LEMAITRE VASCULAR INC
Form 10-K
March 31, 2009
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2008

or

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to .

Commission File Number 001-33092

LEMAITRE VASCULAR, INC.

(Exact name of registrant as specified in its charter)

Delaware	**04-2825458**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
63 Second Avenue, Burlington, Massachusetts	**01803**
(Address of principal executive offices)	**(Zip Code)**

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

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

Title of each class	**Name of each exchange on which registered**
Common Stock, $0.01 par value per share	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: þ

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: þ

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: þ No: ¨

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule12b-2 of the Exchange Act.

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule12b-2 of the Act). Yes: ¨ No: þ

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 30, 2008: $24,632,573. At March 26, 2008, the Registrant had 15,665,806 shares of Common Stock, par value $0.01 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

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

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LEMAITRE VASCULAR

2008 FORM 10-K ANNUAL REPORT

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PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements (within the meaning of the federal securities law) that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this Annual Report on Form 10-K regarding our strategy, future operations, future financial position, future net sales, projected costs, projected expenses, prospects and plans and objectives of management are forward-looking statements. The words anticipates, believes, estimates, expects, intends, may, plans, p 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;
- our ability to successfully identify, acquire, and integrate new products, businesses, and technologies and realize expected benefits;
- 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 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

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section entitled Risk Factors, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, or investments we may make. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law.

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, LeverEdge, MollRing Cutter, NovaSil, OptiLock, Periscope, Pruitt, Pruitt-Inahara, Reddick, TT, UniFit, VascuTape, and the LeMaitre Vascular logo are registered trademarks of LeMaitre Vascular, and AlboGraft, aSpire, Biomateriali, EndoHelix, EndoRE, F3, Martin, TAArget, and VCS are unregistered trademarks of LeMaitre Vascular. This Annual Report on Form 10-K also includes the registered and unregistered trademarks of other persons.

Item 1. Business

Overview

LeMaitre Vascular is a global provider of medical devices and implants for the treatment of peripheral vascular disease. We develop, manufacture, and market vascular devices to address the needs of vascular surgeons. Our diversified portfolio of peripheral vascular devices consists of brand name products that are used in arteries and veins outside of the heart and are well known to vascular surgeons, including the Expandable LeMaitre 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 and developing 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 aortic stent graft product lines, which are endovascular implants used to treat aortic aneurysms and dissections, and in 2007 we acquired our EndoRE remote endarterectomy devices, 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 product lines of third parties that address markets that we estimate approximate $75 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 prior to the recent economic downturn we estimate had been growing at 8% per year. We believe that our strong brands, established 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 52 field sales representatives in North America, the European Union, and Japan as of December 31, 2008. 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, 2008, approximately 88% of our net sales were generated through direct sales, and no customer accounted for more than 3% of our net sales.

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Corporate Information

We were incorporated in Massachusetts on November 28, 1983, as Vascutech, Inc. On June 16, 1998, we were reincorporated in Delaware, and on April 6, 2001, we changed our name to LeMaitre Vascular, Inc. Our principal executive offices are located at 63 Second Avenue, Burlington, Massachusetts 01803, and our telephone number is (781) 221-2266.

Where You Can Find More Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available through the investor relations portion of our website (www.lemaitre.com) free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, 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 perform 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.

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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. We believe that this trend is likely to continue, as new vascular surgeons complete courses of study that include endovascular training and older vascular surgeons less likely to adopt these techniques retire. 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, Dr. LeMaitre s son, George W. LeMaitre, our Chairman and Chief Executive Officer, 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.

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, 2008, we have continued to execute on our primary business strategies by increasing the number of our field sales representatives from 36 to 52; hiring our first direct sales personnel in Austria, France, Italy, and Sweden; increasing the number of research

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and development engineers; launching new products; and completing four acquisitions in 2007. Most significantly:

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 Biomateriali, S.r.l., a privately held Italian manufacturer of the AlboGraft Vascular Graft, a line of polyester prosthetic grafts for vessel replacement in the peripherals, abdomen, and thorax, which at the time were distributed exclusively by Edwards Lifesciences AG. In 2009, we reached agreement with Edwards Lifesciences to terminate their distribution of this product line as of March 27, 2009, and we commenced direct-to-hospital sales on March 30, 2009.

Due in part to these efforts, we generated net sales of $41.4 million and $48.7 million for the years ended December 31, 2007 and 2008, respectively. We currently offer 14 product lines across three product categories. In addition, we further leverage our sales organization by distributing the Powerlink System, an abdominal stent graft manufactured by Endologix, Inc., in several European countries, and the PeriPatch Biologic Vascular Patch, a line of bovine and equine tissue-based vascular patches manufactured by Neovasc Inc., in the United States and several European countries. We hold an option commencing January 2, 2014 to acquire the PeriPatch Biologic Vascular Patch product line from Neovasc Inc.

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:

Acquire Complementary Products. 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 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 are also seeking clearance for the sale of our AlboGraft Vascular Graft product line in the United States.

Expand Our Direct Sales Force. We sell our products primarily through a direct sales force comprised as of December 31, 2008, of 52 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. In the near-term it is unlikely that we will significantly expand the size of our sales force; however, as a long-term strategy, we intend to further expand our sales force. 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.

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Our Products

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

			Available for Sale in		
Product Category	**Product Line**	**Primary Use**	**United States**	**European Union**	**Japan**
Endovascular	TAArget Thoracic Stent Graft	Endovascular repair of thoracic aortic aneurysm and dissection	Application submitted(1)	ü	
	UniFit Abdominal Stent Graft	Endovascular repair of abdominal aortic aneurysm	In clinical studies(2)	ü	
	aSpire Covered Stent	Holding open major leg arteries that have had blockages removed(3)	ü	ü	
	LeverEdge Contrast Injector	Injection of media to monitor blood flow and determine vessel location	ü	ü	
	VascuTape Radiopaque Tape	Improvement in precision and accuracy of endovascular procedures	ü	ü	ü
	AnastoClip Vessel Closure System	Attachment of blood vessels, primarily for dialysis access	ü	ü	ü
Vascular	AlboGraft Vascular Graft	Synthetic vessels for use in bypass and replacement procedures	Application submitted(4)	ü	
	EndoRE Remote Endarterectomy Devices	Removal of blockages in the major arteries of the leg	ü	ü	
	InvisiGrip Vein Stripper	Single-incision removal of varicose veins	ü	ü	ü
	Expandable LeMaitre Valvulotome	Destruction of vein valves to create vein bypass graft	ü	ü	ü
	Pruitt-Inahara, Pruitt F3, and Flexcel Carotid Shunts	Facilitation of blood flow to brain during carotid plaque removal	ü	ü(5)	ü(5)
	LeMaitre Balloon Catheters	Removal of blood clots; occlusion, and facilitation of blood flow	ü	ü	ü
General Surgery	OptiLock Implantable Port	Central venous infusion of drugs and nutrients	ü	ü	
	Reddick Cholangiogram Catheter	Introduction of dye into the cystic duct	ü	ü	Application submitted(6)

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(1) We have submitted an IDE application to the FDA to begin a feasibility study of the TAArget Thoracic Stent Graft. In July 2008, we received a letter from the FDA indicating that it could not approve our application until deficiencies identified in the letter are resolved to the FDA s satisfaction. We are working with the FDA to resolve these deficiencies, although there can be no assurance that the FDA will approve our application. See Clinical Studies for a description of this clinical study.
(2) 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.
(3) 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.
(4) We have submitted an application for 510(k) clearance of the AlboGraft Vascular Graft product line with the FDA.
(5) The Pruitt F3 Carotid Shunt is only available for sale in the United States. The Flexcel Carotid Shunt is available for sale in the United States and the European Union, but is not yet available for sale in Japan.
(6) We have submitted an application for Shonin registration with the Japan Ministry of Health, Labor and Welfare.

Effective January 1, 2007, we became the exclusive distributor for the Powerlink System a bifurcated 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 TAArget 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.

Effective January 26, 2009, we became the exclusive distributor for the vascular surgery sizes of the PeriPatch Biologic Vascular Patch a line of bovine and equine tissue-based vascular patches manufactured by Neovasc Inc. in the United States and several European countries. We believe that the PeriPatch Biologic Vascular Patch complements our carotid shunt product line, both of which are used by vascular surgeons in a carotid endarterectomy procedure, which is the open surgical removal of plaque from a diseased carotid artery. We hold an option commencing January 2, 2014 to acquire the PeriPatch Biologic Vascular Patch.

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

Endovascular

Endovascular

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

TAArget Thoracic Stent Graft

The TAArget Thoracic Stent Graft is an endovascular graft 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. The TAArget Thoracic Stent Graft, introduced in 2008, replaces our EndoFit Thoracic Stent Graft in most markets. The TAArget Thoracic Stent Graft features our new TT Tortuous Tracker Delivery System for more precise deployment of the stent graft and a new, optional uniform top stent design for improved external fixation against the wall of the aorta. TAArget s flexible, encapsulated design, in contrast to devices currently available commercially, uses expanded polytetrafluoroethylene (ePTFE), which is designed to prevent the stent scaffolding from contacting either the blood stream or the vessel wall. This design also allows us to offer a wide range of stent grafts sizes,

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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, 2008, approximately 47% of our TAArget and UniFit stent grafts were custom-built. We acquired TAArget s predecessor EndoFit product line through our acquisition of Endomed in February 2005.

Our TAArget Thoracic Stent Graft product line is currently sold in the European Union and a small number of foreign jurisdictions. We have submitted an IDE application to the FDA to begin a feasibility study of the TAArget Thoracic Stent Graft. In July 2008, we received a letter from the FDA indicating that it could not approve our application until deficiencies identified in the letter are resolved to the FDA s satisfaction. We are working with the FDA to resolve these deficiencies, although there can be no assurance that the FDA will approve our application. See Clinical Studies for a description of this clinical study.

In February 2009 the EndoFit Thoracic Stent Graft was approved for sale in China by the State Food and Drug Administration (SFDA) following a clinical study conducted by our Chinese distributor on our behalf. We are preparing to commence sales of this device in China, although there can be no assurance that we will be successful in entering or effectively penetrating the Chinese stent graft market. See Risk Factors 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.

UniFit Abdominal Stent Graft

The UniFit Abdominal Stent Graft is a non-bifurcated endovascular graft 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 TAArget device, with a flexible, encapsulated design and similar manufacturing advantages that allow us to offer a wide range of stent graft sizes and custom-built devices. The UniFit Abdominal Stent Graft is also available with the TT Tortuous Tracker Delivery System and a new, optional uniform top stent. We acquired the previous generation of our UniFit product line through our acquisition of Endomed in February 2005.

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.

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.

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

aSpire Covered Stent

The aSpire Covered Stent is a spiral-shaped nitinol stent covered 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, is less likely to cut off supply to arterial side branches, which could cause tissue damage. We acquired the aSpire Covered Stent product line and related operations through our acquisition of the business of Vascular Architects in September 2007.

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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 contrast delivery 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.

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 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 Covidien, then 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

We distribute the Powerlink System, 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.

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

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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 original 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. The Pruitt F3 Carotid Shunt is only available for sale in the United States. The Flexcel Carotid Shunt is available for sale in the United States the European Union, and many other foreign jurisdictions, but is not yet available for sale in Japan.

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.

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 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 a vascular surgeon.

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

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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 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. We acquired the AlboGraft Vascular Graft product line through our acquisition of Biomateriali S.r.l. in December 2007.

Our AlboGraft Vascular Graft product line is currently sold in the European Union and many other foreign jurisdictions. We have submitted an application for 510(k) clearance of the AlboGraft Vascular Graft product line with the FDA. Until recently, this product line was sold through an exclusive distribution agreement with Edwards Lifesciences AG. In March 2009, we paid $3.5 million to Edward Lifesciences in exchange for the early termination of this distribution agreement, the purchase of their AlboGraft customer list and certain customer contracts, and their provision of sales and marketing services. We also repurchased most of their remaining AlboGraft inventory. We commenced direct-to-hospital sales on March 30, 2009.

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 a single incision in the groin. Our EndoRE devices are used to separate the sclerotic blockage from the vessel, cut the far end of the blockage to free it for removal, and then withdraw the blockage from the vessel. 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 preserves the patient s own veins for future use in an unrelated bypass procedure. 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.

PeriPatch Biological Vascular Patch

We distribute the PeriPatch Biologic Vascular Patch, a patch made from either bovine or equine pericardium and used in conjunction with endarterectomy and vascular reconstruction procedures. The patch is exceptionally strong, uniform and easy to handle and suture.

The PeriPatch Biologic Vascular Patch is manufactured by Neovasc Inc. in Vancouver, Canada and distributed by us in the United States, the European Union, and select other European markets.

General Surgery Products

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. 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.

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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.

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. We currently have one active U.S. clinical study with respect to our UniFit Abdominal Stent Graft called the UNITE Trial. Recently we have begun efforts to initiate a U.S. feasibility study of our TAArget Thoracic Stent Graft called the ENTRUST Trial.

In October 2002, the previous owner of our UniFit Abdominal Stent Graft 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 of the feasibility study 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 call the UNITE trial. As of March 26, we had enrolled 29 patients in the trial. We plan to enroll 90 patients at up to 21 institutions. The primary effectiveness endpoint of the study is based on aneurysm exclusion as evaluated through one-year follow-up.

Additionally, in May 2008, we submitted an IDE application to the FDA to begin a feasibility study, which we call the ENTRUST study, to evaluate the safety of the TAArget Thoracic Stent Graft in the treatment of thoracic aortic aneurysms. Because the TAArget Thoracic Stent Graft is a significant risk device for regulatory purposes, we cannot start our feasibility study for the device until we receive the FDA s approval of our application. In July 2008, we received a letter from the FDA indicating that it could not approve our application until deficiencies identified in the letter are resolved to the FDA s satisfaction. We are working with the FDA to resolve these deficiencies and resubmit an application, although there can be no assurance that the FDA will approve our application.

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 stent graft products require,

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are in, or 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. In June 2008, the FDA issued a public Warning Letter regarding many of the matters cited in the Form FDA-483. After receiving this Warning Letter, we submitted a response letter to the FDA detailing our implementation of corrective actions, and in July 2008, we received a letter from the FDA indicating that the corrective actions that we have developed and implemented appear to be adequate. However, our corrective actions remain subject to verification as part of any future FDA inspection, and we cannot assure you that we will continue to 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, they may take enforcement action against us, and the conduct of our clinical trial could be interrupted or discontinued.

Sales and Marketing

As of December 31, 2008, we employed 52 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. In the near-term it is unlikely that we will significantly expand the size of our sales force; however, as a long-term strategy, we intend to further expand our sales force. 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 unbranded polyester vascular graft components to Sorin Biomedica SpA under a private label manufacturing program.

We believe that our direct marketing efforts are critical to our brand development and continued success. Prior to 1999, 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 manufacturing efficiencies and increasing automation. Our current product development efforts are largely focused on the endovascular space, including improvements to our TAArget and UniFit Stent Grafts. More recently, we have begun to increase investment in product research and development, with the goal of more rapidly developing new products, line extensions, and next-generation devices in our endovascular and vascular 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 2006, 2007, and 2008, our research and development expenditures, including clinical study expenditures, were $3.3 million, $4.6 million and $5.3 million, respectively, and represented between 10% and 11% of net sales. As of December 31, 2008, our research and development staff consisted of 12 full-time engineers and technicians.

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Manufacturing

Our manufacturing facilities are located in Burlington, Massachusetts, where most of our product lines are produced in a 5,556 square foot ISO 14644-1 Class 8 clean room, and in Brindisi, Italy, where we produce our AlboGraft Vascular Graft product line and perform select other manufacturing processes in a 7,535 square foot ISO 14644-1 Class 8 clean room.

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 practical, we believe that we can maintain better quality control, ensure compliance with applicable regulatory standards and our internal specifications, limit outside access to our proprietary technology, ensure adequate product supply, and make design modifications in a timely manner. We have custom-designed proprietary manufacturing and processing equipment and have developed proprietary enhancements for existing production machinery.

Nearly all of our products are built to stock. The only exceptions are the aortic stent grafts that we custom build for specific anatomies as requested by physicians. For the year ended December 31, 2008, about 47% of our aortic stent grafts were custom built. We believe that our custom manufacturing of stent grafts is a competitive advantage that engenders physician loyalty and brand awareness.

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, 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 (described below) to ensure compliance with domestic and non-U.S. regulatory requirements. See Government Regulation.

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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, Cardiovascular Systems Inc., Cook Group Incorporated, C.R. Bard, Inc., Edwards Lifesciences Corporation, Getinge AB, Medtronic, Inc., Terumo Medical Corporation, Uresil, LLC, 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 certain extent, on the development and maintenance of proprietary aspects of our technologies. We rely on a combination of patents, trademarks, trade secret laws, and confidentiality and invention assignment agreements to protect our intellectual property rights.

As of December 31, 2008, we actively maintained 44 issued patents and 6 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

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

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

We rely on trade secret protection for certain unpatented aspects of other proprietary technology. 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

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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, which in the case of PMA applications can be very costly.

510(k) Clearance. To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent in intended use and 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.

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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 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.

In May 2008, we submitted an IDE application to the FDA to begin a feasibility study to evaluate the safety of our TAArget Thoracic Stent Graft in the treatment of thoracic aortic aneurysms. Because the TAArget Thoracic Stent Graft is a significant risk device for regulatory purposes, we cannot start our feasibility study for the device until we receive the FDA s approval of our application. In July 2008, we received a letter from the FDA indicating that it could not approve our application until deficiencies identified in the letter are resolved to the FDA s satisfaction. We are working with the FDA to resolve these deficiencies, although there can be no assurance that the FDA will approve our application.

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

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. In June 2008, the FDA issued a public Warning Letter regarding many of the matters cited in the

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Form FDA-483. After receiving this Warning Letter, we submitted a response letter to the FDA detailing our implementation of corrective actions, and in July 2008, we received a letter from the FDA indicating that the corrective actions that we have developed and implemented appear to be adequate. However, our corrective actions remain subject to verification as part of any future inspection, and we cannot assure you that we will continue to 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, they may take 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 TAArget Thoracic Stent Graft undergo the PMA process.

Postmarket Regulation

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

- manufacturing establishment registration and device listing with the FDA;
- the QSR, which requires finished device manufacturers, including third-party or contract manufacturers, to follow stringent design, testing, control, documentation, and other quality assurance procedures in all aspects of manufacturing;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved, or off-label uses and other requirements related to promotional activities;
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur; and
- corrections and removal reporting regulations, which require that manufacturers report to the FDA any field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health.

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

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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 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

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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 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

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

Fraud and Abuse Laws

We may directly or indirectly be subject to various federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws. In particular, the federal healthcare program Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending a good or service for which payment may be made in whole or part under federal healthcare programs, such as the Medicare and Medicaid programs. Penalties for violations include criminal penalties and 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

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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 200 full-time employees at December 31, 2008. Of these employees, 80 were in manufacturing and research and development, 80 were in sales and marketing, 17 were in clinical, regulatory, and quality assurance, and 23 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.

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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 may experience significant fluctuations in our quarterly results and we may not maintain our recent profitability.

As of December 31, 2008, we had an accumulated deficit of approximately $16.2 million. While we reported positive operating and net income in the three months ended December 31, 2008, we had an operating and a net loss for the year ended December 31, 2008. Moreover, in 2009, we reached agreement with Edwards Lifesciences AG to terminate their distribution of our AlboGraft Vascular Graft product line as of March 27, 2009, and it is likely that this transaction will cause us to record significant expenses that will make it difficult for us to report either an operating or a net profit for the first three months or the full year 2009. Although, excluding the effects of this transaction, we intend to maintain our profitability in 2009, there can be no assurance we will achieve significant net sales or maintain either operating or net profitability. Our recent operating and net profitability results from extensive operating expense reduction. Control of operating expenses will need to be maintained in order to maintain or improve operating profitability, and decreased investment levels may inhibit future growth in net sales and earnings. We intend to increase operating expenses in 2009 in areas such as research and development and clinical and regulatory affairs. Additionally, our ability to maintain profitability will be influenced by many factors, including:

- the level and timing of future sales, manufacturing costs and operating expenditures;
- market acceptance of our new products;
- 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.

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

For the full year ended December 31, 2008, 45% of net sales were derived from sales occurring outside of the Unites States. 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 rarely engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U.S. dollar. Over recent months, the value of foreign currencies against the U.S. dollar has fluctuated dramatically. For example, the value of the euro against the U.S. dollar declined by nearly 10% during the month of October 2008. A decline in the value of the euro against the U.S. dollar could be expected to have a negative impact on our revenue and earnings growth as euro-denominated revenues and earnings, if any, would be translated into U.S. dollars at a reduced value.

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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 resulted in a 22% reduction, 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 2009, we entered into a series of agreements with Edwards Lifesciences AG to terminate their distribution of our AlboGraft Vascular Graft, which is manufactured by Biomateriali, and for which Edwards Lifesciences had exclusive rights through 2011 pursuant to agreement with Biomateriali entered in to prior to our acquisition. We paid $3.5 million to Edward Lifesciences in exchange for this early termination, the purchase of their AlboGraft customer list and certain customer contracts, and their provision of sales and marketing services. We also repurchased most of their AlboGraft inventory. Even though Edwards Lifesciences has agreed to provide us with sales and marketing services to transition the AlboGraft Vascular Graft customer base, there can be no assurance that we will be successful in doing so, and difficulties that we might encounter could negatively affect our business.

We also may experience other difficulties related to our acquisitions. For example, in connection with our acquisition of our TAArget and UniFit Stent Graft product lines, we acquired an ongoing clinical study related to the UniFit Abdominal Stent Graft. 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 addition, 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, as a result of our review of preliminary 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. There can be no assurance that we will not experience similar clinical setbacks in connection with future clinical programs we may acquire.

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.

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;

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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 completed ten acquisitions 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 or products 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 and products 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 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

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distribution agreements are typically exclusive with terms of up to five years. These agreements may temporarily constrain our ability to convert certain countries or products from a distributor to a direct sales model. 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 an agreement with our exclusive distributor in Italy to end its distribution of our products in January 2008. Among the payments made under this agreement were consulting and transition services fees. These payments were not required under an existing contract or Italian law. 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 any distribution relationship, we may encounter difficulties in transitioning to a direct-sales model in any country in question. It may take us longer than expected to find sufficient qualified sales personnel to establish an effective sales force, which could negatively impact projected sales. If a distributor sold our products through a network of sales agents, rather than exclusively through its own personnel, we may not be able to establish relationships with all members of that network, temporarily limiting 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 these risks, there can be no assurance that we will be successful in transitioning to a direct sales model in the countries or for the products that we select, and difficulties that we encounter in this transition could negatively affect our business.

In March 2009, we entered into a series of agreements with Edwards Lifesciences AG to terminate their distribution of our AlboGraft Vascular Graft in Europe and certain other international markets, for which Edwards Lifesciences had exclusive rights through 2011. We paid $3.5 million to Edward Lifesciences in exchange for this early termination, the purchase of their AlboGraft customer list and certain customer contracts, and their provision of sales and marketing services. We also repurchased most of their AlboGraft inventory. As a result of the risks described above, even though Edwards Lifesciences has agreed to provide us with sales and marketing services to transition the AlboGraft Vascular Graft customer base, there can be no assurance that we will be successful in transitioning to a direct sales model for the AlboGraft Vascular Graft, and difficulties that we might encounter in this transition could negatively affect our business.

Recent adverse changes in US, global, or regional economic conditions could have an adverse effect on our business.

Recent global market and economic conditions have become increasingly negative with tighter credit conditions and recession in most major economies continuing into 2009. Continued concerns about the systemic impact of potential long-term and wide-spread recession, energy costs, geopolitical issues, the availability and cost of credit, and the global housing and mortgage markets have contributed to increased market volatility and diminished economic expectations. In the second half of 2008, added concerns fueled by the U.S. government conservatorship of the Federal Home Loan Mortgage Corporation and the Federal National Mortgage Association, the declared bankruptcy of a large financial institution, U.S. government financial assistance to major banks, insurance companies, other financial institutions and other federal government interventions in the U.S. financial system led to increased market uncertainty and instability in both the United States and international capital and credit markets. These conditions, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have contributed to volatility of unprecedented levels.

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As a result of these market conditions, the cost and availability of credit has been and may continue to be adversely affected by illiquid credit markets and wider credit spreads. Concern about the stability of the markets generally and the strength of counterparties specifically has led many lenders and institutional investors to reduce, and in some cases, cease to provide credit to businesses and consumers. These factors have led to a decrease in spending by businesses and consumers. Continued turbulence in the United States and international markets and economies and prolonged declines in business and consumer spending could result in lower healthcare spending and, consequently, lower sales of our products, longer sales cycles, difficulties in collecting accounts receivable, additional excess and obsolete inventory, gross margin deterioration, slower adoption of new technologies, increased price competition and/or supplier difficulties, any of which may have a negative effect on our financial condition 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 or if our agreement is not renewed, our net sales and results of operations could be adversely impacted.

We are party to an agreement with Endologix, Inc., to distribute the Powerlink System in several European countries, including Germany, France, and the United Kingdom, that is scheduled to expire on December 31, 2010. 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 early, or is not extended or renewed, our net sales and results of operations would likely suffer. If we do not meet our performance requirements under the agreement (and do not cure this deficiency), the agreement may be terminated by Endologix. In fact, we have not met these performance requirements from time to time during the course of our agreement with Endologix and are not currently in compliance. Were Endologix to declare a default under our agreement with them, we would be permitted to cure the performance requirement by purchasing additional inventory in order to avoid a termination, and these required purchases may be material in amount, reducing our cash reserves. 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.

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

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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 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.

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

In the fiscal years ended December 31, 2007 and 2008, a material portion of our increases in net sales was driven by higher average selling prices to our hospital customers across several of our product lines, particularly with respect to sales occurring in the United States. We have in the past been able to rely upon our intellectual property position, our well-known brands, our established reputation in the vascular surgery device marketplace, and, in some cases, an absence of competition, to implement price increases. If healthcare spending in reduced, particularly in the United States, in response either to government-enacted healthcare reform or to general economic conditions, if the reimbursement rates for the medical procedures in which our products are used are reduced or constrained, or if competitors introduce lower-priced products of comparable safety and efficacy, we may become unable to implement further increases in the selling prices of our products. If we become unable to raise selling prices, it might reduce our rate of net sales growth, which could adversely affect our operating results.

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 TAArget 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

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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 and perform select other manufacturing processes 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 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 2011, 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

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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.

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.

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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 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 cleared 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

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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.

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 full year ended December 31, 2008, 45% 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 obtained approval from the Chinese State Food and Drug Administration to market our EndoFit Thoracic Stent Graft in China. We

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expect to initially market our device using one or more distributors. Conducting business in China will 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;
- 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.

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 12% of our net sales for the year ended December 31, 2008. 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.

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We may not maintain 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.

There can be no assurance that we will continue to increase our cash and marketable securities balance in the near term, and, as a result, we may require additional capital, which may not be available on terms acceptable to us or at all. Failure to attract additional capital on terms acceptable to us could impair our growth.

While we reported an increase to our cash and marketable securities in the three months ended December 31, 2008 and we had positive cash flow from operating activities for the full year ended December 31, 2008, we may require additional capital to execute our strategies and further expand our business. In particular, we depend on access to capital to acquire products and technologies that complement our existing product lines. 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, particularly those related to potential future acquisitions, we will require additional debt or equity financing. The availability of such financing depends in large measure on capital markets and liquidity factors over which we can exert little control. Events over the past several months, including recent failures and near failures of a number of large financial service companies have made the capital markets increasingly volatile. As a result, many medical device companies are finding financing to be increasingly expensive and difficult to obtain. Equity financing, if available, may be dilutive to our stockholders. 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 acceptable 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

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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 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.

As of December 31, 2008, the liability for unrecognized tax benefits was approximately $30,000 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

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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.

While in the short term we are unlikely to expand the size of our sales force significantly, 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.

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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 TAArget 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 TAArget and UniFit products must receive PMA approval before being commercially distributed in the United States. To successfully obtain PMA approval of our TAArget and UniFit devices and other devices that we may develop or acquire that are not approved for sale in the United States, such as the AlboGraft Vascular Graft, we may 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 TAArget 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. 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.

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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 stent graft products require, are in, or have recently completed, clinical studies. If our clinical study applications are not approved, if our ongoing clinical studies are not successful, 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 such studies, these products may not come to market on a timely basis or at all, and our business prospects may suffer.

We have recently applied for FDA approval to commence a feasibility study of our TAArget Thoracic Stent Graft, which we call ENTRUST, and we cannot assure you that the FDA will permit us to begin this feasibility study. We also currently have an ongoing clinical study to support a possible PMA application for our UniFit Abdominal Stent Graft. We cannot assure you that the ongoing UniFit study will be successful or that the FDA 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 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 discontinue a clinical study and/or the development of a product.

In May 2008, we submitted an IDE application to the FDA to begin a feasibility study, which we call the ENTRUST study, to evaluate the safety of the TAArget Thoracic Stent Graft in the treatment of thoracic aortic aneurysms. Because the TAArget Thoracic Stent Graft is a significant risk device for regulatory purposes, we cannot start our feasibility study for the device until we receive the FDA s approval of our application. In July 2008, we received a letter from the FDA indicating that it could not approve our application until deficiencies identified in the letter are resolved to the FDA s satisfaction. We are working with the FDA to resolve these deficiencies and resubmit an application, although there can be no assurance that the FDA will approve our application.

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 March 26, 2009, we had enrolled 29 patients in the trial. We plan to enroll 90 patients at 21 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.

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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. In June 2008, the FDA issued a public Warning Letter regarding many of the matters cited in the Form FDA-483. After receiving this Warning Letter, we submitted a response letter to the FDA detailing our implementation of corrective actions, and in July 2008, we received a letter from the FDA indicating that the corrective actions that we have developed and implemented appear to be adequate. However, our corrective actions remain subject to verification as part of any future inspection, and we cannot assure you that we will continue to 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, they may take enforcement action against us, and the conduct of our clinical trial could be interrupted or discontinued.

Our ability to market our stent graft products in the United States will depend upon a number of factors, including our ability to demonstrate the safety and effectiveness of our products with valid clinical data. Our ability to market our products outside of the United States is also subject to regulatory approval, including our ability to demonstrate the safety of our products in the clinical setting. Our products may not be found to be safe and, where required, effective in clinical studies, and may not ultimately be approved for marketing by U.S. or foreign regulatory authorities. In particular, if we do not meet our study success criteria or obtain FDA approval or clearance with respect to our products, our future growth may be significantly hampered. Our failure to develop safe and effective new products that are approved for marketing on a timely basis would have a negative impact on our sales and our business prospects may suffer materially.

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.

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

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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 2007, we initiated a voluntary recall of our LeverEdge Contrast Injector in April 2007 due 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 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 Carotid Shunt. 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.

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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 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;

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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 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.

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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. For example, our TAArget and UniFit stent graft do not have approved reimbursement codes in France, and, as a result, many hospital customers are unable or unwilling to purchase such products. Although we are seeking to obtain the appropriate reimbursement codes, there can be no assurance that we will be successful in doing so in timely fashion or at all, and, if we are not successful our ability to grow our stent graft sales in this market would be impaired.

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

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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;
- 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.

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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 TAArget 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 TAArget 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 TAArget 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.

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 TAArget 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 TAArget and UniFit products could adversely affect our business and results of operations, perhaps materially.

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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.

We may experience significant fluctuations in our quarterly results, which may cause our stock price to decline.

We reported a net loss for the year ended December 31, 2008, and there can be no assurance that we will not report a net loss in 2009. These losses, together with fluctuations in our quarterly and annual results of operations have resulted and will continue to result from numerous factors, including:

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;

changes in the mix of products we sell;

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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;

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.

Volatility in our stock price could require us to record an impairment charge if changes in circumstances or events indicate that the carrying values of our goodwill and intangible assets exceed their fair value and are not recoverable.

Our market capitalization has been significantly impacted by extreme volatility in the U.S. equity and credit markets and has recently been below our net book value. These conditions have not been sustained for an extended period of time. Under U.S. generally accepted accounting principles, we may be required to record an impairment charge if changes in circumstances or events indicate that the carrying values of our goodwill and intangible assets exceed their fair value and are not recoverable. Any significant and other than temporary decrease in our market capitalization could be an indicator that the carrying values of our goodwill and intangible assets exceed their fair value, which may result in our recording an impairment charge. In this time of economic uncertainty, we are unable to predict economic trends, but we continue to monitor the impact of changes in economic and financial conditions on our operations and on the carrying value of our goodwill and intangible assets. Should the value of one or more of our acquired intangibles become impaired, our consolidated earnings and net worth may be materially adversely affected.

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

Our directors, officers, and affiliated stockholders holding more than 5% of our common stock collectively control a majority of our outstanding common stock, assuming the exercise of all options held by such persons. As a result, these stockholders, if they act together, would be able to control the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control, might adversely affect the market price of our common stock, and may not be in the best interests of our other stockholders.

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 2009 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. If we are not able to maintain the requirements of Section 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 have implemented may not comply with all of the relevant rules and regulations of the SEC and the NASDAQ Global Market. If we fail to maintain effective controls and procedures, we may be unable to provide the required financial information in a timely and reliable manner.

For example, as part of our evaluation of internal controls, as of December 31, 2007, we conducted an assessment of the effectiveness of our internal control over financial reporting. 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

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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. Due to the identification of a material weakness in internal control over financial reporting, as described above, we also concluded that, as of December 31, 2007, our disclosure controls and procedures were not effective. We therefore instituted remedial actions to ensure that the controls in the financial statement close process have been strengthened.

We evaluated the effectiveness of our disclosure controls and procedures and our internal control over financial reporting as of December 31, 2008, and, based on these evaluations, we have concluded that our disclosure controls and procedures and internal control over financial reporting were effective as of December 31, 2008. However, 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. If we do not maintain effective controls and procedures, 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, 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.

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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

None.

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 2011 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.

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PART II

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

Market Information

Our common stock began trading on The NASDAQ Global Market under the symbol LMAT on October 19, 2006. The following table sets forth the high and low sales closing prices of our common stock as reported on The NASDAQ National Market for the eight quarters ending December 31, 2008:

	High	Low
Year ended December 31, 2007:		
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
Year ended December 31, 2008:		
First quarter ended March 31, 2008	$ 6.71	$ 3.20
Second quarter ended June 30, 2008	$ 4.69	$ 2.66
Third quarter ended September 30, 2008	$ 3.71	$ 2.74
Fourth quarter ended December 31, 2008	$ 3.21	$ 1.86

Holders of Record

On March 26, 2009, the closing price per share of our common stock was $2.75, as reported on The NASDAQ Global Market, and we had approximately 373 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, 2008. Each of our equity compensation plans is an employee benefit plan as defined by Rule 405 of Regulation C of the Securities Act of 1933.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	1,916,077	$ 5.17	18,540

Equity compensation plans not approved by security holders				
Total	1,916,077	$	5.17	18,540

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Stock Price Performance Graph

Set forth below is a graph comparing the cumulative total stockholder return on LeMaitre s common stock with the NASDAQ US Composite Index, the NASDAQ Medical Equipment Index and a peer group for the period covering LeMaitre s initial public offering on October 19, 2006, through the end of LeMaitre s fiscal year ended December 31, 2008. 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.

	10/20/06	12/31/06	12/31/07	12/31/08
LeMaitre Vascular, Inc	100.00	93.03	96.12	35.78
NASDAQ Composite	100.00	107.66	117.66	68.66
NASDAQ Medical Equipment	100.00	105.00	134.38	74.14
Peer Group	100.00	102.87	89.81	60.26

LeMaitre s fiscal year ends on the last day of December each year; data in the above table reflects market values for our stock and NASDAQ and peer group indices as of the close of trading on the last trading day of year presented.

The 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.

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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, 2008, we have spent $19.8 million, including $6.0 million for acquisitions, $3.9 million to pay down all outstanding indebtedness under two term loans and a revolving line of credit, $1.9 million for the early termination of our Italian distributor, $1.7 million for equipment, $1.3 million for payment of expenses related to our initial public offering, $0.8 million for the acquisition of licenses and technology (of which $0.4 million was expensed on the date of acquisition as in-process research and development), $0.3 million to pay down the revolving line of credit of our Biomateriali subsidiary (which was outstanding on the acquisition date), $0.4 million for severance payments associated with our 2008 restructuring activities, and $3.5 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, 2008 we had approximately $21.3 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. In 2009, we expect to use $0.8 million to fund deferred acquisition payments and $3.5 million for the early termination of our AlboGraft distributor relationship with Edwards Lifesciences. We may also 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 quarter ending December 31, 2008, we repurchased 13,718 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
November 1, 2008 through November 30, 2008	953	$ 2.85	N/A	N/A
December 1, 2008 through December 31, 2008	12,765	$ 2.13	N/A	N/A
Total	13,718	$ 2.18	N/A	

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

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Item 6. Selected Financial Data

You should read the following selected consolidated financial data in conjunction with our consolidated financial statements and the related notes which are included elsewhere in this Annual Report and the Management s Discussion and Analysis of Financial Condition and Results of Operations section of this Annual Report. We have derived the consolidated statement of operations data for the years ended December 31, 2006, 2007, and 2008, and the consolidated balance sheet data as of December 31, 2007 and 2008, 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, 2004 and 2005, and the consolidated balance sheet data as of December 31, 2004, 2005, and 2006 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,				
	2004	2005	2006	2007	2008
	(in thousands, except per share data)				
Consolidated Statements of Operations Data:					
Net sales	$ 26,183	$ 30,727	$ 34,628	$ 41,446	$ 48,720
Cost of sales	7,780	8,927	9,367	10,739	14,817
Gross profit	18,403	21,800	25,261	30,707	33,903
Operating expenses:					
Sales and marketing	9,654	10,960	15,183	19,443	19,762
General and administrative	5,037	6,405	7,105	9,534	9,999
Research and development	2,120	3,015	3,301	4,591	5,328
Purchased research and development				373	
Restructuring charges	435	998	257	1,042	1,147
Impairment charge			94	7	597
Total operating expenses	17,246	21,378	25,940	34,990	36,833
Income (loss) from operations	1,157	422	(679)	(4,283)	(2,930)
Other income (expense):					
Interest income	9	4	299	1,299	530
Interest expense	(137)	(182)	(296)	(1)	(61)
Investment Impairment					(168)
Foreign currency gain (loss)	169	(217)	228	292	(139)
Other income (expense), net	(57)	551	(72)	(9)	(53)
Total other income (expense)	(16)	156	159	1,581	109
Income (loss) before income tax	1,141	578	(520)	(2,702)	(2,821)
Provision for income taxes	214	523	652	232	493
Net income (loss)	$ 927	$ 55	$ (1,172)	$ (2,934)	$ (3,314)
Net income (loss) per share available for common shareholders:					
Basic	$ 0.10	$ 0.01	$ (0.15)	$ (0.19)	$ (0.21)
Diluted	$ 0.10	$ 0.01	$ (0.15)	$ (0.19)	$ (0.21)
Weighted-average shares outstanding:					
Basic	7,941	8,246	9,904	15,398	15,572
Diluted	8,354	8,701	9,904	15,398	15,572

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	2004	2005	December 31, 2006	2007	2008
			(in thousands)		
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 1,024	$ 817	$ 17,636	$ 6,397	$ 15,895
Marketable securities			13,182	16,198	5,359
Current assets	9,102	10,817	43,641	41,766	37,116
Total assets	20,501	25,068	56,963	60,857	54,399
Revolving line of credit and current portion of long-term debt	432	1,142		262	
Current liabilities (excluding revolving line of credit and current portion of long-term debt)	3,374	3,953	5,378	9,783	6,933
Long-term liabilities	1,882	1,437	886	2,226	1,718
Total liabilities	5,688	6,532	6,264	12,271	8,651
Total stockholders equity	14,813	18,536	50,699	48,586	45,748

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 approaches $1 billion and that the annual worldwide market for all peripheral vascular devices approximates $3 billion, which we estimate had been growing at 8% per year prior to the recent economic downturn. 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 most of our product lines in our Burlington, Massachusetts, headquarters, with the exceptions of the AlboGraft Vascular Graft, which is manufactured at our facility in Brindisi, Italy, and the LeverEdge Contrast Injector and the remote endarterectomy suite of devices, for which manufacturing is outsourced.

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, and have pursued a strategy of selling directly to hospitals in our major markets.

In January 2007 we commenced distribution of the Endologix Powerlink System, an abdominal stent graft, in several European countries, including Germany, France and the United Kingdom. We believe that this product complements our TAArget Thoracic Stent Graft and UniFit Abdominal Stent Graft product lines, allowing our European sales force to offer a complete range of stent grafts for the entire aorta. In 2008 we extended this distribution agreement through December 31, 2010.

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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 used in remote endarterectomy, a hybrid open/endovascular procedure for the minimally invasive removal of plaque, typically in the superficial femoral artery in the thigh.

In October 2007 we reached an agreement to launch a direct sales force in Italy effective January 2008. Prior to January 2008, we had sold our products in Italy through an exclusive distribution agreement with Serom Medical Technologies, S.r.l. 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.

In December 2007 we purchased certain patents and in-process research and development from Arizona Heart Innovative Technologies, LLC related to a pre-commercial endovascular device.

In December 2007 we also acquired Biomateriali, S.r.l., a privately held Italian company that manufactured the AlboGraft Vascular Graft graft for vessel replacement in the peripherals, abdomen, and thorax. Biomateriali s manufacturing operations are located in Brindisi, Italy, and through 2008 its products were sold in Europe under an exclusive distribution agreement with Edwards Lifesciences AG and an original equipment manufacturing arrangement with Sorin Biomedica SpA.

In December 2008 we entered into an agreement with Neovasc Inc. to distribute its biological patches for use in vascular surgery, including carotid endarterectomy, in the United States, the European Union, and select other European markets. This seven year agreement became effective January 26, 2009. We were also granted an option to acquire this product commencing in 2014.

In March 2009, we entered into a definitive agreement with Edwards Lifesciences to terminate its distribution of our AlboGraft polyester prosthetic graft for vessel replacement in the peripherals, abdomen, and thorax. We paid $3.5 million to Edward Lifesciences in exchange for this early termination, the purchase of their AlboGraft customer list, certain customer contracts and remaining AlboGraft inventory, and their provision of sales and marketing services.

Below is a listing of our product lines and product categories:

Our **Endovascular** product category includes our TAArget Thoracic Stent Graft, UniFit Abdominal Stent Graft, VascuTape Radiopaque Tape, AnastoClip Vessel Closure System, LeverEdge Contrast Injector, and aSpire Covered Stent. We also report the results of our distribution of the Endologix Powerlink System within this 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 which include our Martin Dissector, Periscope Dissector, EndoHelix Retrieval Device, MollRing Cutter Transection Device, and Ring Dissector, and the AlboGraft Vascular Graft. We also report the results of our distribution of the Peripatch Biologic Vascular Patch within this category.

Our **General Surgery** product category includes our Reddick Cholangiogram Catheter and related accessories and OptiLock Implantable Port.

We evaluate the sales performance of our various product lines utilizing criteria that vary 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.

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Our business opportunities include the following:

- the addition of complementary products through acquisition;
- the updating of existing products and introduction of new products through research and development;
- the long-term growth of our sales force in North America, Europe and Japan; 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.

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, 2008, our sales force was comprised of 52 sales representatives in North America, the European Union and Japan. 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 2008, approximately 88% of our net sales was generated through markets in which we employ direct sales representatives.

Approximately 45% of our 2008 net sales were denominated in currencies other than the U.S. dollar, primarily the euro and the yen. Accordingly, our results of operations are influenced by changes in 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:

(amounts in thousands)	2008				2007				2006			
	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1
Total net sales	12,111	12,023	12,739	11,847	11,104	10,144	10,315	9,883	8,757	8,540	8,760	8,571
Impact of currency exchange rate fluctuations(1)	(448)	452	836	674	439	253	267	322	232	135	(1)	(287)
Net impact of acquisitions, distributed sales and discontinued products, excluding currency exchange rate fluctuations(2)	235	703	929	1,133	1,116	635	567	455	(252)	(383)	(107)	37

(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.

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(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, based on 12 months sales following the date of the event or transaction, and shown in the current period only.

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 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, intangible amortization expense, and insurance expense.

Research and development. Research and development expense includes costs associated with the design, development, testing, enhancement, and regulatory approval of our products 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 distribution agreement 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, investment impairment charges, foreign currency gains (losses), and other miscellaneous gains (losses).

Income tax expense. We are subject to federal and state income taxes for earnings generated in the U.S., which include operating losses in certain foreign jurisdictions for certain years depending on tax elections made, and foreign taxes on earnings of our wholly-owned German, French, Italian, and Japanese subsidiaries. Our consolidated tax expense is affected by the mix of our taxable income (loss) in 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.

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Results of Operations

Comparison of the year ended December 31, 2008, to the year ended December 31, 2007

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:

	2008	2007 ($ in thousands)	Percent change
Net sales	$ 48,720	$ 41,446	18%
Net sales by product category:			
Endovascular	$ 15,946	$ 14,143	13%
Vascular	28,573	23,420	22%
General Surgery	3,928	3,883	1%
Total Branded Products	48,447	41,446	17%
OEM	273		*
Total	$ 48,720	$ 41,446	18%
Net sales by geography:			
United States and Canada	$ 26,899	$ 25,141	7%
Outside the United States and Canada	21,821	16,305	34%
Total	$ 48,720	$ 41,446	18%

* Not a meaningful percentage relationship.

Net sales. Net sales increased 18% to $48.7 million in 2008 from $41.4 million in 2007. Sales in our Endovascular product category increased by 13%, while sales in our Vascular and General Surgery product categories grew by 22% and 1%, respectively, over the previous year. New acquisitions and business development activities added 7% to year-over-year sales growth, changes in foreign currency exchange rates added 4% and organic sales increased 7%. Sales increases were driven in part by the inclusion of our 2007 acquisitions excluding the effects of currency exchange rate fluctuations of approximately $3.0 million, higher average selling prices, the favorable impact of foreign currency fluctuations of approximately $1.5 million, and significant sales growth in various international markets, including the United Kingdom, Japan and France, and were partially offset by a decline in unit sales in several of our product lines. Due to volatility of the euro as compared to the dollar in 2008 we experienced significant changes throughout the year in the value of our sales in Europe when translated into U.S. dollars. This volatility may continue into 2009. In addition, we expect that the early termination of our AlboGraft distributor agreement with Edwards Lifesciences may reduce sales from our Biomateriali subsidiary in the first quarter of 2009.

Net sales by geography. Net sales in the United States and Canada increased 7% to $26.9 million in 2008, as compared to $25.1 million in 2007. The increase was driven primarily by the full-year inclusion of our 2007 acquisitions of the LeverEdge Contrast Injector, aSpire Stent, and EndoRE product lines, as well as higher average selling prices and strong results from our valvulotome and embolectomy catheter product lines. Net sales outside of the United States and Canada increased 34% to $21.8 million for 2008 compared to $16.3 million in 2007. The increase outside the United States and Canada was driven primarily by growth within our endovascular product category which includes our next generation TAArget and UniFit stent grafts, the Powerlink System, the inclusion of AlboGraft Vascular Graft sales to Edwards Lifesciences, the impact of foreign currency fluctuations of approximately $1.5 million and strong results from our French, Japanese and U.K. subsidiaries. Direct-to-hospital net sales represented 73% of the total net sales outside the United States and Canada in 2008, as compared to 74% in 2007. We believe that, in the near-term, sales outside the United States and Canada are likely to increase at a faster rate than sales inside the United States and Canada due to our ability

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to sell our faster-growing stent graft product lines in Europe, the addition of the AlboGraft product line to our European direct-to-hospital product offerings, and the likelihood that new product introductions, if and as they occur in 2009, are likely to occur first in Europe.

	2008	2007	$ Change	Percent change
		($ in thousands)		
Gross profit	$ 33,903	$ 30,707	$ 3,196	10.4%
Gross margin	69.6%	74.1%	*	(4.5)%

* Not a meaningful percentage relationship.

Gross profit. Gross profit increased 10% to $33.9 million in 2008 from $30.7 million in 2007. The gross profit increase was driven primarily by greater net sales, higher average selling prices across several product categories, and favorable foreign currency fluctuations for the full year. The improvement was partially offset by manufacturing inefficiencies at our Burlington manufacturing facility, the write-off of $1.0 million of excess and obsolete inventory largely related to product improvements related to our TAArget and UniFit stent grafts and our TT Tortuous Tracker Delivery System, and the inclusion of Biomateriali in our consolidated results. Gross profit in 2007 was negatively impacted by a $0.1 million inventory charge in December related to the Biomateriali acquisition. The total gross margin as a percentage of net sales was 69.6% in 2008, compared with 74.1% in 2007. The decrease from 2007 was largely a result of the inclusion of the AlboGraft sales in 2008, the write-off of $1.0 million of excess and obsolete inventory largely related to product improvements, and continued strength in the Company s international business; partially offset by higher average selling prices across several product categories.

	2008	2007	$ change	Percent change	2008 as a % of Revenue	2007 as a % of Revenue
				($ in thousands)		
Sales and marketing	$ 19,762	$ 19,443	$ 319	2%	41%	47%
General and administrative	9,999	9,534	465	5%	21%	23%
Research and development	5,328	4,591	737	16%	11%	11%
Purchased research and development		373	(373)	*	0%	1%
Restructuring charges	1,147	1,042	105	*	2%	3%
Impairment charge	597	7	590	*	1%	0%
	$ 36,833	$ 34,990	$ 1,843	5%	76%	84%

* Not a meaningful percentage relationship.

Sales and marketing. Sales and marketing expense increased 2% to $19.8 million in 2008, from $19.4 million in 2007. The increase was driven primarily by the addition of our direct sales efforts in France and Italy, as well as foreign currency exchange rate fluctuations of $0.5 million, and largely offset by a decrease in the total number of sales and marketing professionals and associated management during 2008. At the end of 2008, we employed 52 field sales representatives and 11 sales managers worldwide, as compared to 57 and 17, respectively, at the end of 2007. We expect sales and marketing expense to decline in 2009 as a percentage of net sales as we seek further efficiencies in our sales organization and as we move to a multi-tiered sales representative model in the United States.

General and administrative. General and administrative expense increased 5% to $9.9 million in 2008 from $9.5 million in 2007. The increase was primarily due to the inclusion of Biomateriali in our consolidated results of $0.6 million, as well as the addition of our French and Italian direct sales efforts, which require local administrative support, and negative foreign currency exchange rate fluctuations of $0.1 million, and was partially offset by a decrease in the number of general and administrative personnel.

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Research and development. Research and development expense increased 16% to $5.3 million in 2008 from $4.6 million in 2007. The increase was driven by increases in regulatory and clinical expenses and personnel costs, the inclusion of Biomateriali in the consolidated results, increased royalties of $0.1 million, higher product development costs largely related to the introduction of the TT delivery system, and foreign currency exchange rate fluctuations of $0.1 million. These increases were partially offset by decreases in process development costs. We anticipate increased spending in research and development in 2009 as we continue to invest in product development and support our clinical trial efforts.

Restructuring. Restructuring charges increased to $1.1 million in 2008 from $1.0 million in 2007. 2008 charges included $0.7 million related to the early termination of our distributor in Italy, and $0.4 million related to our reductions in force in February and July. Expenses for 2007 included charges related to the buy-out of our distributors in Ireland and Italy due to our decision to sell directly to hospitals in those countries. We anticipate that we will incur significant restructuring charges in 2009 in connection with the early termination of our AlboGraft Vascular Graft distribution agreement with Edwards Lifesciences.

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 charges. We recorded an impairment charge of $0.6 million in 2008. The charge was the result of the write-down of intangible assets at our Biomateriali subsidiary related to the Sorin customer relationship totaling $0.5 million, as well as the write-down of selected patents of $0.1 million.

Other income (expense). In 2008 interest income was $0.4 million compared to $1.3 million in 2007. The change was due to a decrease in average cash on hand throughout the year, significantly reduced yields on portfolio investments, the write-down of portfolio investments of $0.2 million which was attributed to the other-than-temporary decline in one specific asset backed security which we held as available-for-sale in our marketable securities portfolio at December 31, 2008, and increased interest expense associated with acquisition related debt at our Biomateriali subsidiary of $0.1 million. Losses on foreign currency exchange were due to a relative decrease in the strength of the euro as compared to the U.S. dollar. Other income (expense) for 2008 was primarily due to losses on the disposal of capital equipment of $41,000.

Income tax expense. We recorded a provision for taxes of $0.5 million in 2008 compared to $0.2 million in 2007 despite pre-tax losses of $2.8 million in 2008 and $2.7 million in 2007. The 2008 provision was the result of a number of factors, including taxes on profits on certain of our foreign subsidiaries that are profitable, deferred tax liabilities related to the amortization of goodwill for U.S. tax purposes, which cannot be used to reduce existing deferred tax assets, 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, but are not limited to transfer pricing and various state and foreign matters.

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

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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 material adjustment in the liability for unrecognized income tax benefits.

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:

	2007	2006	Percent change
		($ in thousands)	
Net sales	$ 41,446	$ 34,628	20%
Net sales by product category:			
Endovascular	$ 14,143	$ 9,833	44%
Vascular	23,420	20,992	12%
General Surgery	3,883	3,803	2%
Total	$ 41,446	$ 34,628	20%
Net sales by geography:			
United States and Canada	$ 25,141	$ 22,362	12%
Outside the United States and Canada	16,305	12,266	33%
Total	$ 41,446	$ 34,628	20%

* Not a meaningful percentage relationship.

Net sales. Net sales increased 20% to $41.4 million in 2007 from $34.6 million in 2006. Sales in our Endovascular product category increased by 44%, while sales in our Vascular and General Surgery product categories grew by 12% 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 System 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 2007 compared to $12.3 million in 2006. The increase outside the United States and Canada was driven primarily by growth within our Endovascular product category, which includes the Powerlink System 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.

	2007	2006	$ Change	Percent change
		($ in thousands)		
Gross profit	$ 30,707	$ 25,261	$ 5,446	21.6%
Gross margin	74.1%	72.9%	*	1.2%

* Not a meaningful percentage relationship.

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

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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 System, 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.

	2007	2006	$ change	Percent change	2007 as a % of Revenue	2006 as a % of Revenue
			($ in thousands)			
Sales and marketing	$ 19,443	$ 15,183	$ 4,260	28%	47%	44%
General and administrative	9,534	7,105	2,429	34%	23%	21%
Research and development	4,591	3,301	1,290	39%	11%	10%
Purchased research and development	373		373	*	1%	0%
Restructuring charges	1,042	257	785	*	3%	1%
Impairment charge	7	94	(87)	*	0%	0%
	$ 34,990	$ 25,940	$ 9,050	35%	84%	75%

* Not a meaningful percentage relationship.

Sales and marketing. Sales and marketing expense 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 several research and development engineers and related product development expenses, focused largely on our Endovascular product lines.

Restructuring. Restructuring expense 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 sell directly to hospitals in those countries. 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.

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

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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 offered 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 on certain of our foreign subsidiaries that are profitable, 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.

Liquidity and Capital Resources

At December 31, 2008, our cash, cash equivalents and marketable securities were $21.3 million as compared to $22.6 million at December 31, 2007. 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, 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 commercial paper or auction-rated securities in our investment portfolio as of December 31, 2008.

The majority of our marketable securities have remaining maturities of two years or less. The weighted average maturity of the portfolio was 6.5 months as of December 31, 2008, a reduction of 24 months from December 31, 2007. As of December 31, 2008, our investment portfolio included $1.6 million of asset-backed securities collateralized by first-lien mortgages, credit card debt, and auto loans. In order to limit our credit risk exposure, we reduced our asset-backed securities holdings in 2008 by $3.6 million, from $5.2 million 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. In 2008, we recognized a loss of $0.2 million related to a single asset-backed security in our portfolio which experienced an other-than-temporary decline in market value. We continually monitor the asset allocation of our holdings in an attempt to mitigate our credit and interest rate exposures, and we intend to continue to closely

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monitor future developments in the credit markets and make appropriate changes to our investment policy as necessary. Although the highly unusual degree of volatility in the current global financial markets can affect the marketability of selected securities, we do not anticipate that these events will result in significant portfolio liquidity limitations or write-downs, although we can make no assurances to this effect.

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.

From the effective date of the registration statement through December 31, 2008, we have spent $19.8 million, including $6.0 million for acquisitions, $3.9 million to pay down all outstanding indebtedness under two term loans and a revolving line of credit, $1.9 million for the early termination of our Italian distributor, $1.7 million for equipment, $1.3 million for payment of expenses related to our initial public offering, $0.8 million for the acquisition of licenses and technology (of which $0.4 million was expensed on the date of acquisition as in-process research and development), $0.3 million to pay down the revolving line of credit of our Biomateriali subsidiary (which was outstanding on the acquisition date), $0.4 million for severance payments associated with our 2008 restructuring activities, and $3.5 million for working capital purposes. Our cash balances may decrease as we continue to use cash to fund our operations, make acquisitions, and make deferred payments related to prior acquisitions. In 2009, we expect to use $0.8 million to fund deferred acquisition payments and $3.5 million for the early termination of our AlboGraft distributor relationship with Edwards Lifesciences.

In August 2007 we amended our revolving line of credit with Brown Brothers Harriman & Co. 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 part of this facility increased to $3 million. In August 2008, the maturity date for amounts borrowed was extended to August 2009. Loans made under this revolving line of credit bear interest 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, 2008, 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 2008, we were in compliance with these covenants. Our credit facility is scheduled to expire in August 2009, and in view of the current economic environment, which has negatively impacted the credit markets, there can be no assurance that our facility will be renewed on terms that are acceptable to us or at all.

Net cash provided by operating activities. Net cash provided by operating activities was $0.6 million in 2008 and consisted of a $3.3 million net loss adjusted for non-cash related items of $4.4 million, including depreciation and amortization of $1.6 million, provision for inventory write-offs of $1.0 million, stock-based compensation of $0.8 million, intangibles impairment charges of $0.6 million, investment impairment write-offs of $0.2 million, a deferred income tax provision of $0.2 million, and partially offset by the accretion of discounts on marketable securities of $0.1 million. Net cash used from changes in operating assets and liabilities was $0.5 million. The net cash used from changes in operating assets and liabilities was primarily a result of the payment of restructuring-related liabilities and an overall decrease in operating expense spending in 2008, offset by reduced levels inventory of $1.5 million.

Net cash provided by investing activities. Net cash provided by investing activities was $9.0 million in 2008. This was primarily due to sales and maturities of marketable securities of $14.9 million, and partially offset by purchases of marketable securities of $4.3 million, purchases of property and equipment of $0.6 million, payments made related to prior year acquisitions of $0.8 million, and the purchase of technology and other intangible assets of $0.1 million. The net proceeds from the sale and maturities of marketable securities of $10.6

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million were reinvested into cash equivalents such as time deposits and investments in money market funds with commercial banks and financial institutions. In 2009 we expect to pay approximately $0.8 million of non-contingent deferred purchase price obligations related to the Biomateriali acquisition.

Net cash used in financing activities. Net cash used in financing activities was $24,000 in 2008. This was primarily due to the repayment of the revolving line of credit at our Italian subsidiary of $0.3 million, and offset by proceeds from the issuance of common stock related to the exercise of common stock options and our employee purchase plan of $0.3 million.

We recognized a net operating profit of $170,000 and $354,000 for the three months ended September 30, 2008 and December 31, 2008, respectively; however, we recognized an operating loss of $2.9 million for the year ended December 31, 2008. Although it is our intention to continue to generate an operating profit, excluding the impact of strategic acquisitions and distributor terminations, there can be no assurance that we will not generate a net operating loss in the future due to our continued investment in growing our business. We expect to fund any increased costs and expenditures from our existing cash and cash equivalents and marketable securities; though, our future capital requirements depend on numerous factors. These factors include, but are not limited to, the following: the revenues generated by sales of our products; the costs associated with expanding our manufacturing, marketing, sales, and distribution efforts; the rate of progress and cost of our research and development activities; 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, timing, and nature of acquisitions and other strategic transactions. On March 27, 2009, we paid $3.5 million to Edward Lifesciences in exchange for the early termination of this distribution agreement, the purchase of their AlboGraft customer list and certain customer contracts, and their provision of sales and marketing services.

We maintain a $10.0 million revolving line of credit that provides for up to $3.0 million in letters of credit. This facility matures in August, 2009. The loan agreement requires that we meet certain financial and operating covenants. As of December 31, 2008, we did not have an outstanding balance under this facility and were in compliance with these covenants. We believe that our current cash and cash equivalents and marketable securities 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 issuance of debt. We cannot assure you that additional financing will be available when needed or that, if available, such financing will be obtained on 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 occur.

***Contractual obligations*.** Our principal contractual obligations consist of operating leases, acquisition-related obligations, inventory purchase commitments, and income tax obligations under FIN 48 for unrecognized tax benefits. The following table summarizes our commitments to settle contractual obligations as of December 31, 2008:

Contractual obligations	Total	Less than 1 year	1-3 years	3-5 years
		(in thousands)		
Operating leases	$ 2,090	$ 1,013	$ 1,061	$ 16
Purchase commitments for inventory	8,187	4,246	3,941	
Acquisition-related obligations	793	793		
FIN48 unrecognized tax benefits	30	30		
Total contractual obligations	$ 11,100	$ 6,082	$ 5,002	$ 16

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The commitments under our operating leases 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 2011; our Sulzbach, Germany office, expiring in 2010; and our Tokyo, Japan office, expiring in 2010.

We failed to meet our minimum purchase requirements of an exclusive distribution agreement with Endologix, Inc. by $0.6 million in 2008. The manufacturer has the right to terminate the distribution agreement based upon this breach. We have a right to cure the breach by purchasing the contractual requirements upon notice from the manufacturer.

The table above excludes the $3.5 million payment to Edward Lifesciences in exchange for this early termination, the purchase of their AlboGraft customer list, certain customer contracts and remaining AlboGraft inventory, and their provision of sales and marketing services and the minimum inventory purchase requirement of $0.4 million related to the Neovasc Inc distribution agreement, both of which resulted from events subsequent to December 31, 2008.

Subsequent Events

In January 2009, we commenced a seven-year agreement with Neovasc Inc. to distribute its biological patches for use in vascular surgery, including carotid endarterectomy. The agreement contains minimum purchase requirements which incrementally increase from $0.4 million in 2009 to $1.0 million in 2015. We were also granted an option to acquire this product line commencing in 2014.

In March 2009, we entered into a series of agreements with Edwards Lifesciences AG to terminate their distribution of our AlboGraft Vascular Graft product line in Europe and certain other international markets, for which Edwards Lifesciences had exclusive rights through 2011. We paid $3.5 million to Edwards Lifesciences in exchange for this early termination, the purchase of their AlboGraft customer list, certain customer contracts and remaining AlboGraft inventory, and their provision of sales and marketing services.

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 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

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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) collectability 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 90 days of invoice and are stated at amounts due from customers, net of an allowance for doubtful accounts and sales returns, other than in certain European markets where longer payment terms are customary. 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 collectability. The provision for the allowance for doubtful accounts is recorded in general and administrative expenses.

Inventory

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

Stock-based Compensation

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.,

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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.

Effective January 1, 2006, we adopted 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. 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. We use the Black-Scholes option pricing model to estimate the fair value of these stock-based awards consistent with the provisions of SFAS No. 123(R), *Share-Based Payment.* We estimate expected volatility based on the historical volatility of the company s stock. The expected lives of the options were estimated using the simplified method for plain vanilla options. The risk-free interest rate is based on U.S. Treasury zero-coupon issues with a remaining term which approximates the expected life assumed at the date of grant. Changes in these input variables would affect the amount of expense associated with stock-based compensation. The compensation expense recognized for all stock-based awards is net of estimated forfeitures. We estimate forfeiture rates based on historical analysis of option forfeitures. Stock-based compensation charges will be adjusted in future periods to reflect the results of actual forfeitures and vesting. For the year ended December 31, 2008, we recorded expense of approximately $0.8 million in connection with share-based payment awards. The future expense of non-vested options of approximately $2.4 million is to be recognized over a weighted-average period of 3.6 years.

We account 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 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

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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 2008 we granted stock options at a weighted average exercise price of $3.47 and restricted stock units with fair value weighted average price of $3.46.

Valuation of Goodwill, Other Intangibles

When we acquire a business, 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 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, 2008. The test for impairment requires us to make several estimates about fair value, principally related to the determination that we operate as a single reporting unit and the estimated far value of that reporting unit. Historically, the market capitalization of the Company as a whole has exceeded the carrying amount, and on that basis we concluded that goodwill was not impaired. At December 31, 2008, the market capitalization of the Company was less than the carrying amount. We therefore used a market approach to determine the estimated fair value of the reporting unit, including a control premium that an investor would pay to obtain control of the Company. The significant assumptions utilized in the market approach include the determination of appropriate market comparables, the estimated multiples of revenue a willing buyer is likely to pay, and the estimated control premium a willing buyer is likely to pay. Based on these estimates, we concluded that the estimated fair value of the reporting unit exceeded its carrying amount, and therefore goodwill was not impaired. While we believe the estimates and assumptions we used are reasonable and supportable, the use of different estimates or assumptions could have resulted in a different conclusion. Goodwill was $10.9 million as of December 31, 2007, and $11.0 million as of December 31, 2008.

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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 intangible assets quarterly to determine if any adverse conditions exist for a change in circumstances has occurred that would indicate impairment. Conditions that may indicate impairment include, but are not limited to, a significant adverse change in legal factors or business climate that could affect the value of the asset, a change in the operating cash flows associated with the asset, or adverse action or assessment by a regulator. If an impairment indicator exists we test the intangible asset for recoverability. If the carrying value of the intangible asset exceeds the undiscounted cash flows expected to result from the use and eventual disposition of the intangible asset, we will write the carrying value down to the fair value in the period identified. We generally calculate fair value of our intangible assets as the present value of estimated future cash flows we expect to generate from the asset using a risk-adjusted discount rate. In determining our estimated future cash flows associated with our intangible assets, we use estimates and assumptions about future revenue contributions, cost structures, and remaining useful lives of the asset. These estimates and assumptions require significant judgment and actual results may differ from assumed or estimated amounts. Other intangible assets, net of accumulated amortization, were $3.9 million as of December 31, 2007, and $2.9 million as of December 31, 2008. We recognized impairment charges on our intangible assets of $0.6 million in 2008.

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 determine a loss is probable and we can reasonably estimate these costs. During the years ended December 31, 2006, 2007, and 2008, 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 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

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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 material 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 $5.4 million in 2008 and $2.8 million in 2007.

Marketable Securities

We account for our investments in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. Our investments consist primarily of marketable debt securities and U.S. government securities, and are classified as available-for-sale and are carried at fair market value at December 31, 2008. 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. When a marketable security incurs a significant unrealized loss for a sustained period of time, we review the instrument to determine if it is other-than-temporarily impaired. If we conclude an instrument is other-than-temporarily impaired, we record the unrealized loss in the consolidated statement of operations.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of December 31, 2008. 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 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 business combinations consummated after December 31, 2008. 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

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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.

In March 2008 the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 161, *Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB statement No. 133 (SFAS No. 161).* SFAS No. 161 requires enhanced disclosures regarding an entity derivative instruments and related hedging activities. These enhanced disclosures include information regarding how and why an entity uses derivative instruments; how derivative instruments and related hedge items are accounted for under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities,* and its related interpretations; and how derivative instruments and related hedge items affect an entity s financial position, financial performance, and cash flows. SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. The adoption of SFAS No. 161 will not have a material impact on consolidated results of operations and financial condition.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, or SFAS 162. SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements that are presented in conformity with U.S. generally accepted accounting principles. We do not expect the adoption of SFAS 162 will have a material effect on our consolidated results of operations and financial condition.

In December 2007 the FASB ratified Emerging Issues Task Force (EITF) Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1*)*. EITF 07-1 provides guidance on collaborative arrangements within the scope of this issue on the classification of the payments between participants in the arrangement, the appropriate income statement presentation as well as disclosures related to these arrangements. EITF 07-1 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 of EITF 07-01 on our financial position and results of operations.

In February 2008, the FASB issued Staff Position (FSP) No. 157-2, *Effective Date of FASB Statement No. 157*, or FSP 157-2, which delays the effective date of Statement No. 157 for all nonfinancial assets and nonfinancial liabilities, except for those that are recognized or disclosed at fair value in the financial statements on a recurring basis. The Company is required to apply the provisions of Statement No. 157 to nonfinancial assets and nonfinancial liabilities as of January 1, 2009. We do not expect the adoption of FSP 157-2 will have a material effect on our consolidated results of operations and financial condition.

In April 2008, the FASB issued FSP FAS 142-3, *Determination of the Useful Life of Intangible Assets* (FSP FAS 142-3), to provide guidance for determining the useful life of recognized intangible assets and to improve consistency between the period of expected cash flows used to measure the fair value of a recognized intangible asset and the useful life of the intangible asset as determined under FASB Statement 142, *Goodwill and Other Intangible Assets* (FAS 142). The FSP requires that an entity consider its own historical experience in renewing or extending similar arrangements. However, the entity must adjust that experience based on entity-specific factors under FAS 142. FSP FAS 142-3 is effective for fiscal years and interim periods that begin after November 15, 2008. The Company intends to adopt FSP FAS 142-3 effective January 1, 2009 and to apply its provisions prospectively to recognized intangible assets acquired after that date. We do not expect that the adoption of FSP FAS 142-3 will have a material effect on our consolidated results of operations or financial condition.

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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. For the year ended December 31, 2008, approximately 45% of our sales were denominated in foreign currencies. We expect that foreign currencies will continue to represent a similarly significant percentage of our sales in the future. Selling, marketing, and administrative costs related to these sales are largely denominated in the same respective currency, thereby partially mitigating our transaction risk exposure. We therefore believe that the risk of a significant impact on our operating income from foreign currency fluctuations is moderated. 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. If we price our products in U.S. dollars and competitors price their products in local currency, an increase in the relative strength of the U.S. dollar could result in our price not being competitive in a market where business is transacted in the local currency.

The majority of sales recorded in foreign currencies for the year ended December 31, 2008 were 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 $0.1 million foreign currency loss and $0.3 million foreign currency gain for the years ended December 31, 2008 and 2007, respectively, 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, 2008 is related primarily to our investment portfolio. Our investment portfolio includes fixed rate debt instruments of the U.S. government and corporate issuers and consists primarily of 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 decline in the fair value of our investment portfolio. The majority of our marketable securities have remaining maturities of two years or less. Our investment portfolio includes $1.6 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, 2008. 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.

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Item 8. Financial Statements and Supplementary Data

See the consolidated financial statements filed as part of this Annual Report on Form 10-K as listed under Item 15 below.

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

Not Applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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. Our management, with the participation of the 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 Exchange Act of 1934) as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2008. 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.

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 15d-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.

As of December 31, 2007, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting. 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

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certain accruals and related inadequate reconciliation and review procedures of the financial statement close process. 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 to the December 31, 2007 consolidated financial statements.

Since December 31, 2007, we have implemented enhancements to our internal control over financial reporting to address the material weakness described above and to provide reasonable assurance that errors and control deficiencies of this type will not recur. These steps included:

- Hiring new finance personnel.
- Providing additional training for finance personnel.
- Instituting policies and procedures to enhance systematic review of certain accruals, reconciliations, and the review of the financial statement close.

We will continue to monitor the effectiveness of these procedures and will continue to make any changes that management deems appropriate.

Our management, including our Chief Executive and Chief Financial Officer, has conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2008. 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 and those criteria, our management concluded that our internal control over financial reporting was effective as of December 31, 2008.

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.

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

Changes in Internal Control over Financial Reporting

There was no change in the our internal control over financial reporting that occurred during the fiscal quarter ended December 31, 2008, that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

In addition, the quarter ended December 31, 2008 was the fourth full quarter that included the results of Biomateriali S.r.l., acquired on December 20, 2007, in our consolidated financial statements. We have incorporated Biomateriali into our corporate closing and consolidation process, and have included this subsidiary in our testing related to our internal controls over financial reporting.

Item 9B. Other Information

None.

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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 2009 definitive proxy statement (the 2009 Definitive Proxy Statement) for the 2009 annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days after the year ended December 31, 2008.

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 2009 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 2009 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 2009 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 2009 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 2009 Definitive Proxy Statement.

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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

Exhibit Number	Description
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 **	Managing Director Employment Agreement dated October 1, 2008, by and between LeMaitre Vascular GmbH and Peter Gebauer, as amended
10.9 (1)	Employment Agreement dated June 20, 2006, by and between the Registrant and David Roberts

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Exhibit Number	Description
10.10 (1)	Employment Agreement dated April 20, 2006, by and between the Registrant and Joseph P. Pellegrino (corrected)
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)	Letter Agreement with Brown Brothers Harriman & Co. dated September 25, 2006
10.26(1)	Amendment to Guaranty of Vascutech Acquisition LLC in favor of Brown Brothers Harriman & Co. dated September 25, 2006
10.28(1)	Security Agreement of Vascutech Acquisition LLC in favor of Brown Brothers Harriman & Co. dated March 29, 2001, as amended
10.29**	Letter Agreement with Brown Brothers Harriman & Co. dated August 23, 2008
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
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(6)	Third Amendment of Lease dated February 26, 2008, by and between Rodger P. Nordblom and Peter C. Nordblom, as Trustees of Northwest Associates, and Registrant
10.36**	Fourth Amendment of Lease dated October 31, 2008, by and between Rodger P. Nordblom and Peter C. Nordblom, as Trustees of Northwest Associates, and Registrant
10.37 **	First Amendment to Executive Retention and Severance Agreement dated December 23, 2008, by and between the Registrant and George W. LeMaitre
10.38 **	First Amendment to Employment Agreement dated December 19, 2008, by and between the Registrant and David Roberts
10.39 **	First Amendment to Employment Agreement dated December 19, 2008, by and between the Registrant and Joseph P. Pellegrino
21.1**	List of Subsidiaries

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Exhibit Number	Description
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.
(6) Previously filed as an exhibit to Form 8-K filed April 10, 2008, and incorporated herein by reference.
Indicates a management contract or any compensatory plan, contract, or arrangement.
** Filed herewith

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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, 2009.

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.

Signature	Title	Date
/s/ GEORGE W. LEMAITRE **George W. LeMaitre**	Chief Executive Officer and Chairman of the Board Principal Executive Officer	March 31, 2009
/s/ JOSEPH P. PELLEGRINO, Jr. **Joseph P. Pellegrino, Jr.**	Chief Financial Officer	March 31, 2009
/s/ RUSSELL D. HAYS **Russell D. Hays**	Director	March 31, 2009
/s/ MICHAEL C. JACKSON **Michael C. Jackson**	Director	March 31, 2009
/s/ LAWRENCE J. JASINSKI **Lawrence J. Jasinski**	Director	March 31, 2009
/s/ CORNELIA W. LEMAITRE **Cornelia W. LeMaitre**	Vice President, Human Resources and Director	March 31, 2009
/s/ GEORGE D. LEMAITRE, M.D. **George D. LeMaitre, M.D.**	Director	March 31, 2009
/s/ JOHN J. O CONNOR **John J. O Connor**	Director	March 31, 2009
/s/ DAVID B. ROBERTS **David B. Roberts**	President and Director	March 31, 2009

/s/ William N. Thorndike, Jr.	Director	March 31, 2009

William N. Thorndike, Jr.

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Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying consolidated balance sheets of LeMaitre Vascular, Inc. as of December 31, 2008 and 2007, 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, 2008. 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, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, 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*.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 30, 2009

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LeMaitre Vascular, Inc.

Consolidated Balance Sheets

	December 31 2008	December 31 2007
	(in thousands, except share data)	
Assets		
Current assets:		
Cash and cash equivalents	$ 15,895	$ 6,397
Marketable securities	5,359	16,198
Accounts receivable, net of allowances of $160 at December 31, 2008, and $219 at December 31, 2007	7,244	7,020
Inventory	6,959	9,589
Prepaid expenses and other current assets	1,659	2,562
Total current assets	37,116	41,766
Property and equipment, net	2,327	2,891
Goodwill	11,022	10,942
Other intangibles, net	2,883	3,886
Other assets	1,051	1,372
Total assets	$ 54,399	$ 60,857
Liabilities and stockholders equity		
Current liabilities:		
Revolving line of credit	$	$ 262
Accounts payable	606	2,271
Accrued expenses	5,543	6,661
Acquisition-related obligations	784	851
Total current liabilities	6,933	10,045
Long-term debt	78	42
Deferred tax liabilities	1,260	996
Other long-term liabilities	380	1,188
Total liabilities	8,651	12,271
Stockholders equity:		
Preferred stock, $0.01 par value; authorized 5,000,000 shares; none outstanding		
Common stock, $0.01 par value; authorized 100,000,000 shares; issued 15,703,522 shares at December 31, 2008, and 15,516,412 shares at December 31, 2007	157	155
Additional paid-in capital	62,290	61,187
Accumulated deficit	(16,194)	(12,880)
Accumulated other comprehensive income (loss)	(272)	291
Treasury stock, at cost; 50,284 shares at December 31, 2008, and 26,852 shares at December 31, 2007	(233)	(167)
Total stockholders equity	45,748	48,586
Total liabilities and stockholders equity	$ 54,399	$ 60,857

See accompanying notes to consolidated financial statements.

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LeMaitre Vascular, Inc.

Consolidated Statements of Operations

	Year ended December 31,		
	2008	2007	2006
	(in thousands, except per share data)		
Net sales	$ 48,720	$ 41,446	$ 34,628
Cost of sales	14,817	10,739	9,367
Gross profit	33,903	30,707	25,261
Sales and marketing	19,762	19,443	15,183
General and administrative	9,999	9,534	7,105
Research and development	5,328	4,591	3,301
Purchased research and development		373	
Restructuring charges	1,147	1,042	257
Impairment charge	597	7	94
Total operating expenses	36,833	34,990	25,940
Loss from operations	(2,930)	(4,283)	(679)
Other income (expense):			
Interest income	530	1,299	299
Interest expense	(61)	(1)	(296)
Investment impairment	(168)		
Foreign currency gain (loss)	(139)	292	228
Other expense, net	(53)	(9)	(72)
Loss before income taxes	(2,821)	(2,702)	(520)
Provision for income taxes	493	232	652
Net loss	$ (3,314)	$ (2,934)	$ (1,172)
Net loss available for common shareholders:			
Basic	$ (0.21)	$ (0.19)	$ (0.15)
Diluted	$ (0.21)	$ (0.19)	$ (0.15)
Weighted-average shares outstanding:			
Basic	15,572	15,398	9,904
Diluted	15,572	15,398	9,904

See accompanying notes to consolidated financial statements.

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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	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
Net loss							(1,172)				(1,172)
Unrealized losses on available for sale securities								(6)			(6)
Foreign currency translation adjustment								146			146
Comprehensive 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
Conversion 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)
Effect of adoption of SFAS 123(R) for redemption feature of common stock awards							(6,474)				(6,474)
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									20,331	(159)	(159)
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.

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LeMaitre Vascular, Inc.

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

(in thousands, except share data)

	Series A Convertible Preferred Stock Shares	Series A Convertible Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Stock Shares	Treasury Stock Amount	Total Stockholders Equity
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 loss											(2,716)
Initial public offering costs					(121)						(121)
Issuance of common stock for stock options exercised			140,020	2	171						173
Issuance of common stock for employee stock plan purchases			13,357		72						72
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.

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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, 2007	0	$ 0	15,516,412	$ 155	$ 61,187	$ 0	($ 12,880)	$ 291	26,852	($ 167)	$ 48,586
Net Loss							(3,314)				(3,314)
Unrealized loss on available for sale securities								(190)			(190)
Foreign currency translation adjustment								(373)			(373)
Comprehensive loss											(3,877)
Issuance of common stock for stock options exercised			99,640	1	204						205
Issuance of common stock for employee stock plan purchases			22,047		98						98
Vested restricted stock units			65,423	1							1
Stock based compensation expense					801						801
Repurchase of common stock at cost									23,432	(66)	(66)
Balance at December 31, 2008	0	$ 0	15,703,522	$ 157	$ 62,290	$ 0	($ 16,194)	($ 272)	50,284	($ 233)	$ 45,748

See accompanying notes to consolidated financial statements.

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LeMaitre Vascular, Inc.

Consolidated Statements of Cash Flows

	Year ended December 31,		
	2008	2007	2006
		(in thousands)	
Operating activities			
Net loss	$ (3,314)	$ (2,934)	$ (1,172)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation and amortization	1,593	1,394	1,308
Stock-based compensation	801	561	404
Accretion of discount on marketable securities	(99)	(223)	(23)
Investment impairment charges	168		
Impairment charges	597	7	94
Provision for losses in accounts receivable	27	197	21
Provision for inventory write-downs	1,048	503	449
Provision for deferred income taxes	249	639	(6)
Loss on disposal of property and equipment	41	6	83
(Gain) Loss on sales of marketable securities	(5)	3	
Changes in operating assets and liabilities, net of effect of business acquisitions:			
Accounts receivable	(353)	(1,679)	(710)
Inventory	1,473	(1,800)	(1,229)
Prepaid expenses and other assets	1,050	(920)	(1,031)
Accounts payable and other liabilities	(2,695)	2,126	1,263
Net cash provided by (used in) operating activities	581	(2,120)	(549)
Investing activities			
Purchase of property and equipment	(624)	(1,120)	(969)
Cash paid for business acquisitions, net of cash acquired	(835)	(5,109)	
Proceeds from sale of property and equipment		6	34
Proceeds from sale of impaired assets			323
Purchase of technology and licenses	(114)	(273)	
Sales and maturities of marketable securities	14,909	9,402	295
Purchase of marketable securities	(4,323)	(12,094)	(13,431)
Other assets			76
Net cash provided by (used in) investing activities	9,013	(9,188)	(13,672)
Financing activities			
Net proceeds from issuance of common stock			47
Proceeds from issuance of common stock pursuant to stock plans	304	245	
Proceeds from initial public offering			35,805
Proceeds (repayment) under revolving line of credit	(262)		(710)
Proceeds from long-term debt			2,500
Principal payments on long-term debt			(3,580)
Principal payments on capital lease obligations		(32)	(87)
Expenses associated with equity transactions		(121)	(2,644)
Purchase of treasury stock, net	(66)	(82)	(159)
Net cash provided by (used in) financing activities	(24)	10	31,172
Effect of exchange rate changes on cash and cash equivalents	(72)	69	(142)
Net increase (decrease) in cash and cash equivalents	9,498	(11,229)	16,809
Cash and cash equivalents at beginning of year	6,397	17,626	817

Cash and cash equivalents at end of year	$ 15,895	$ 6,397	$ 17,626

Supplemental disclosures of cash flow information (see Note 16).

See accompanying notes to consolidated financial statements.

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LeMaitre Vascular, Inc.

Notes to Consolidated Financial Statements

December 31, 2008

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, arterial prostheses, remote endarterectomy devices, covered stents, contrast injectors, balloon catheters, vascular grafts, vein strippers, cholangiogram catheters and vascular access ports. We also distribute in 12 European countries an abdominal stent graft manufactured by a third party. In addition, we distribute in the United States and European Union a biological vascular patch manufactured by a third party. Our offices are located in Burlington, Massachusetts, Sulzbach, Germany, Rome, Italy, Brindisi, Italy, and Tokyo, Japan.

Consolidation and Basis of Presentation

Our consolidated financial statements include the accounts of LeMaitre Vascular and the accounts of our wholly-owned subsidiaries, LeMaitre Vascular GmbH, LeMaitre Vascular GK (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), and LeMaitre Vascular Limited (dissolved in 2006). 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 ($0.1) million in 2008, $0.3 million in 2007, and $0.2 million in 2006 and are included in other income (expense) in the accompanying consolidated statements of operations.

Estimates

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

Revenue Recognition

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

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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, although, for the year ended December 31, 2008, approximately 47% of our TAArget and UniFit stent grafts were custom-built.

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. During the periods presented in our consolidated financial statements 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 2008, $0.6 million in 2007, and $1.0 million in 2006.

Cash and Cash Equivalents

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

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Marketable Securities

We account for our investments in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. Our investments consist primarily of marketable debt securities and U.S. government securities, and are classified as available-for-sale and are carried at fair market value at December 31, 2008. 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 at the time of purchase to be short-term investments. When a marketable security incurs a significant unrealized loss for a sustained period of time, we review the instrument to determine if it is other-than-temporarily impaired. If we conclude an instrument is other-than-temporarily impaired, we record the unrealized loss in the consolidated statement of operations.

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 90 days or less at the date of purchase. Marketable securities are investment grade, interest-earning securities and are diversified by type and industry. Credit risk related to cash, cash equivalents, and marketable securities are limited based on the creditworthiness of the financial institutions at which these funds are held.

Our accounts receivable are with customers based in the United States and internationally. Accounts receivable generally are due within 30 to 90 days of invoice and are stated at amounts due from customers, net of an allowance for doubtful accounts and sales returns, other than in certain European markets where longer payment terms are customary. 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

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provision for excess and obsolete inventory based primarily on product expiration dating and our estimated sales forecast, which is based on sales history and anticipated future demand. Our estimates of future product demand may not be accurate, and we may understate or overstate the provision required for excess and obsolete inventory. Accordingly, any significant unanticipated changes in demand could have a significant impact on the value of our inventory and results of operations.

Property and Equipment

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

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

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

Valuation of Business Combinations

We 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.

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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. As a result of our review, 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, Inc., now known as Advansource Biomaterials Corporation, for total consideration of $0.4 million plus a 5 percent royalty on the 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 in pre-commercial clinical trials in Europe, 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 resulting in a net impairment charge of $0.1 million. The sale of inventory resulted in an adjustment to cost of sales for $12,000.

In January 2008 we were notified by one of the customers of our Biomateriali subsidiary that they would no longer purchase a certain product line from us, and, as a result, we incurred an impairment charge of $0.4 million due to the write-down of related intangible assets. As of December 31, 2008, we determined that an impairment indicator existed with respect to the remaining product line with this Biomateriali customer. Consequently, we recorded an impairment charge of $84,000 to reduce the carrying value of these assets to fair value to net realizable value of $0.1 million. Fair value was determined by projected future cash flows discounted to their net present value. In 2008, we also recognized impairment charges of $78,000 related to patents and trademarks which were deemed to have no value based upon a lack of future expected economic benefits.

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 ended December 31, 2008, 2007, or 2006.

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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 recognize 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.

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 the historical volatility of the company s stock. The interest rate for periods within the contractual life of the award is based on the U.S. Treasury risk-free interest rate in effect at the time of grant. The expected lives of the options were estimated using the simplified method for plan vanilla options. Computation of expected forfeitures is based on historical forfeiture rates of our stock options. For both 2007 and 2008, we used an expected forfeiture rate of approximately 20%. 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:

	2008	2007	2006
		(in thousands)	
Stock option awards to employees under SFAS No. 123(R)	$ 310	$ 241	$ 132
Common stock awards under SFAS No. 123(R)	499	303	262
Employee stock purchase plan		8	
Stock option awards to non-employees under SFAS No. 123	(8)	9	10
Total stock-based compensation	$ 801	$ 561	$ 404

We expect to record the unamortized portion of share-based compensation expense of $2.4 million for existing stock options and RSUs outstanding at December 31, 2008, over a weighted-average period of 3.6 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

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matters. We record charges for the costs we anticipate incurring in connection with litigation and claims against us when we conclude a loss is probable and we can reasonably estimate these costs. During the years ended December 31, 2008, 2007, and 2006, we were not subject to any material litigation or claims and assessments.

Income Taxes

We account for income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes.* This statement requires the use of the asset and liability method of accounting for income taxes. Under the asset and liability method, deferred taxes are determined based on the difference between the financial reporting and tax bases of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. The provision for income taxes includes taxes currently payable and deferred taxes resulting from the tax effects of temporary differences between the financial statement and tax bases of assets and liabilities. We maintain valuation allowances where it is more likely than not that all or a portion of a deferred tax asset will not be realized. Changes in the valuation allowances are included in our tax provision in the period of change. In determining whether a valuation allowance is warranted, the Company evaluates factors such as prior earnings history, expected future earnings, carry-back and carry-forward periods and tax strategies that could potentially enhance the likelihood of the realization of a deferred tax asset.

On January 1, 2007, we adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109*, (FIN 48). FIN 48 prescribes a comprehensive model for how a company should recognize, measure, present and disclose in its financial statements, uncertain tax positions that it has taken or expects to take on a tax return. This interpretation requires that a company recognize in its financial statements the impact of tax positions that meet a more likely than not threshold, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position should be measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate settlement.

Our policy is to classify interest and penalties related to unrecognized tax benefits as income tax expense, which is consistent with that of prior years.

Comprehensive Income (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).

As of December 31, 2008, accumulated other comprehensive loss consisted of unrealized losses on available-for-sale securities of $91,000 and foreign currency translation adjustment losses of $181,000. As of December 31, 2007, accumulated other comprehensive income consisted of unrealized gains on available-for-sale securities of $88,000 and foreign currency translation adjustment gains of $203,000.

Restructuring

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

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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.

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 our 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.

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Net loss per share is based on the following:

	Year ended December 31,		
	2008	2007	2006
	(in thousands)		
Numerator:			
Net loss as reported	$ (3,314)	$ (2,934)	$ (1,172)
Allocation of net loss:			
Basic:			
Redemption value of common stock awards	$	$	$ 295
Net income applicable to participating stockholders			295
Net loss applicable to common stockholders	(3,314)	(2,934)	(1,467)
Net loss	$ (3,314)	$ (2,934)	$ (1,172)
Diluted:			
Redemption value of common stock awards	$	$	$ 295
Net income applicable to participating stockholders			295
Net loss applicable to common stockholders	(3,314)	(2,934)	(1,467)
Net loss	$ (3,314)	$ (2,934)	$ (1,172)
Denominator:			
Weighted-average shares of common stock outstanding:	15,572	15,398	9,904
Common stock equivalents:			
Weighted-average shares of common stock issuable upon exercise of outstanding stock options			
Shares used in computing diluted net loss per common share, if dilutive	15,572	15,398	9,904

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

	Year ended December 31,		
	2008	2007	2006
	(in thousands, except per share data)		
Basic:			
Net loss available for common stockholders	$ (3,314)	$ (2,934)	$ (1,467)
Weighted average shares outstanding	15,572	15,398	9,904
Basic net loss per share	$ (0.21)	$ (0.19)	$ (0.15)
Diluted:			
Net loss available for common stockholders	$ (3,314)	$ (2,934)	$ (1,467)
Weighted-average shares outstanding	15,572	15,398	9,904
Common stock equivalents, if dilutive			

Shares used in computing diluted net loss per common share	15,572	15,398	9,904
Diluted net loss per share	$ (0.21)	$ (0.19)	$ (0.15)

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

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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.

For 2008 shares used in computing diluted net loss per common share excludes 394,257 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 232,845 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 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 business combination transactions consummated after December 31, 2008. The adoption of SFAS No. 141(R) is expected to significantly affect our 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 or financial condition.

In March 2008 the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 161, *Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB statement No. 133 (SFAS No. 161).* SFAS No. 161 requires enhanced disclosures regarding an entity derivative instruments and related hedging activities. These enhanced disclosures include information regarding how and why an entity uses derivative instruments; how derivative instruments and related hedge items are accounted for under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities,* and its related interpretations; and how derivative instruments and related hedge items affect an entity s financial position, financial performance, and cash flows. SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. We do not expect that the adoption of SFAS No. 161 will have a material impact on our consolidated results of operations or financial condition.

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In May 2008 the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, or SFAS 162. SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements that are presented in conformity with U.S. generally accepted accounting principles. We do not expect the adoption of SFAS 162 will have a material effect on our consolidated results of operations or financial condition.

In December 2007 the FASB ratified Emerging Issues Task Force (EITF) Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1*)*. EITF 07-1 provides guidance on collaborative arrangements within the scope of this issue on the classification of the payments between participants in the arrangement, the appropriate income statement presentation as well as disclosures related to these arrangements. EITF 07-1 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 of EITF 07-01 on our financial condition and results of operations.

In February 2008 the FASB issued Staff Position (FSP) No. 157-2, *Effective Date of FASB Statement No. 157*, or FSP 157-2, which delays the effective date of Statement No. 157 for all nonfinancial assets and nonfinancial liabilities, except for those that are recognized or disclosed at fair value in the financial statements on a recurring basis. We are required to apply the provisions of Statement No. 157 to nonfinancial assets and nonfinancial liabilities as of January 1, 2009. We do not expect that the adoption of FSP 157-2 will have a material effect on our consolidated results of operations or financial condition.

In April 2008 the FASB issued FSP FAS 142-3, *Determination of the Useful Life of Intangible Assets* (FSP FAS 142-3), to provide guidance for determining the useful life of recognized intangible assets and to improve consistency between the period of expected cash flows used to measure the fair value of a recognized intangible asset and the useful life of the intangible asset as determined under FASB Statement 142, *Goodwill and Other Intangible Assets* (FAS 142). The FSP requires that an entity consider its own historical experience in renewing or extending similar arrangements. However, the entity must adjust that experience based on entity-specific factors under FAS 142. FSP FAS 142-3 is effective for fiscal years and interim periods that begin after November 15, 2008. We intend to adopt FSP FAS 142-3 effective January 1, 2009 and to apply its provisions prospectively to recognized intangible assets acquired after that date. We do not expect that the adoption of FSP FAS 142-3 will have a material effect on our consolidated results of operations or financial condition.

2. Marketable Securities

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

	As of December 31, 2008				As of December 31, 2007			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)							
U.S. treasury obligations	$ 1,669	$	$	$ 1,669	$ 4,251	$ 78	$	$ 4,329
Federal agency obligations	999	1		1,000	4,001	15		4,016
Corporate bonds	1,126		(59)	1,067	2,720	1	(33)	2,688
Asset backed securities	1,656		(33)	1,623	5,132	33		5,165
Total marketable securities	$ 5,450	$ 1	$ (92)	$ 5,359	$ 16,104	$ 127	$ (33)	$ 16,198

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 for 2008, 2007, and 2006.

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In 2008, we recorded an investment impairment charge of $0.2 million which was attributed to the other-than-temporary decline in one asset backed security which we held as available-for-sale in our marketable securities portfolio at December 31, 2008.

The amortized cost and estimated fair value of available-for-sale marketable securities as of December 31, 2008, by contractual maturity, were as follows:

	2008	
	Amortized Cost	Fair Value
	(in thousands)	
Contractual maturities:		
Due in 1 year or less	$ 3,068	$ 3,056
Due in 1 2 years	2,293	2,214
Due in 2 5 years		
Due after 5 years	89	89
Total	$ 5,450	$ 5,359

3. Acquisitions

Biomateriali

In December 2007 we acquired all of the stock of Biomateriali, S.r.l. (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 will leverage our sales network and complement 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 in cash 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 was paid in 2008 and $0.6 million is payable in 2009; $0.2 million of direct acquisition costs; and $0.2 million for a deferred purchase price payment which is payable in 2009. The current portion of the deferred payments has been included in Acquisition-related Obligations in the December 31, 2008 and 2007 balance sheets. The long-term portion has been included in Other Long-term Liabilities in the December 31, 2007 balance sheet.

The purchase agreement included contingent payments to the sellers in connection with the expiration or termination of a distribution agreement (the Agreement). We were required to pay the sellers a fee for either the early termination or the expiration of the Agreement. The potential fee ranged from $1.1 million to $2.2 million (denominated in euros), depending on the circumstances. Had the Agreement remained in place for its full term and expired on December 31, 2011, we were required to pay $2.2 million to the sellers. In accordance with the guidance with SFAS No. 141, we established a liability of $0.1 million for contingent obligations in purchase accounting, which was the amount of the excess purchase price.

In March 2008, we provided notice of an indemnity claim 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 with Sorin Biomedica SpA (Sorin). In 2008, we made additional indemnity claims to the sellers regarding inventory and government subsidies. On December 12,

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2008, we reached an agreement to settle the indemnity claims in exchange for the elimination of the contingent liability and a reduction of the deferred portion of the purchase price, resulting in a net payment of $0.2 million (denominated in euros) payable on December 20, 2009.

The deferred payments are denominated in euros 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 final purchase accounting for the fair value of the assets acquired and liabilities assumed at the date of the acquisition:

	Allocated Fair Value (in thousands)
Current assets	$ 2,205
Property, plant, and equipment	456
Intangible assets	1,238
Other assets	1,186
Goodwill	100
Total assets acquired	5,185
Current liabilities	(1,417)
Other liabilities	(388)
Total liabilities assumed	(1,805)
	$ 3,380

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

	Allocated Fair Value (in thousands)	Weighted Average Useful Life
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	$ 1,238	

Based on developments since the date of acquisition, we recorded impairment charges of $0.5 million on the Biomateriali intangible assets in 2008 as discussed in Note 1.

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

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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 resulted in goodwill to be recognized in the transaction.

The aggregate purchase price was $2.9 million in cash and assumed liabilities. 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 $0.3 million was paid on the first anniversary of the signing in September 2008.

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

	Allocated Fair Value (in thousands)
Current assets	$ 543
Property, plant, and equipment	3
Intangible assets	658
Goodwill	1,758
Total assets acquired	2,962
Total current liabilities assumed	(72)
	$ 2,890

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

	Allocated Fair Value (in thousands)	Weighted Average Useful Life
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	$ 658	

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 in cash. 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 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.

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

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

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 in cash at the acquisition date and certain earn-out payments associated with the receipts of approvals to commercialize the device in the European Union and the United States. 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 acquired in the transaction. The fair value of the acquired in-process research and development 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 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 entered into a consulting agreement with the seller 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 required the development of a first prototype of the product within 150 days of the agreement effective date. We met the first milestone and no payment was required. The second milestone requires regulatory approval in the European Union within 17 months of the effective date; if the milestone is missed, we must pay $50,000 to the seller. The third milestone requires us to make the first commercial sale of the product within 20 months of the effective date of the agreement; if the milestone is missed, we may pay $50,000 to the seller in order to retain the intellectual property rights, subject to further milestone and extension payments. In addition, we are contractually obligated to make royalty payments on any sales from the technology purchased. Neither the second nor the third milestones have been achieved as of December 31, 2008.

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4. Inventory

Inventory consists of the following:

	As of December 31, 2008	2007
	(in thousands)	
Raw materials	$ 1,982	$ 2,374
Work-in-process	975	1,540
Finished products	4,002	5,675
Total inventory	$ 6,959	$ 9,589

5. Property and Equipment

Property and equipment consists of the following:

	As of December 31, 2008	2007
	(in thousands)	
Computer hardware	$ 1,883	$ 1,943
Machinery and equipment	4,103	4,325
Leasehold improvements	1,175	1,251
Gross property and equipment	7,161	7,519
Less accumulated depreciation	4,834	4,628
Property and equipment, net	$ 2,327	$ 2,891

Depreciation expense amounted to approximately $1.1 million in each of 2008, 2007, and 2006.

6. Goodwill and Other Intangibles

Goodwill consists of the following:

	As of December 31, 2008	2007
	(in thousands)	
Balance at beginning of year	$ 10,942	$ 8,853
Additions for acquisitions		2,089
Adjustments to purchase price on prior year acquisitions	80	
Balance at end of year	$ 11,022	$ 10,942

Other intangibles consist of the following:

	2008			2007		
	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	$ 2,247	$ 768	$ 1,479	$ 2,184	$	