LEMAITRE VASCULAR INC
Form 10-K
March 30, 2007
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2006

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: x

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: x

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 than the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes: x No: ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer (as defined in Rule12b-2 of the Exchange Act)

Large accelerated filer ¨ Accelerated filer ¨ Non-accelerated filer x

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

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, 2006: Not applicable. Trading of the registrant s Common Stock on The NASDAQ Global Market did not commence until October 19, 2006. At March 28, 2007, the Registrant had 15,353,089 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

2006 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 laws that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this Annual Report on Form 10-K regarding our strategy, future operations, future financial position, future net sales, projected costs, projected expenses, prospects and plans and objectives of management are forward-looking statements. The words anticipates, believes, estimates, expects, intends, may, plans, projects, wi 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;
- the ability to keep pace with a rapidly evolving marketplace and to develop or acquire and then successfully market new and enhanced products;
- a highly competitive market for medical devices;
- the effect of a disaster at our manufacturing facility;
- the loss of any significant suppliers, especially sole-source suppliers;
- our inability to adequately grow our operations and attain sufficient operating scale;
- our inability to obtain adequate profit margins;
- our inability 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 inability to raise sufficient capital when necessary or at satisfactory valuations;

loss of key personnel; and

other factors discussed elsewhere in this Annual Report on Form 10-K.

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

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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, Pruitt-Inahara, EndoFit, VascuTape, Expandable LeMaitre Valvulotome, Glow N Tell, Reddick, Expedial, OptiLock, InvisiGrip, Pruitt, AnastoClip and the LeMaitre Vascular logo are registered trademarks of LeMaitre Vascular, and UniFit and F3 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 for the treatment of peripheral vascular disease. We develop, manufacture and market disposable and implantable vascular devices to address the needs of vascular surgeons and interventionalists. 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 and the Pruitt-Inahara Carotid Shunt.

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

We have sought to take advantage of the trend towards endovascular techniques and other innovative procedures that utilize more complex, higher priced devices by acquiring new product lines. For example, we recently acquired our EndoFit and UniFit Aortic Stent Grafts, which are endovascular devices used to treat aortic aneurysms and dissections. 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 exceeds $3 billion and that the annual worldwide market addressed by our ten current product lines exceeds $500 million. In addition, we distribute an additional product line of a third party that addresses a market that we estimate to be in excess of $50 million in the territories where we have exclusive distribution rights. The increasing incidence and diagnosis of peripheral vascular disease is driving the growth of the market for peripheral vascular devices, which we estimate is growing at 8% per year. We believe that our strong brands, 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 47 bag-carrying sales representatives in the United States, Canada, the European Union and Japan as of December 31, 2006. We also sell our products through a network of distributors in various countries outside of the United States and Canada. For the year ended December 31, 2006, approximately 87% of our net sales were generated through direct sales, and no customer accounted for more than approximately 4% of our net sales.

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.

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Where You Can Find More Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available through the investor relations portion of our website (ir.lemaitre.com) free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or SEC. Information on our investor relations page and on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein 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. 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 twelve million people in the United States and seven 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 growing prevalence of diabetes, among other factors, has also led to an increase in the number of people suffering from end-stage renal disease. Patients with end-stage renal disease require a regular regimen of dialysis, an intravenous therapy that removes toxins and excess fluids from the bloodstream. Dialysis frequently requires the patient to undergo vascular procedures to create and preserve vessel access sites.

The Vascular Device Market and the Role of the Vascular Surgeon

We estimate that the worldwide market for peripheral vascular devices exceeds $3 billion. We believe 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. In the United States there are more than 2,000 board-certified vascular surgeons and several thousand general surgeons who perform vascular procedures. We estimate 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.

Conventional vascular surgery involves opening the body, cutting vessels and suturing, and include procedures such as lower extremity bypass surgery, carotid endarterectomy and 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.

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

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

Our History

We were founded in 1983 by George D. LeMaitre, M.D., a vascular surgeon who designed and developed the predecessor to our Expandable LeMaitre Valvulotome. We sold this device exclusively during the 1980s, and in 1992 we generated annual net sales of $0.8 million. We accomplished this with four employees, sharing space with Dr. LeMaitre s private surgical practice in Andover, Massachusetts.

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

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

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

In order to execute on these three initiatives, we raised $16.4 million of equity capital through a series of 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 ten product lines were acquired via these acquisitions. We have completed the integration of each of these product lines and businesses, consolidating all of our 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. In December 2006, we entered into a three-year distribution agreement with Endologix, Inc., effective January 1, 2007, for the exclusive distribution of the Powerlink System an abdominal stent graft manufactured by Endologix in ten European countries, including Germany, France and the United Kingdom. The Powerlink System expands our participation in the endovascular stent graft market and leverages our growing direct sales force in Europe. For the year ended December 31, 2006, we generated net sales of $34.6 million, and we currently offer ten product lines across three product categories, excluding Powerlink.

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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 strategies:

Further Expand Our Direct Sales Force in the United States, the European Union and Japan. We sell our products primarily through a direct sales force comprised as of December 31, 2006 of 47 bag-carrying sales representatives in the United States, Canada, the European Union and Japan. We intend to accelerate the expansion of our sales force in these markets. We also intend to convert selected countries from distributor to direct sales. We believe that direct-to-hospital sales engender closer customer relationships, allow for higher selling prices and gross margins and are not subject to the risk of customer churn resulting from distributor turnover.

Add Complementary Products through Acquisitions. We believe our significant experience in acquiring and integrating product lines and businesses is one of our principal competitive advantages. Since 1998, we have completed six acquisitions. We actively track industry developments and plan to acquire additional product lines and businesses as a means of further accessing the $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 on extending our reach into the $3 billion peripheral vascular device market. Our current research and development efforts include improvements and additions to our endovascular and dialysis access product lines. 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 for our UniFit Abdominal Stent Graft currently sold under the EndoFit trademark pending regulatory approval of its rebranding and in China for our EndoFit Thoracic Stent Graft.

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Our Products

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

Product Category	Product Line	Primary Use	Available for Sale in United States	Available for Sale in European Union	Available for Sale in Japan
Endovascular & Dialysis Access	EndoFit Thoracic Stent Graft	Endovascular repair of thoracic aortic aneurysm and dissection		ü	
	UniFit Abdominal Stent Graft	Endovascular repair of abdominal aortic aneurysm	In clinical studies(1)	ü(2)	
	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	Expandable LeMaitre Valvulotome	Destruction of vein valves to create vein bypass graft	ü	ü	ü
	Pruitt-Inahara and Pruitt F3 Carotid Shunts	Facilitation of blood flow to brain during carotid plaque removal	ü	ü(3)	ü(3)
	InvisiGrip Vein Stripper	Single-incision removal of varicose veins	ü	ü	Application submitted(4)
	LeMaitre Balloon Catheters	Removal of blood clots; occlusion and facilitation of blood flow	ü	ü	ü
General Surgery	Reddick Cholangiogram Catheter	Introduction of dye into the cystic duct	ü	ü	Application submitted(4)
	OptiLock Implantable Port	Central venous infusion of drugs and nutrients	ü	ü	

(1) We are conducting a clinical study in the United States on the UniFit Abdominal Stent Graft. See Clinical Studies for a description of this clinical study.
(2) The UniFit Abdominal Stent Graft is currently sold in the European Union under the EndoFit trademark, pending regulatory approval of its rebranding.
(3) The Pruitt F3 Carotid Shunt is only available for sale in the United States.
(4) We have submitted an application for Shonin registration to be filed with the Japan Ministry of Health, Labor and Welfare.

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

Endovascular & Dialysis Access Products

Endovascular

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

EndoFit Thoracic Stent Graft

The EndoFit Thoracic Stent Graft is a line of endovascular grafts used to treat an aortic aneurysm, a weakening and ballooning of the aorta, or an aortic dissection, a separation of the layers of the aortic wall that often leads to rupture and death, in each case in the upper part of the aorta, known as the thoracic aorta. EndoFit s flexible, encapsulated design, in contrast to devices currently available commercially, uses ePTFE, or expanded polytetrafluoroethylene, which is designed to prevent stent scaffolding from contacting either the blood stream or the vessel wall. This design also allows us to offer a wide range of stent grafts sizes, including tapered grafts, which fit a wider range of patient anatomies than many of our competitors products. Our design also allows us to rapidly build the device to fulfill custom orders, and, for the year ended December 31, 2006, about 34% of our EndoFit and UniFit stent grafts were custom-made. We acquired our EndoFit product line through our acquisition of Endomed in February 2005.

Our EndoFit Thoracic Stent Graft product line is currently sold in the European Union and a small number of foreign jurisdictions. We are currently conducting a clinical study in China for the EndoFit device.

UniFit Abdominal Stent Graft

The UniFit Aorta-uni-iliac Stent Graft is a line of non-bifurcated endovascular grafts used to treat aneurysms in the lower part of the aorta, known as the abdominal aorta, and the iliac arteries. The UniFit device is similar in design to the EndoFit device, with a flexible, encapsulated design and similar manufacturing advantages that allows us to offer a wide range of stent graft sizes and custom-built devices. We acquired our UniFit product line through our acquisition of Endomed in February 2005. Until recently we referred to this product as part of our EndoFit line of endovascular grafts, but are in the process of rebranding the device as UniFit to more accurately reflect that it is a different product line indicated for use in a different section of the aorta.

This product line is currently sold in the European Union and a small number of foreign jurisdictions under the EndoFit trademark pending completion of the rebranding. 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 vascular surgeons and 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.

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VascuTape Radiopaque Tape was invented by our founder, George D. LeMaitre, M.D., and received 510(k) clearance from the United States Food and Drug Administration, or FDA, in 1993.

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

Powerlink System

The Powerlink System is a one-piece, self-expandable 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 and the United Kingdom.

Dialysis Access

Dialysis is an intravenous therapy, typically performed three or more times per week, that removes toxins and excess fluids from the bloodstream in end-stage renal disease patients. Dialysis requires access to the patient s bloodstream through large needles or catheters. Our dialysis access product is used in surgical procedures that facilitate the creation of dialysis access sites, typically in a patient s arm. Vascular surgeons perform a critical role in the care and treatment of end-stage renal disease by creating and maintaining these access sites.

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 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.

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 foot. The Expandable LeMaitre Valvulotome is the only self-sizing, self-centering valvulotome available. We believe 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,

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thereby reducing the length of hospital stays and the likelihood of wound complications. The Expandable LeMaitre Valvulotome is the sixth generation of the fixed-diameter valvulotome developed by our founder, George D. LeMaitre, M.D.

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

Pruitt-Inahara and Pruitt F3 Carotid Shunts

The Pruitt-Inahara and Pruitt F3 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 shunts feature occlusion balloons which eliminate the need for clamps, thereby reducing vessel trauma. 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.

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

InvisiGrip Vein Stripper

The InvisiGrip Vein Stripper is a single-incision, inversion vein stripper, which is 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 Robertus Welten, M.D., a vascular surgeon.

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

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 embolectomy catheters. The dual lumen embolectomy catheter allows clot removal and simultaneous irrigation or guide-wire trackability. We acquired our LeMaitre Embolectomy Catheter product line and related operations in part from Vermed in June 1999 and in part from Horizon Medical in March 2001.

Occlusion catheters temporarily occlude blood flow to allow the vascular surgeon time and space to complete a given procedure. Perfusion catheters temporarily perfuse blood and other liquids into the vasculature. Our Pruitt Occlusion and Perfusion Catheters reduce vessel trauma by using internal balloon fixation rather than traditional external clamp fixation. We acquired our Pruitt Occlusion and Perfusion Catheter product lines and related operations from Horizon Medical in March 2001.

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

General Surgery Products

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

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abdomen. We also offer two laparoscopic accessories used in laparoscopic gall bladder removal, the Reddick-Saye Screw and the Grice Suture Needle, which we license from third parties. We acquired the Reddick Cholangiogram Catheter and laparoscopic accessory product lines and related operations from Horizon Medical in March 2001.

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

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 are currently conducting two clinical studies:

UniFit Abdominal Stent Graft (U.S. Clinical Study). In October 2002, the previous owner of our UniFit product line commenced a feasibility study in the United States to support a possible PMA application for the UniFit Abdominal Stent Graft. (See Government Regulation for more on the PMA process.) We took over this study at the time of our acquisition of Endomed, Inc. in February 2005. In this study, we are seeking to demonstrate successful aneurysm exclusion without perioperative death, myocardial infarction, stroke, limb loss or surgical conversion. We may enroll up to 60 patients in this feasibility study and have enrolled 49 patients as of December 31, 2006. 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, 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 September 2006, we received conditional approval from the FDA to commence the pivotal trial, which we refer to as the UNITE study, provided that we resolve the issues identified in the conditional approval letter to the FDA s satisfaction. On this basis, we have begun enrollment in the UNITE study. We plan to enroll 90 patients at up to 14 institutions. The primary effectiveness endpoint of the study is based on aneurysm exclusion as evaluated through one-year follow-up.

EndoFit Thoracic Stent Graft (Chinese Clinical Study). In August 2005, we commenced a clinical study to obtain approval from the Chinese State Food and Drug Administration, or SFDA, of our EndoFit Thoracic Stent Graft. 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 planned 30 patients in the study in November 2006. There is a six-month follow-up period for each patient implanted with the device.

We are also sponsoring a multi-center, non-randomized pilot registry in the European Union, which we refer to as the DEDICATED registry, to evaluate the use of the EndoFit Thoracic Stent Graft in treating type B aortic dissections. Certain configurations of our EndoFit Thoracic Stent Graft are already indicated for use in the treatment of type B dissections. The registry is intended to support an enhanced marketing claim and provide the

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medical community with safety and efficacy data specific to this particular pathology. We plan to enroll 100 patients and have enrolled 16 patients as of December 31, 2006. There are one-, three- and six-month follow-up periods after the procedure.

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

Sales and Marketing

As of December 31, 2006, we employed 47 bag-carrying sales representatives. We believe the expansion of our direct sales force has been a key factor in our success and it remains one of our primary strategies. We intend to accelerate the expansion of our sales force. In the United States, for example, we sell directly to hospitals but do not have sales coverage in several large markets. Outside the United States, we expect to significantly expand direct sales coverage. Outside our direct markets, we sell our products through a network of country-specific distributors. We typically sign exclusive distribution agreements with terms of up to three years specifying minimum annual sales volumes and pricing. These agreements are only renewable by mutual agreement.

We believe that our direct marketing efforts are critical to our brand development and continued success. Until 1998, we had no direct sales force and instead relied on direct marketing to generate brand awareness and product loyalty. We believe that our history as a direct marketer of medical devices serves us well today, allowing us to market to vascular surgeons beyond the reach of our direct sales force.

Research and Development

Our research and development has primarily focused on developing improvements and extensions to our product lines and improving manufacturing techniques and processes. Our product development efforts are currently focused on next-generation improvements to our EndoFit and UniFit Stent Grafts, including design modifications to the stent grafts and to the delivery system, and new products in the endovascular and dialysis access space.

Our products are subject to our design control validation 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 2004, 2005 and 2006, our research and development expenditures, including our clinical study expenditures, were $2.1 million, $3.0 million and $3.3 million, respectively, and constituted between 8% and 10% of net sales. As of December 31, 2006, our research and development staff consisted of twelve full-time engineers and technicians.

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Manufacturing

Our manufacturing facilities are located in Burlington, Massachusetts and include a 5,556 square foot ISO 14644-1 Class 8 clean room and a 2,100 square foot ISO 14644-1 Class 7 clean room.

As a result of the six acquisitions we executed between 1998 and 2005, we have operated factories in a variety of locations including France; the United Kingdom; St. Petersburg, Florida; Lawrence, Massachusetts; and Phoenix, Arizona. All of our manufacturing operations have been relocated to our Burlington, Massachusetts headquarters in an effort to reduce costs and bring manufacturing closer to our research and development personnel.

We manufacture certain proprietary components and assemble, inspect, test and package our finished products. By designing and manufacturing many of our products from raw materials, and assembling and testing our subassemblies and products, 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.

All of our products are built to stock. In addition, for the year ended December 31, 2006, about 34% of our EndoFit and UniFit Aortic Stent Grafts were custom-made for specific anatomies as requested by physicians. We believe our custom manufacturing of stent grafts is a competitive advantage that engenders surgeon 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 all parts of the manufacturing process through delivery of the product to the customer.

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

We purchase components from third parties. Most of our components are readily available from several supply sources, but we rely on single and limited source suppliers for several of our key product components. We do not have contractual arrangements with most of these suppliers, and we order our supplies 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 Burlington 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

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Notified Body to ensure compliance with domestic and non-U.S. regulatory requirements. See Government Regulation.

Competition

The markets in which our ten 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, and including both publicly-traded and privately held device companies. Notable competitors include C.R. Bard, Inc., Edwards LifeSciences Corporation, W. L. Gore & Associates, Medtronic, Inc., Cook Group Incorporated, Applied Medical Resources Corporation, VNUS Medical Technologies, Inc. and Uresil, LLC.

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 our direct sales channel, acquire or develop additional vascular device product lines, obtain patent or other product protections, obtain regulatory and reimbursement approvals, maintain sufficient inventory to meet customer demand, and attract and retain skilled personnel.

Many of our competitors have substantially greater financial, technological, research and development, regulatory, marketing, sales and personnel resources than we do. Certain of these competitors may also have greater experience in developing products, obtaining regulatory approvals, and manufacturing and marketing such products. Certain of these competitors may obtain patent protection or regulatory approval or clearance, or achieve product commercialization, before us, any of which could materially adversely affect us.

Intellectual Property

We believe that our success is dependent, to a great extent, on the development and maintenance of proprietary aspects of our technologies. We rely on a combination of patents, trademarks, trade secret laws, and confidentiality and invention assignment agreements to protect our intellectual property rights.

As of December 31, 2006, we had 88 issued patents and 15 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, is uncertain and involves 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 circumvented by a more basic patent, thus requiring us to obtain a license to produce and sell the product. Generally, patent applications can be maintained in secrecy for at least 18 months after their earliest priority date. In addition, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent the subject

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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. In 2005 and 2006, respectively, Boston Scientific Corporation initiated opposition proceedings in the European Patent Office to oppose our granted European patent number 1,202,682, or the 682 patent, related to an ePTFE intraluminal device such as certain of our EndoFit and UniFit stent grafts, and to oppose our granted European patent number 1,148,838, or the 838 patent, related to an ePTFE vascular prosthesis such as certain of our EndoFit and UniFit stent grafts. Depending on the course of the opposition proceedings, the granted patent claims in the 682 patent will be amended or may be cancelled while the 838 patent may survive unamended, may be amended, or may be cancelled. We can not assure you that we will be successful in defending these oppositions.

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 owns the patent. 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 the subjects 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 aortic stent graft products 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. In addition, our arrangement with Bard also precludes us from assigning the agreement to a third party, including in connection with the sale of 30% or more 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 aortic stent graft products could adversely affect our business and results of operations, perhaps materially. We also manufacture, market and sell our AnastoClip Vessel Closure System pursuant to a license with a third-party patent holder.

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

We rely on trade secret protection for certain unpatented aspects of other proprietary technology. There can be no assurance that others will not independently develop or otherwise acquire substantially equivalent proprietary information or techniques, that others will not gain access to our proprietary technology or disclose such technology, or that we can meaningfully protect our trade secrets. We have a policy of requiring key employees and consultants to execute confidentiality agreements upon the commencement of an employment or consulting relationship with us. Our confidentiality agreements also require our employees to assign to us all rights to any inventions made or conceived during their employment with us. We also generally require our consultants to assign to us any inventions made during the course of their engagement by us. There can be no

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

510(k) Clearance. To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent in intended use and in safety and effectiveness to a predicate device, (*i.e.*, a previously 510(k) cleared class I or class II device or a preamendment class III device for which the FDA has not yet called for PMA applications). The FDA s 510(k) clearance pathway usually takes from four 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 to date are marketed in the United States 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 or could require a PMA approval. 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 or PMA approval. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained. Also, the manufacturer may be subject to significant regulatory fines or penalties.

PMA Approval. The PMA approval pathway requires proof of the safety and effectiveness of the device to the FDA s satisfaction. The PMA approval pathway is much more costly, lengthy and uncertain. A PMA application must provide extensive preclinical and clinical trial data and also information about the device and its

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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 in 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 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 in the event of a modification to the device, its labeling or its manufacturing process. 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.

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

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 never used the more burdensome PMA procedure for any of the products that we currently market or sell in the United States. We expect that the FDA will require both our UniFit Abdominal Stent Graft and EndoFit Thoracic Stent Graft to 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:

- establishment registration and device listing with the FDA;

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

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

Other U.S. Regulations

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

We are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain hazardous and potentially

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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. The member states of the European Union have implemented the directives into their respective national law, and have each established a Competent Authority to apply the directive in its territory.

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

A manufacturer of low risk devices typically may demonstrate conformity to the essential requirements based on a self-declaration. The European Standardization Committees have adopted numerous harmonized standards for specific types of medical devices. Compliance with relevant standards establishes a presumption of conformity with the essential requirements. 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 in connection in those countries 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, or MHLW, regulates medical devices through the Pharmaceutical Affairs Law, or PAL, 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 regulations have resulted in longer lead times for product development.

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.

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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 the 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. However, in many cases, third-party payors operate by reimbursing patients for all or part of the charges that patients pay for procedures and 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 by improving health outcomes, including quality of life or functional ability, in a safe and cost-effective manner. Even if a device has received clearance or approval for marketing by the FDA, there is no assurance that third-party payors will cover the cost of the device and related procedures in which the device is used.

In many instances, third-party payors cover the procedures performed using our products using price fee schedules that do not vary reimbursement to reflect the cost of the products and equipment used in performing those procedures. In other instances, payment or reimbursement is separately available for the products and equipment used, in addition to payment or reimbursement for the procedure itself. Even if coverage is available, third-party payors may place restrictions on the circumstances where 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 reimbursements for the procedures they cover. We believe that the minimally invasive procedures in which 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.

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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 rely on the distributors who sell our products to obtain reimbursement approval for those countries in which they will sell our products. There can be no assurance that reimbursement approval will be received.

Fraud and Abuse Laws

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

Employees

We had 218 full time employees at December 31, 2006. Of these employees, 106 were in manufacturing and research and development, 77 were in sales and marketing, 10 were in clinical, regulatory and quality assurance and 25 were in general and administrative. We have never had a work stoppage and none of our employees is covered by a collective bargaining agreement. We believe 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 do not expect to achieve profitability in the near term, especially as we expand our direct sales force, conduct our clinical studies and acquire and develop new product offerings, businesses or technologies.

We expect to make substantial expenditures to expand our direct sales force, conduct our clinical studies and acquire and develop new product offerings, businesses or technologies. As a result, we do not expect to be profitable in the near term, and we will need to generate significant net sales in future periods to achieve and maintain profitability. Our ability to achieve and maintain profitability will be influenced by many factors, including:

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

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

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 six acquisitions. Our operating results are largely dependent on these acquired product lines, and this dependence exposes us to risks and uncertainties.

For example, we have only recently completed the relocation of the manufacturing operations related to our EndoFit Thoracic Stent Graft and UniFit Abdominal Stent Graft, which we acquired from Endomed, Inc. in February 2005. We now manufacture this product line solely in our Burlington, Massachusetts headquarters. Due to our limited experience with manufacturing the device ourselves, we may encounter difficulties or delays that could negatively impact product quality or impair our ability to manufacture sufficient quantities to satisfy demand, either of which in turn could have a material adverse effect on our financial condition or results of operations.

We also may experience other difficulties related to these acquisitions. For example, in connection with our Endomed acquisition, we acquired an ongoing clinical study related to the UniFit Abdominal Stent Graft. See

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Business Clinical Studies. Our experience in conducting clinical studies is limited and we may experience difficulties or delays in transitioning this study or future studies. Also, we may determine that the design of this acquired study does not meet our business objectives. Any difficulties or delays we experience in connection with this clinical study could negatively impact our ability to obtain regulatory approval to market the UniFit Abdominal Stent Graft in certain markets. In addition, the products that we have acquired may need to be improved in order to gain broader market acceptance or may not compete effectively with existing products. We have limited experience with certain technologies underlying the acquired products. There can be no assurance that we will be successful developing the desired product improvements in a timely manner, if at all.

In April 2003, we acquired the Expedial Vascular Access Graft product line from Credent Limited, a UK company. At the time of the acquisition, the Expedial Vascular Access Graft had already received a *Conformité Européenne*, or CE mark, and was being sold in the European Union and other foreign jurisdictions. In May 2004, we commenced a clinical study in the United States to collect data to submit to the FDA in support of 510(k) clearance for this device. In July 2006, we received preliminary data from the clinical study conducted for the period from April 8, 2004 to June 28, 2006 suggesting that the device may not compare favorably to ePTFE grafts. There were no significant safety issues identified in the preliminary data collected in the clinical study. As a result of our review of the clinical study results and less than planned sales of the product in Europe, we decided to forego further enrollment in the clinical study and cease the production and sale of this device. In October 2006, we sold certain manufacturing equipment, inventory and intellectual property related to our Expedial Vascular Access Graft product line to CardioTech International, Inc. for total consideration of $350,000 plus a five percent royalty on CardioTech s net sales of its CardioPass brand coronary artery bypass graft for a period of five years following the first commercial sale of a CardioPass graft. Clinical trials on the CardioPass graft have only recently been initiated and there can be no assurance that it will ever be commercialized.

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

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

We may not be able to compete effectively with our competitors unless we can keep pace with existing or new products and technologies in the vascular device market. Our success in developing and commercializing new products and new versions of our existing products is affected by our ability to:

- identify in a timely manner new market trends and customer needs;
- keep pace with technological changes and industry standards;
- obtain regulatory clearance or approval of new products and technologies;
- successfully develop cost-effective manufacturing processes for such products;
- commercially introduce such products and technologies; and
- achieve market acceptance.

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

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

In order to expand our product offerings, we have acquired six businesses since 1998, and a key part of our strategy is to acquire additional businesses, products or technologies in the future. Our growth strategy depends

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in part upon our ability to identify, negotiate, complete and integrate suitable acquisitions. 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;
- diversion of our management s time and attention from other business concerns;
- challenges resulting from limited or no direct prior experience in new markets or countries we may enter;
- higher costs of integration than we anticipated;
- difficulties in retaining key employees of the acquired business who are necessary to manage these acquisitions;
- difficulties in acquiring the right to and protecting intellectual property; or
- difficulties if the acquired company is remote or inconvenient to our Burlington, Massachusetts headquarters.

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

If we fail to convert additional countries from distributor sales to direct sales, our results of operations could suffer.

We intend to convert selected countries from distributor sales to direct sales, which could result in disruptions in our sales. This transition may also have an adverse effect on our cash flow from operations because distributors, unlike direct sales personnel, pay us for inventory that they stock for later sale. In addition, switching to a direct sales force may subject us to longer customer collection times and larger bad debt expense since we would be required to collect customer payments directly rather than through a distributor. Also, our distribution agreements are typically exclusive with terms of up to three years. These agreements may temporarily constrain our ability to convert certain countries from a distributor to a direct sales model. As a result, there can be no assurance that we will be successful in transitioning to a direct sales model in the countries that we select, and difficulties that we encounter in this transition could negatively affect our business.

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

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

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

Some of our devices have been recently introduced into the market, and we cannot assure you that they will achieve market acceptance. The same is true of new devices that we may acquire or internally develop in the future. The marketing of our products requires a significant amount of time and expense in order to identify and develop relationships with the physicians who may use our products, invest in training and education with these physicians and employ a sales force that is large enough to interact with the targeted physicians, with no assurance of success. In some cases, our devices may face competition from devices marketed by our competitors, and our customers may not prefer our device. In other cases, our devices may be used in new procedures and techniques and if physicians do not adopt these procedures and techniques, demand for these devices would fail to develop. For example, in 2004 we launched our InvisiGrip Vein Stripper, which has not 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 six 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 require us to transition to new enterprise management software. Such growth could place a strain on our administrative and operational infrastructure. We may not be able to make improvements to our management information and control systems in an efficient or timely manner, and we may discover deficiencies in existing systems and controls. If we cannot scale and manage our business appropriately, our anticipated growth may be impaired and our financial results could suffer.

We depend on single and limited source suppliers for some of the components to our products, 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. For example, we obtain from a third party supplier all of the nitinol stents used in and from another third-party supplier all of the stent graft delivery systems that are used with our EndoFit Thoracic Stent Graft and UniFit Abdominal Stent Graft. There are relatively few, or in some cases no, alternative, validated sources of supply for these components. 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 at any time. We do not carry a significant inventory of these components. Identifying and qualifying additional or replacement suppliers for any of these components, if required, may not be accomplished quickly or at all and could involve significant additional costs. Any supply interruption from our vendors or failure to obtain additional vendors for any of the components used to manufacture our products would limit our ability to manufacture our products, may result in production delays and increased costs and may limit our ability to deliver products to our customers. If we are unable to identify alternate sources of supply for the components, we would have to modify our products to use substitute components, which may cause delays in shipments, increase design and manufacturing costs and increase prices for our products. We can not 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.

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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. 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 2008 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 their 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, President and Chief Executive Officer, George W. LeMaitre, but not on our other key personnel.

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

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

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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 an increasing 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, and easier to use, less expensive or more readily accepted than ours. Their products could make our technology and products obsolete or noncompetitive. Our competitors may also be able to achieve more efficient manufacturing and distribution operations than we can and may offer lower prices than we could offer profitably. In addition, many of our products face competition from alternative procedures that utilize a different kind of medical device that we do not currently sell. Any of these competitive factors could adversely impact our business, net sales and results of operations.

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

We have entered into a three-year agreement with Endologix, Inc., to distribute the Powerlink System in ten European countries, including Germany, France and the United Kingdom. Our success in marketing the

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

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

We 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 several months in advance of customer orders. In addition, lead times for product components 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.

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As is the case with other medical device companies, product liability claims could be brought against us. If our products are defectively designed, manufactured or labeled, contain defective components or are misused, or if our products are found to have caused or contributed to injuries or death, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management s attention from our core business, be expensive to defend and result in sizable damage awards against us. Claims of this nature may also adversely affect our reputation, which could damage our position in the market and subject us to product recalls.

We cannot assure you that our product liability insurance coverage will be sufficient to satisfy any claim made against us. Further, we may not be able to maintain the same level of coverage, and we may not be able to obtain adequate coverage at a reasonable cost and on reasonable terms, if at all. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing coverage in the future. Additionally, if any such product liability claim or series of claims is brought against us for uninsured liabilities or is in excess of our insurance coverage, our business could be harmed.

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

We derive a significant portion of our net sales from operations in markets outside of the United States and Canada. For the year ended December 31, 2006, 35% 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 the company does business that would restrict or prohibit continued business with the sanctioned country, company, person or entity;
- a shortage of high-quality sales people 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;

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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 are currently conducting a clinical study to obtain approval from the Chinese State Food and Drug Administration to market our EndoFit Thoracic Stent Graft in China. If and when this product is approved for sale in China, we expect to initially market our device using one or more distributors. Conducting business in China, if we seek to enter that market, would expose us to a variety of risks and uncertainties that are unique to China. The Chinese economy differs from the economies of most developed countries in many respects, including:

level of government involvement;

economic structure;

allocation of resources;

level of development;

inflation rates;

growth rate; and

control of foreign exchange.

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

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

Because the majority of our sales outside of the United States are denominated in local currencies, our reported sales and earnings are subject to fluctuations in foreign exchange rates. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our sales and earnings. At present, we do not manufacture our products outside the United States nor do we engage in hedging

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transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U.S. dollar.

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

Sales of our products through independent distributors represented 13% of our net sales for the year ended December 31, 2006. Our success in these markets depends largely upon marketing arrangements with distributors, in particular their sales and service expertise and relationships with their respective customers in the marketplace. Although we intend to replace some of these distributors with a direct sales force, this will take time and we may keep a distribution model in some markets. We do not control our distributors and they may not be successful in implementing our marketing plans.

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

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

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

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

The efficient operation of our business is dependent on our management information systems. We rely on our management information systems to effectively manage accounting, financial, human resources and sales and marketing functions; manage order entry, order fulfillment and inventory replenishment processes; and maintain our research and development and clinical data. We do not maintain redundant management information systems. The failure of our management information systems to perform as we anticipate could disrupt our business and

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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. As of March 2007, we continue to provide information relating to the audit and have not received or agreed upon any final adjustment from the IRS.

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.

At December 31, 2006, we accrued $0.9 million in our financial statements in connection with amounts we may owe in connection with our tax liabilities worldwide. The assessment of additional taxes, interest and penalties as a result of audits, litigation or otherwise, could be materially adverse to our current and future results of operations and financial condition.

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

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

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

One of our business strategies is to expand our direct sales force, particularly in markets where we believe we are currently underrepresented. For example, there are several large markets in the United States where we do

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

Risks Related to the Regulatory Environment

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

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

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

issuing public warning letters to us;

imposing fines and penalties on us;

issuing an injunction preventing us from manufacturing or selling our products;

bringing civil or criminal charges against us;

delaying the introduction of our new products into the market;

ordering a recall of, or detaining or seizing, our products; or

withdrawing or denying approvals or clearances for our products.

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

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

Our products require premarket clearance or approval in the United States and 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 four 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

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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.

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

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

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

Even if regulatory approval or clearance of a product is granted, the approval or clearance could limit the uses or the claims for which the product may be labeled and promoted, which may limit the market for our products. If we do not obtain and maintain foreign regulatory or FDA approval with respect to our products, as applicable, we will not be able to sell our products and our future growth will be significantly hampered.

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

Any modification to a 510(k) cleared device that could significantly affect its safety or effectiveness, or would constitute a major change in its intended use, requires the submission of another 510(k) or PMA application to address the change. The FDA requires every manufacturer to make its own determination as to whether a modification requires a new 510(k) clearance or PMA. Although in the first instance we may determine that a change does not rise to a level of significance that would require us to make a submission, the FDA may review and disagree with our determination and can require us to submit a 510(k) or a PMA for a significant technological change or major change or modification in intended use. If the FDA requires us to submit a 510(k) or a PMA for any modification to a previously cleared device, we may be required to cease marketing the device, recall it, and not resume marketing until we obtain clearance or approval from the FDA for the modified version of the device. Delays in our receipt of regulatory clearance or approval will cause delays in

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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 EndoFit and UniFit products are in 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.

We currently have two ongoing clinical studies to support clearance or approval for products that we expect to contribute significantly to our sales in the future. These studies include a U.S. pivotal study to support a possible PMA application for our UniFit Abdominal Stent Graft and a Chinese clinical study to support approval from the Chinese State Food and Drug Administration, or SFDA, of our EndoFit Thoracic Stent Graft for marketing in China. We cannot assure you that these studies will be successful or that the FDA or SFDA or other relevant regulatory agencies will accept the results and approve or clear the devices for sale. Further, we continue to evaluate the potential financial benefits and costs of our clinical studies and the products being evaluated in them. If we determine that the costs associated with attaining regulatory approval of a product exceed the potential financial benefits of that product, or if the projected development timeline is inconsistent with our investment horizon, we may choose to stop a clinical study and/or the development of a product.

In May 2006, we submitted an investigational device exemption, or IDE, supplemental application to the FDA to begin a pivotal clinical trial to evaluate the safety and effectiveness of the UniFit Abdominal Stent Graft in the treatment of aorto, aorto-iliac and/or iliac aneurysms. In September 2006, we received conditional approval from the FDA to commence the pivotal trial, which we refer to as the UNITE study, provided that we resolve the issues identified in the conditional approval letter to the FDA s satisfaction. On this basis, we have begun enrollment in the UNITE study. We plan to enroll 90 patients at up to 14 institutions. The primary effectiveness endpoint of the study is based on aneurysm exclusion as evaluated through one-year follow-up.

If our UniFit and EndoFit clinical studies are unsuccessful, or if the FDA or other regulatory agencies do not accept or approve the results of such studies, these products will not successfully come to market and our business prospects may suffer.

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 for three days. 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

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other quality problems, and we had an incomplete procedure for implementing and recording actions taken to correct and prevent identified quality problems. While we have revised our procedures and conducted additional training to address the FDA s findings, we cannot assure you that we have been successful in implementing these changes or that the FDA will agree that our implementation is adequate. If the FDA finds that we are not in substantial compliance with the Quality System Regulation, the FDA may issue a public warning letter or take other enforcement action against us and our operations could be disrupted and our manufacturing delayed.

We are also subject to the FDA s general prohibition against promoting our products for unapproved or off-label uses and to the medical device reporting, or MDR, regulations that require us to report to the FDA if our products may have caused or contributed to a death or serious injury, or if our device malfunctions and a recurrence of the malfunction would likely result in a death or serious injury. We must also file reports with the FDA of some device corrections and removals and we must adhere to the FDA s rules on labeling and promotion. If we fail to comply with these or other FDA requirements or fail to take adequate corrective action in response to any significant compliance issue raised by the FDA, the FDA can take significant enforcement actions, which could harm our business, results of operations and our reputation.

In addition, most other countries, such as Japan, require us to comply with manufacturing and quality assurance standards for medical devices that are similar to those in force in the United States before marketing and selling our products in those countries. If we fail to comply, we would lose our ability to market and sell our products in those foreign countries.

Even after receiving regulatory clearance or approval, our products may be subject to product recalls, which may harm our reputation and divert managerial and financial resources.

The FDA and similar governmental authorities in other countries have the authority to order mandatory recall of our products or order their removal from the market if the governmental entity finds that our products would cause serious adverse health consequences or death. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design defects, including labeling defects. For example, in 2005 we initiated three voluntary recalls. Two of these recalls related to packaging flaws that compromised the sterility of the products, and the third recall arose from a labeling error. 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. Currently, we are awaiting revised CE mark certificates from our Notified Body for certain products the manufacturing of which has been transferred to

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our Burlington, Massachusetts facility. A Notified Body is an independent third party designated by governmental authorities to assess conformity with the Medical Devices Directive.

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, or 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 to death or serious deterioration in health, or incidents that could have led to death or serious deterioration in health. Under certain circumstances, we could be required to initiate a recall or removal of our product from the market in order to address product deficiencies or malfunctions. Any recall of our products may harm our reputation with customers and divert managerial and financial resources.

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

Our manufacturing facilities are subject to periodic inspection by European regulatory authorities and Notified Bodies, and we must demonstrate compliance with the Medical Devices Directive. Any failure by us to comply with European requirements in this regard may entail our taking corrective action, such as modification of our policies and procedures. In addition, we may be required to cease all or part of our operations for some period of time until we can demonstrate that appropriate steps have been taken. There can be no assurance that we will be found in compliance with such standards in future audits. Our failure to comply may have a material adverse effect on our business, financial condition and results of operations.

In Japan, the Ministry of Health, Labor and Welfare, or MHLW, regulates medical devices through the Pharmaceutical Affairs Law, or PAL, 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 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;

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federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us, because we provide coding and billing advice to customers;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to health care matters and which also imposes regulatory and contractual requirements relating to the privacy, security and transmission of individually identifiable health information;

state laws analogous to each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by non-governmental third-party payors, including commercial insurers, and state laws governing the privacy of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;

federal physician self-referral prohibitions, such as The Ethics in Patient Referral Act of 1989, commonly referred to as the federal physician self-referral law or the Stark law, which under certain circumstances prohibit physicians from referring patients for services paid for by Medicare or Medicaid to any entity in which the physician or an immediate family member has an ownership, compensation or other financial interest, unless a specific statutory or regulatory exception applies; and

international regulations similar in nature and scope to the above-referenced requirements, including the European Union directive on data privacy, which imposes restrictions on the collection, use, disclosure and processing of personal data.

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

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

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

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

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

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

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

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

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

Risks Related to Intellectual Property

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

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

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

permit us to gain or maintain a competitive advantage.

The issuance of a patent is not conclusive as to its validity or enforceability. Any patents we have obtained or will obtain in the future might also be invalidated or circumvented by third parties. In addition, our pending patent applications may not issue as patents or, if issued, may not provide commercially meaningful protection,

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as competitors may be able to design around our patents to produce alternative, non-infringing designs. Should such challenges to our patents be successful, competitors might be able to market products and use manufacturing processes that are substantially similar to ours. Additionally, we may not be able to effectively protect our rights in unpatented technology, trade secrets and confidential information. We have a policy of requiring key employees and consultants and corporate partners with access to trade secrets or other confidential information to execute confidentiality agreements. Our confidentiality agreements also require our employees to assign to us all rights to any inventions made or conceived during their employment with us. We also generally require our consultants to assign to us any inventions made during the course of their engagement by us. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for us in the event of unauthorized use, transfer or disclosure of confidential information or inventions.

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

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

The medical device industry is litigious with respect to patents and other intellectual property rights. Companies operating in our industry routinely seek patent protection for their product designs, and many of our principal competitors have large patent portfolios. Companies in the medical device industry have used intellectual property litigation to gain a competitive advantage. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. We face the risk of claims that we have infringed on third parties intellectual property rights, and we cannot assure you that our products or methods do not infringe the patents or other intellectual property rights of third parties. Prior to launching major new products in our key markets, we typically evaluate existing intellectual property rights. However, our competitors may also have filed for patent protection that is not as yet a matter of public knowledge or claim trademark rights that have not been revealed through our availability searches. Our efforts to identify and avoid infringing on third parties intellectual property rights may not always be successful. Any claims of patent or other intellectual property infringement, even those without merit, could:

- be expensive and time consuming to defend;
- result in us being required to pay significant damages to third parties for past use of the asserted intellectual property;
- 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 our manufacturing facility.

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

In addition, we may become subject to interference proceedings conducted in the United States Patent Office or opposition proceedings conducted in foreign patent offices challenging the priority of invention or the validity of our patents. For example, Boston Scientific Corporation initiated opposition proceedings in 2005 and 2006, respectively, in the European Patent Office to oppose the Company s granted European patent number 1,202,682, or the 682 patent, related to an ePTFE intraluminal device such as certain of our EndoFit and UniFit stent grafts, and to oppose the Company s granted European patent number 1,148,838, or the 838 patent, related to an ePTFE vascular prosthesis such as certain of our EndoFit and UniFit stent grafts. Depending on the course of the opposition proceedings, the granted patent claims in the 682 patent will be amended or may be cancelled while the 838 patent may survive unamended, may be amended or may be cancelled. We can not assure you that we will be successful in defending these oppositions.

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, including our agreement with Bard Peripheral Vascular, Inc., we may lose the ability to manufacture, market or sell some of our products. Our arrangement with Bard also precludes us from assigning the agreement 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.

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 aortic stent grafts pursuant to a sublicense we receive 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 precludes us from assigning the agreement 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 aortic stent graft 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 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, or SEC;
- 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, 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.

Our quarterly operating results are volatile, which may cause our stock price to decline.

Our quarterly results of operations have varied significantly in the past and are likely to vary significantly in the future due to a number of factors, many of which are outside of our control, including:

changes in our ability to obtain products and product components that are manufactured for us by third parties, as well as variations in prices of these products and product components;

delays in the development or commercial introduction of new versions of our products or components we use in our products;

our ability to attain and maintain production volumes and quality levels for our products and product components;

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

changes in the demand for our products;

changes in the mix of products we sell;

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

delays in obtaining regulatory clearance for new versions of our products;

increased product and price competition;

changes in the availability of third-party reimbursement for our products;

the loss of key sales personnel or distributors; and

seasonality in the sales of our products.

Due to the factors summarized above, we do not believe that period-to-period comparisons of our results of operations are necessarily meaningful, or should necessarily be relied upon to predict future results.

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

As of February 1, 2007, our directors, officers and principal stockholders holding more than 5% of our common stock collectively control approximately 50.9% 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, or the Exchange Act, the Sarbanes-Oxley Act of 2002 as well as 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

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

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.

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

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

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our principal worldwide executive, distribution and manufacturing operations are located at a 27,098 square foot leased facility and a nearby 7,477 square foot leased facility, located in Burlington, Massachusetts. In

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addition, our international operations are headquartered at a 12,841 square foot leased facility located in Sulzbach, Germany, and our Asia operations are located at a 2,140 square foot leased facility located in Tokyo, Japan. The leases for our two Burlington facilities expire in 2008 and the leases for our Sulzbach and Tokyo facilities expire in 2010 and 2007, respectively. 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, for the period indicated, the high and low sales closing prices of our common stock on The NASDAQ National Market.

Year Ended December 31, 2006	High	Low
Fourth Quarter (from October 19 to December 31)	$ 6.45	$ 5.50

Holders of Record

On March 28, 2007, the closing price per share of our common stock was $5.96, as reported on The NASDAQ Global Market, and we had approximately 289 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, 2006. 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	1,601,254	$ 6.07	612,928
Equity compensation plans not approved by security holders			
Total	1,601,254	$ 6.07	612,928

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, 2006. 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 of a peer group.

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	10/20/06	12/31/06
LeMaitre Vascular, Inc	100.00	93.02
NASDAQ Composite	100.00	107.40
NASDAQ Medical Equipment	100.00	107.34
Peer Group	100.00	92.23

LeMaitre s fiscal year ends on the last day of December each year; data in the above table reflects market values for the Company s 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., Integra Lifesciences, Kensey Nash Corp. and Vascular Solutions Inc.

Recent Sales of Unregistered Securities

In April 2006, we issued 1,443 shares of our common stock to a consultant in consideration of services provided to us. The issuance of these shares was exempt either pursuant to Rule 701, as a transaction pursuant to a compensatory benefit plan, or pursuant to Section 4(2), as a transaction by an issuer not involving a public offering.

In connection with our initial public offering, all outstanding shares of our Series A convertible preferred stock were converted into 1,274,620 shares of common stock.

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The issuance of securities described above were deemed to be exempt from registration under the Securities Act of 1933 in reliance on Section 4(2) of the Securities Act of 1933 as transactions by an issuer not involving any public offering. The recipients of securities in each such transaction represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the share certificates and other instruments issued in such transactions. The sales of these securities were made without general solicitation or advertising.

During the period from January 1, 2006 through the closing of our initial public offering on October 19, 2006, we granted options to purchase an aggregate of 106,143 shares of our common stock pursuant to our stock option plans, at a weighted average exercise price of $12.36 per share. In addition, from January 1, 2006 through October 19, 2006, we also issued 20,004 shares of common stock in connection with the exercise of outstanding options under our stock option plans by optionees, at a weighted exercise price of $0.28 per share. These option exercises resulted in aggregate proceeds to us of approximately $6,000. No underwriters were involved in the foregoing stock or option issuances. The foregoing stock and option issuances were exempt from registration under the Securities Act of 1933, as amended, either pursuant to Rule 701 under the Act, as transactions pursuant to a compensatory benefit plan, or pursuant to Section 4(2) under the Act, as a transaction by an issuer not involving a public offering.

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 $2.9 million for 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% or more of our common stock or to any affiliates of ours. From the effective date of the registration statement through December 31, 2006, we used $3.9 million of the net proceeds of our initial public offering to pay down all outstanding debt. No payments for such expenses were 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, 2006, we had approximately $30.8 invested in cash equivalents and marketable securities.

Issuer Purchases of Equity Securities

During the quarter ended December 31, 2006, there were no purchases made by us or on our behalf, or by any affiliated purchasers of shares of our common stock.

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Item 6. Selected Financial Data

You should read the following selected consolidated financial data in conjunction with our consolidated financial statements and the related notes which are included elsewhere in this Annual Report and the Management s Discussion and Analysis of Financial Condition and Results of Operations section of this Annual Report. We have derived the consolidated statement of operations data for the years ended December 31, 2004, 2005 and 2006 and the consolidated balance sheet data as of December 31, 2005 and 2006 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, 2002 and 2003 and the consolidated balance sheet data as of December 31, 2002, 2003 and 2004 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,				
	2002	2003	2004	2005	2006
	(in thousands, except per share data)				
Consolidated Statement of Operations Data:					
Net sales	$ 17,364	$ 20,664	$ 26,183	$ 30,727	$ 34,628
Cost of sales	6,080	6,208	7,780	8,927	9,367
Gross profit:	11,284	14,456	18,403	21,800	25,261
Operating expenses:					
Sales and marketing	5,592	7,252	9,654	10,960	15,183
General and administrative	3,564	4,530	5,037	6,405	7,105
Research and development	1,295	2,265	2,120	3,015	3,301
Restructuring charges		733	435	998	257
Impairment charge					94
Total operating expenses	10,451	14,780	17,246	21,378	25,940
Income (loss) from operations:	833	(324)	1,157	422	(679)
Other income (expense):					
Interest income	5	3	9	4	299
Interest expense	(154)	(144)	(137)	(182)	(296)
Foreign currency gain (loss)	311	191	169	(217)	228
Other income (expense), net	(34)	(22)	(57)	551	(72)
Total other income	128	28	(16)	156	159
Income (loss) before income tax:	961	(296)	1,141	578	(520)
Provision for (benefit from) income taxes	478	(74)	214	523	652
Net income (loss)	$ 483	$ (222)	$ 927	$ 55	$ (1,172)
Net income (loss) per share available for common shareholders:					
Basic	$ 0.06	$ (0.03)	$ 0.10	$ 0.01	$ (0.15)
Diluted	$ 0.05	$ (0.03)	$ 0.10	$ 0.01	$ (0.15)
Weighted-average shares outstanding:					
Basic	7,291	7,525	7,941	8,246	9,904
Diluted	7,693	7,525	8,354	8,701	9,904

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	December 31,				
	2002	2003	2004	2005	2006
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 337	$ 559	$ 1,024	$ 817	$ 15,391
Marketable securities					15,417
Current assets	5,936	7,029	9,102	10,817	43,641
Total assets	12,718	16,894	20,501	25,068	56,963
Revolving line of credit and current portion of long-term debt	932	522	432	1,142	0
Current liabilities (excluding revolving line of credit and current portion of long-term debt)	2,362	2,977	3,374	3,953	5,378
Long-term liabilities	1,400	3,121	1,882	1,437	886
Total liabilities	4,694	6,620	5,688	6,532	6,264
Total stockholders equity	8,024	10,274	14,813	18,536	50,699

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 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 ten current product lines exceeds $500 million and that the annual worldwide market for all peripheral vascular devices exceeds $3 billion and is growing at 8% per year. We have used acquisitions as a primary means of further accessing the larger peripheral vascular device market, and we expect to continue to pursue this strategy in the future. We currently manufacture all of our product lines in our Burlington, Massachusetts headquarters.

Our products are used by vascular surgeons who treat peripheral vascular disease through both open surgical methods as well as more recently adopted endovascular techniques. In contrast to interventional cardiologists and interventional radiologists, neither of whom are certified to perform open surgical procedures, vascular surgeons can perform both open surgical and minimally invasive endovascular procedures, and are therefore uniquely positioned to provide patients with a wider range of treatment options.

We believe that the purchasing volume of the vascular surgeon will increase and that the changing product needs of the vascular surgeon present us with attractive opportunities to sell new devices. As a result, we have sought out and acquired new products and businesses that address these needs, such as our acquisition of the EndoFit Thoracic Stent Graft and UniFit Abdominal Stent Graft product lines and related operations in 2005, and our signing of a three year distribution agreement, commencing January 1, 2007, as the exclusive distributor of the Endologix Powerlink System in ten European countries.

We currently offer ten product lines across three product categories, excluding Powerlink. We attribute our sales growth to the expansion of our direct sales force, conversion of the United States and certain foreign markets from a distributor sales model to a direct sales model, sales of newly acquired products and the higher

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selling prices of these newly acquired products. Prior to September 2005, we also derived a limited amount of revenue from manufacturing devices under private label, although we have discontinued nearly all of these activities.

We evaluate the sales performance of our various product lines utilizing criteria that varies based upon the position of each product line in its expected life cycle. For established products, such as our Pruitt-Inahara Carotid Shunt product line, we typically review unit sales and selling prices. For more recently introduced products, such as our EndoFit and UniFit Aortic Stent Grafts, we typically focus instead upon new account generation and customer retention.

Our business opportunities include the following:

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

We are currently pursuing each of these opportunities.

These opportunities are balanced by several challenges, such as the penetration of our product offerings in current and new markets, the recruitment and retention of key employees and competition from other products and techniques. In addition, our clinical studies may not succeed, our established products may be overtaken by new technologies, and we may not successfully compete against companies which possess substantially greater resources. Furthermore, our results of operations may suffer if we are unable to identify, negotiate, complete and integrate suitable acquisitions.

To address these risks, we will seek to expand our sales and marketing efforts, continue to pursue research and development as well as acquisition opportunities to expand our product offerings and further fund our clinical studies.

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.

In April 2003, we acquired the Expedial Vascular Access Graft product line from Credent Limited, a UK company, for total consideration of $1.9 million. At the time of the acquisition, the Expedial Vascular Access Graft had already received a CE mark and was being sold in the European Union and other foreign jurisdictions. In May 2004, we commenced a clinical study in the United States to collect data to submit to the FDA in support of 510(k) clearance for this device. In July 2006, we received preliminary data from the clinical study conducted for the period from April 8, 2004 to June 28, 2006 suggesting that the device may not compare favorably to ePTFE grafts. There were no significant safety issues identified in the preliminary data collected in the clinical study. As a result of our review of the clinical study results and less than planned sales in Europe, we decided to forego further enrollment in the clinical study and cease the production and sale of this device. As a result, during the second quarter of 2006, we recognized non-cash charges to operations of $0.7 million. Net sales of this device were approximately $26,000 for 2006 and $0.4 million for 2005 and 2004, respectively. During the fourth quarter of 2006, we sold certain manufacturing equipment, inventory and intellectual property related to our Expedial Vascular Access Graft product line to CardioTech International, Inc. for total consideration of $0.4 million plus a five percent royalty on CardioTech s net sales of its CardioPass brand coronary artery bypass graft for a period of five years following the first commercial sale of a CardioPass graft. Clinical trials on the

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CardioPass graft have only recently been initiated and there can be no assurance that it will ever be commercialized. As a result of the sale, we subsequently adjusted the impairment charge for $0.3 million for the gain on the sale of the intellectual property and equipment which is recorded as a adjustment to restructuring charges and adjusted $12,000 against cost of sales for the inventory sale.

We sell our products primarily through a direct sales force. As of December 31, 2006, our sales force was comprised of 47 bag-carrying sales representatives in the United States, Canada, 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 a sales office located in Tokyo, Japan. For the year ended December 31, 2006, approximately 87% of our net sales were generated through direct sales.

Sales and Expense Components

The following is a description of the primary components of our net sales and expenses.

Net sales. We derive our net sales from the sale of our products, less discounts and returns. Most of our sales are generated by our direct sales force and are shipped and billed to hospitals or clinics throughout the world. In countries where we do not have a direct sales force, sales are primarily generated by shipments to distributors who, in turn, sell to hospitals and clinics. In those limited cases where our products are held on consignment at a hospital or clinic, we generate sales at the time the product is used in surgery rather than at shipment.

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

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

General and administrative. General and administrative expense consists primarily of executive, finance and human resource expense, legal and accounting fees, information technology expense and insurance expense.

Research and development. Research and development expense includes costs associated with the design, development, testing, enhancement and regulatory approval of our products and amortization of patents costs. It also includes costs associated with design and execution of clinical studies and regulatory submissions, and costs to register, maintain and defend our intellectual property.

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

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

Income tax expense. We are subject to federal and state income taxes for earnings generated in the United States, which includes the results of our operations in the United Kingdom until 2005, and foreign taxes on earnings of our wholly-owned German and Japanese subsidiaries. Our consolidated tax expense is affected by the mix of our taxable income (loss) between the United States, Germany and Japan, permanent items, discrete items, and amortization of goodwill for U.S tax reporting purposes.

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Results of Operations

Comparison of the Year Ended December 31, 2006 to the Year Ended December 31, 2005

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

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

Net sales. Net sales increased 13% to $34.6 million for the year ended 2006 from $30.7 million for the year ended 2005. Excluding the discontinued Expedial Vascular Access Graft product line and private label sales, 2006 net sales increased 17% over 2005 net sales. Sales in our endovascular and dialysis access product category increased by 45%, while sales in our vascular and general surgery product categories grew by 7% and 6%, respectively, over the same period in the previous year. Increases were driven by increased unit sales in the endovascular and dialysis access product category, an expansion of the world wide sales force, higher average selling prices across all product categories and an increase in direct marketing efforts during 2006. Direct to hospital net sales also increased from 84% of total revenues in 2005, to 87% in 2006.

Net sales by geography. Net sales in the United States and Canada increased 12% to $22.4 million in 2006 compared to $20.1 million in 2005. Net sales outside of the United States and Canada increased 15% to $12.3 million

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for 2006 compared to $10.7 million in 2005. Direct to hospital net sales represented 64% of the total net sales outside the United States and Canada in 2006, compared to 59% in 2005.

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

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

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

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

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

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

Other income (expense). For 2006, interest income was $0.3 million compared to $4,000 in 2005. This was largely a result of the increase in cash and marketable securities from the initial public offering completed on October 19, 2006. Interest expense in 2006 increased by $0.1 million compared to 2005 due to an increase in our outstanding line of credit and term notes payable for the period prior to the public offering. Gain on foreign currency was due to a relative increase in the strength of the Euro as compared to the U.S. dollar, over the year. Other income (expense) for 2006 was primarily due to losses on the disposal of fixed assets in 2006, while 2005 amounts were largely due to the foreign exchange gain of $0.6 million that we recognized as a result of the dissolution of our French subsidiary.

Income tax expense. Our provision for income taxes in 2006 was $0.7 million compared to $0.5 million in 2005. The effective rate in 2006 was negative 125% as compared with 91.0% in 2005. The U.S. federal statutory

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rate is 34.0%. The 2006 tax provision was a result of many factors, including the losses at one of our foreign subsidiaries for which no tax benefit is recognizable, and the effects of permanent and discrete tax items related to uncertain international tax positions. In addition, deferred tax liabilities related to the amortization of goodwill for U.S. tax reporting purposes, may not be used to reduce existing deferred tax assets which requires higher valuation allowances than otherwise needed. We monitor the mix of profitability by tax jurisdiction and adjust our annual expected rate on a quarterly basis.

Comparison of the Year Ended December 31, 2005 to the Year Ended December 31, 2004

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

	2005	2004	Percent change
Net sales	$ 30,727	$ 26,183	17%
Cost of sales	8,927	7,780	15%
Gross profit	21,800	18,403	18%
Operating expenses:			
Sales and marketing	10,960	9,654	14%
General and administrative	6,405	5,037	27%
Research and development	3,015	2,120	42%
Restructuring charges	998	435	129%
Income from operations	422	1,157	(64%)
Other income (expense):			
Interest income	4	9	(56%)
Interest expense	(182)	(137)	33%
Foreign currency (loss) gain	(217)	169	NM
Other income (expense)	551	(57)	NM
Income before income taxes	578	1,141	(49%)
Provision for income taxes	523	214	144%
Net income	$ 55	$ 927	(94%)
Net Sales by Product Category:			
Endovascular & Dialysis	$ 6,774	$ 3,340	103%
Vascular	19,654	18,233	8%
General Surgery	3,600	3,682	(2%)
Branded Sales	30,028	25,255	19%
Private Label	699	928	(25%)
	$ 30,727	$ 26,183	17%
Net Sales by Geography:			
United States and Canada	$ 20,056	$ 17,689	13%
Outside the United States and Canada	10,671	8,494	26%
	$ 30,727	$ 26,183	17%

Net sales. Net sales increased 17% to $30.7 million in 2005 as compared to $26.2 million in 2004. Sales growth was primarily driven by growth of our products across all product lines and to a lesser degree our acquisition of the EndoFit and UniFit Aortic Stent Graft product lines and

related operations from Endomed, Inc. in February 2005, and strong performance of the AnastoClip Vessel Closure System product line which we acquired, together with the related operations, from Tyco Healthcare LP in February 2004. Sales growth was also driven by higher average selling prices across nearly all product lines due to our stronger brand recognition and

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customer loyalty, and our first full year of direct sales in Japan. Additionally, the increased adoption of endovascular techniques by vascular surgeons benefited our VascuTape Radiopaque Tape and EndoFit and UniFit Aortic Stent Graft product lines. Sales of our AnastoClip Vessel Closure System increased due to better targeting of new customers and more effective surgeon training.

Net sales by geography. Net sales in the United States and Canada increased 13% to $20.1 million in 2005 as compared to $17.7 million in 2004. Net sales outside the United States and Canada increased 26% to $10.7 million in 2005 as compared to $8.5 million in 2004, driven by the sales of our aortic stent graft product lines, as well as by sales in Japan resulting from the opening of our Tokyo office in June 2004. Direct net sales represented 59% of total net sales outside the United States and Canada in 2005 and increased by 16% over 2004. Net sales to distributors represented 41% of the total net sales in 2005 outside the United States and Canada and increased by 44% over 2004. This increase was primarily a result of our acquisition of the EndoFit and Unfit Aortic Stent Graft product lines, substantially all of which we sold through distributors in 2005.

Gross Profit. Gross profit increased from $18.4 million in 2004 to $21.8 million in 2005, a 18% increase. This gross margin increase was driven primarily by higher average selling prices and, to a lesser extent, reduced cost of sales. Cost of sales decreased primarily due to our 2004 consolidation of our Neuilly-en-Thelle, France manufacturing facility into our Burlington, Massachusetts headquarters, and the associated elimination of overhead costs, partially offset by increased product build times resulting from this move. We also experienced higher manufacturing costs related to our acquisition of the Endomed, Inc. At the acquisition date, Endomed carried a lower gross margin than LeMaitre Vascular. We expect product build times to decrease at our Burlington, Massachusetts facility as direct labor employees gain further experience manufacturing and assembling products from our relocated factories.

Sales and marketing. Sales and marketing expense increased 14% to $11.0 million in 2005 as compared to $9.7 million in 2004. Sales and marketing expense increased in 2005 primarily as a result of higher marketing costs in Europe, the United States and Canada, and also as a result of increased compensation to our sales representatives, partially offset by a reduced number of sales representatives. As of December 31, 2005, we employed 30 bag-carrying sales representatives compared to 33 bag-carrying sales representatives as of December 31, 2004.

General and administrative. General and administrative expense increased 27% to $6.4 million in 2005 as compared to $5.0 million in 2004. General and administrative expense increased primarily as a result of expenses relating to the EndoFit and UniFit Aortic Stent Graft product line, higher compensation expenses and higher expenses from our Japanese subsidiary in its first full calendar year of operations. Those increases were partially offset by $0.3 million of stock-based compensation charges in 2004 that did not recur in 2005.

Research and development. Research and development expense increased 42% to $3.0 million in 2005 compared to $2.1 million in 2004. Research and development expense increased primarily as a result of increased clinical study costs in the United States, specifically relating to clinical trials for our EndoFit and UniFit Aortic Stent Grafts and Expedial Vascular Access Graft product lines, increased testing expenses and increased royalty payments relating to the EndoFit and UniFit Aortic Stent Graft and AnastoClip Vessel Closure System product lines.

Restructuring. Restructuring charges increased to $1.0 million in 2005 compared to $0.4 million in 2004, due to costs from the closing of our manufacturing plants in St. Petersburg, Florida and Wales, United Kingdom in 2005, including a one-time payment of $0.5 million as consideration for the early termination of the lease of the manufacturing facility in St. Petersburg, Florida.

Other income (expense). Other income (expense) increased to $0.2 million in 2005 as compared to a loss of approximately $16,000 in 2004, due principally to favorable foreign currency translation adjustment income of

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$0.6 million from the dissolution of our French foreign subsidiary. This gain was partially offset by foreign currency losses from the weaker Euro in 2005.

Income tax expense. Our effective income tax rates were 91% in 2005 and 19% in 2004 compared to the federal statutory rate of 34%. Our low effective rate in 2004 was attributable to the use of U.S. and German net-operating loss and tax credit carryforwards to substantially reduce income tax liability in both tax jurisdictions. In 2005, the rate exceeded the statutory rate due to unfavorable permanent items and the effect of uncertain international tax positions.

Liquidity and Capital Resources

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 of our common stock. We received aggregate net proceeds of approximately $35.8 million, after deducting underwriting discounts and commission of approximately $2.7 million. We incurred approximately $2.9 million for additional expenses associated with our initial public offering.

At December 31, 2006, our cash and cash equivalents were $30.8 million as compared to $0.8 million at De