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

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

or

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

Commission File Number 001-33092

LEMAITRE VASCULAR, INC.

(Exact name of registrant as specified in its charter)

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

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

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

Title of each class	**Name of each exchange on which registered**
Common Stock, $0.01 par value per share	The NASDAQ Stock Market LLC

Securities registered under Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes: ¨ No: þ

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes: ¨ No: þ

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes: þ No: ¨

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the last sale price for such stock on June 30, 2008: $24,632,573. At March 26, 2008, the Registrant had 15,665,806 shares of Common Stock, par value $0.01 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

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

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LEMAITRE VASCULAR

2008 FORM 10-K ANNUAL REPORT

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PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements (within the meaning of the federal securities law) that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this Annual Report on Form 10-K regarding our strategy, future operations, future financial position, future net sales, projected costs, projected expenses, prospects and plans and objectives of management are forward-looking statements. The words anticipates, believes, estimates, expects, intends, may, plans, p will, would, and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We have based these forward-looking statements on our current expectations and projections about future events. Although we believe that the expectations underlying any of our forward-looking statements are reasonable, these expectations may prove to be incorrect, and all of these statements are subject to risks and uncertainties. Should one or more of these risks and uncertainties materialize, or should underlying assumptions, projections, or expectations prove incorrect, actual results, performance, or financial condition may vary materially and adversely from those anticipated, estimated, or expected. We have identified below some important factors that could cause our forward-looking statements to differ materially from actual results, performance, or financial conditions:

- the unpredictability of our quarterly net sales and results of operations;
- our ability to keep pace with a rapidly evolving marketplace and to develop or acquire and then successfully market new and enhanced products;
- our ability to successfully identify, acquire, and integrate new products, businesses, and technologies and realize expected benefits;
- a highly competitive market for medical devices;
- the effect of a disaster at any of our manufacturing facilities;
- the loss of any significant suppliers, especially sole-source suppliers;
- the loss of any distributor or any significant customer, especially in regard to any product that has a limited distributor or customer base;
- our ability to adequately grow our operations and attain sufficient operating scale;
- our ability to obtain adequate profit margins;
- our ability to effectively protect our intellectual property and not infringe on the intellectual property of others;
- possible product liability lawsuits and product recalls;

inadequate levels of third-party reimbursement to healthcare providers;

our ability to initiate, complete, or achieve favorable results from clinical studies of our products;

our ability to obtain and maintain U.S. and foreign regulatory clearance for our products and our manufacturing operations;

our ability to raise sufficient capital when necessary or at satisfactory valuations;

loss of key personnel; and

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

We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the

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

Unless the context requires otherwise, references to LeMaitre Vascular, we, our, and us in this Annual Report on Form 10-K refer to LeMaitre Vascular, Inc. and its subsidiaries.

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

Item 1. Business

Overview

LeMaitre Vascular is a global provider of medical devices and implants for the treatment of peripheral vascular disease. We develop, manufacture, and market vascular devices to address the needs of vascular surgeons. Our diversified portfolio of peripheral vascular devices consists of brand name products that are used in arteries and veins outside of the heart and are well known to vascular surgeons, including the Expandable LeMaitre Valvulotome, the Pruitt-Inahara Carotid Shunt, and VascuTape Radiopaque Tape.

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

We have sought to take advantage of the trend towards endovascular techniques that utilize more complex, higher-priced devices by acquiring new product lines. For example, in 2005 we acquired our aortic stent graft product lines, which are endovascular implants used to treat aortic aneurysms and dissections, and in 2007 we acquired our EndoRE remote endarterectomy devices, which are primarily used in the minimally invasive treatment of blockages in the major arteries of the leg. Our vascular surgeon customers are increasingly performing minimally invasive endovascular procedures, presenting us with attractive opportunities to sell new devices that address their changing product needs.

We estimate that peripheral vascular disease affects more than 20 million people worldwide. We estimate that the annual worldwide market for all peripheral vascular devices is approximately $3 billion and that the annual worldwide market addressed by our 14 current product lines approaches $1 billion. In addition, we distribute product lines of third parties that address markets that we estimate approximate $75 million in the territories where we have distribution rights. The increasing incidence and diagnosis of peripheral vascular disease is driving the growth of the market for peripheral vascular devices, which prior to the recent economic downturn we estimate had been growing at 8% per year. We believe that our strong brands, established sales force, expanding suite of peripheral vascular devices, and broad network of vascular surgeon customers uniquely position us to capture an increasing share of this large and growing market.

We sell our products primarily through a direct sales force. Our sales force was comprised of 52 field sales representatives in North America, the European Union, and Japan as of December 31, 2008. We also sell our products through a network of distributors in various countries outside of the United States and Canada. For the year ended December 31, 2008, approximately 88% of our net sales were generated through direct sales, and no customer accounted for more than 3% of our net sales.

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Corporate Information

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

Where You Can Find More Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available through the investor relations portion of our website (www.lemaitre.com) free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or SEC. Information on our investor relations page and on our website is not part of this Annual Report or Form 10-K or any of our other securities filings unless specifically incorporated herein or therein by reference. In addition, our filings with the Securities and Exchange Commission may be accessed through the Securities and Exchange Commission s Electronic Data Gathering, Analysis and Retrieval (EDGAR) system at www.sec.gov. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Industry Background

We estimate that peripheral vascular disease affects more than 20 million people worldwide, including 12 million people in the United States and 7 million people in Europe. The disease encompasses a number of conditions in which the arteries or veins that carry blood to or from the legs, arms, or organs other than the heart become narrowed, obstructed, weakened, or otherwise compromised. In many cases peripheral vascular disease goes undetected, sometimes leading to life-threatening events such as stroke, ruptured aneurysm, or pulmonary embolism or death.

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

The Vascular Device Market and the Role of the Vascular Surgeon

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

Vascular surgeons primarily treat peripheral vascular disease, but also perform vascular procedures associated with other diseases, such as end-stage renal disease. We estimate that there are more than 2,000 board-certified vascular surgeons and several thousand general surgeons who perform vascular procedures in the United States, and that there are more than 3,000 vascular surgeons in Europe and Japan. In contrast to interventional cardiologists and interventional radiologists, neither of whom are certified to perform open surgical procedures, vascular surgeons can perform both open surgical and minimally invasive endovascular procedures and are therefore uniquely positioned to provide patients with a wider range of treatment options. The ability to perform conventional surgery also allows vascular surgeons to convert to an open vascular approach should the need arise during an interventional procedure.

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

Vascular surgeons are increasingly adopting new endovascular techniques. According to the Healthcare Cost and Utilization Project, of the 1.1 million surgical procedures for peripheral vascular disease performed in the United States in 2003, over 38% were endovascular procedures, as compared to 25% in 1997. We believe that this trend is likely to continue, as new vascular surgeons complete courses of study that include endovascular training and older vascular surgeons less likely to adopt these techniques retire. Due in part to the reduced hospital stays that they enable, endovascular devices typically command significantly higher prices than vascular surgery devices.

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

Our History

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

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

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

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

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

In October 2006, we completed our initial public offering, raising net proceeds of approximately $36 million before expenses. From our initial public offering through December 31, 2008, we have continued to execute on our primary business strategies by increasing the number of our field sales representatives from 36 to 52; hiring our first direct sales personnel in Austria, France, Italy, and Sweden; increasing the number of research

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

In September 2007, we acquired our EndoRE line of remote endarterectomy products, which are used in a hybrid open/endovascular procedure for the minimally invasive removal of plaque from the major arteries of the leg, as part of the business of Vascular Architects.

In December 2007, we acquired Biomateriali, S.r.l., a privately held Italian manufacturer of the AlboGraft Vascular Graft, a line of polyester prosthetic grafts for vessel replacement in the peripherals, abdomen, and thorax, which at the time were distributed exclusively by Edwards Lifesciences AG. In 2009, we reached agreement with Edwards Lifesciences to terminate their distribution of this product line as of March 27, 2009, and we commenced direct-to-hospital sales on March 30, 2009.

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

Our Business Strategies

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

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

Acquire Complementary Products. We believe our significant experience in acquiring and integrating product lines and businesses is one of our competitive advantages. Since 1998, we have completed ten acquisitions. We actively track industry developments and plan to acquire additional product lines and businesses as a means of further accessing the approximately $3 billion peripheral vascular device market. We intend to pursue acquisitions in a disciplined manner to expand and diversify our product offerings and add new technology platforms.

Extend Our Market Reach through Research and Development and Additional Regulatory Approvals. By refining our current product lines and developing new applications for our existing technologies, we plan to extend our reach into the peripheral vascular device market. Our current research and development efforts include improvements and additions to the products in our endovascular product category. We also intend to obtain regulatory approvals for our devices in new markets. For example, we currently market our aortic stent graft devices in the European Union and have focused our near-term efforts on obtaining regulatory approval for these products in the United States. We are also seeking clearance for the sale of our AlboGraft Vascular Graft product line in the United States.

Expand Our Direct Sales Force. We sell our products primarily through a direct sales force comprised as of December 31, 2008, of 52 field sales representatives in North America, the European Union, and Japan. At the time of our October 2006 initial public offering we had 36 sales representatives. In the near-term it is unlikely that we will significantly expand the size of our sales force; however, as a long-term strategy, we intend to further expand our sales force. We believe that direct-to-hospital sales engender closer customer relationships, allow for higher selling prices and gross margins, and are not subject to the risk of customer churn resulting from distributor turnover.

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Our Products

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

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

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(1) We have submitted an IDE application to the FDA to begin a feasibility study of the TAArget Thoracic Stent Graft. In July 2008, we received a letter from the FDA indicating that it could not approve our application until deficiencies identified in the letter are resolved to the FDA s satisfaction. We are working with the FDA to resolve these deficiencies, although there can be no assurance that the FDA will approve our application. See Clinical Studies for a description of this clinical study.
(2) We are conducting a clinical study in the United States on the UniFit Abdominal Stent Graft. See Clinical Studies for a description of this clinical study.
(3) This is the approved use for the aSpire Covered Stent in the European Union, where it is often used in conjunction with our EndoRE line of remote endarterectomy devices. In the U.S., the device is approved for use in lung airways that have been narrowed by disease.
(4) We have submitted an application for 510(k) clearance of the AlboGraft Vascular Graft product line with the FDA.
(5) The Pruitt F3 Carotid Shunt is only available for sale in the United States. The Flexcel Carotid Shunt is available for sale in the United States and the European Union, but is not yet available for sale in Japan.
(6) We have submitted an application for Shonin registration with the Japan Ministry of Health, Labor and Welfare.

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

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

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

Endovascular

Endovascular

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

TAArget Thoracic Stent Graft

The TAArget Thoracic Stent Graft is an endovascular graft used to treat an aortic aneurysm, a weakening and ballooning of the aorta, or an aortic dissection, a separation of the layers of the aortic wall that often leads to rupture and death, in each case in the upper part of the aorta, known as the thoracic aorta. The TAArget Thoracic Stent Graft, introduced in 2008, replaces our EndoFit Thoracic Stent Graft in most markets. The TAArget Thoracic Stent Graft features our new TT Tortuous Tracker Delivery System for more precise deployment of the stent graft and a new, optional uniform top stent design for improved external fixation against the wall of the aorta. TAArget s flexible, encapsulated design, in contrast to devices currently available commercially, uses expanded polytetrafluoroethylene (ePTFE), which is designed to prevent the stent scaffolding from contacting either the blood stream or the vessel wall. This design also allows us to offer a wide range of stent grafts sizes,

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including tapered grafts, which fit a wider range of patient anatomies than many of our competitors products. Our design also allows us to rapidly build the device to fulfill custom orders; for the year ended December 31, 2008, approximately 47% of our TAArget and UniFit stent grafts were custom-built. We acquired TAArget s predecessor EndoFit product line through our acquisition of Endomed in February 2005.

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

In February 2009 the EndoFit Thoracic Stent Graft was approved for sale in China by the State Food and Drug Administration (SFDA) following a clinical study conducted by our Chinese distributor on our behalf. We are preparing to commence sales of this device in China, although there can be no assurance that we will be successful in entering or effectively penetrating the Chinese stent graft market. See Risk Factors Any operations that we conduct in China will expose us to the risk of adverse changes in political, legal, and economic policies of the Chinese government, which changes could reduce the demand for our products in China and materially and adversely affect our competitive position in China.

UniFit Abdominal Stent Graft

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

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

VascuTape Radiopaque Tape

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

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

aSpire Covered Stent

The aSpire Covered Stent is a spiral-shaped nitinol stent covered by ePTFE that is used to keep blood vessels and lung airways open after blockages have been removed. Due to its spiral shape, the aSpire Covered Graft is highly flexible, conforms to varying airway and vessel diameters, and, unlike tube-shaped covered stents, is less likely to cut off supply to arterial side branches, which could cause tissue damage. We acquired the aSpire Covered Stent product line and related operations through our acquisition of the business of Vascular Architects in September 2007.

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

LeverEdge Contrast Injector

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

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

AnastoClip Vessel Closure System

The AnastoClip Vessel Closure System is a titanium clip implanted by vascular surgeons to attach vessels, native and prosthetic, to each other. The AnastoClip Vessel Closure System creates an interrupted anastomosis, or a vessel attachment that expands and contracts as the vessel pulses, which we believe improves the durability of the anastomosis. The AnastoClip Vessel Closure System has the further advantage that it does not puncture the vessel wall and disrupt blood flow. A retrospective 1,110-patient clinical study published in the August 2003 *Journal of Vascular Surgery* found that the AnastoClip Vessel Closure System improved 24-month patency versus traditional continuous sutures from approximately 34% to 54% in arterio-venous fistulae, which are surgical attachments of arteries and veins, and from approximately 17% to 36% in prosthetic grafts attachments. Patency data was collected from a total of 1,385 vascular access anastomoses. We acquired the AnastoClip Vessel Closure System product line and related operations from Covidien, then Tyco Healthcare, in February 2004.

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

Powerlink System

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

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

Vascular Products

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

Expandable LeMaitre Valvulotome

The Expandable LeMaitre Valvulotome cuts valves in the saphenous vein, a vein that runs from the ankle to the groin, so that it can function as a bypass vessel to carry blood past diseased arteries to the lower leg or the

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foot. The Expandable LeMaitre Valvulotome is the only self-sizing, self-centering valvulotome available. We believe that the Expandable LeMaitre Valvulotome reduces costs for hospitals by enabling less invasive bypass surgery to be performed with several one-inch incisions rather than one continuous ankle-to-groin incision, thereby reducing the length of hospital stays and the likelihood of wound complications. The Expandable LeMaitre Valvulotome is the sixth generation of the original valvulotome developed by our founder, George D. LeMaitre, M.D.

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

Pruitt-Inahara, Pruitt F3, and Flexcel Carotid Shunts

The Pruitt-Inahara, Pruitt F3, and Flexcel Carotid Shunts are used to temporarily divert, or shunt, blood to the brain while the surgeon removes plaque from the carotid artery in a carotid endarterectomy surgery. Our Pruitt-Inahara and Pruitt F3 shunts feature internal balloon fixation that eliminates the need for clamps, thereby reducing vessel trauma. Our Flexcel shunt is a non-balloon shunt offered for surgeons who prefer to secure their shunt using the traditional method of externally placed clamps. We acquired the Pruitt-Inahara Carotid Shunt product line and related operations from Horizon Medical in March 2001. We introduced the Pruitt F3, our next-generation model of the Pruitt-Inahara Carotid Shunt, in January 2007 and our Flexcel Carotid Shunt in August 2007.

Our Pruitt-Inahara Carotid Shunts are currently sold in the United States, the European Union, Japan, and many other foreign jurisdictions. The Pruitt F3 Carotid Shunt is only available for sale in the United States. The Flexcel Carotid Shunt is available for sale in the United States the European Union, and many other foreign jurisdictions, but is not yet available for sale in Japan.

LeMaitre Embolectomy Catheters and Pruitt Occlusion and Perfusion Catheters

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

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

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

InvisiGrip Vein Stripper

The InvisiGrip Vein Stripper is a single-incision, inversion vein stripper designed to provide a less traumatic alternative to standard vein strippers for the removal of the saphenous vein. Our InvisiGrip device enables the surgeon to complete the procedure in a minimally invasive fashion with just one incision versus a traditional two-incision procedure. We developed this device internally based on a patent we licensed from a vascular surgeon.

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

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AlboGraft Vascular Graft

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

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

EndoRE Remote Endarterectomy Devices

The EndoRE line of remote endarterectomy devices are used to remove severe atherosclerotic blockages from the major arteries of the leg in a minimally invasive procedure requiring a single incision in the groin. Our EndoRE devices are used to separate the sclerotic blockage from the vessel, cut the far end of the blockage to free it for removal, and then withdraw the blockage from the vessel. A retrospective 133-patient clinical study published in the February 2006 *Journal of Vascular Surgery* found that, compared to bypass procedures, this minimally invasive procedure leads to less trauma to the patient and reduced hospital stays. It also preserves the patient s own veins for future use in an unrelated bypass procedure. We acquired the EndoRE product line through our acquisition of the business of Vascular Architects in September 2007.

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

PeriPatch Biological Vascular Patch

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

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

General Surgery Products

Reddick Cholangiogram Catheter and Laparoscopic Accessories

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

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

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OptiLock Implantable Port

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

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

Clinical Studies

We conduct clinical studies in order to obtain regulatory approval and provide marketing data for our product lines. The goal of a clinical study is to evaluate the safety and/or clinical effectiveness of a device or the substantial equivalence to another device. We currently have one active U.S. clinical study with respect to our UniFit Abdominal Stent Graft called the UNITE Trial. Recently we have begun efforts to initiate a U.S. feasibility study of our TAArget Thoracic Stent Graft called the ENTRUST Trial.

In October 2002, the previous owner of our UniFit Abdominal Stent Graft product line commenced a feasibility study in the United States to support a possible PMA application for the UniFit Abdominal Stent Graft. (See Government Regulation for more on the PMA process.) We took over this study at the time of our acquisition of Endomed, Inc. in February 2005. In this study, we are seeking to demonstrate successful aneurysm exclusion without perioperative death, myocardial infarction, stroke, limb loss, or surgical conversion. We completed enrollment of the feasibility study in November 2006 and are currently monitoring follow-up visits for the duration of this study. A feasibility study is a preliminary study and is not a pivotal trial, which would be the principal basis for PMA approval. In May 2006, we submitted an investigational device exemption (IDE) supplemental application to the FDA to begin a pivotal clinical trial to evaluate the safety and effectiveness of the UniFit Abdominal Stent Graft in the treatment of aorto, aorto-iliac, and/or iliac aneurysms. In May 2007, we received final approval from the FDA to commence the pivotal trial, which we call the UNITE trial. As of March 26, we had enrolled 29 patients in the trial. We plan to enroll 90 patients at up to 21 institutions. The primary effectiveness endpoint of the study is based on aneurysm exclusion as evaluated through one-year follow-up.

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

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

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

In January 2008, the FDA audited the conduct of the feasibility study and pivotal clinical trial of our UniFit Abdominal Stent Graft. As a result of this audit, the FDA issued a formal notification, or Form FDA-483, listing nine observations. Specifically, the FDA observed that we had not adequately supervised participating sites, made all required reports to those sites and the FDA, or adequately maintained all records required by FDA regulations. In June 2008, the FDA issued a public Warning Letter regarding many of the matters cited in the Form FDA-483. After receiving this Warning Letter, we submitted a response letter to the FDA detailing our implementation of corrective actions, and in July 2008, we received a letter from the FDA indicating that the corrective actions that we have developed and implemented appear to be adequate. However, our corrective actions remain subject to verification as part of any future FDA inspection, and we cannot assure you that we will continue to be successful in implementing these changes or that the FDA will agree that our implementation is adequate. If the FDA finds that we are not in substantial compliance with IDE requirements, they may take enforcement action against us, and the conduct of our clinical trial could be interrupted or discontinued.

Sales and Marketing

As of December 31, 2008, we employed 52 field sales representatives. We believe that the expansion of our direct sales force has been a key factor in our success and it remains one of our primary long-term strategies. In the near-term it is unlikely that we will significantly expand the size of our sales force; however, as a long-term strategy, we intend to further expand our sales force. Outside our direct markets, we generally sell our products through a network of country-specific distributors. We typically sign exclusive distribution agreements with terms of up to five years specifying minimum annual sales volumes and pricing. These agreements are only renewable by mutual agreement. As exceptions to our direct sales and country-specific distribution models, we sell unbranded polyester vascular graft components to Sorin Biomedica SpA under a private label manufacturing program.

We believe that our direct marketing efforts are critical to our brand development and continued success. Prior to 1999, we had no direct sales force and instead relied on direct marketing to generate brand awareness and product loyalty. We believe that this direct marketing approach continues to serve us well, allowing us to market to vascular surgeons beyond the reach of our direct sales force.

Research and Development

Our research and development has historically focused on developing enhancements and extensions to our existing product lines and introducing manufacturing efficiency changes. We remain dedicated to improving manufacturing efficiencies and increasing automation. Our current product development efforts are largely focused on the endovascular space, including improvements to our TAArget and UniFit Stent Grafts. More recently, we have begun to increase investment in product research and development, with the goal of more rapidly developing new products, line extensions, and next-generation devices in our endovascular and vascular product categories.

Our products are subject to our design control procedures throughout the various stages of product development. These procedures may include bench testing, animal testing, human use testing conducted by independent physicians, and post-market surveillance of product performance, as appropriate. We may use feedback received from independent physicians to demonstrate product functionality, safety, and effectiveness before commencing full-scale marketing of any product.

For fiscal 2006, 2007, and 2008, our research and development expenditures, including clinical study expenditures, were $3.3 million, $4.6 million and $5.3 million, respectively, and represented between 10% and 11% of net sales. As of December 31, 2008, our research and development staff consisted of 12 full-time engineers and technicians.

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Manufacturing

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

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

We manufacture certain proprietary components, assemble most of our devices ourselves, and inspect, test, and package all of our finished products. By designing and manufacturing many of our products from raw materials, and assembling and testing as many of our subassemblies and products as practical, we believe that we can maintain better quality control, ensure compliance with applicable regulatory standards and our internal specifications, limit outside access to our proprietary technology, ensure adequate product supply, and make design modifications in a timely manner. We have custom-designed proprietary manufacturing and processing equipment and have developed proprietary enhancements for existing production machinery.

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

Our management information systems provide us with the ability to evaluate our performance, collect business intelligence, and make better strategic decisions. These systems include order entry, invoicing, on-line inventory management, lot traceability, purchasing, shop floor control, and shipping and distribution analysis, as well as various accounting-oriented functions. During day-to-day operations, these systems enable us to track our products from the inception of an order through the manufacturing process and then through delivery of the product to the customer.

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

We purchase components from, and have certain product lines manufactured by, third parties. Most of our components are readily available from several supply sources, but we do rely on single- and limited-source suppliers for several of our key product components and our third-party-manufactured products. We do not have contractual arrangements with most of these suppliers and manufacturers, and we order our supplies and product on an as-needed basis. To date, we have been able to obtain adequate supplies of all product and components in a timely manner from existing sources.

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

Our manufacturing facilities have been certified to ISO 13485:2003 quality management system standards, which enables us to satisfy certain regulatory requirements of the European Union, Canada, and other foreign jurisdictions. If we were to lose these certifications, we would no longer be able to sell our products in these countries until we made the necessary corrections to our operations or, in the case of the European Union, satisfactorily completed an alternate approval route that did not rely on compliance with quality system standards. Our manufacturing facilities are subject to periodic inspections by regulatory authorities and our Notified Body (described below) to ensure compliance with domestic and non-U.S. regulatory requirements. See Government Regulation.