity cost.

In September 2007 we entered into termination agreements with two former European distributors. We estimate the termination fee payments to be approximately \$1.1 million in total. These payments are subject to adjustment by us based on actual data and commence on December 2007 through April 2008. In addition, we have agreed with a former distributor to exercise a non-compete agreement and also entered into a consulting

[Table of Contents](#)

agreement for six months beginning in February 2008. We estimate these costs to be approximately \$0.6 million. These amounts will be expensed during the periods over which the services are provided or benefits are realized.

The components of the restructuring charges are as follows:

	Year ended December 31,		
	2007	2006 (in thousands)	2005
Severance	\$ —	\$ 87	\$ 323
Lease termination costs	—	—	546
Distributor termination costs	1,054	—	—
Other	(12)	170	129
Total	\$ 1,042	\$ 257	\$ 998

Activity related to restructuring costs is as follows:

	Year ended December 31,		
	2007	2006 (in thousands)	2005
Balance at beginning of year	\$ 46	\$ 217	\$ 79
Plus:			
Current year restructuring costs	1,042	257	998
Other	75	—	—
Less:			
Payments for termination of contractual obligations	—	—	537
Payment of employee severance costs	34	149	111
Other	—	279	212
Balance at end of year	\$ 1,129	\$ 46	\$ 217

14. Segment and Enterprise-wide Disclosures

SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*, 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. All revenues were generated in the U.S., Europe, and Japan; and substantially all assets are located in the United States.

We sell products in three product categories, Endovascular & Dialysis Access, Vascular and General Surgery, and have also derived a limited amount of revenue from manufacturing devices under private label arrangements. Net sales in these product categories were as follows:

	Year ended December 31,		
	2007	2006 (in thousands)	2005
Endovascular & Dialysis Access	\$ 14,166	\$ 9,833	\$ 6,774
Vascular	23,397	20,992	19,654
General Surgery	3,883	3,803	3,600
Branded product sales	41,446	34,628	30,028
Private Label	—	—	699
Total	\$ 41,446	\$ 34,628	\$ 30,727

[Table of Contents](#)

Net sales to unaffiliated customers by geographic area are as follows:

	Year ended December 31,		
	2007	2006	2005
United States and Canada	\$25,141	\$22,362	\$20,056
Rest of world (principally Europe)	16,305	12,266	10,671
Total	<u>\$41,446</u>	<u>\$34,628</u>	<u>\$30,727</u>

Total assets are held in the following geographic areas as follows:

	Year ended December 31,		
	2007	2006	2004
United States and Canada	\$51,061	\$51,768	\$20,725
Rest of world (principally Europe)	10,090	5,195	4,343
Total assets	<u>\$61,151</u>	<u>\$56,963</u>	<u>\$25,068</u>

15. Related-Party Transactions

We leased our St. Petersburg, Florida, manufacturing facility from a related party who owned approximately 0.5 percent of our common stock and who also acted as a consultant to us. The rents paid to this landlord amounted to \$0.3 million in 2005 and 2004. On November 15, 2005, we entered into a lease termination agreement with the related party to terminate this lease for \$0.5 million. In addition, we agreed to purchase 47,279 shares of the related party's common stock at \$11.30 per share, the then fair market value of our common stock, totaling approximately \$0.6 million. No consulting fees were paid in 2007, 2006, and 2005.

For 2005 several of our European sales distributors owned shares of our common stock. No single distributor owned more than 2 percent of our common stock during the year period ended December 31, 2005. Total sales, valued at amounts intended to be arms-length, to these distributors amounted to \$3.1 million in 2005 or approximately 10 percent of our consolidated sales. Amounts due from these distributors totaled \$0.5 million as of December 31, 2005, 13 percent of our consolidated accounts receivable. As of December 31, 2007 and 2006, and at all times since our initial public offering, there were no sales distributors that owned more than 5 percent of our common stock.

16. Supplemental Cash Flow Information

Supplemental disclosures of cash flow information are as follows:

	Year ended December 31,		
	2007	2006	2005
Cash paid for income taxes, net	\$ 920	\$ 249	\$ 3
Cash paid for interest	1	307	184
Supplemental non-cash financing activities:			
Common stock issued in connection with acquisitions	—	—	2,000
Reclassification of deferred compensation upon adoption of SFAS No. 123(R)	—	84	—
Effect of adoption of SFAS 123(R) for redemption feature of common stock awards	—	6,474	—
Increase in redemption feature of common stock awards	—	295	—
Cancellation of redemption feature as a result of the initial public offering	—	(6,769)	—
Initial public offering costs included in accounts payable and accrued expenses	—	271	—
Cancellation of treasury stock	—	857	—
Acquisition-related obligations to sellers	1,646	—	—
Common stock repurchased for RSU tax withholdings	82	—	—

[Table of Contents](#)**17. Subsequent Events (unaudited)**

In January 2008 we were notified by one of our Biomateriali customers that they would no longer be purchasing a certain product line from us. This notification resulted in a write-down of the related inventory in the fourth quarter of 2007 of \$0.1 million. As a result of this development, we have determined that as of the date of the notification, related intangibles of \$0.4 million have been impaired and will be written off during the first quarter of 2008.

In March 2008 we provided notice of an indemnity claim under the Biomateriali purchase agreement to the sellers of Biomateriali, contending that the sellers breached certain representations and warranties in the purchase agreement by failing to adequately disclose material information regarding a customer relationship. We have demanded the payment of damages of approximately \$0.5 million (denominated in a foreign currency) and have ceased making certain post-closing payments to the sellers pending resolution of this indemnity claim.

In January 2008 we initiated a plan to reorganize our worldwide operations and, as a result, incurred severance costs of \$0.4 million associated with the reduction of approximately 32 employees or 13% of our worldwide workforce.

18. Quarterly Financial Data (unaudited)

<u>2007</u>	<u>Three months ended</u>			
	<u>March 31</u>	<u>June 30</u>	<u>September 30</u>	<u>December 31</u>
	(in thousands, except per share data)			
Total net sales	\$ 9,883	\$ 10,315	\$ 10,144	\$ 11,104
Gross profit	7,370	7,613	7,581	8,143
Income (loss) from operations	(977)	(447)	(1,541)	(1,318)
Net income (loss)	(629)	227	(1,354)	(1,178)
Net income (loss) available to common stockholders:				
Basic	(\$ 0.04)	\$ 0.01	(\$ 0.09)	(\$ 0.08)
Diluted	(\$ 0.04)	\$ 0.01	(\$ 0.09)	(\$ 0.08)

<u>2006</u>	<u>Three months ended</u>			
	<u>March 31</u>	<u>June 30</u>	<u>September 30</u>	<u>December 31</u>
	(in thousands, except per share data)			
Total net sales	\$ 8,571	\$ 8,760	\$ 8,540	\$ 8,757
Gross profit	6,310	6,095	6,261	6,595
Income (loss) from operations	462	(1,050)	342	(433)
Net income (loss)	370	(1,090)	220	(674)
Net income (loss) available to common stockholders:				
Basic	\$ 0.02	(\$ 0.14)	\$ 0.01	(\$ 0.05)
Diluted	\$ 0.02	(\$ 0.14)	\$ 0.01	(\$ 0.05)

SCHEDULE II
LEMAITRE VASCULAR
VALUATION AND QUALIFYING ACCOUNTS
FOR THE YEARS ENDED DECEMBER 31, 2007, 2006, AND 2005

<u>Description</u>	<u>COLUMN A</u> Balance at Beginning of Period	<u>COLUMN B</u> Additions Charged to Income	<u>COLUMN C</u> Deductions from Reserves	<u>COLUMN D</u> Balance at End of Period
(in thousands)				
Reserves deducted from assets to which they apply:				
Allowance for doubtful accounts and sales returns:				
Year ended December 31, 2007	\$ 102	\$ 197	\$ 80	\$ 219
Year ended December 31, 2006	120	21	39	102
Year ended December 31, 2005	145	16	41	120

EXHIBIT INDEX

- 10.35 Supply and Distribution Agreement dated January 1, 2005, by and between Biomateriali Srl and Edwards Lifesciences AG, as amended
- 21.1 Subsidiaries of the Registrant
- 23.1 Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
- 31.1 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification pursuant to 18 U.S.C. Section 1350
- 32.2 Certification pursuant to 18 U.S.C. Section 1350

[****] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE EXCHANGE ACT OF 1934, AS AMENDED.

SUPPLY AND DISTRIBUTION AGREEMENT

This agreement is made as of January 1, 2005 (the "Effective Date") by and between Biomateriali Srl, an Italian limited liability company having its registered offices at Cittadella della Ricerca s.s.7 per Mesagne, 72100 Brindisi, Italy ("BIOMATERIALI") and Edwards Lifesciences AG, a corporation organised under the laws of Switzerland and having its business office at Chemin du Glapin 6, 1162 Saint-Prex, Switzerland ("EDWARDS").

WHEREAS, BIOMATERIALI is a manufacturer of medical devices for vascular surgical procedures and has developed, manufactured and marketed proprietary interventional medical device products as set forth in Exhibit A (the "Products").

WHEREAS, EDWARDS desires and has the facilities, personnel and expertise to distribute the Products on a comprehensive basis throughout the Territory.

WHEREAS, BIOMATERIALI wishes to appoint EDWARDS, and EDWARDS wishes to be appointed as a distributor of the Products in the territory set forth in Exhibit B (the "Territory").

NOW, THEREFORE, in consideration of the mutual undertakings, obligations and covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are acknowledged, the parties agree as follows ("Agreement"):

1. APPOINTMENT

- 1.1 Scope. Subject to the terms and conditions contained in this Agreement, BIOMATERIALI hereby appoints EDWARDS, and EDWARDS hereby accepts appointment, as BIOMATERIALI's exclusive distributor of the Products listed in Exhibit A in the Territory listed in Exhibit B during the term of this Agreement. BIOMATERIALI agrees that it will not sell or distribute the Products in the Territory, directly or through third parties, nor shall it to appoint any other agents, representatives or distributors for the purpose of selling the Products in the Territory.
- 1.2 Additional Territory. BIOMATERIALI recognizes EDWARDS as a prior and primary partner for the distribution of the Products therefore commits to offer any distribution rights for the Products in countries outside the Territory initially to EDWARDS to accept or refuse such distribution right within 90 ninety days from the written notification of BIOMATERIALI.
- 1.3 Sub-distributors. EDWARDS may appoint sub-distributors or agents to promote and/or distribute the Products within the Territory.

FOIA CONFIDENTIAL TREATMENT REQUESTED

2. OBLIGATIONS/LIMITATIONS OF EDWARDS

- 2.1 Marketing Efforts. EDWARDS shall have the following obligations with respect to the marketing and distribution of the Products:
- (a) To use reasonable commercial efforts to further the promotion, marketing, and distribution of the Products in the Territory;
 - (b) To provide adequate and appropriate training to its staff concerning the Products;
 - (c) To use sales and technical literature as well as promotional artwork and training materials provided by BIOMATERIALI. EDWARDS may alter such materials or develop any other materials in connection with the marketing and distribution of Products (product brochures and sales aids), which shall be subject to BIOMATERIALI's prior written approval. BIOMATERIALI retains all right, title and interest in and to such materials thereof;
 - (d) To provide twice any calendar year BIOMATERIALI with a report showing the purchased Products allocated to Group A and Group B Territory.
 - (e) Where appropriate according to EDWARDS' own judgement, to translate Product-related materials into the language or languages of any parts of the Territory and provide BIOMATERIALI with copies of such translations. Should this Agreement be terminated prior to its term for reasons other than EDWARDS' malfeasance, BIOMATERIALI will reimburse EDWARDS for such translations. BIOMATERIALI retains all right, title and interest in and to such translated versions thereof.
- 2.2 Inventory. EDWARDS shall at all times make his best efforts to maintain an inventory of the Products sufficient to meet anticipated demand but calculated to result in the minimum possible return of Products under Section 2.5.
- 2.3 Customer Service. EDWARDS shall provide customer service, including, but not limited to, taking orders, responding to customer inquiries, fulfilling requests for quotes on Product pricing, forwarding Product complaints to BIOMATERIALI on a timely basis and providing such assistance and information as is reasonably requested.
- 2.4 Defective Products. EDWARDS shall process and return any defective Products to BIOMATERIALI for credit or replacement, as EDWARDS shall determine. Should the Product in question be defective, all expenses related to its return and replacement shall be borne by BIOMATERIALI.

FOIA CONFIDENTIAL TREATMENT REQUESTED

-
- 2.5 Expired Products. EDWARDS shall not sell any Products beyond their stated expiration date. Expired products will be handled according to the verified EDWARDS quality control systems guidelines and will be discarded. Alternatively, at EDWARDS' election, the products will be shipped back to BIOMATERIALI for disposal.
 - 2.6 Alteration of Products. EDWARDS shall not alter the Products or any Product packaging or labelling except with the prior written consent of BIOMATERIALI.
 - 2.7 Target Purchase Quantities. During the term of this Agreement, Edwards shall use its commercially reasonable effort to purchase the target quantities of [*****] ([***)] units of Product ("Target Purchase Quantity") at the prices shown in Exhibit A, for any twelve month period starting with the Effective Date of the Agreement ("Supply Year").
 - 2.8 Forecasts. EDWARDS agrees to provide BIOMATERIALI with a non-binding twelve (12) month forecast indicating EDWARDS' projected purchase of Products for the Territory. Such forecast shall be updated by EDWARDS on a rolling quarterly basis for each succeeding twelve (12) month period, and each updated forecast must be received by BIOMATERIALI no later than thirty (30) days prior to the first day of the period to which it relates. Such forecasts by EDWARDS shall be used for purposes of facilitating BIOMATERIALI and its suppliers' planning to meet lead times delivery for the Products, and shall not constitute binding commitments to purchase upon EDWARDS. EDWARDS will use its best efforts to notify BIOMATERIALI promptly of any changes in its forecast.
 - 2.9 Import and Others Sales Governmental Requirements. Except as otherwise agreed by BIOMATERIALI in writing, EDWARDS shall be responsible for compliance with applicable requirements for importing the Products into, marketing and distributing the Products within the Territory, including but not limited to all custom requirements. BIOMATERIALI shall provide EDWARDS with assistance in this matter as EDWARDS may reasonably request. EDWARDS shall obtain any necessary import licenses, at its own expense.
 - 2.10 Notice of Intellectual Property Infringement. EDWARDS shall promptly notify BIOMATERIALI in writing of any patent, copyright infringement or unauthorized use of BIOMATERIALI's trade secrets or trademarks in the Territory of which EDWARDS has become aware. BIOMATERIALI reserves the right in its sole discretion to institute any proceedings against such third party infringers in its name and on its behalf. EDWARDS shall cooperate fully with BIOMATERIALI in any legal action taken by BIOMATERIALI against such third parties, provided that BIOMATERIALI shall pay all expenses of such action and all damages relating to damage suffered personally by BIOMATERIALI which may be awarded or agreed upon in settlement of such action shall accrue to BIOMATERIALI, without prejudice to the right of EDWARDS to initiate any proceedings against third party infringers in order to obtain compensation for damages suffered.

FOIA CONFIDENTIAL TREATMENT REQUESTED

-
- 2.11 Compliance with Laws of the Territory. Upon knowledge, EDWARDS will do its commercial reasonable efforts to inform BIOMATERIALI of any legal requirements in the Territory that may affect the use or distribution of the Products, marketing materials or Product packaging and labelling. Notwithstanding the above BIOMATERIALI will remain fully responsible to comply with any legal and regulatory requirements related to the Products in the countries belonging to the European Union.
 - 2.12 Insurance. EDWARDS shall maintain in force, during the term of this Agreement, one or more policies of liability insurance in amounts adequate to cover all obligations of EDWARDS hereunder.
 - 2.13 Adverse Reactions. In the event that either party receives any complaint regarding the Product, it shall notify the other party immediately after becoming aware of it. EDWARDS will make an assessment of each complaint it receives, provide BIOMATERIALI with these complaint assessments and will coordinate all follow-up and customer communication that it deems appropriate. EDWARDS will assist BIOMATERIALI in its decision process about whether a complaint shall have to be notified to a local competent authority and the Notified Body or not and for implementing of appropriate Field Corrective Actions.

In the event that any customer of EDWARDS rejects or returns a Product to EDWARDS as a result of a Product performance problem, EDWARDS shall immediately so notify BIOMATERIALI and confirm in writing. If the reason for such performance problem is reasonably determined to be failure of the Product to meet its specifications, then BIOMATERIALI will replace, at its sole expense, the non-conforming Product which EDWARDS elects to so replace. In such case, BIOMATERIALI will pay all shipping and handling costs of EDWARDS relating to the handling, replacement and return of the rejected Product.

3. OBLIGATIONS OF BIOMATERIALI

- 3.1 Sales and Technical Literature. BIOMATERIALI shall provide to EDWARDS reasonable quantities of such sales, advertising and technical literature and materials as BIOMATERIALI may have prepared and shall make available copies of promotional artwork it may have prepared. If available, BIOMATERIALI may provide the same to EDWARDS in electronic format. Any adjustments or modifications of sales, advertising and technical literature to the requirements of EDWARDS shall be charged to and covered by EDWARDS in full.
- 3.2 Marketing and Training Support. BIOMATERIALI shall provide EDWARDS with marketing and training support to enable EDWARDS to perform its obligations under this Agreement. In addition, BIOMATERIALI shall provide EDWARDS with all necessary training and technical assistance related to the Products and related services at BIOMATERIALI's sole cost.

FOIA CONFIDENTIAL TREATMENT REQUESTED

-
- 3.3 Sterile Samples for Customers. BIOMATERIALI shall provide EDWARDS with a maximum annual volume of sterile samples equal to 5% of the agreed Target Purchase Quantity in Section 2.7 at the special prices for Samples listed in Exhibit A in order for EDWARDS to perform its commercial obligations. The annual volume of sterile samples shall be included in the calculation of the Target Purchase Quantity.
- 3.4 Non-sterile Demonstration Samples. BIOMATERIALI shall provide, free of charge and upon EDWARDS' request, up to a maximum of 50 non-sterile demonstration sample sets each year (1 sample set consist of: 1 AMC 1809, 1 ATC 1528, 1 AMC1508 graft) for the duration of this Agreement.
- 3.5 Product Specifications, Packaging and Labelling.
- (a) Product Release. BIOMATERIALI is responsible for producing and releasing the Product in compliance with the specifications as communicated to and agreed with EDWARDS. BIOMATERIALI warrants that the Product will (i) conform to specifications and may be used for, and in the manner identified in, the Product Label and directions for use (if any), (ii) be free from defects in design, formulation, workmanship and material, and (iii) are manufactured and tested, and at the time of delivery to EDWARDS will be, in accordance/conformity with the state of the scientific and technological art as well as the EC-guidelines for good manufacturing and practice for drugs, and applicable provisions for quality and documentation for approved registration/regulatory files.
 - (b) Packaging and Labelling. BIOMATERIALI, at its expense, shall provide EDWARDS with any product instruction for use and labelling required for the distribution in the Territory. BIOMATERIALI shall take care of all the appropriate changes on all product instructions for use and labelling of the Products, if any, in order to comply with European and national regulations. The Product labelling shall include the statement "Manufactured exclusively for EDWARDS Lifesciences by BIOMATERIALI" and be provided in a multi-language format that will enable it to be sold throughout the Territory.
- 3.6 Insurance. BIOMATERIALI shall obtain and maintain in force, during the term of this Agreement, and for so long as necessary to cover any claims that may be made thereafter regarding the Products sold by EDWARDS, for coverage, a product liability insurance policy in a amount not less than Euro [*****] ([*****]) each occurrence and in the aggregate, in a form reasonable acceptable to EDWARDS. BIOMATERIALI's insurance policy will be considered primary. The insurance carrier(s) shall be a reputable international company reasonably acceptable by EDWARDS and will have an AM Best rating of no less than A-. A copy of the above BIOMATERIALI confirmation of coverage shall be given to EDWARDS at the Effective Date and then as soon as practicable at the beginning of each new policy term.

FOIA CONFIDENTIAL TREATMENT REQUESTED

During the term of this Agreement and for so long as necessary to cover any claims that may be made thereafter regarding the Products, EDWARDS, its Affiliates and subsidiaries shall be additionally insured (so-called vendor endorsement). EDWARDS shall be provided with 30 days prior written notice of any cancellation, non-renewal or material change in the terms of such policy.

For the purpose of this Agreement, the term "Affiliates or Affiliate Entity" shall mean (i) any other entity/person of which the securities or other ownership interests representing fifty percent (50%) or more of the equity or fifty percent (50%) or more of the ordinary voting power or fifty percent (50%) or more of the general partnership interests are, at the time of such determination, owned, controlled or held, directly or indirectly, by such entity/person, or (ii) any other entity/person, which at the time of such determination, is controlling, controlled by or under common control with such entity/person. As used herein, the term "Control", whether used as a noun or verb, refers to the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of a entity/person, whether through the ownership of voting securities, by contract or otherwise.

4. PURCHASES AND PAYMENT TERMS

- 4.1 Orders. EDWARDS shall order Products by means of written, individual Purchase Orders. The Purchase Order shall specify applicable prices, quantities by catalogue number, shipping schedule, shipping instructions, and, if applicable, any relevant export control information or documentation to enable BIOMATERIALI to comply with Territory export control laws and regulations, any special requirements and other similar matters that are necessary for the individual transaction in accordance with this Agreement to be adequately described.
- 4.2 Order Acceptance. BIOMATERIALI shall accept or refuse in writing EDWARDS' issuance of any Purchase Order within ten (5) business days from the date when the order has been received and shall not be refused without just cause. Any Purchase Order that is not rejected within the above stated period shall be deemed accepted. BIOMATERIALI shall accept Purchase Orders and deliver the Products that the EDWARDS has ordered in accordance with this Agreement but shall have no liability to EDWARDS with respect to purchase orders that exceed the Target Purchase Quantity in Section 2.7 by twenty percent (20%). No accepted Purchase Order may be modified or cancelled except as agreed in writing by the parties. EDWARDS' Purchase Orders or mutually agreed change Purchase Orders shall be subject to all provisions of this Agreement. Any terms or conditions of such Purchase Order or change Purchase Order that conflict the terms or conditions of this Agreement shall be deemed excluded.
- 4.3 Shipment and Delivery Terms. BIOMATERIALI shall use its best efforts to fill orders that are within EDWARDS' forecast plus ten percent (10%), within sixty (60) calendar days from the confirmation of the relevant Purchase Order. In addition BIOMATERIALI shall use its reasonable efforts to fill orders to the extent

FOIA CONFIDENTIAL TREATMENT REQUESTED

they exceed EDWARDS' by ten percent (10%) the forecast. Unless otherwise agreed in writing by BIOMATERIALI and EDWARDS, all deliveries of the Products shall be FCA, INCOTERMS 2000, at Biomateriali's facilities in Brindisi, Italy and, upon request, BIOMATERIALI shall organize and coordinate the shipment to EDWARDS' premises according to EDWARDS' reasonable instructions provided that shipping charges shall be paid by EDWARDS.

- 4.4 Acceptance of the Products. EDWARDS shall inspect each shipment of Products and give BIOMATERIALI written notice of any defects in or non-conformity of any Products receipt at EDWARDS' warehouse within thirty (30) days from their delivery. All Products or parts thereof claimed to be non-conforming with the Product specifications, with the Purchase Order, damaged or in whatever manner defective, must be kept at EDWARDS' warehouse for inspection by BIOMATERIALI. EDWARDS shall return any non-conforming or defective Products as directed by BIOMATERIALI and at BIOMATERIALI's expense for credit or replacement at EDWARDS' discretion. In case of replacement, BIOMATERIALI will ship the replaced Product within a reasonable time, DDU at EDWARDS' warehouse in Nijmegen, The Netherlands, according to INCOTERMS 2000. The parties understand and agree that Products shipped to EDWARDS with an use-before-period (shelf-life) of less than twenty (20) months will not be accepted.
- 4.5 Prices and Annual True-Up. Pricing will be in Euro. EDWARDS shall pay BIOMATERIALI the prices as stated in Exhibit A for Products (including Sterile Samples) sold in Group A and Group B countries. BIOMATERIALI will invoice for, and EDWARDS shall initially pay, all delivered and accepted Products (including Sterile Sample) at prices set forth for Group A country in the Territory during each Supply Year irrespective where in the Territory the Products are finally sold. Not later than February 28th of each next Supply Year, EDWARDS shall provide BIOMATERIALI with the report of the total sales of the Products in Group A and Group B countries in the Territory for the previous Supply Year, in order to calculate the annual payment adjustments and credit EDWARDS with the amount based on the difference between the amount actually invoiced and the amount that should have in fact been invoiced and paid by EDWARDS in accordance with the then-current related prices listed in the Exhibit A, as amended, and considering the volume of Products sold in the Group A, Group B countries in the Territory and the Sterile Samples in Section 3.3. Any special packing or handling requested by EDWARDS shall be at the sole expense of EDWARDS.
- 4.6 Price Adjustments. The prices set forth in Exhibit A shall be firm for the first Supply Year and afterwards adjusted for each subsequent Supply Year based on changing market conditions and competition as well as material and production costs. The revised prices shall be mutually agreed upon the parties at least thirty (30) days prior to commencement of the succeeding Supply Year and will be applied to Purchase Orders executed after the date of the agreed price adjustment. Increased prices shall not apply to any Purchase Order issued prior to the agreed

FOIA CONFIDENTIAL TREATMENT REQUESTED

applicable date of such price increase. It is furthermore understood and agreed by the parties that the Target Purchase Quantity in Section 2.7 are strictly related to the purchase prices of the Products; therefore, in case of any price increase, the annual Target Quantities for the subsequent Supply Year will be reviewed accordingly.

In the event the parties fail to agree on the purchase prices for the subsequent Supply Year on or before December 1st of each Supply Year, the purchase prices for such subsequent Supply Year shall remain the purchase prices in force plus [**] of the inflation rate in Italy of the previous year as published by the Italian institute of statistic (ISTAT) and both parties may terminate this Agreement with twelve month notice in accordance Article 11.1 below.

The parties may at any time agree to negotiate fixed prices other than as specified in Exhibit A, in response to changing market conditions (including if labour costs or raw material costs increase by more than [****] ([****])) or facing a high-volume opportunity.

- 4.7 Payment Terms. BIOMATERIALI shall issue an invoice for each shipment and EDWARDS shall make payment of relevant invoice within sixty (60) days after receipt of BIOMATERIALI's invoice by wire transfer to an Italian bank designated by BIOMATERIALI. All payments shall be made in Euro.
- 4.8 Resale Prices. EDWARDS may offer the Products in the Territory at such prices as EDWARDS, in its sole discretion, shall determine.
- 4.9 Product Changes. Provided that BIOMATERIALI gives ninety (90) days prior notice to EDWARDS and indemnifies and holds harmless EDWARDS for all legal and contractual consequences or other commitments for Products made by EDWARDS prior to the date such notice becomes effective, BIOMATERIALI may at its sole discretion:
- (a) Change the specification or discontinue the production of one or more Products. In such case of changed or discontinued Product, BIOMATERIALI and EDWARDS shall evaluate in good faith the ongoing supply contract with the EDWARDS' customers and shall make all reasonable commercial efforts to secure, supply of the changed or discontinued product for existing supply contracts with EDWARDS' customers.
 - (b) Commence the development and distribution of new products or of modifications or improvements to the Products having features which may make the Products wholly or partially obsolete. Subject to the terms set forth below, EDWARDS shall have exclusive right to distribute new products and modifications or improvements to Products. The parties shall negotiate in good faith for the applicable prices for such new products.

FOIA CONFIDENTIAL TREATMENT REQUESTED

5. REGULATORY AFFAIRS

- 5.1 CE-Mark. BIOMATERIALI shall obtain and maintain in its own name the CE mark and other required regulatory approvals for the Products in the European Union. All costs incurred for the CE marking application are BIOMATERIALI's. BIOMATERIALI agrees to notify EDWARDS immediately upon any action or situation that may change the CE marking compliance status, such as regulatory or Notified Body inspection findings or manufacturing malfunctions which materially affect the quality of shipped Products or result in the material deterioration of Product performance. BIOMATERIALI shall be responsible for creating and maintaining the Technical Documentation for the Product and agrees to provide EDWARDS with four copies of technical files and any documentation in case of request from an Authority (Ministry of Health or Notified Body). BIOMATERIALI will certify via a Declaration of Conformity that the Product conforms to the relevant Harmonized Standards.
- 5.2 Other Approvals. BIOMATERIALI will use best efforts to obtain approval of the Products for any other country if so requested by EDWARDS and agreed to by BIOMATERIALI. No representation is made as to whether approvals for countries that are not accepting the CE-Mark can be achieved. If required, BIOMATERIALI will promptly notify EDWARDS to the regulatory authorities as the exclusive distributor of the Products in the Territory.
- 5.3 Regulatory Support. EDWARDS or the respective sub-distributors of EDWARDS shall provide BIOMATERIALI with all reasonable required support to comply with any local regulatory law and requirement including but not limited to assisting and executing all documents necessary to satisfy all regulatory requirements in the jurisdictions in which the Products are distributed, whenever is mandatory or necessary to register the Products in such country.
- 5.4 Compliant Use. EDWARDS shall make all reasonable commercial efforts to inform its customer for proper use of the Products and in full compliance with BIOMATERIALI instructions for the use and the handling of the Products. Neither Party shall be responsible to the other for any application outside the national regulatory approvals or any use without any regulatory approval.
- 5.5 Changes in Regulations. BIOMATERIALI is under no obligation to adapt the Products to more restrictive regulatory requirements entering into force after conclusion of this Agreement, that trigger more than insignificant additional costs. In such cases, BIOMATERIALI may stop selling the Products to EDWARDS for ultimate sale or distribution into those countries which require such restrictive requirements.

6. QUALITY MANAGEMENT SYSTEM, TRACEABILITY

- 6.1 Product Quality. BIOMATERIALI shall use its best efforts to maintain the highest standard of quality for the Products. BIOMATERIALI shall communicate to

FOIA CONFIDENTIAL TREATMENT REQUESTED

EDWARDS any significant changes in the production and quality assurance team for the Products in existence at the time the present Agreement is executed, including but not limited to the team members and quality assurance procedures. Such communication is to be made on a timely basis prior to making any projected changes. Should EDWARDS be dissatisfied with any projected changes, the parties agree to review and discuss them. The parties agree to attempt to resolve their differences within a period not to exceed six (6) weeks, after which, should no agreement be reached, the distribution Agreement may be amicably terminated.

- 6.2 Quality Management System. BIOMATERIALI has established and maintains a Quality Management System in accordance with EN ISO 9001, EN 46001 and ISO 13485 and other relevant quality management standards and legal provisions. BIOMATERIALI represents that the actual production of the Products takes place under the CE-certified Quality Management System.
- 6.3 Compliance Inspection. BIOMATERIALI shall inspect and test Products prior to delivery to EDWARDS to ensure compliance with the Product Specifications.
- 6.4 Traceability. EDWARDS is responsible for product traceability to its customers. In accordance with the relevant quality standards and internal BIOMATERIALI procedures, traceability of critical or major components, processes, manufacturing and release inspection results will be maintained by BIOMATERIALI to the individual Product identified by serial or lot number. The collected records will be archived by BIOMATERIALI for a period of at least one year after the expiration date of the respective Product.
- 6.5 Product Storage Conditions. EDWARDS shall preserve BIOMATERIALI guidelines for storage conditions in its warehouses, which shall not be below 0°C and above 30°C. EDWARDS will inform all its sub-distributors regarding adequate storage conditions for the product. BIOMATERIALI acknowledges that EDWARDS is using third party warehouse facilities and logistic services, therefore subject to acceptance of this service provider of any visit request during normal business hours and BIOMATERIALI compliance with its third party access policy, EDWARDS will allow BIOMATERIALI to visit the warehouse premises to verify the above said storage conditions only.

7. REPORTING, VIGILANCE, RECALL

- 7.1 Reporting. It is BIOMATERIALI sole responsibility to file Medical Device Reports or Vigilance Reports to any legal authority for the Products in order to comply with the applicable laws and regulations in the Territory. Only, if EDWARDS by any applicable law or regulation is obliged to report medical device incidents, this Agreement shall not prevent EDWARDS to do so.
- 7.2 Safety Notification. In case a Product is potentially deviating from its Specification, or under any other circumstance where such Product might cause, or already has caused harm to a patient, user or other person, each party shall notify

FOIA CONFIDENTIAL TREATMENT REQUESTED

the other party in writing (“Safety Notification”), irrespective of the time or location of detection of the potentially faulty Product, as soon as the respective party gains knowledge of such circumstance. Safety Notifications and any other complaints on the Products are to be effected to the following addresses:

BIOMATERIALI Srl, Mr. Cosimo Saponaro
Citadella della Ricerca s.s.7 per Mesagne
72100 Brindisi
Italy (tel. +39 0831 588 028, Fax: +39 0831 588 030)
email: m.saponaro@tiscali.it

Edwards Lifesciences S.L., Mrs. Maite Llacer
Avda. Juan de la Cierva 27
Parque Tecnológico de Valencia
46980 Paterna, Valencia
Spain (tel. +34 9 63 05 37 14, Fax +34 9 63 05 37 07)
email: maite_llacer@edwards.com

- 7.3 No Statement. In the event of a (alleged) malfunction or defect of a Product, EDWARDS or its representatives or agents will not make any statement as to the cause, before having informed BIOMATERIALI and having received BIOMATERIALI written analysis of the malfunction or defect, and will then not render statements different from the results of such analysis.
- 7.4 Sales Records. EDWARDS will maintain complete and accurate lists and records reflecting all Product sales and related transactions as may be required by law and to comply with the EU regulations, regulations of the EC-Council Directive concerning medical devices or other legal requirements applicable for a country of the Territory to secure full traceability of each Product.
- 7.5 Product Recall. If either party believes that a recall of any Products in the Territory is desirable or required by law in the Territory or elsewhere, it shall immediately notify the other party. The parties shall then discuss reasonably and in good faith whether such recall is appropriate or required and the manner in which any mutually agreed recall shall be handled. BIOMATERIALI will be responsible for making the decision whether to inform the local competent authority and the Notified Body or not. EDWARDS shall make commercially reasonable efforts to assist BIOMATERIALI in giving effect to the recall, including communication with any customer or user. BIOMATERIALI shall bear all costs and expenses of any recall, including, without limitation, expenses or obligations to third parties, the costs of notifying customers and costs associated with the shipment of recalled Product from customer to EDWARDS or BIOMATERIALI, and replacement of such Products.
- 7.6 Remedial Actions. It is BIOMATERIALI exclusive right and obligation to issue recalls, safety alerts, advisory notices or similar remedial actions on the Products. In such case, EDWARDS will support and fully co-operate with BIOMATERIALI

FOIA CONFIDENTIAL TREATMENT REQUESTED

to comply with the applicable laws and regulations. Furthermore, in such case EDWARDS will notify its customers and, upon BIOMATERIALI's request retrieve identified Products. BIOMATERIALI shall bear all direct costs and expenses of any recall, including, without limitation, expenses or obligations to third parties, the costs of notifying customers and costs associated with the shipment of recalled Product from customer to EDWARDS or BIOMATERIALI, and replacement of such Products.

7.7 Survival. The provisions of this section Reporting, Vigilance, Recall shall survive the termination of the Agreement.

8. LIABILITY AND INDEMNIFICATION

- 8.1 Indemnification by BIOMATERIALI. Notwithstanding anything else in this Agreement to the contrary, BIOMATERIALI shall defend, indemnify and hold the EDWARDS and its affiliated entities, and each of their officers, directors, agents and employees harmless against any and all claims, demands, losses, liabilities, damages, costs and expenses (including reasonable attorneys' fees) made or incurred by a third party resulting from (a) any breach by BIOMATERIALI of this Agreement, (b) personal injury or death resulting from the use of a Product, (c) Product defects, (d) infringement of patents, copyrights, trademarks, or other intellectual property rights, (e) product recalls, (f) failure by BIOMATERIALI to maintain the regulatory approvals. The indemnification contained in this Section shall survive the expiration or termination of this Agreement for any reason whatsoever.
- 8.2 Indemnification by EDWARDS. EDWARDS shall defend, indemnify and hold BIOMATERIALI its officers, directors, employees, and agents harmless against any and all claims, demands, suits, proceedings, losses, liabilities, damages, costs and expenses (including reasonable attorneys' fees) resulting from (a) any breach by EDWARDS of this Agreement, or (b) any act, error or omission of EDWARDS or any of its officers, directors, employees, agents, or representatives, with respect to the marketing, distribution, sale of the Products within the Territory, including, failure to train customers on how to use the Products. The indemnification contained in this Section shall survive the expiration or termination of this Agreement for any reason whatsoever.
- 8.3 Indemnification Procedure. A party seeking indemnification (an "indemnified party") shall give the other party (an "indemnifying party") written notice of any Legal Action within ten (10) days of first knowledge thereof. The indemnifying party shall have sole and exclusive control of the defense of any Legal Action, including the choice and direction of legal counsel. The indemnified party shall have the right to engage its own counsel, at its own expense. The indemnified party may not settle or compromise any Legal Action without the written consent of the indemnifying party.

FOIA CONFIDENTIAL TREATMENT REQUESTED

9. CONFIDENTIALITY

9.1 Confidential Information: Term. All Confidential Information (as defined below) shall be deemed confidential and proprietary to BIOMATERIALI or EDWARDS (The “Disclosing Party”). The Party receiving any Confidential Information (the “Receiving Party”) may use these Confidential Information during the term of this Agreement only as permitted or required for its performance hereunder and shall not disclose or provide any Confidential Information to any third party and shall take reasonable measures to prevent any unauthorized disclosure by its employees, agents, contractors or consultants, including appropriate individual nondisclosure agreements. The foregoing duty shall survive any termination or expiration of this Agreement for three (3) years.

9.2 Definition. As used in this Agreement, the term “Confidential Information” shall mean all information disclosed by BIOMATERIALI to EDWARDS and vice versa or embodied in the Products when clearly marked by BIOMATERIALI as being confidential in nature, relating to the other Party’s markets, customers, products, patents, inventions, procedures, methods, designs, strategies, plans, assets, liabilities, prices, costs, revenues, profits, organisation, employees, agents, resellers or business in general. The following shall not be considered Confidential Information for purposes of this Section 9:

- (a) Information which is or becomes in the public domain through no fault or act of Receiving Party;
- (b) Information which was independently developed by Receiving Party without the use of or reliance on Confidential Information;
- (c) Information which was provided to Receiving Party by a third party under no duty of confidentiality to the Disclosing Party; or
- (d) Information which is required to be disclosed by law, provided, however, prompt prior notice thereof shall be given to Disclosing Party and disclosure shall be limited to the maximum extent possible.

10. TRADEMARKS

10.1 Use of Trademarks. BIOMATERIALI hereby grants to EDWARDS, and EDWARDS hereby accepts from BIOMATERIALI, a non-exclusive, non-transferable, and royalty-free license to use BIOMATERIALI trademark (Albograft™) as the same may be revised by BIOMATERIALI from time to time, during the term of this Agreement, solely in connection with the distribution, promotion and advertising of the Products. EDWARDS may use the BIOMATERIALI trademark in promotional brochures and in connection with trade fairs. EDWARDS shall not use any other marks or trade names in connection with the marketing and distribution of the Products except for EDWARDS’ proprietary trade names and marks. BIOMATERIALI may inspect and monitor EDWARDS’

FOIA CONFIDENTIAL TREATMENT REQUESTED

use of the BIOMATERIALI trademark. EDWARDS shall not remove or alter any BIOMATERIALI trade names, trademarks, copyright notices, serial numbers, labels, tags or other identifying marks, symbols or legends affixed to any Products, documentation or containers or packages. EDWARDS shall not adopt, use or register any words, phrases or symbols, which are identical to or confusingly similar to any of BIOMATERIALI's trademarks.

11. TERM AND TERMINATION

- 11.1 Term. This Agreement shall come into force on the date first written above (the "Effective Date") and shall continue in force for a period of five (5) years (the "Initial Term"), unless earlier terminated as provided in this Article 11.2. To the extent permitted by the laws in any single country of the Territory, this Agreement, the exclusive rights and non-compete provisions thereof shall be automatically for an indefinite period at the end of the Initial Term, unless either party provides the other party with twelve (12) months prior written notice of its intent to terminate the Agreement.
- 11.2 Termination. Either party may terminate this Agreement at any time with immediate effect by either party:
- (a) if the other party shall be or become bankrupt or insolvent or if there are instituted by or against it proceedings in bankruptcy or under insolvency laws or for its reorganization, receivership, liquidation or dissolution;
 - (b) if the other party is in serious material breach of this Agreement and has failed to cure such breach within sixty (60) days of receipt of written notice thereof from the first party;
 - (c) either party or either party's employees, officers, sub-distributors or agents engages in unethical business conduct or is convicted of a crime (other than a misdemeanour) that, in the reasonable discretion of either party, is likely to cause or has caused harm or disrepute to the reputation of the other party, or harm to the public;
 - (d) there is a major material change in the management of or operation of either party's business; or
 - (e) any law or government-enacted regulation or decree renders the performance by either party of its respective obligations hereunder unduly onerous or otherwise inexpedient.
- 11.3 Additionally BIOMATERIALI may terminate this Agreement immediately upon written notice to EDWARDS if EDWARDS breaches any obligation to BIOMATERIALI regarding BIOMATERIALI's intellectual property, alters any Product or the labelling therefore without BIOMATERIALI's prior written consent or sells a Product beyond its expiration date; or

FOIA CONFIDENTIAL TREATMENT REQUESTED

11.4 Rights and Obligations on Termination. In the event of termination of this Agreement for any reason, and subject to Article 11.6 below concerning the sell-off period, the parties shall have the following rights and obligations:

- (a) Neither party shall be released from the obligation to make payment of all amounts then or thereafter due and payable;
- (b) The duties of confidentiality under Article 10 and the duties of both parties concerning dispute resolution under Article 13 shall survive the termination of this Agreement;
- (c) Except as provided in Section 11.6, EDWARDS shall cease to distribute the Products and shall return to BIOMATERIALI all copies of promotional and technical materials and artwork provided by BIOMATERIALI;
- (d) BIOMATERIALI will repurchase EDWARDS' inventory of non-obsolete and non-expired Products at the price paid by EDWARDS for such Products or direct EDWARDS to sell them to the third party or parties selected by BIOMATERIALI;
- (e) EDWARDS shall return or, if requested by BIOMATERIALI, destroy all Confidential Information, including, if applicable all electronic copies thereof and shall certify in writing that it has done so; and
- (f) EDWARDS shall cease any use of the BIOMATERIALI trademark in any manner. In addition, EDWARDS hereby empowers BIOMATERIALI and shall assist BIOMATERIALI, if requested, to cancel, revoke or withdraw any governmental registration or authorisation, permitting EDWARDS to use BIOMATERIALI trademark in the Territory.

11.5 Sell-off Period. Notwithstanding the above, upon expiration or termination of this EDWARDS shall have the right to continue to distribute its existing inventory of non-expired Products for an unlimited period after the expiration or termination and until the inventory exists, either is in his possession or in consignment at client premises. In addition, if termination arises other than through breach by EDWARDS and EDWARDS has outstanding contracts or tenders for Products, the terms and conditions of this Agreement shall remain in effect with respect only to the supply of Products for such contracts or tenders for the remaining term of such contracts or tenders.

12. CHANGE OF CONTROL, RIGHT OF FIRST REFUSAL

12.1 If BIOMATERIALI ceases, or threatens to cease, to carry on its business or the production of the Products, BIOMATERIALI shall immediately inform EDWARDS of its intention before informing any third party and, in such cases; EDWARDS shall have the option right to place an offer to acquire BIOMATERIALI or part of its business related to the Products. EDWARDS shall

FOIA CONFIDENTIAL TREATMENT REQUESTED

notify BIOMATERIALI its intention to exercise such option right within sixty (60) days from the notification of BIOMATERIALI intention to abandon or sell in full or in part its business.

- 12.2 In the event BIOMATERIALI receives a bona fide offer for all or part of its business from any third party, during the term of this Agreement, EDWARDS shall have the right of first refusal to purchase business. If this occurs EDWARDS shall notify BIOMATERIALI its intention to proceed with a due diligence on BIOMATERIALI business and eventually match the purchase offer of such third party within sixty (60) days from the date it receives the notification of the intended transaction.
- 12.3 Notwithstanding Articles 12.1 and 12.2 above, in the event of a Change of Control (as defined below) of either party occurs, the party with respect to which the Change of Control has occurred shall give notice to the other party (the "Non-Affected Party") within thirty (30) days after the occurrence of such Change of Control. The Non-Affected Party may terminate the Agreement upon the expiry of a twelve (12) months' notice. In the event of a Change in Control of BIOMATERIALI, if this Agreement is terminated on notice to EDWARDS, BIOMATERIALI shall pay EDWARDS a cancellation fee (the "Cancellation Fee") in an amount equal to EDWARDS' purchase orders for Products (the "Product Purchases") for the twelve (12) months immediately preceding the date on which EDWARDS is notified by BIOMATERIALI of such Change of Control. For the purpose of this Article 11.3, "Change of Control" shall mean:
- (i) the acquisition, directly or indirectly, by any individual or legal entity of at least fifty percent (50%) of the voting stock of any party to this Agreement or any individual or legal entity that controls either party.
 - (ii) a merger involving either party which, directly or indirectly, controls or is controlled by or is under the same control as either party hereto, "control" meaning the ability to exercise or to procure the exercise, directly or indirectly, of at least fifty percent (50%) of the voting stock of a company.

13. GOVERNING LAW AND ARBITRATION

- 13.1 This Agreement shall be governed by and construed and enforced in accordance with the Italian law.
- 13.2 Any dispute, controversy or claim arising under, out of or relating to this contract and any subsequent amendments of this contract, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, shall be referred to and finally determined by arbitration in accordance with the WIPO Arbitration Rules. The arbitral tribunal shall consist of three arbitrators and the place of arbitration shall be Geneva, Switzerland. The language to be used in the arbitral proceedings shall be English.

FOIA CONFIDENTIAL TREATMENT REQUESTED

13.3 The arbitral award will be final and binding on the parties, and the prevailing party shall be entitled to recover attorney's fees and costs awarded by the arbitration. The provision of this Section shall not restrict the right of either party to seek and obtain provisional remedies from any court of competent jurisdiction.

14. MISCELLANEOUS

14.1 Compliance with Laws. EDWARDS and BIOMATERIALI shall comply with all applicable laws affecting this Agreement and its performance hereunder and, without limiting the generality of the foregoing, shall maintain all registrations with governmental agencies, commercial registries, chambers of commerce, or other offices which may be required under local law in order to enable it lawfully to conduct its business and perform its obligations under this Agreement. Upon written notice from either party hereto, the notified party shall provide such information, as it may reasonably consider necessary to verify compliance by the other party with the provisions of this Section.

14.2 Force Majeure. If the performance of this Agreement or any obligation hereunder (other than the payment of monies due owing hereunder) is prevented, restricted or interfered with by reason of any event or condition beyond the reasonable control of such party (including without limitation acts of state or governmental action, riots, disturbance, war, strikes, lockouts, slowdowns, prolonged shortage of energy or other supplies, epidemics, fire, flood, hurricane, typhoon, earthquake, lightning and explosion or any refusal or failure of any governmental authority to grant any export license legally required), the party so affected shall be excused from such performance, only for so long as and to the extent that such a force prevents, restricts or interferes with the party's performance and provided that the party affected gives notice thereof to the other party and uses diligent efforts to remedy such event or conditions.

14.3 Relationship. This Agreement does not make either party the employee, agent or legal representative of the other for any purpose whatsoever. Neither party is granted any right or authority to assume or to create any obligation or responsibility, express or implied, on behalf of or in the name of the other party. Each party is acting as an independent contractor.

14.4 Assignment. Either party shall not have the right to assign or otherwise transfer its rights and obligations under this Agreement except with the prior written consent of the other party. Any prohibited assignment shall be null and void.

FOIA CONFIDENTIAL TREATMENT REQUESTED

14.5 Notices. Notices permitted or required to be given hereunder shall be given:

- (a) by EDWARDS to BIOMATERIALI's statutory seat at the address set forth on page 1 or such other address of which BIOMATERIALI may notify EDWARDS in writing;
- (b) by BIOMATERIALI to EDWARDS' statutory seat at the address set forth on page 1 or such other address of which EDWARDS may notify BIOMATERIALI in writing.

Notices shall be deemed sufficient if given by (a) registered or certified mail, postage prepaid, return receipt requested, (b) private courier service, or (c) facsimile with electronic confirmation of receipt, addressed to the respective addresses of the parties as first above written or at such other addresses as the respective parties may designate by like notice from time to time. Notices so given shall be effective upon (a) receipt by the party to which notice is given, or (b) on the fifth (5th) day following domestic mailing or the tenth (10th) day following international mailing, as may be the case, whichever occurs first.

- 14.6 Entire Agreement. This Agreement, including the Exhibits hereto which are incorporated herein, constitutes the entire agreement of the parties with respect to the subject matter hereof and supersedes the European Distribution Agreement effective as of November 9, 2000 (including all its amendments), as well as all proposals, oral or written, and all negotiations, conversations, discussions or previous distribution agreements or arrangements heretofore between the parties. EDWARDS hereby acknowledges that it has not been induced to enter into this Agreement by any representations or statements, oral or written, not expressly contained herein.
- 14.7 Amendment. This Agreement may be modified, amended, rescinded, cancelled or waived, in whole or in part, by written amendment signed by both parties.
- 14.8 Severability. If any provision of this Agreement is found unenforceable under any of the laws or regulations applicable thereto, such provision terms shall be deemed stricken from this Agreement, but such invalidity or unenforceability shall not invalidate any of the other provisions of this Agreement.
- 14.9 Counterparts. This Agreement may be executed in two or more counterparts in the English language, and each such counterpart shall be deemed an original hereof. In case of any conflict between the English version and any translated version of this Agreement, the English version shall govern.
- 14.10 Waiver. No failure by either party to take any action or assert any right hereunder shall be deemed to be a waiver of such right in the event of the continuation or repetition of the circumstances giving rise to such right.

FOIA CONFIDENTIAL TREATMENT REQUESTED

14.11 Employee Solicitation. During the term of this Agreement and for one (1) year after its termination for any reason, neither party will solicit or hire the other's employees involved in performance of the agreement, without prior written consent of the other party.

FOIA CONFIDENTIAL TREATMENT REQUESTED

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives below.

BIOMATERIALI SRL

EDWARDS LIFESCIENCES AG

/s/ Pierpaolo Cerani

/s/ Patrick Verguet

Pierpaolo Cerani
Managing Director

Patrick Verguet
President Europe

FOIA CONFIDENTIAL TREATMENT REQUESTED

List of Exhibits

- A. Products, Prices
- B. Territory

FOIA CONFIDENTIAL TREATMENT REQUESTED

BIOMATERIALI

EXHIBIT A - PRODUCTS, PRICES

Graft Type/Length		Unit Price		Sterile Sample Price	
		Group A	Group B	Group A	Group B
		Albograft without Collagen (AMO, ATO)			
Straight tube	Any length	[***]€	[***]€	[***]	[***]
Bifurcation		[***]€	[***]€	[***]	[***]
		Albograft with Collagen (AMC, ATC)			
Straight tube	7.5cm length	[***]€	[***]€	[***]€	[***]€
	15cm length	[***]€	[***]€	[***]€	[***]€
	30cm length	[***]€	[***]€	[***]€	[***]€
	40 cm length	[***]€	[***]€	[***]€	[***]€
	60 cm length	[***]€	[***]€	[***]€	[***]€
	100cm length	[***]€	[***]€	[***]€	[***]€
Bifurcation		[***]€	[***]€	[***]€	[***]€
		Albopass with Collagen (ATC 90XX)			
Tube with side arm	60cm tube/ 40cm side arm	[***]€	[***]€	[***]€	[***]€

FOIA CONFIDENTIAL TREATMENT REQUESTED

EXHIBIT B—DISTRIBUTION TERRITORY

GROUP A		GROUP B
Europe	Europe	Middle East / Far East and Africa
Andorra	All EU Accession countries	All Middle East countries acc. to British definition
Austria	Albania	China
Belgium	Armenia	Hong-Kong
Denmark	Azerbaijan	Indonesia
Finland	Belarus	Korea
France	Bosnia-Herzegovina	Malaysia
Germany	Bulgaria	Morocco
Greece	Croatia	Philippines
Lichtenstein	Georgia	Singapore
Luxembourg	Iceland	South Africa
Monaco	Ireland	Taiwan
Norway	Italy	Thailand
San Marino	Macedonia	Tunisia
Spain	Moldova	Vietnam
Sweden	Montenegro	
Switzerland	Netherlands	
	Portugal	
	Romania	
	Russia	
	Serbia	
	Turkey	
	United Kingdom (UK)	
	Ukraine	
	Vatican City	

FOIA CONFIDENTIAL TREATMENT REQUESTED

AMENDMENT TO THE SUPPLY AND DISTRIBUTION AGREEMENT

entered into between

Biomateriali Srl, an Italian limited liability company having its registered offices at Cittadella della Ricerca s.s.7 per Mesagne, 72100 Brindisi, Italy

and

Edwards Lifesciences AG, a corporation organised under the laws of Switzerland and having its business office at Chemin du Glapin 6, 1162 Saint-Prex, Switzerland.

By signing this Amendment, the Parties agree to amend their "Supply and Distribution Agreement" made as of January 1, 2005 (hereinafter: "the Agreement") as follows:

1. The amendments to the Agreement stated hereafter shall take effect on January 1, 2007.
2. The Agreement shall last until December 31, 2011, this date referring to the "Initial Term" as mentioned under section 11.1.
3. The following sections of the Agreement shall not be effective anymore:
 - 2.1. d)
 - 3.3.
 - 3.4.
4. Section 2.7 is amended and replaced as follows:

"Target Purchase Quantities. During the term of this Agreement, Edwards shall use its commercially reasonable effort to purchase the target quantities of [***] ([***) units of Product ("Target Purchase Quantity") at the prices shown in Exhibit A, for any twelve month period starting on January 1, 2007 ("Supply Year")."
5. Section 4.5 is amended and replaced as follows:

"Prices. Pricing will be in Euro. BIOMATERIALI shall invoice for, and EDWARDS shall pay BIOMATERIALI all delivered and accepted Products at prices set forth in Exhibit A in the Territory set forth in Exhibit B during each Supply Year. Any special packing or handling requested by EDWARDS shall be at the sole expense of EDWARDS."

FOIA CONFIDENTIAL TREATMENT REQUESTED

6. Exhibits A and B of the Agreement are replaced by the Exhibits A and B attached to the present Amendment.

BIOMATERIALI SRL

EDWARDS LIFESCIENCES AG

/s/ Pierpaolo Cerani

/s/ Patrick Verguet

Pierpaolo Cerani
Managing Director

Patrick Verguet
President Europe

Place and Date:

23 Jan 2007
Place and Date:

FOIA CONFIDENTIAL TREATMENT REQUESTED

List of Exhibits

- A. Products, Prices
- B. Distribution Territory

FOIA CONFIDENTIAL TREATMENT REQUESTED

EXHIBIT A—PRODUCTS AND PRICES

<u>Graft Type / Length</u>		<u>Unit Price</u> <u>effective from Jan 1, 2007</u>
Albograft without Collagen (AMO, ATO)		
Straight tube	Any length	[***]€
Bifurcation		[***]€
Albograft with Collagen (AMC, ATC)		
Straight tube	7.5cm length	[***]€
	15cm length	[***]€
	30cm length	[***]€
	40cm length	[***]€
	60cm length	[***]€
	100cm length	[***]€
Bifurcation		[***]€
Albograft with Collagen (ATC 90XX)		
Straight tube with 1 side arm	60cm tube length/ 40cm side arm	[***]€

FOIA CONFIDENTIAL TREATMENT REQUESTED

EXHIBIT B—DISTRIBUTION TERRITORY

	<u>Europe</u>	<u>Middle East / Far East and Africa</u>
Andorra	All EU Accession countries	All Middle East countries acc. to British definition
Austria	Albania	China
Belgium	Armenia	Hong-Kong
Denmark	Azerbaijan	Indonesia
Finland	Belarus	Korea
France	Bosnia-Herzegovina	Malaysia
Germany	Bulgaria	Morocco
Greece	Croatia	Philippines
Lichtenstein	Georgia	Singapore
Luxembourg	Iceland	South Africa
Monaco	Ireland	Taiwan
Norway	Italy	Thailand
San Marino	Macedonia	Tunisia
Spain	Moldova	Vietnam
Sweden	Montenegro	
Switzerland	Netherlands	
	Portugal	
	Romania	
	Russia	
	Serbia	
	Turkey	
	United Kingdom (UK)	
	Ukraine	
	Vatican City	

FOIA CONFIDENTIAL TREATMENT REQUESTED

SUBSIDIARIES OF THE REGISTRANT

The following is a list of our subsidiaries:

<u>Name</u>	<u>State or Other Jurisdiction of Incorporation</u>	<u>Name Under Which Does Business</u>
Biomateriali S.r.l.	Italy	Same
LeMaitre UK Acquisition LLC	Delaware	Same
LeMaitre Vascular GmbH	Germany	Same
LeMaitre Vascular GK	Japan	Same
LeMaitre Acquisition LLC	Delaware	Same
LeMaitre Vascular SAS	France	Same
LeMaitre Vascular S.r.l.	Italy	Same
Vascutech Acquisition LLC	Delaware	Same

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements (Form S-8 Nos. 333-138181 and 333-146395) of our report dated March 27, 2008 with respect to the consolidated financial statements and schedule of LeMaitre Vascular, Inc. included in the Annual Report (Form 10-K) for the year ended December 31, 2007.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 27, 2008

CERTIFICATIONS

I, George W. LeMaitre, certify that:

1. I have reviewed this Annual Report on Form 10-K of LeMaitre Vascular, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ GEORGE W. LEMAITRE

George W. LeMaitre
Chairman of the Board
and Chief Executive Officer

Date: March 31, 2008

CERTIFICATIONS

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

1. I have reviewed this Annual Report on Form 10-K of LeMaitre Vascular, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ JOSEPH P. PELLEGRINO, JR.

Joseph P. Pellegrino, Jr.
Chief Financial Officer

Date: March 31, 2008

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

In connection with the Annual Report of LeMaitre Vascular, Inc. (the "Company") on Form 10-K for the period ending December 31, 2007, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, George W. LeMaitre, Chairman and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

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

/s/ GEORGE W. LEMAITRE

George W. LeMaitre
Chief Executive Officer

March 31, 2008

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

In connection with the Annual Report of LeMaitre Vascular, Inc. (the "Company") on Form 10-K for the period ending December 31, 2007, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph P. Pellegrino, Jr., Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

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

/s/ JOSEPH P. PELLEGRINO, JR.

Joseph P. Pellegrino, Jr.
Chief Financial Officer

March 31, 2008