UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2009

☐ **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to .

Commission file number 000-51348

ev3 Inc.

(Exact name of registrant as specified in its charter)

Delaware	**32-0138874**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3033 Campus Drive **Plymouth, Minnesota**	**55441**
(Address of principal executive offices)	(Zip Code)

(763) 398-7000

(Registrant's telephone number, including area code)

Securities registered pursuant to section 12(b) of the Act:

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

Securities registered pursuant to section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☒ NO ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES ☐ NO ☒

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES ☐ NO ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☒	Accelerated filer ☐
Non-accelerated filer (Do not check if a smaller reporting company) ☐	Smaller reporting company ☐

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Act). YES ☐ NO ☒

The aggregate market value of the registrant's common stock, excluding outstanding shares beneficially owned by affiliates, computed by reference to the closing sale price at which the common stock was last sold as of July 3, 2009 (the last business day of the registrant's second fiscal quarter) as reported by the NASDAQ Global Select Market, was approximately $772.1 million.

As of February 18, 2010, 112,618,003 shares of common stock of the registrant were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this annual report on Form 10-K incorporates by reference information (to the extent specific sections are referred to in this annual report) from the registrant's proxy statement for its 2010 annual meeting of stockholders.

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This annual report on Form 10-K contains and incorporates by reference not only historical information, but also forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the safe harbor created by those sections. We refer you to the information under the heading "Part I. Item 1. Business—Forward-Looking Statements."

As used in this report, references to "ev3," the "company," "we," "our" or "us," unless the context otherwise requires, refer to ev3 Inc. and its subsidiaries.

We own or have rights to various trademarks, trade names or service marks, including the following: ev3®, PROTEGE®, EVERFLEX™, PARAMOUNT™ MINI, PRIMUS™, SPIDERFX, THE CLOT BUSTER®, GOOSE NECK®, VISI-PRO™, NITREX®, NEXUS™, PIPELINE EMBOLIZATION DEVICE™, ONYX®, MORPHEUS™, NXT™, ECHELON™, ULTRAFLOW™, MARATHON™, HYPERFORM™, REBAR™ HYPERGLIDE™, MIRAGE™, AXIUM™, APOLLO™, SOLITAIRE™, SILVERSPEED®, X-PEDION™, X-CELERATOR™, FOXHOLLOW®, SILVERHAWK®, MEC™ TECHNOLOGY, RINSPIRATOR®, ROCKHAWK™, TURBOHAWK™, EVERCROSS™, NANOCROSS™, POWERCROSS™, TRAILBLAZER™ and BEVEL 360™ . The trademarks PLETAL®, PLAVIX® and ACCULINK® referred to in this annual report on Form 10-K are the registered trademarks of others.

PART I

ITEM 1. BUSINESS

Company Overview

ev3 Inc. is a leading global endovascular company focused on identifying and treating peripheral vascular disease, including, in particular, lower extremity arterial disease and neurovascular disease. Since our founding in 2000, we have been dedicated to developing innovative, breakthrough and clinically proven technologies and solutions for the treatment of peripheral vascular and neurovascular diseases, a strategy that we believe is uncommon in the medical device industry. We believe our unique approach of focusing on emerging and under-innovated opportunities which treat peripheral vascular and neurovascular disease allows us to compete with smaller companies that have narrow product lines and lack an international sales force and infrastructure, yet also compete with larger companies that do not have our focus and agility.

The competitive strengths that have been responsible for our past success and the strategies that we believe will drive our future growth include:

- targeting under-innovated and emerging markets;
- leveraging our products across major endovascular sub-markets;
- investing in clinical research to demonstrate the benefits of our products;
- expanding our business through product innovation and strategic acquisitions;
- driving our global organization and presence; and
- leading our business by an experienced management team.

Our product portfolio includes a broad spectrum of over 100 products consisting of over 1,500 stock keeping units (SKUs), including plaque excision, stents, embolic protection and thrombectomy devices, carotid stenting solutions, percutaneous transluminal angioplasty (PTA) balloons and other procedural support products for the peripheral vascular market and embolic coils, flow diversion and flow restoration devices, liquid embolics, flow directed and other micro catheters, occlusion balloon systems, guidewires, neuro stents and retrieval devices for the neurovascular market.

Our customers include a broad cross-section of physicians, including interventional radiologists, neuroradiologists, vascular surgeons, neuro surgeons, other endovascular specialists and interventional cardiologists. We sell our products in more than 65 countries through a direct sales force in the United States, Canada, Europe, Australia and other countries and distributors in selected other international markets. As of December 31, 2009, our U.S. sales organization consisted of 114 sales representatives selling our peripheral vascular products and 25 sales representatives selling our neurovascular products and our international sales organization consisted of 43 sales representatives selling our peripheral vascular products, 31 sales representatives selling our neurovascular products and seven sales representatives selling both.

We have organized our company into two business segments: peripheral vascular and neurovascular. We manage our business and report our operations internally and externally on this basis. Our peripheral vascular segment includes products that are used primarily in peripheral vascular procedures by interventional radiologists, vascular surgeons and interventional cardiologists and in targeted cardiovascular procedures. Our neurovascular segment includes products that are used primarily by neuroradiologists, interventional neurologists and neurosurgeons. During 2009 and 2008, these combined segments generated net sales of $449.1 million and $422.1 million, respectively.

In June of 2009, we acquired Chestnut Medical Technologies, Inc. (Chestnut), a privately-held California-based company focused on developing minimally invasive therapies for interventional neuroradiology. We acquired 100 percent of the equity interests of Chestnut for total consideration valued at $116.7 million, consisting of upfront consideration of common stock and cash valued at $79.4 million, as well as an additional milestone-based contingent payment of up to $75.0 million, payable in a combination of common stock and equity, upon FDA pre-market approval of the Pipeline Embolization Device. The transaction broadens our neurovascular product portfolio by adding the Pipeline Embolization Device for the treatment of cerebral aneurysms and the Alligator Retrieval Device for foreign body retrieval to our existing neurovascular embolic products and neuro access technologies.

The following represents net sales (in thousands) by our two business segments and revenues from our former research collaboration with Merck & Co., Inc. as well as by geography during the periods indicated:

Net Sales by Segment	For the Year Ended December 31, 2009	2008	Percent Change	For the Year Ended December 31, 2008	2007	Percent Change
Net product sales:						
Peripheral vascular (1)	$ 279,531	$269,929	3.6%	$269,929	$173,775	55.3%
Neurovascular	169,541	132,304	28.1%	132,304	104,451	26.7%
Total net product sales	449,072	402,233	11.6%	402,233	278,226	44.6%
Research collaboration (2)	—	19,895	-100.0%	19,895	5,957	234.0%
Total	$ 449,072	$422,128	6.4%	$422,128	$284,183	48.5%

Net Sales by Geography	For the Year Ended December 31, 2009	2008	Percent Change	For the Year Ended December 31, 2008	2007	Percent Change
United States	$ 270,961	$ 275,433	-1.6%	$ 275,433	$ 177,198	55.4%
International	178,111	146,695	21.4%	146,695	106,985	37.1%
Total	$ 449,072	$ 422,128	6.4%	$ 422,128	$ 284,183	48.5%

(1) Peripheral vascular net product sales in 2007 include plaque excision (formerly referred to as atherectomy) net product sales from October 4, 2007, the date of our FoxHollow Technologies, Inc. acquisition, through December 31, 2007.

(2) Research collaboration revenue was derived from our former collaboration and license agreement with Merck & Co., Inc., which we assumed as a result of our acquisition of FoxHollow Technologies, Inc. on October 4, 2007. Our collaboration and license agreement with Merck was terminated by Merck effective July 22, 2008. We subsequently reached an arrangement with Merck to accomplish an orderly wind-down of our research collaboration activities during the remainder of 2008. Research collaboration for the year ended December 31, 2007 includes revenue earned from October 4, 2007 through December 31, 2007. For further information see Note 2 to our consolidated financial statements.

For additional financial information regarding each of our segments and our foreign operations, see Note 19 to our consolidated financial statements.

The Endovascular Market

Vascular disease can involve either an artery or a vein, and is generally manifested as an occlusion (closure) or rupture of a blood vessel. It may occur in any part of the body, and is a progressive, pathological condition that leads most often to blood vessel narrowing and obstruction, but can also lead to blood vessel wall weakening and rupture. Vascular disease can occur in the blood vessels of every organ and anatomic area of the body, and can cause a range of conditions including pain, functional impairment, amputation and death.

When the treatment for vascular disease is performed from within a vessel, it is referred to as an endovascular procedure. Endovascular procedures are minimally invasive means of treating the two major problems that can develop within blood vessels: an occlusion, or stenosis, where the vessel is blocked or narrowed, and an aneurysm, or focal expansion of the vessel wall. Endovascular procedures are performed by utilizing an easily accessible artery to reach an occlusion or aneurysm and may or may not require general anesthesia. During most endovascular procedures, a catheter is placed into the femoral artery in the groin. X-ray imaging or fluoroscopy is used to help the physician advance the catheter to the area to be treated. Endovascular procedures are less invasive and require a

smaller incision than conventional, open surgery and we believe have a number of distinct benefits over surgery, including:

- the use of local or regional anesthesia frequently instead of general anesthesia;
- reduced patient discomfort and shorter recovery times;
- the reduced need for blood products and transfusions;
- shorter hospital stays for recovery;
- lower risks of patient complications related to procedures; and
- potentially lower costs.

The endovascular device markets which we serve are conventionally divided into three specialties based on anatomic location. We principally focus and serve the peripheral vascular and neurovascular markets.

- The *peripheral vascular* market includes products used to treat arterial and venous disease in the legs, pelvis, neck, kidney and any other vascular anatomy other than that in the brain or the heart.
- The *neurovascular* market includes products used to treat vascular disease and disorders in the brain, including arterio-venous malformations, or AVMs, and strokes caused by either vascular occlusion (ischemic) or rupture (hemorrhagic).
- The *cardiovascular* market includes products used to treat coronary artery disease, atrial fibrillation and other disorders in the heart and adjacent vessels.

Our Peripheral Vascular Markets

Peripheral Vascular Disease

Peripheral vascular disease is characterized by the narrowing or total occlusion of blood vessels outside of the heart or brain and can cause conditions including pain, loss of function, amputation and death. Mortality from peripheral vascular disease can occur as a result of stroke, kidney failure or diabetes related vascular complications. The most common type of peripheral vascular disease is peripheral artery disease, which is often used interchangeably with the term peripheral vascular disease, although technically a subset of peripheral vascular disease.

A common cause of peripheral artery disease is atherosclerosis, or “hardening of the arteries.” Atherosclerosis is a complex, progressive and degenerative condition resulting from the build-up of cholesterol and other obstructive materials, known as plaque, on the walls of the arteries. The accumulation of plaque narrows the interior or lumen of arteries, thereby reducing blood flow. In addition, plaque may rupture and trigger the release of a blood clot that can further narrow or block an artery.

Plaque occurs in the arteries in several different forms and may be located in many different anatomies throughout the arterial system. Plaque varies in composition, with portions that are hard and brittle, referred to as calcified plaque, and other portions that are fatty or fibrous. Plaque lesions can be long or short, focused or diffuse and can be present in all types of arteries, including straight or curved arteries of varying diameters. Atherosclerosis in arteries outside of the heart and brain causes peripheral artery disease.

Peripheral artery disease is most common in the arteries of the pelvis and legs. Occlusive disease of the iliac arteries, the main vessels descending through the pelvis, is a peripheral artery disease that affects the flow of blood to the legs. Patients with this condition often experience leg pain and numbness or tingling. Restoring the flow of blood in these occluded vessels is essential to maintaining leg function and avoiding complications such as significantly reduced mobility and/or gangrene, which in severe cases can lead to amputation.

Other types of peripheral artery disease involve arteries in the legs, including the superficial femoral artery, or SFA. The legs receive their supply of blood through the femoral arteries, which originate at the groin. The SFA extends from the iliac arteries in the upper thigh down the leg to the knee. At the knee, the SFA becomes the popliteal artery, which branches into arteries that supply blood to the lower leg and foot. Arteries above the knee are generally long, straight and relatively wide although subjected to extreme torsion and compression, while arteries below the knee are shorter and branch into arteries that are progressively smaller in diameter, although still subject to compression.

Plaque build-up in the pelvic and leg arteries reduces blood flow to the surrounding tissue, causing claudication, the most common early symptom of peripheral artery disease. Claudication refers to pain, cramping or tiredness in the leg or hip muscles while walking. Symptoms may progress to include numbness, tingling or weakness in the leg and, in severe cases, burning or aching pain in the foot or toes while resting. Restoring the flow of blood in these occluded arteries and vessels is essential to maintaining leg function or quality of life and avoiding complications such as gangrene, which in severe cases can lead to amputation.

As peripheral artery disease progresses, additional signs and symptoms occur, including loss of hair on the legs, cooling or color changes in the skin of the legs or feet, and sores on the legs and feet that do not heal. If untreated, peripheral artery disease may lead to critical limb ischemia, or CLI, a condition in which the limb does not receive enough oxygenated blood being delivered to the limb to keep the tissue alive.

The carotid arteries are another common site of peripheral artery disease. Carotid arteries are located on each side of the neck and provide the primary blood supply to the brain. In carotid artery disease, plaque accumulates in the artery walls, narrowing the artery and disrupting the blood supply. This disruption in blood supply, together with plaque debris breaking off the artery walls and traveling to the brain, are the primary causes of stroke.

While peripheral vascular disease is most common in the arterial side where arteries carry oxygenated blood to various organs, it can also occur on the venous side where veins carry blood back to the heart and lungs. Peripheral venous disease is a general term for damage, defects or blockages in the peripheral veins. Like peripheral artery disease, it can occur almost anywhere in the body but is most often found in the arms and legs. The most common form of peripheral venous disease is the formation of blood clots that block the flow of blood in the vessel. Clots that occur in veins close to the surface of the skin are referred to as superficial venous thrombophlebitis, while clotting of veins deep within the body are called deep vein thrombosis. Treatment options for blood clots in the veins are similar to those used to treat clots in arteries.

Peripheral Vascular Market

According to the American Heart Association, or AHA, peripheral vascular disease, including peripheral artery disease, affects approximately eight million people in the United States. Primary risk factors associated with peripheral vascular disease are diabetes and smoking. Other significant risk factors include advanced age, high cholesterol, high blood pressure, obesity and physical inactivity. A family history of cardiovascular disease may also put individuals at higher risk for peripheral vascular disease.

Approximately 20% to 30% of patients with peripheral arterial disease in the U.S. today are undergoing treatment for the disease, according to the AHA. Underdiagnosis is due in large part to the fact that over one-half of the peripheral vascular disease population does not display classic symptoms of the disease. In addition, others dismiss their symptoms as part of the normal aging process or attribute them to another cause.

Over the next several years, we expect to see continued growth in the peripheral vascular disease patient population, driven by three specific trends: growing prevalence of the disease, increased diagnosis rate and approximately 6% to 8% growth in the use of endovascular treatments for infrainguinal peripheral artery disease. While today only approximately 25% of patients with peripheral vascular disease are diagnosed, we believe that the following factors are contributing to a growing diagnosed peripheral vascular disease patient population:

- *Increased Awareness.* Recent emphasis on peripheral vascular disease education from medical associations, insurance companies and online medical communities, as well as publication in medical journals, is increasing public and physician awareness of peripheral vascular disease risk factors, symptoms

and treatment options. The Legs for Life®, P.A.D. Peripheral Arterial Disease Coalition, and Save a Leg Save a Life Foundation™ are examples of organizations working to increase the awareness and screening for peripheral arterial disease. The American Diabetes Association, or ADA, recommends that all diabetics over the age of 50 be screened for peripheral vascular disease.

- *Evolving Physician Practice Patterns.* Given that many patients with coronary artery disease also have peripheral vascular disease, we believe that interventional cardiologists and vascular surgeons are increasingly screening patients for both diseases. As a consequence, we believe that physicians are diagnosing more cases of peripheral vascular disease. In addition, heightened awareness of peripheral vascular disease, its symptoms and treatment options is leading to increased referrals from general practitioners, podiatrists who treat patients with pain and lesions in the feet that may be caused by peripheral vascular disease, and nephrologists, diabetologists and endocrinologists, who treat diabetics often experiencing complications resulting from peripheral vascular disease.

- *Increased Peripheral Vascular Disease Screening.* Studies and medical articles have advocated increased peripheral vascular disease screening by primary care physicians using an ankle-brachial index, or ABI, a simple technique that compares blood pressure in a patient's foot to blood pressure in the patient's arm to determine how well blood is flowing to the foot. In addition to the ABI, physicians are increasingly using established techniques, such as angiography and ultrasound, to either diagnose or confirm diagnosis of peripheral vascular disease.

Peripheral Vascular Disease Treatment Options

Peripheral vascular disease is treated depending upon the severity of the disease with either non-invasive management, including lifestyle changes and/or drug treatment, for mild to moderate peripheral vascular disease, or minimally invasive endovascular procedures or surgery for more severe peripheral vascular disease.

Non-Invasive Management. For some patients, lifestyle changes and/or drug treatment may slow or reverse the progression of peripheral vascular disease. Lifestyle changes include improving diet, exercising regularly and quitting smoking. Although these adjustments can be effective, many people are unable to maintain this new lifestyle. In addition to lifestyle changes, physicians often prescribe medications that increase blood flow but do not treat the underlying obstruction. Pletal, a commonly prescribed medication for claudication, should not be taken if the patient also has heart disease, which often exists in peripheral vascular disease patients. In addition, physicians often prescribe cholesterol-lowering drugs and drugs for high blood pressure. Patients generally need to take the prescribed drugs for the rest of their lives.

Minimally Invasive Endovascular Procedures. Minimally invasive endovascular procedures for the treatment of peripheral vascular disease consist primarily of angioplasty, stenting and atherectomy, and to a lesser extent, other procedures, such as stents, angioplasty and atherectomy combined with embolic protection devices, laser therapy, drug-eluting stents and vascular cryotherapy. In angioplasty, a catheter with a balloon tip is inserted into the blocked or narrowed part of the artery over a previously positioned guidewire that directs the catheter to the affected area. The balloon is then inflated to compress the plaque and to stretch the artery wall, thereby enlarging, or dilating, the opening of the vessel and restoring blood flow. Stenting is often performed in tandem with angioplasty. Stents are tubular mesh devices typically consisting of interconnected metal struts, which are inserted inside the artery to act as scaffolding in order to hold the vessel open. Atherectomy is a procedure for opening up an artery by removing the plaque that can block arteries throughout the body. It can be performed by various methods of inserting a catheter into the artery. Plaque excision, a form of atherectomy, uses a tiny rotating blade to shave away plaque from inside the artery. The plaque is collected in a reservoir nosecone located at the tip of the device and is subsequently removed from the patient. Laser atherectomy uses a laser beam to reduce the plaque to relatively small particles which are released in the bloodstream. Rotational atherectomy uses a rotating shaver to sand the plaque to relatively small particles which depending on the device are released into the bloodstream or aspirated back into the device.

Other interventional treatments for peripheral vascular disease include:

- stents, angioplasty and atherectomy combined with embolic protection systems, which protect against plaque and debris from traveling downstream, blocking off the vessel and disrupting blood flow;

- drug-eluting stents, where a stent is coated with a slow-to-moderate release drug formulation intended to reduce restenosis, which occurs when the treated vessel becomes blocked again;

- drug-coated balloons, where an angioplasty balloon is coated with a drug formulation intended to reduce restenosis; and

- vascular cryotherapy, where an angioplasty balloon is inflated with nitrous oxide in an attempt to reduce inflammation caused by treatment of the lesion.

We estimate that in 2009 over 900,000 endovascular procedures to treat peripheral vascular disease were performed in the United States.

Surgical Procedures. Surgery is used when non-invasive management or minimally invasive endovascular procedures have failed or if the patient is diagnosed when the peripheral vascular disease has progressed to an advanced state. The three main types of surgical procedures include bypass surgery, endarterectomy and amputation.

In bypass surgery, the surgeon reroutes blood around a lesion using a vessel from another part of the body or a tube made of synthetic fabric. Bypass surgery is not advisable for some patients because of the inherent risks of surgery, the symptoms are not deemed to be critical enough to warrant such an intervention, or the existence of other diseases. Bypass surgery has a high risk of procedure-related complications from blood loss, post-procedural infection or reaction to general anesthesia and may require patients to remain hospitalized for several days.

Endarterectomy involves the surgical removal of plaque. While endarterectomy is sometimes used, the procedure is highly invasive and subjects the patient to the same procedural risks and complications as bypass surgery. Endarterectomy is rarely used below the knee because the arteries below the knee are generally too small to accommodate the procedure.

If CLI progresses to an advanced state, bypass surgery or endarterectomy may not be used. In this case, physicians may amputate all or a portion of the limb.

Our Peripheral Vascular Product Portfolio

Our peripheral vascular product portfolio includes products for peripheral vascular procedures which, in some instances, may also be used for selected cardiovascular procedures. Our strategy is to provide a broad portfolio of products for the peripheral vascular market that includes devices used in frequently performed procedures and also innovative devices for use in emerging therapies. We opportunistically pursue selected cardiovascular markets where some of these products can be used by our cardiologist customers. We do not compete in cardiovascular markets in which several large companies are firmly entrenched, such as coronary stents. The increase in the breadth of our portfolio of peripheral vascular devices has significantly expanded our participation in the peripheral markets over the last few years. Our peripheral vascular product portfolio includes atherectomy plaque excision products, stents, embolic protection and thrombectomy products, carotid stenting solutions, PTA balloons and other procedural support products.

Atherectomy Plaque Excision Products

We offer atherectomy plaque excision products, which are designed to remove plaque from artery walls in order to re-establish blood flow. Unlike most treatments for peripheral artery disease that leave the plaque in the artery, atherectomy plaque excision products are designed to remove the plaque, instead of compressing it against the vessel walls.

SilverHawk Plaque Excision System. The SilverHawk Plaque Excision System is a minimally invasive, catheter system that treats peripheral artery disease by removing plaque in order to reopen narrowed or blocked arteries. The SilverHawk uses a tiny rotating blade to shave away plaque from inside the artery. It is the only currently available device that both allows the operator to remove the disease and is directional during treatment. SilverHawk also creates the largest vessel opening for blood flow of the currently available atherectomy devices. The plaque is collected in a reservoir nosecone located at the tip of the device and is subsequently removed from the patient. The SilverHawk is capable of removing significant amounts of plaque without overstretching the artery, which could lead to dissection or perforation. Plaque excision has helped alleviate severe leg pain for thousands of patients and in many cases has successfully saved the legs of patients who were scheduled for limb amputation after other peripheral interventions had failed.

The SilverHawk provides a treatment approach for peripheral artery disease that we believe offers significant benefits, including:

- *Safety*. The SilverHawk is designed not to stretch or damage the artery walls, which can lead to dissection or perforation of the artery. The SilverHawk procedure is minimally-invasive and typically performed under local anesthesia. Therefore, it does not have many of the risks associated with more invasive surgeries and general anesthesia. To date, we have not conducted studies designed to directly compare the safety of the SilverHawk against alternative procedures, such as angioplasty, stenting or bypass grafting.

- *Efficacy*. Unlike most treatments for peripheral artery disease that leave plaque behind in the artery, the SilverHawk removes plaque. The SilverHawk has removed over 700 milligrams of plaque in a single procedure, with an average of approximately 100 milligrams of plaque per procedure. We believe that excising plaque without causing stretch injury to the artery wall may minimize restenosis and the need for reintervention. We also believe that the efficacy of the SilverHawk, measured by low 12-month reintervention rates is supported by the results of five single site studies as well as our TALON registry. In order to further evaluate the long term efficacy data of the SilverHawk during endovascular treatment of peripheral arterial disease, we are conducting the DEFINITIVE LE (Lower Extremity) Study, a prospective, multi-center, non-randomized, single-arm study to evaluate the intermediate and long-term effectiveness of stand-alone SilverHawk Plaque Excision for endovascular treatment of peripheral arterial disease in femoropopliteal or tibial-peroneal arteries. The primary effectiveness endpoint for patients with claudication is expected to be primary patency at one year as defined by duplex ultrasound peak velocity ratio. The primary effectiveness endpoint for patients with critical limb ischemia is amputation-free survival at 12 months. We commenced enrollment for the DEFINITIVE LE Study during the second quarter of 2009.

- *Ability to Treat Difficult to Treat Lesions*. The SilverHawk enables physicians to remove plaque from long, bifurcated and difficult to treat lesions in a wide variety of locations, including arteries behind and below the knee and in the foot. Approximately one-third of SilverHawk procedures to date have been performed below the knee, an area where lesions have traditionally gone untreated until they require bypass surgery or amputation. Certain treatment locations, such as arteries below the knee or in the foot, are not suited for physicians with limited experience using the device.

- *Utilizes Familiar Techniques*. The SilverHawk procedure employs techniques similar to those used in angioplasty, which are familiar to approximately 12,000 interventional cardiologists, vascular surgeons and interventional radiologists in the United States who are generally trained in endovascular techniques. This significantly increases the number of physicians who are able to perform the procedure compared to surgical alternatives that must be performed by highly-trained vascular surgeons. In addition, the SilverHawk was designed to be easy to use. The SilverHawk operates with one switch that controls all device functionality, and has a unique torque shaft designed for a one-to-one correlation between the handle and the tip, providing physicians with precise control of the position of the cutting blade. We continue to focus on providing further enhancements to the SilverHawk as part of our research and development efforts.

- *Cost and Time Efficient*. A single SilverHawk device can be used to treat multiple and long lesions where more than one stent might otherwise be required. Compared to surgical alternatives, the SilverHawk procedure reduces cost by allowing physicians to treat patients in a catheterization lab instead of an operating room, decreasing the length of hospitalization and reducing complications.

- *Allows for Follow-Up Treatment Options*. Physicians can, and sometimes do, use adjunctive angioplasty and occasionally stenting during a SilverHawk procedure. When the SilverHawk procedure is performed without stenting, which we estimate is greater than 90% of the time, increased future treatment options remain available in the event that restenosis does occur and reintervention is required as there is no metal left behind post procedure, as is the case with stenting.

- *Captures and Removes Plaque*. The patient and the physician get immediate feedback by seeing the volume of plaque removed, visibly reinforcing the benefits of the procedure.

In the United States, the SilverHawk is approved for use in the peripheral vasculature. This means that our product may not be marketed in the United States for use in the heart, brain or in specific peripheral anatomy without additional clearances from the FDA. In the United States, the SilverHawk is contraindicated, and should therefore not be used, for in-stent restenosis, which is restenosis after the use of stents, or for use in the carotid, iliac and renal arteries.

The SilverHawk family of products includes MEC (Micro Efficient Compression) Technology, a novel advancement which features precision laser-drilled vent holes in the tip of the catheter. These micro vent holes release fluid pressure, providing more space for the collection of tissue in the tip of the device. This technology has the potential to reduce overall procedure time by enabling physicians to increase tissue collection during plaque removal procedures in large vessels above the knee.

The SilverHawk family of products also includes several different catheters, which enable the treatment of both calcified and non-calcified lesions of any length, pending the specific device indication. The catheters vary in diameter to treat a wide range of peripheral vessel sizes. The devices also vary in tip length to accommodate lesions with heavier or lighter plaque burden.

TurboHawk Plaque Excision System. During third quarter of 2009, we announced the U.S. launch of the TurboHawk Plaque Excision System for surgical use. The TurboHawk features four angled, Super Cutter blades that are designed to increase the efficiency of directional plaque excision for above the knee interventions, including severely calcified lesions in varying vessel diameters for which very limited options are available to date. In November of 2009, the TurboHawk Plaque Excision System was cleared for endovascular use in mild to moderate calcium. We also received FDA approval to include the TurboHawk in our DEFINITIVE Ca^{++} IDE study. We have expanded availability for the TurboHawk Plaque Excision System to international markets and plan to launch the TurboHawk Plaque Excision System for below the knee use in the second half of 2010.

Stents

Although our stents, like most of our competitors' stents, have been approved by the FDA for the palliative treatment of malignant neoplasms in the biliary tree, even though not promoted or marketed for such use, they are used by physicians not only in the biliary duct, which transports bile from the liver and gall bladder to the small intestines, but also "off label" in various other locations in the body, including renal arteries, which transport blood from the aorta to the kidneys; iliac, femoral and popliteal arteries, which are major arteries in the legs and subclavian arteries, which are major vessels of the upper body, originating at the aortic arch. We believe that our portfolio of self-expanding stents is differentiated from our competitors' offerings due to their fracture resistance, flexibility and lengths, and that both our self-expanding and balloon expandable stent platforms provide advanced radiopacity (visibility under fluoroscopy), placement accuracy, deliverability and strong clinical performance.

Protégé EverFlex, Protégé GPS and Protégé GPS BIGGS. Our self-expanding stent portfolio includes our Protégé EverFlex Self-Expanding Stent and our Protégé GPS Family of Self-Expanding Stents, all of which are "shape memory" nitinol stents that expand to a predetermined diameter upon deployment. Nitinol is a highly flexible metal

with shape retention and fatigue resistance properties. We offer a number of sizes of the EverFlex, Protégé GPS and Protégé GPS BIGGS stents. The EverFlex stent has enhanced flexibility and resistance to fractures, which we believe provides superior performance in vessels that are subjected to repeated flexing and bending. The EverFlex stent encompasses a unique spiral cell geometry, which is constructed to withstand extreme movement.

We believe the design of our EverFlex stents is unique in that it features:

- Spiral cell interconnections that greatly enhance flexibility;
- New wave peak structure that more efficiently distributes stress and resists compression; and
- Longer lengths (up to 200 mm and all 6 French compatible), which minimize the need for overlapping stents when treating long lesions.

In October 2008, 12-month follow-up results were reported for our European DURABILITY I clinical study, the world's first prospective study to specifically test the efficacy and integrity of a long stent in challenging femoral lesions. It is also the first study to specifically evaluate the use of a single stent up to 15 centimeters long per patient. A total of 151 patents were treated in 13 European centers. At 12 months follow-up, primary patency was 72%, which compares quite favorably to other studies and was notable considering the average lesion length was almost 10 centimeters and 40% of the vessel were occluded. We are currently conducting our DURABILITY II study in the U.S. with the objective of expanding our Protégé EverFlex Self-Expanding Stent's indication for use to include treatment of peripheral artery disease in the superficial femoral and proximal popliteal arteries of the leg. Additionally, we have received conditional approval for our PROVE-IT study in the U.S., which will study the use of both the Protégé EverFlex Self-Expanding Stent and the Visi-Pro Balloon Expandable Stent in iliac arteries.

PRIMUS and Visi-Pro Balloon Expandable Stents. Our balloon expandable stent portfolio includes stents that incorporate embedded tantalum markers to provide superior visualization under fluoroscopy, allowing the physician to quickly confirm the correct placement. The inclusion of markers is a unique feature in the balloon expandable stent market. We plan to evaluate in our PROVE-IT study the use of both the Protégé EverFlex Self-Expanding Stent and the Visi-Pro Balloon Expandable Stent in iliac arteries. To our knowledge, this will be the first study of its kind, which evaluates the use of two different stent platforms in one study.

Embolic Protection and Thrombectomy Products

During peripheral vascular and cardiovascular procedures, plaque and debris may dislodge or embolize, potentially blocking blood flow and damaging distal tissue. Embolic protection devices are intended to trap plaque and debris from traveling downstream, blocking off the vessel and disrupting blood flow. Similarly, thrombectomy devices are designed to remove blood clots, or thrombus, in order to re-establish blood flow or to prevent a clot from breaking up and blocking smaller downstream vessels. We offer thrombectomy tools for peripheral vascular and cardiovascular procedures that meet a broad spectrum of physician needs, including the mechanical removal of thrombus and the delivery of peripheral blood clot therapies designed to help dissolve the clot.

SpiderFX Embolic Protection Devices. The SpiderFX family of embolic protection devices are low-profile devices featuring a unique braided nitinol embolic filter compatible with most guidewires on the market. Filter-based embolic protection devices allow blood to continue flowing in the artery while the filter traps the debris, minimizing downstream tissue damage and improving clinical outcomes. We believe that the SpiderFX family has a significant competitive advantage because it permits physicians to use their guidewire of choice, allowing improved durability and a more efficient procedure. We believe the SpiderFX also exhibits superior trackability, enhanced visibility and excellent stability.

The SpiderFX is indicated for use as a guidewire and embolic protection system to contain and remove embolic material, such as thrombus or debris, while performing angioplasty and stenting procedures in carotid arteries, as well as indicated for use as protection, while performing percutaneous transluminal coronary angioplasty or stenting procedures in coronary saphenous vein bypass grafts. We are currently conducting the DEFINITIVE Ca++ clinical study to evaluate the safety and effectiveness of the SilverHawk with Calcium Tip (i.e. RockHawk and TurboHawk)

Plaque Excision System when used in conjunction with the SpiderFX Embolic Protection Device for capture, containment and removal of excised plaque and embolic debris during endovascular treatment of moderate to severely calcified peripheral arterial disease in the superficial femoral and/or popliteal arteries. This study, if successful, should support approval for a combined RockHawk and SpiderFX system, thereby expanding the indication of the SpiderFX into the periphery. The SpiderFX is currently indicated for general vascular use outside the United States.

Blood Clot Therapy Products or Infusion Catheters. Our blood clot therapy products include flexible catheters with small holes that can allow for the delivery of drugs to help dissolve or break up a clot. Referred to as infusion catheters, this form of treatment relies on various pharmacologic agents to restore blood flow rather than physically removing or compressing the clot.

Carotid Stenting Solutions

Carotid artery stenting represents an emerging minimally invasive treatment option for carotid artery disease. We believe it has the opportunity to become a significant alternative to carotid endarterectomy, where a surgeon accesses the blocked carotid artery though an incision in the neck, and then surgically removes the plaque. Endovascular techniques using stents and embolic protection systems, which protect against plaque and debris from traveling downstream, blocking off the vessel and disrupting blood flow, have been developed and are in an early stage of adoption. The use of a stent with an embolic protection system avoids open surgery and we believe will increase the number of patients being treated. In 2005, the Centers for Medicare & Medicaid Services, or CMS, expanded reimbursement of percutaneous transluminal angioplasty of the carotid artery concurrent with stent placement outside of trial settings for patients who are at high risk for carotid endarterectomy in certain circumstances. Coverage is limited to procedures at CMS-approved facilities performed using FDA-approved carotid artery stenting, or CAS, systems and embolic protection devices, which has limited the CAS near-term market potential.

Our carotid stenting product offering (Protégé RX straight and tapered stents used together with our SpiderFX embolic protection devices) are available in the United States, Europe and certain other countries. In support of our FDA pre-market approval submission, we conducted the CREATE Pivotal clinical trial, which was designed to evaluate the use of our carotid stenting technology in patients who are high-risk candidates for carotid endarterectomy. We also have received FDA 510(k) clearance of our SpiderFX embolic protection device for use in carotid artery stenting in conjunction with the Guidant RX ACCULINK stent. We are currently conducting the CREATE Post Approval Study with the objective of further studying the Protégé GPS and Protégé RX Carotid Stent Systems and SpiderFX in the treatment of carotid artery disease in subjects at high risk for complications during surgical treatment of carotid artery disease.

PTA Balloons and Other Procedural Support Products

As part of our peripheral vascular marketing strategy, we market and sell a number of products to be used in conjunction with our other peripheral vascular portfolio products, including balloon angioplasty catheters, snares, microsnares, guidewires and other accessories.

Balloon Angioplasty Catheters. Balloon angioplasty catheters are designed to open up the vessel via balloon dilation. In angioplasty, a catheter with a balloon tip is inserted into the blocked or narrowed part of the artery over a previously positioned guidewire that directs the catheter to the affected area. The balloon is then inflated to compress the plaque and to stretch the artery wall, thereby enlarging, or dilating, the opening of the vessel and restoring blood flow.

In January of 2009, we globally launched our EverCross and NanoCross percutaneous transluminal angioplasty (PTA) balloons. In the United Sates and internationally, these balloon catheters are cleared for non-coronary dilatation of the vascular anatomy excluding the carotid arteries.

The EverCross is a PTA catheter system with 0.035 guidewire compatibility. We believe the design of our EverCross PTA balloon is unique in that it features:

- unmatched longer lengths (up to 200 cm) which allows a physician to use a single balloon once (vs. a shorter length balloon multiple times);
- low tip entry and crossing profile optimizing the ability to cross tight lesions; and
- robust catheter shaft and flexible balloon design enhancing the ability to reach the desired treatment area.

The NanoCross is a PTA catheter system with 0.014 guidewire compatibility. We believe the design of our EverCross PTA balloon is unique in that it features:

- Bevel 360 technology optimizing the ability to cross tight lesions;
- catheter design providing optimal pushability and trackability to reach the target vessel area of the diseased vessel; and
- increased inner diameter catheter lumen allowing for dramatically reduced deflation times.

In the first quarter of 2010, we launched our PowerCross PTA catheter system with 0.018 guidewire compatibility.

Prior to January of 2009, we offered in the United States a portfolio of peripheral vascular balloon angioplasty catheters, which we purchased from Invatec pursuant to a distribution agreement, which expired on December 31, 2008. Our distribution agreement with Invatec allowed us to continue distribution of our remaining inventory of these products through June 30, 2009.

Goose Neck Snares and Microsnares. Foreign objects can be retrieved from the vascular system by using snares and other devices. Examples of foreign objects that require retrieval include broken catheter or guidewire tips, as well as stents that are dislodged from their delivery system and carried downstream. Our Goose Neck snares and microsnares incorporate a single, radiopaque (visible under fluoroscopy) loop mounted at the tip of a guidewire. The loop is deployed and retrieved through a catheter. We believe that our snares are unique because the loop remains positioned at a 90 degree angle relative to the wire. This increases the ability of the loop to encircle the foreign object, thereby improving the rate of success of retrieval. Nitinol shaft technology used in the wire provides kink resistance and durability. Our Goose Neck snares and microsnares are available in a wide variety of sizes for optimal fit within the vessel. Our Goose Neck snares are approved for use in the cardiovascular system or hollow viscus to retrieve and manipulate foreign objects. Our Goose Neck microsnares are also approved for use in the retrieval and manipulation of atraumatic foreign bodies located in the coronary and peripheral cardiovascular system and the extra-cranial neurovascular anatomy.

Nitrex Guidewires. Guidewires are threaded through vessels as a first step in most endovascular procedures. Balloon and stent catheters are advanced over guidewires to the target treatment area. For this reason, they are an indispensable component in the catheterization laboratory. Our Nitrex guidewires are characterized by both flexibility and kink resistance which are particularly useful when negotiating tortuous vascular anatomy. Some interventional procedures demand a wire with maximum lubricity, while others require enhanced purchase or ability to maintain placement in a vessel. Our Nitrex guidewires offer the ability to maintain placement in the vessel and maximum control through the procedure. Our proprietary manufacturing processes create a wire with a gently tapered, continuous solid nitinol core that extends from the proximal end through the distal tip. Gold tungsten coils provide excellent radiopacity for enhanced visualization and to ensure precise navigation through the vasculature. Our Nitrex guidewires are versatile since they are available in a variety of tip lengths and angles for broad applications and are used in a wide range of endovascular procedures.

Our Neurovascular Markets

Neurovascular Disease and Strokes

The most devastating complication of neurovascular disease is stroke. A stroke usually occurs when the flow of oxygen rich blood to the brain is suddenly interrupted. There are two types of stroke:

- *Ischemic stroke*, which is caused by the blockage of an artery to the brain; or
- *Hemorrhagic stroke*, which is caused by a sudden rupture of a brain artery, leading to bleeding into or around the brain.

If either stroke is left untreated for more than a few minutes, brain cells may die due to the lack of blood flow. Both forms of stroke may result in permanent brain damage or even death. Patients who survive a stroke are often left with disabilities, including paralysis, coma, impaired cognition, decreased coordination, loss of visual acuity, loss of speech, loss of sensation or some combination of these conditions. A significant need for effective prevention and treatment of stroke exists because of the severity of the disorder, its prevalence in society, the shortcomings of current therapies and the high cost of treatment and care.

Ischemic strokes can be caused by several different kinds of disease, with the most common being a narrowing of the arteries caused by atherosclerosis or gradual cholesterol deposits. If arteries become too narrow, clots may form. There are two different types of ischemic stroke: thrombotic (cerebral thrombosis) and embolic (cerebral embolism). A thrombotic stroke is the most common and occurs when arteries in the brain become blocked by the formation of a clot within the brain. An embolic stroke occurs when a clot or small piece of plaque formed in one of the arteries leading to the brain, such as the heart or carotid artery, travels through the bloodstream to the brain where it lodges in narrower brain arteries and blocks blood flow.

Transient ischemic attack, commonly referred to as a TIA, is a warning sign of the potential for a future stroke. By definition, the symptoms of a TIA may last up to 24 hours, but they often last only a few minutes. TIA occurs when the blood supply to part of the brain is briefly interrupted. TIA symptoms are similar to those of stroke but do not last as long. Most symptoms of a TIA disappear within an hour. About one-third of strokes are preceded by one or more TIAs that can occur days, weeks or even months before a stroke.

Two common causes of hemorrhagic stroke are ruptures of cerebral aneurysms and arterio-venous malformations, or AVMs. An aneurysm is a weakening of the vessel wall that forms a balloon-shaped pouch, which fills with blood. Aneurysms typically grow over time and, due to pressure placed on the wall of the aneurysm, are prone to rupture. Ruptured aneurysms can easily result in death as a result of massive intracranial bleeding and loss of perfusion to the brain in the area affected by the aneurysm rupture. Brain aneurysms are all different. They vary in size, shape and location. Small aneurysms are less than 5 mm (1/4 inch) but can grow as large as 25 mm (1¼ inches) or more. Aneurysms can be saccular (sac-like), with a well-defined neck, or saccular with a wide neck or fusiform (spindle shaped) without a distinct neck. An aneurysm is usually located along the major arteries deep within brain structures. Aneurysms can occur in the front part of the brain (anterior circulation) or the back part of the brain (posterior circulation). If an aneurysm ruptures, it leaks blood into the space around the brain. This is called a "subarachnoid hemorrhage." If the hemorrhage bleeds into the brain itself causing damage to the brain directly, this results in a hemorrhagic stroke. Once an aneurysm bleeds, there is a 30% to 40% chance of death, and a 20% to 35% chance of moderate to severe brain damage, even if the aneurysm is treated. If the aneurysm is not treated quickly enough, another bleed may occur from the already ruptured aneurysm.

In an AVM, the flow of blood between arteries and veins, which normally occurs through very small capillary vessels, is short circuited by the development of a network of larger vessels directly connecting the arteries and veins. The higher blood pressure flowing directly to the veins makes these vessels highly prone to rupture. Although all blood vessel malformations involving the brain and its surrounding structures are commonly referred to as AVMs, they are actually several types, including: (1) a true arteriovenous malformation, which is the most common brain vascular malformation and consists of a tangle of abnormal vessels connecting arteries and veins with no normal intervening brain tissue; (2) an occult or cryptic AVM or cavernous malformation, which is a vascular

malformation in the brain that does not divert large amounts of blood, but may bleed and often produce seizures; (3) venous malformation, which is an abnormality only of the veins, which are either enlarged or appear in abnormal locations within the brain; (4) hemangioma, which are abnormal blood vessel structures usually found at the surface of the brain and on the skin or facial structures and represent large and abnormal pockets of blood within normal tissue planes of the body; and (5) dural fistula, which is an abnormal connection between blood vessels that involve the covering of the brain called "dura matter."

Neurovascular Market

According to the American Heart Association, there are approximately 795,000 strokes annually in the United States, making stroke the third leading cause of death and a leading cause of long-term disability. Acute ischemic stroke affects approximately 690,000 patients annually while hemorrhagic stroke is a less common disorder, affecting approximately 105,000 patients per year in the United States.

While an estimated 25,000 hemorrhagic stroke deaths in the United States in 2009 were caused by ruptured cerebral aneurysms, autopsy studies suggest that unruptured aneurysms may exist in approximately 1.5% to 6% of the general population in the United States. Annually, between 0.5% to 3% of people with a brain aneurysm may suffer from bleeding. If you have one aneurysm, there is a 15-20% chance that you have at least one or more additional aneurysms. It is unknown whether the presence of multiple aneurysms affects their rupture rates. We believe that with the development of new diagnostic and interventional technologies, the pool of patients that may benefit from intervention will continue to expand to include increasing numbers of those with unruptured aneurysms discovered in conjunction with other examinations.

It is estimated that in the United States, one in 200-500 individuals have an AVM in the brain. About 5-10% of AVMs are discovered by accident while the individual is being tested for other unrelated medical problems. Patients with AVMs may have additional vascular anomalies that increase the complexity of treatment.

Treatment Options

Current interventional therapies serve primarily the hemorrhagic stroke market while some of the recent developments are focused on the larger and underserved ischemic stroke market.

Ischemic Strokes. Ischemic strokes are treated with either non-invasive management, including lifestyle changes and/or drug treatment, surgery or minimally invasive endovascular procedures.

For some patients, lifestyle changes and/or drug treatment may slow or reverse the progression of neurovascular disease. Lifestyle changes include improving diet, exercising regularly and quitting smoking. Although these adjustments can be effective, many people are unable to maintain this new lifestyle. In addition to lifestyle changes, physicians often prescribe medications, such as clot-dissolving medications, anticoagulants or antiplatelet drugs. If used intravenously, therapy with clot-busting drugs for the treatment of an ischemic stroke must be started within three hours of the onset of ischemia. After that, the risks of bleeding or other complications from this type of therapy begin to outweigh potential benefits. After three hours, these medications may sometimes be given directly into the site of the clot (intra-arterial therapy). Anticoagulants, often called blood thinners, such as warfarin, may be prescribed by physicians following a stroke. By reducing the ability of the blood to clot, they may help to keep blood vessels open and delivering oxygen and nutrients to brain cells. Antiplatelet drugs, such as aspirin, may be administered during or immediately after a stroke to help prevent clot formation. While they work differently from anticoagulants, the result is similar. They help to keep blood vessels open and delivering oxygen and nutrients to brain cells.

The two main types of surgical procedures include bypass surgery or revascularization and endarterectomy. In bypass surgery or revascularization, the surgeon reroutes blood around a lesion using a vessel from another part of the body or a tube made of synthetic fabric. Bypass surgery is not advisable for some patients because of the inherent risks of surgery, the symptoms are not deemed to be critical enough to warrant such an intervention, or the existence of other diseases. Bypass surgery has a high risk of procedure-related complications from blood loss, post-procedural infection or reaction to general anesthesia and may require patients to remain hospitalized for several

days. Endarterectomy involves the surgical removal of plaque. While endarterectomy in an internal carotid artery is sometimes used, the procedure is highly invasive and subjects the patient to the same procedural risks and complications as bypass surgery. Carotid endarterectomy could even trigger a stroke because the operation may dislodge clots or other material that can then travel through the bloodstream and block an artery.

Minimally invasive endovascular procedures for the treatment of ischemic strokes currently utilize several different medical device options. In such procedures, often a stent with an umbrella filter is placed in the carotid artery. The stent helps keep the artery open and the filter catches blood clots and prevents them from reaching the brain and causing a stroke. Sometimes snare-like devices are used to access and remove blood clots. Another treatment option is a tiny corkscrew-shaped device that is attached to a catheter, threaded to the clot, and used to snag the clot. The clot is then drawn out through the catheter. In addition, the removal of blood clots from the cerebral vasculature often utilizes aspiration catheters that promote recanalization.

Hemorrhagic Strokes. Hemorrhagic strokes are treated based upon the cause of the stroke.

The best treatment for an aneurysm depends upon many things, including whether the aneurysm has ruptured or not. If an aneurysm has not ruptured, the treatment decision depends upon its size, location and shape, and the patient's symptoms. Small, unruptured aneurysms that are not creating any symptoms may not need treatment unless they grow, trigger symptoms or rupture. A ruptured aneurysm usually requires treatment right away, because the re-bleeding rate remains quite high. However, the treatment time and options for treatment depend upon the size, location and shape of the aneurysm, as well as the patient's overall medical condition.

Depending on an individual's risk factors, surgical clipping, a microsurgery, of an aneurysm may be recommended. In this procedure, patients are placed under general anesthesia, an opening is made in the skull, the brain tissue is spread apart, and the aneurysm is surgically exposed. The neurosurgeon then places a surgical clip around the aneurysm's base. The clip seals off the aneurysm so blood cannot enter. Possible complications from surgical clipping include infection at the incision site, rupturing the aneurysm during surgery and damage to the artery and bleeding into the brain which could result in brain damage. As with other surgical procedures, the anesthesia used during the procedure also has risks.

Driven by rapid advances in device technology and results from the International Subarachnoid Aneurysm Trial, or ISAT, the results of which were published in *The Lancet* in October of 2002, the treatment of aneurysms, as well as AVMs, has been shifting from open surgical techniques, such as surgical clipping, to minimally invasive, endovascular techniques, such as embolic coiling. The ISAT was an independent, randomized clinical trial involving 2,143 patients in Europe, North America and Australia that compared aneurysm clipping with embolic coiling as a method of treating cerebral aneurysms. The trial concluded, based on a survey of patients participating in the trial, endovascular intervention with detachable platinum coils resulted in a 23% relative and 7% absolute reduction in the risk of major brain injury or death compared with neurosurgical clipping of the aneurysm at one-year follow up. The seven-year follow up data published in *The Lancet* in September 2005 indicated a continued clinical advantage for patients who underwent coiling versus clipping procedures. The market transition to endovascular techniques, such as embolic coiling, has been more rapid in geographies outside of the United States. The primary endovascular procedure for treating both aneurysms and AVMs uses a repair technique called embolization, the objective of which is to induce a blood clot, or thrombus, in the diseased vasculature. The purpose of the thrombus is to limit blood flow through the diseased vascular anatomy, thereby reducing blood pressure and flow to a ruptured area or the likelihood of rupture in an unruptured area.

The endovascular embolization of cerebral aneurysms usually involves the deployment of small coils composed of metal or a combination of metal and polymer. We believe that embolic coils represent one of the largest categories of products in the neurovascular device market and were used in over 70,000 procedures worldwide in 2009. Embolic coils are used in virtually all endovascular treatments of aneurysms and in some AVMs. During a coiling procedure, the physician accesses the femoral artery through a tiny incision in the groin or inner thigh where a tiny hollow tube or sheath is inserted into the artery wall to allow the introduction of a catheter which is inserted and guided by a guidewire and with the use of computer-aided X-ray scanners through the artery and up towards the brain. Once the catheter is in place, the guidewire is removed, leaving the catheter in place. A contrast dye is introduced via the catheter into the bloodstream in order to make the artery and the aneurysm clearly visible and to aid in obtaining clear radiographic images. A microcatheter is then introduced through the larger catheter and used

to deliver coils through the neck and into the sac of the aneurysm. The coils are approximately twice the thickness of a human hair and there are several types of coils which vary in shape, pliability and levels of softness. They are attached to the end of the microcatheter. The coils placed are generally of progressively smaller sizes. They are individually placed and often detached from the microcatheter by a small electric current or a mechanical detachment mechanism. Within the microcatheter the coils are straight but, after placement in the aneurysm, they bend in a helix shape and conform to the shape of the aneurysm walls. This process is repeated until approximately 35% to 45% of the volume of the aneurysm is filled with coils. The coils then form a mesh similar to steel wool. Eventually, blood cells are caught and clot on the mesh in a process called "thrombosis," effectively filling and sealing off the aneurysm from the artery circulation. The procedure requires a high level of precision and skill to avoid either under or over-filling the aneurysm, since over-filling may cause rupture or painful pressure on adjacent tissue and under-filling may permit the aneurysm to reform or grow. Balloon-assisted coiling involves a tiny balloon catheter which covers the neck or entrance to the aneurysm, holding the coils in place. Stent-assisted coiling involves a small cylindrical mesh tube which acts as scaffolding along the neck of the aneurysm to hold the mass of coils in place. The development of supple, more flexible stents and balloons has allowed stent-assisted and balloon-assisted coiling of irregular fusiform and wide-necked aneurysms in some cases. Coiling does not involve surgically opening the head and may be done under local or general anesthesia. Possible complications include rupture of the aneurysm during treatment and damage to the artery and bleeding into the brain which could result in brain damage, as well as risks from the anesthesia. However, because coiling is a less invasive procedure than surgical clipping and results in lower treatment costs, shorter recovery times and less trauma to the patient, it has become a widely accepted treatment for aneurysms.

Embolic coiling, however, is not as effective in treating large and giant, wide-neck or non-saccular aneurysms. In addition, incomplete aneurysm occlusion and recurrence are major shortcomings of embolic coiling, as well as other current therapy options. An alternative treatment to coiling or one that could be used in conjunction with coiling is flow diversion. Flow diversion represents a new class of cerebral embolization device that is designed to divert blood flow away from an aneurysm in order to provide a complete and durable aneurysm embolization while maintaining patency of the parent vessel. Although flow diversion devices are used in certain European countries to treat aneurysms, they have not yet gained regulatory approval in the United States.

The best treatment for an AVM depends upon what type it is, the symptoms it may be causing, its location and size and whether the AVM has bled before. If there are no symptoms or almost none, or if an AVM is in an area of the brain that cannot be easily treated, no medical intervention may be recommended. Instead, the person is often advised to simply avoid any activities that may excessively elevate blood pressure, such as heavy lifting or straining, and avoid blood thinners, like warfarin. If an AVM has bled, there is an increased risk that it will bleed again thus prompting a more aggressive approach to treatment. If the AVM is located in an area that can be easily operated upon, then surgical resection, or removal, may be recommended. An AVM that is not too large, but is in an area that is difficult to reach by regular surgery, may be treated by performing stereotactic radiosurgery. In this procedure, a cerebral angiogram is done to localize the AVM and focused-beam high energy sources are then concentrated on the brain AVM to produce direct damage to the vessels that will cause a scar and allow the AVM to "clot off." Finally, as with aneurysms, minimally invasive, endovascular techniques are increasingly being used to treat AVMs and may be used in conjunction with surgical resection or radiosurgery. In such procedures, a catheter is placed inside the blood vessels that supply the AVM, and the abnormal blood vessels are intentionally blocked to stop blood flowing to the AVM with a variety of different materials, such as liquid glues, liquid polymers or other very small polymer particles, microcoils and other materials.

Our Neurovascular Product Portfolio

Our neurovascular product portfolio includes embolic coils, flow diversion and restoration devices, liquid embolics, flow directed and other micro catheters, occlusion balloon systems, guidewires, neuro stents and retrieval devices.

Embolic Coils

Our embolic coil products are delivered using a combination of our minimally invasive guidewires, microcatheters, stents and balloons. During an aneurysm procedure, the embolization coils are attached to a hypotube and are passed through a delivery catheter into the aneurysm space. The coil is then detached from the hypotube, the hypotube is removed and the next coil is advanced through the catheter.

Axium Detachable Coil System. We launched our Axium Detachable Coil System on a worldwide basis in the fourth quarter of 2007. During the fourth quarter of 2009, we concluded our physician preference testing for two new versions of the Axium coil, the Axium PGLA and Axium Nylon microfilament coils, in the U.S. and Europe and are in the process of launching these products for broad commercial availability. Our Axium coils are intended for the endovascular embolization of intracranial aneurysms and the embolization of other neurovascular abnormalities, such as AVMs and arteriovenous fistulae. They are also indicated for use in the European Union for the treatment of peripheral vascular abnormalities. We designed our Axium coils in an effort to meet the performance criteria of a diverse group of leading neurosurgeons and interventional neuroradiologists. Unique features and benefits of our Axium coils include:

- a high degree of coil conformability, which facilitates the physician's goal of more easily and completely filling and packing the aneurysm, regardless of its shape and size;

- coil softness combined with stretch resistance, which allows the coil to be positioned or re-positioned within the aneurysm without adding to the risk of bleeding or hemorrhagic stroke;

- ease of coil placement though the microcatheter, providing the physician with enhanced control and deliverability; and

- rapid, safe and simple detachment of the coil through a proprietary, micro-machined mechanical detachment system that offers instantaneous coil detachment without the use of wires or syringes. This facilitates precise and rapid coil deployment thereby minimizing procedure time, which may be especially important in a ruptured aneurysm or when blood flow to the brain has been restricted.

Nexus Embolic Coils. We also offer our Nexus line of coils in the United States and international markets, including our latest addition to the Nexus family, the Nexus Morpheus. Our Nexus coils are intended for the endovascular embolization of intracranial aneurysms that because of their morphology, their location or the patient's general medical condition are considered by the treating neurosurgical team to be very high risk for management by traditional operative techniques or inoperable. Our Nexus coils are also intended for the embolization of other neurovascular abnormalities, such as AVMs and arteriovenous fistulae. Our Nexus line of coils consists of framing, filling and finishing coil offerings, allowing physicians to treat a wide range of aneurysm shapes and sizes. All Nexus coils incorporate a nitinol filament, which offers improved shape retention and increased resistance to coil compaction. Nexus also incorporates a bioactive microfilament technology to enhance aneurysm healing. The Morpheus is a three-dimensional soft and conformable coil that does not sacrifice the compaction resistance inherent with the nitinol core.

NXT. We also offer our older generation NXT line of detachable coils in the United States and international markets. The NXT family includes framing, filling and finishing coils and are sold in a wide range of shapes and configurations. Many of the NXT products incorporate the use of nitinol technology, resulting in less stretching for more confident positioning and better resistance to compaction, while its enhanced shape memory provides a more supportive basket and optimal bridging of the neck of the aneurysm, compared to coils without nitinol.

Flow Diversion Devices

Pipeline Embolization Device. As a result of our acquisition of Chestnut Medical Technologies, Inc. in June of 2009, we market and sell the Pipeline Embolization Device in Europe and on a limited basis in other international markets such as Canada, Australia and the Middle East and are in the process of conducting two clinical studies under U.S. FDA investigational device exemptions (IDE) to gain approval for the Pipeline Embolization Device in the United States. Our Pipeline Embolization Device is a new class of cerebral embolization device that is designed to divert blood flow away from an aneurysm in order to provide a complete and durable aneurysm embolization while maintaining patency of the parent vessel. The Pipeline Embolization Device is a self-expanding, microcatheter-delivered, cylindrical mesh device composed of individual braided cobalt chromium and platinum strands. Multiple devices can be deployed within each other (telescoped) to create a composite endovascular construct. The degree of metal surface area coverage can be manipulated by varying the technique of device deployment, as well as by choosing the number of overlapping devices placed in a particular vascular segment.

Because the Pipeline Embolization Device reconstructs the entire length of the treated parent vessel, it has proven effective despite the neck width of the aneurysm, large or giant size, or the presence of intra-aneurysmal thrombus. The flexibility of the Pipeline Embolization Device allows it to be delivered and used in tortuous anatomy and because it is an "intravascular" as opposed to "intrasaccular" therapy, the device can be used to treat even thin walled aneurysms.

In a trial known as the PITA trial, 31 patients at four study sites received the Pipeline Embolization Device for the treatment of difficult-to-treat intracranial aneurysms. All patients had either wide-necked saccular aneurysms or aneurysms that had failed to respond to previous endovascular coiling. The average aneurysm size was 11.5 mm, with an average neck width of 5.8 mm; thus, the study was predominantly one of large, wide-necked aneurysms. Overall, the device was delivered successfully in 100% of the cases, with a 6% rate of periprocedural complications (two strokes, no deaths). At 6-month follow-up, 28 of 30 lesions (93%) available for evaluation demonstrated complete angiographic occlusion.

PUFS and COCOA are two clinical studies we are currently conducting under IDEs from the FDA. These studies are investigating the use of the Pipeline Embolization Device in the treatment of uncoilable aneurysm and coilable aneurysm, respectively. We expect to submit the results of the PUFS study to the FDA in first quarter of 2010. Outside of these clinical studies, there is commercial use of the Pipeline Embolization Device in our international markets as well as compassionate use cases within the United States.

Liquid Embolics

We estimate that liquid embolics were used in approximately 15,000 worldwide neurovascular procedures in 2009, including the majority of AVM and some aneurysm procedures. One embolization technique for AVMs involves the injection of acrylic-based glue. We believe, however, that glues have multiple drawbacks including the lack of controlled delivery and extreme adhesion to all surfaces, including that of the delivery catheter. Glue solidifies upon contact with blood which reduces physician control during filling and necessitates very rapid withdrawal of the delivery catheter in order to avoid it being permanently glued in place. We believe our Onyx Liquid Embolic System is a superior solution to glue.

Onyx Liquid Embolic System. Onyx is our proprietary biocompatible copolymer which is delivered, in liquid form, through proprietary microcatheters to blood vessels in the brain, where it fills a vascular defect and transforms into a solid polymer cast. Onyx offers a unique form, fill and seal approach to the interventional treatment of aneurysms and AVMs associated with hemorrhagic stroke. Because Onyx is non-adhesive, and solidifies over a few minutes' time, the injection and filling of the vascular defect can take place in a very controlled manner. When the vascular defect is completely filled with the Onyx polymer cast, the delivery catheter is removed. We believe our randomized clinical trial revealed that Onyx was at least as effective as acrylic-based glue in filling aneurysms, had a better percentage reduction in AVMs and resulted in the use of fewer coils. In addition to providing a controlled and measured delivery, other benefits of Onyx include the soft malleable cast for ease of surgical resection and enhanced radiopacity for bright visualization of material.

In April of 2007, we received Humanitarian Device Exemption, or HDE, approval from the FDA for our Onyx HD 500 Liquid Embolic System for the treatment of intracranial aneurysms. This approval allows us to commercialize our Onyx Liquid Embolic System to a population of patients with wide-necked cerebral aneurysms. The approval is limited to saccular, sidewall aneurysms with a dome to neck ratio less than 2 millimeters that are not amenable to treatment with surgical clipping.

Flow Directed and Other Micro Catheters

We market several micro catheters that are intended to allow access to, and treatment in, difficult-to-reach anatomical locations such as the remote vessels in the brain or other challenging vascular structures. In addition to their use with our embolic coils and liquid embolics, these products are compatible with, and are often used with, our competitors' products.

UltraFlow and Marathon Flow Directed Micro Catheters. The UltraFlow Flow Directed Micro Catheter and Marathon Flow Directed Micro Catheter are intended to access the peripheral and neuro vasculature for the

controlled selective infusion of physician-specified therapeutic agents, such as embolization materials and of diagnostic materials, such as contrast media. The UltraFlow micro catheter is specifically designed to enable access to distal locations and to allow super-selective vessel positioning. The Marathon is an improved flow directed micro catheter that contains both a nitinol braid and a stainless steel helical wire, which improves navigability while retaining pushability and tip softness. We believe that both the UltraFlow and Marathon micro catheters provide excellent trackability over a wire.

Echelon and Pre-shaped Echelon Micro Catheters. Using a unique blend of materials and construction, our Echelon family of over-the-wire micro catheters provide what we believe to be one of the largest inner channels in its class while still enabling the physician to access difficult anatomy and deliver a wide range of coils. The pre-shaped Echelon catheter represents a key line extension for our Echelon family of products, and offers improved navigation, deliverability and stability.

Other Micro Catheters. We also market several other micro catheters, including the Rebar Reinforced Micro Catheter which is designed to deliver a wide variety of pharmacologic, diagnostic and therapeutic agents, including detachable coils and the Onyx Liquid Embolic System, and the Nautica Micro Catheter, which is an over-the-wire micro catheter designed to deliver detachable coils. In addition, we have recently developed the Apollo microcatheter. This unique microcatheter is specially designed with a detachable tip for the delivery of the Onyx Liquid Embolic System.

Occlusion Balloon Systems

HyperForm and HyperGlide Occlusion Balloon Systems. Our HyperForm and HyperGlide Occlusion Balloon families are highly flexible balloons designed for use in blood vessels where temporary occlusion is desired. They are useful in selectively stopping or controlling blood flow, and are capable of accessing small diameter and tortuous vessels. Accordingly, they may be used to control blood flow to remote sites to allow for embolization treatment of vascular abnormalities such as aneurysms.

Guidewires

Hydrophilic Guidewires. Our portfolio of neurovascular guidewires includes the Mirage Hydrophilic Guidewire. This guidewire is designed for precise torque control and is compatible with several sizes of flow-directed and over-the-wire micro catheters. It assists the physician in micro catheter navigation and remote vessel access while providing a flexible and shapeable tip. Its durable coating allows it to glide through tortuous vasculature. Other hydrophilic guidewires include the SilverSpeed, Meridian, X-Pedion and the X-Celerator.

Neuro Stents

Solitaire AB Neck Bridging Device. Stenting is of increasing importance in the aneurysm and ischemic stroke markets. The Solitaire is a self-expanding nitinol stent, for use in bridging the neck of aneurysms to facilitate more secure coil placement. The Solitaire AB device is fully retrievable before detachment, allowing for more precise placement and if required, replacement of the stent is possible. Solitaire AB is available in our international markets.

Solitaire FR Revascularization Device. In July of 2009, we received a CE mark for the neurovascular use of the Solitaire FR Revascularization Device. We have initiated commercialization of the Solitaire platform outside the United States. Solitaire FR is used to immediately restore blood flow and assist in the removal of clot burden and with intracranial stenotic disease where vessels within the brain become narrowed. Solitaire FR products are fully retrievable, allowing for more precise placement and if required, replacement of the stent is possible.

Retrieval Devices

Endovascular retrieval devices are used in intravascular foreign body retrieval procedures. Examples of foreign objects that require retrieval include misplaced coils, broken catheter or guidewire tips, as well as stents that are dislodged from their delivery system and carried downstream.

Alligator Retrieval Device. Our Alligator Retrieval Device is a dedicated microforceps which allows intravascular access and retrieval of foreign objects. The Alligator Retrieval Device consists of four small microprecision grasping arms mounted on a flexible microguidewire and is used with a standard 0.21 mm microcatheter. Once the system is advanced adjacent to the foreign body, the microguidewire is held in place and its atraumatic gripping arms are deployed by withdrawing the microcatheter. The Alligator Retrieval Device has been specifically designed and indicated for use in the peripheral and neurovasculature for foreign body retrieval.

Sales, Marketing and Distribution

Structure and Strategy

We have dedicated substantial resources to establish a direct sales capability in the United States, Canada, Europe, Australia and other countries as well as establishing distribution networks in selected international markets. We believe our global presence enables us to embrace and capitalize on the growing market for endovascular devices that exists outside of the United States. In addition, our global strategy allows us to commercialize technologies internationally while pursuing regulatory approval in the United States, increasing near-term sales and helping us refine our commercialization strategies in anticipation of product launches in the United States. Individuals in our sales organization generally have substantial medical device experience and are responsible for marketing our products directly to a variety of specialists engaged in endovascular therapies. Our direct sales representatives provided 84% and 86% of our net sales in 2009 and 2008, respectively, with the balance generated by independent distributors who represent us in certain international markets.

As of December 31, 2009, our global endovascular marketing team was comprised of approximately 54 individuals covering product management, corporate communications and education and training. We devote significant resources to training and educating physicians in the use and benefits of our products. In the United States, we instruct our employees, including our sales professionals, not to discuss the use of our products outside of the FDA-approved indication. If unsolicited questions are posed by physicians, we inform them of the approved use of our products. Although we do not promote or market our products for off-label uses, physicians may choose to use our products as they see fit, including outside of the FDA-approved applications. For example, although our stent products are approved in the United States for use in the biliary duct, as are most competing peripheral stent systems in the United States, some physicians choose to use the stents in peripheral vessels. If the FDA concludes, however, that we promote our device for such off-label uses or that our promotional activities otherwise fail to comply with the FDA's regulations or guidelines, we may be subject to warning letters from, or other enforcement action by, the FDA or the U.S. Department of Justice.

United States

As of December 31, 2009, we had 114 direct sales representatives selling our peripheral vascular products and 25 direct sales representatives selling our neurovascular products in the United States. Our U.S. sales force is organized by geographic sales territories, and each territory is managed by a district sales manager, or direct sales representative, who acts as the primary customer contact. Our regional sales managers supervise the district sales managers and also focus on maintaining key customer relationships.

During 2009, we replaced several U.S. peripheral vascular territory and referral manager positions with several newly created SilverHawk specialist positions. As of December 31, 2009, we had 36 of the "Hawk Specialists". These "Hawk Specialists" partner with each of our regions to drive focused selling and clinical case support for our plaque excision business.

In August of 2007, we were awarded three, three-year contracts by Novation, the health care contracting and services company of VHA Inc. and the University HealthSystem Consortium covering our peripheral interventional, thrombus management and neuro interventional products. In March of 2007, we were awarded a single-source, new technology agreement by Novation for our Onyx Liquid Embolic System. In January of 2009, we were awarded a one-year contract by Premier, a healthcare purchasing network, covering our self-expanding and balloon-expandable stent line. All of these group purchasing organization contracts are up for renewal during 2010.

Europe, Canada and Australia

Our direct selling organization in Europe has a presence in Austria, Belgium, Denmark, Finland, France, Germany, Italy, Luxembourg, the Netherlands, Norway, Poland, Spain, Sweden, Switzerland and the United Kingdom. As of December 31, 2009, our European sales team had 67 direct sales representatives, including 38 selling our peripheral vascular products, 24 selling our neurovascular products and five selling both.

We also sell our products in Canada and Australia through a four and one person direct sales force, respectively, as of December 31, 2009.

Other International

In the major markets of Asia Pacific, Latin America, Eastern Europe and the Middle East, we sell our products through distributors. In addition to sales, these distributors are involved in product launch planning, education and training, physician support and clinical trial management. Through dedicated distributors and several sales managers and support professionals, we have a sales presence in all major other international markets, including Brazil, Argentina, Singapore, Japan and China.

Manufacturing

We currently have a manufacturing facility located in Plymouth, Minnesota, at which we manufacture most of our peripheral vascular products, and a manufacturing facility located in Irvine, California, at which we manufacture most of our neurovascular products and a few of our peripheral vascular products. As a result of our acquisition of Chestnut, we also have a manufacturing facility in Menlo Park, California, where we manufacture our flow diversion and foreign retrieval neurovascular devices. In order to streamline our operations and improve efficiencies, we relocated the sales, manufacturing and research and development activities performed in our former Redwood City, California facility to our existing facilities located in Plymouth and Irvine. We manufacture our products at facilities in a controlled environment and have implemented quality control systems as part of our manufacturing processes. We believe we are in material compliance with FDA Quality System Regulations for medical devices, with ISO 9001 quality standards and applicable medical device directives promulgated by the European Union and Canada and ISO/EN 13485, which facilitates entry of our products into the European Union and Canada. The FDA and European Union competent authorities have recently inspected our manufacturing facilities and found no significant issues. We rely on independent manufacturers for certain product components and processes. On an ongoing basis, to improve yields and cycle times, we are investing in developing internal capabilities and applying lean manufacturing concepts at all of our manufacturing facilities.

Research and Development

Our research efforts are directed toward the development of new endovascular products that expand the therapeutic alternatives available to physicians, and improvements to and extensions of our existing product offerings. Our product development process incorporates teams organized around each of our core technologies, with each team having representatives from research and development, marketing, regulatory, quality, clinical affairs and manufacturing. Consultants are used when additional specialized expertise is required.

Our research and development team has a demonstrated record of new product initiatives and significant product improvements. Specific product improvement initiatives have included:

- broadening acquired technologies in order to address a larger share of the target markets;
- incorporating important features which we believe appeal to the physicians who use our products; and
- leveraging core technologies to develop new product platforms and enter new markets.

Our research and development expenditures were $49.1 million in 2009, compared with $48.8 million and $48.4 million in 2008 and 2007, respectively. Our research and development costs include traditional research and development expenses as well as the cost of our clinical studies.

Clinical Studies

We support many of our new product initiatives with clinical studies in order to obtain regulatory approval and new indications and provide demonstrated medical evidence and best practices on our technologies. The goal of a clinical trial is to meet the primary endpoints, which measures the clinical effectiveness and safety of a device and is the basis for FDA or other regulatory approvals. Primary endpoints for clinical trials are selected based on the intended benefit of the medical device. Although clinical trial endpoints are measurements at an individual patient level, the results are extrapolated to an entire population of patients based on clinical similarities to patients in the clinical trials.

We continually evaluate the potential financial benefits and costs of our clinical trials and the products being evaluated in them. If we determine that the costs associated with attaining regulatory approval of a product or new indication exceed the potential financial benefits of that product or new indication, or if the projected development timeline is inconsistent with our investment horizon, we may choose to stop a clinical trial and/or the development of a product.

The following tables summarize our key current and planned clinical trials.

Peripheral Stent Clinical Trials:

Trial	Product	Study Design	Status
PROVE-IT (Global)	EverFlex stent, Protégé GPS stent and Visi-Pro stent	Prospective, multi-center, global study to evaluate the safety and effectiveness of primary stenting for the treatment of iliac lesions Protocol currently under development	Enrollment anticipated to begin in the second half of 2010
DURABILITY II (Global)	EverFlex Stent	Prospective, multi-center, non-randomized study to evaluate the safety and effectiveness of the primary stenting compared to PTA performance goals for the treatment of SFA lesions Primary safety endpoint of 30-day major adverse event Primary effectiveness endpoint of 12-month patency by duplex	Enrollment and follow-up continuing

Plaque Excision Clinical Trials:

Trial	Product	Study Design	Status
DEFINITIVE Ca^{++} (U.S.)	RockHawk and TurboHawk Peripheral Calcium Tip Plaque Excision System with SpiderFX Embolic Protection Device	U.S. IDE, prospective, multi-center, non-randomized, single-arm study to evaluate the safety and effectiveness of the SilverHawk with Calcium Tip (i.e. RockHawk/TurboHawk)	Enrollment and follow-up continuing

Trial	Product	Study Design	Status
		Plaque Excision System when used in conjunction with the SpiderFX Embolic Protection Device in the treatment of moderate to heavily calcified lesions in the femoropopliteal arteries	
DEFINITIVE LE (Global)	SilverHawk and TurboHawk	Prospective, multi-center, non-randomized, single-arm study to evaluate the intermediate and long-term effectiveness of stand-alone SilverHawk/TurboHawk Plaque Excision Catheter for endovascular treatment of peripheral arterial disease in femoropopliteal or tibial-peroneal arteries.	Enrollment and follow up continuing
DEFINITIVE AR (Europe)	SilverHawk, TurboHawk and drug coated balloon	Treatment of femoropopliteal arteries Protocol currently under development	Enrollment anticipated to begin in the second half of 2010

Carotid Clinical Trials:

Trial	Product	Study Design	Status
CREATE PAS (U.S)	Protégé GPS Stent with an ev3 Embolic Protection Device	Prospective, multi-center single-arm confirmatory post-approval study Primary endpoint of major adverse cardiovascular and cerebral event rate in broad use at investigative centers	Enrollment and follow-up continuing

Neuro Clinical Trials:

Trial	Product	Study Design	Status
SWIFT -- Solitaire With the Intention For Thrombectomy Trial (U.S./Europe)	Solitaire FR Stent	U.S. IDE, prospective, randomized, 2-arm, multi-center study Goal: FDA approval	Enrollment anticipated to begin first quarter 2010
RACER -- Axium Post Market and Expanded Approvals Trial (U.S.)	Axium Coil	Prospective, single-arm, multi-center study Goal: Scientific clinical data for publications and possible outside the United States regulatory submissions	Enrollment completed and follow-up continuing

Trial	Product	Study Design	Status
PUFS -- Pipeline for Uncoilable or Failed Aneurysms (U.S.)	Pipeline Embolization Device	U.S. IDE, non-randomized, single-arm study using historical control 6-mo safety (death and ipsilateral stroke) and effectiveness (complete occlusion –no recurrence) endpoints Goal: Pre-market approval for large aneurysms	Enrollment completed and follow-up continuing
COCOA -- Complete Occlusion of Coilable Aneurysms (U.S.)	Pipeline Embolization Device	U.S. IDE, prospective, randomized 2-arm study (Pipeline Embolization Device vs coils) 6-mo safety (death and ipsilateral stroke) and effectiveness (complete occlusion –no recurrence) endpoints Goal: Pre-market approval for smaller aneurysms (≤10 mm)	Enrollment and follow-up continuing

Government Regulation

United States

Our products are regulated in the United States as medical devices by the FDA and other regulatory bodies. FDA regulations govern, among other things, the following activities that we perform:

- product design, development and manufacture;
- conduct of clinical trials;
- product safety, testing, labeling and storage;
- submission to FDA for pre-marketing clearance or approval;
- record keeping procedures;
- product marketing, sales and distribution; and
- post-marketing surveillance, reporting of deaths or serious injuries and medical device reporting.

Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either prior 510(k) clearance or prior pre-market approval from the FDA. The FDA classifies medical devices into one of three classes, depending on the degree of risk associated with each medical device and the extent of controls that are needed to ensure safety and effectiveness. Devices deemed to pose the least risk are placed in Class I. Intermediate risk devices are placed in class II, which, in most instances, requires the manufacturer to submit to the FDA a pre-market notification requesting authorization for commercial distribution, known as "510(k) clearance." A 510(k) clearance is provided when the device is deemed "substantially equivalent" to a predicate device, i.e. one that was previously cleared by the FDA. Class II 510(k) devices may be subjected to special controls

such as performance standards, guidance documents specific to the device or post-market surveillance. Most Class I and some low-risk Class II devices are exempted from this 510(k) requirement. Class III devices are deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed to be not substantially equivalent to previously cleared 510(k) devices. In general, a Class III device cannot be marketed in the United States unless the FDA approves the device after submission of a pre-market approval application.

510(k) Clearance Pathway. When we are required to obtain 510(k) clearance for devices that we wish to market, we must submit a pre-market notification to the FDA demonstrating that the device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 (or to a pre-1976 class III device for which the FDA has not yet called for the submission of pre-market approval applications). In essence, the basic safety and effectiveness of the predicate device supports clearance of the new product. The 510(k) applicant is typically only required to demonstrate substantial equivalence to the predicate device. The FDA attempts to respond to a 510(k) pre-market notification within 90 days of submission of the notification, but the response may be a request for additional information or data, sometimes including clinical data. As a practical matter, pre-market clearance can take significantly longer than 90 days, including up to one year or more.

After a device receives 510(k) clearance for a specific intended use, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, will require a Special 510(k) clearance, a new 510(k) clearance, or could require pre-market approval. In addition, new "claims" not found in the cleared labeling for the device can be deemed a new intended use and can trigger the requirement for a new 510(k). The FDA requires each manufacturer to make its own determination whether a change requires a new submission, but the FDA can review and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination that a new clearance or approval is not required for a particular modification, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or pre-market approval is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

The FDA recently has requested that the Institute of Medicine perform a study on whether legislative, regulatory or administrative changes are needed to the FDA's 510(k) process. The Institute of Medicine report is due in 2011. The FDA also announced an internal working group to evaluate and improve the consistency of FDA decision making in the clearance process, and recently released an internal report in which FDA officials questioned the 510(k) process in general. Various committees of the U.S. Congress also have indicated that they may consider investigating the FDA's 510(k) process.

Pre-Market Approval Pathway. A pre-market approval, or PMA, application must be submitted if the device cannot be cleared through the 510(k) process. The PMA process is much more demanding than the 510(k) pre-market notification process. A PMA application must be supported by extensive data and information including, but not limited to, technical, pre-clinical, clinical, manufacturing and labeling, to establish to the FDA's satisfaction the safety and effectiveness of the device.

If the FDA determines that a PMA application is complete, the FDA can accept the application and begin an in-depth review of the submitted information. The FDA, by statute and regulation, has 180 days to review an accepted PMA application, although the review generally occurs over a significantly longer period of time, and can take up to several years. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will typically conduct a pre-approval inspection of the manufacturing facility to ensure compliance with the Quality System Regulations. New PMA applications or Supplemental PMA applications are required for significant modifications to the manufacturing process, labeling, use and design of a device that is approved through the PMA process. PMA Supplements often require submission of the same type of information as a pre-market approval, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel.

Clinical Trials. A clinical trial is almost always required to support an original PMA application. Historically, clinical trials were infrequently required for a 510(k) clearance. Today, information from clinical trials is increasingly required to support 510(k) clearance. Clinical trials for a "significant risk" device require submission of an application for an investigational device exemption, or IDE, to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Clinical trials for a significant risk device may begin once the application is approved by the FDA. In addition, the Institutional Review Board, or IRB, overseeing the clinical trial at each clinical site must approve the clinical study and an executed Investigator Agreement must be in place prior to patient enrollment at the site. If the product is deemed a "non-significant risk" device under FDA regulations, only the abbreviated IDE requirements apply. Clinical trials must be monitored by the study sponsor and are subject to extensive record keeping and reporting requirements. Clinical trials must be conducted in accordance with applicable regulations and policies including, but not limited to, the FDA's good clinical practice, or GCP, requirements.

For the protection of human subjects in a clinical trial, the FDA and IRB require patients to be informed of both the benefits and risks of the investigational device and the treatment and/or procedure. This is called "informed consent" and the subject must sign a written document stating that he or she understands the risks and consent to be involved in the trial. In addition, study subjects are protected by the Health Insurance Portability and Accountability Act of 1996, or HIPAA. The study subject is asked to provide authorization to the clinical trial site and manufacturer so they can collect and use certain personally identifiable health information about the patient from the clinical trial for use in seeking FDA approval and any other specified uses outlined in the HIPAA authorization.

The study sponsor, the FDA or the IRB at each site at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. The FDA may inspect a clinical investigation and, if it determines that the study sponsor failed to comply with the FDA regulations governing clinical investigations, it may issue a warning letter to or take other enforcement action against the study sponsor, the clinical investigation site or the principal investigator. There is always a risk that the results of clinical testing may not be sufficient to obtain approval of the product.

De Novo Pathway. There is another pathway that may be used to market a medical device. This is called the "de novo" clearance which was established by the Food and Drug Administration Act of 1997, known as "FDAMA." The de novo pathway is for products that do not qualify for 510(k) clearance because there is no predicate upon which to claim substantial equivalence. If the FDA, after reviewing a 510(k) application, sends a "not substantially equivalent" or "NSE" letter to a manufacturer, that manufacturer can request a de novo clearance. This is done by making the request in writing within 30 days of receipt of the NSE letter. The FDA then has 60 days to review the 510(k) application de novo and decide whether to clear the product. If the product is cleared via this pathway, the FDA publishes the clearance in the Federal Register and the cleared product receives a 510(k) and becomes a predicate for future products. If the product fails to be cleared by this pathway, it can only be approved via the PMA pathway.

Humanitarian Device Exemptions. A Humanitarian Device Exemption, or HDE, authorizes the marketing of a humanitarian use device for a limited patient population. An HDE designation is based on the FDA's determination that a device is intended for the treatment and diagnosis of a disease or condition that affects fewer than 4,000 individuals in the United States per year. Once an HDE designation has been obtained, an applicant may seek marketing approval under an HDE. While the HDE application is similar to a pre-market approval application and requires a demonstration of safety, unlike a pre-market approval application, an HDE does not require a demonstration of effectiveness. Certain limitations apply to the sale and use of devices under an HDE.

Post-Marketing Requirements. After a device is approved for marketing, numerous regulatory requirements apply, including:

- Quality System Regulations, which require manufacturers to follow design, testing, control, documentation and other quality assurance procedures during the manufacturing process;

- labeling, advertising and promotion regulations, which govern product labels and labeling, prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling and 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 it were to recur; and

- notices of correction or removal, and recall regulations.

The advertising and promotion of "restricted" devices, i.e. those requiring a prescription, are regulated by the FDA. The advertising and promotion of all other devices are regulated by the Federal Trade Commission, or FTC, and by state regulatory and enforcement authorities. But the FDA often asserts itself in those situations as well because it has continuing authority over the labeling of a product that can be affected by the way it is advertised. Recently, some promotional activities for FDA-regulated products have been the subject of enforcement actions brought under health care reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act, competitors and others can initiate litigation relating to advertising claims.

We have registered with the FDA as a medical device manufacturer. Compliance with regulatory requirements is tested through periodic, pre-scheduled or unannounced "for cause" facility inspections by the FDA and these inspections may include the manufacturing facilities of our subcontractors. "For cause" inspections are generally conducted when FDA suspects the manufacturer is in serious violations of current Good Manufacturing Practice regulations that have not been remedied. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters, fines, injunctions, and civil penalties;

- repair, replacement, refund, recall or seizure of our products;

- operating restrictions, partial suspension or total shutdown of production;

- refusing a request for 510(k) clearance or pre-market approval of new products;

- withdrawing 510(k) clearance or pre-market approvals that are already granted; and

- criminal prosecution.

International

We conduct sales and marketing activities in various foreign countries. Most major markets have different levels of regulatory requirements for medical devices. Modifications to the approved products often require a new regulatory submission in major markets. The regulatory requirements, and the review times, vary significantly from country to country. Our products also can be marketed in several other countries that have minimal requirements for medical devices. Frequently, we obtain regulatory approval for medical devices in foreign countries first because their regulatory approval is faster and simpler than the FDA. However, as a general matter, foreign regulatory requirements are becoming increasingly stringent.

In the European Union, a single harmonized regulatory approval process has been created according to the New Approach regulations. Devices granted market access can be recognized by the European Conformance (CE) Mark,

under the European Medical Devices Directive, 93/42/EEC as amended 2007/47/EC. Medical devices for human use that receive CE designation in one Member State can be sold in all EU Member States. In the European Union, the European Community uses third parties called "notified bodies," to review products for approval. They are private, independent third parties certified by the "competent authorities" (or Member State representative) to review and approve medical device applications and grant products labeled with the CE Mark to be sold in the European Union. The competent authorities designate and accredit and otherwise oversee the notified bodies they accredit. To obtain a CE Mark in the European Union, defined products must meet minimum standards of safety and quality and then comply with one or more of a selection of conformity routes. The European Community has regulations similar to that of the FDA for pre-market review and approval of medical devices, clinical investigations, and adverse events. Certification of our quality system for product distribution in the European Union is performed by Société Générale de Surveillance (SGS), located in the United Kingdom.

In China, medical devices must be approved by the China State Food and Drug Administration (SFDA) prior to importation and commercial sale. In addition, medical devices must be approved in the country of origin before the registration process can begin in China and as such we must first obtain FDA approval before applying for market approval in China. China requires sample product testing at SFDA Accredited Laboratories for most products. Fees and testing requirements depend on the risk category of the device being registered. Initial registration of medical devices takes approximately 18 to 24 months to obtain marketing approval. Licenses are issued in the name of the device manufacturer for a period of four years. A local after-sale service provider must be located in China and is designated in the registration process. After the device is registered with the health authorities, manufacturers can sell product through multiple distributors. Medical devices imported into China must be labeled in Chinese and include the registration number, product features and the scope of usage for the product. New regulations went into effect on December 30, 2008 which require medical device manufacturers and distributors to include the device shelf life duration on the product labeling as well as adverse event reporting to Chinese authorities. The new regulation has tight reporting deadlines and does not follow the Global Harmonization Task Force recommendations for reporting adverse events. In addition, the Chinese Government has recently suggested that they will require clinical data collected from clinical sites within China prior to approval of new medical devices. If these requirements go into effect, the approval cycle for the market release of new medical devices in China will be significantly increased.

In Japan, medical devices must be approved prior to importation and commercial sale by the Ministry of Health, Labor and Welfare, or MHLW. Manufacturers of medical devices outside of Japan that do not operate through a Japanese entity are required to use a contractually bound in-country caretaker to submit an application for device approval to the MHLW. The MHLW evaluates each device for safety and efficacy. As part of the approval process, the MHLW may require that the product be tested in Japanese laboratories. The approval process ranges in length and certain medical devices may require a longer review period for approval. Once approved, the manufacturer may import the device into Japan for sale by the manufacturer's contractually bound office, importer or distributor. After a device is approved for importation and commercial sale in Japan, the MHLW continues to monitor sales of approved products for compliance with labeling regulations, which prohibit promotion of devices for unapproved uses, and reporting regulations, which require reporting of product malfunctions, including serious injury or death caused by any approved device.

In addition to MHLW oversight, the regulation of medical devices in Japan is also governed by the Japanese Pharmaceutical Affairs Law, or PAL. PAL was substantially revised in July of 2002, and the new provisions were implemented in stages through April of 2005. The revised law changes class categorizations of medical devices in relation to risk, introduces a third-party certification system, strengthens safety countermeasures for biologically derived products and reinforces safety countermeasures at the time of resale or rental.

You should read the information set forth under "Item 1A. Risk Factors—Our products and our product development and marketing activities are subject to extensive regulation as a result of which we may not be able to obtain required regulatory approvals for our products in a cost-effective manner or at all, which could adversely affect our business and operating results."

Fraud and Abuse Laws

A variety of U.S. federal and state laws apply to the sale, marketing and promotion of medical devices that are paid for, directly or indirectly, by federal or state health care programs, such as Medicare, Medicaid and TRICARE. The restrictions imposed by these laws are in addition to those imposed by the FDA, FTC and corresponding state agencies. Some of these laws significantly restrict or prohibit certain types of sales, marketing and promotional activities by medical device manufacturers. Violation of these laws can result in significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties and exclusion or debarment from federal and state health care and other programs.

The principal federal laws include: (1) the Anti-Kickback Statute, which prohibits offers to pay or receive remuneration of any kind for the purpose of inducing or rewarding referrals of items of services reimbursable by a federal healthcare program; (2) the False Claims Act, which prohibits the submission of false or otherwise improper claims for payment to a federally-funded health care program; (3) the Stark law, which prohibits physicians from referring Medicare or Medicaid patients to an entity for the provision of certain designated health services if the physician (or a member of the physician's immediate family) has a financial relationship with that entity, and (4) HIPAA, which prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private payors, and falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

Privacy and Security

HIPAA requires certain "covered entities" to comply with established standards regarding the privacy and security of protected health information, or PHI, and to use standardized code sets when conducting certain electronic transactions. HIPAA further requires that covered entities enter into agreements meeting certain regulatory requirements with their "business associates," which effectively obligate the business associates to safeguard the covered entity's protected health information against improper use and disclosure. While not directly regulated by HIPAA, a business associate may face significant contractual liability pursuant to such an agreement if the business associate breaches the agreement or causes the covered entity to fail to comply with HIPAA. The company often has possession of PHI in situations such as where clinical studies are conducted or sales representatives are asked by a surgeon to be in a surgical suite to provide technical advice on a device during surgery. HIPAA does not require a business associate agreement to be signed in these circumstances. In the course of our business operations, we may become the business associate of one or more covered entities. Accordingly, we may incur compliance related costs in meeting HIPAA-related obligations under business associates agreements to which we become a party.

The European Union has its own privacy standards to which we are subject. Recognizing that our business continues to expand internationally, we intend to review our compliance with these standards and update or enhance our procedures and practices.

Third Party Reimbursement

In the United States, as well as in foreign countries, government-funded or private insurance programs, commonly known as third-party payors, pay the cost of a significant portion of a patient's medical expenses. A uniform policy of reimbursement does not exist among all these payors. Therefore, reimbursement can be quite different from payor to payor. We believe that reimbursement is an important factor in the success of any medical device. Consequently, we seek to obtain reimbursement for all of our products.

Reimbursement in the United States depends on our ability to obtain FDA clearances and approvals to market these products. Reimbursement also depends on our ability to demonstrate the short-term and long-term clinical and cost-effectiveness of our products from the results we obtain from clinical experience and formal clinical trials. We present these results at major scientific and medical meetings and publish them in respected, peer-reviewed medical journals.

The United States Center for Medicare and Medicaid Services, or CMS, sets reimbursement policy for the Medicare program in the United States. CMS policies may alter coverage and payment for vascular device technologies in the future. These changes may occur as the result of National Coverage Decisions issued by CMS headquarters or as the result of local or regional coverage decisions by contractors under contract with CMS to review and make coverage and payment decisions. This administration has a national coverage policy, which provides for the diagnosis and treatment of vascular disease in Medicare beneficiaries.

All third-party reimbursement programs, whether government funded or insured commercially, whether inside the United States or outside, are developing increasingly sophisticated methods of controlling health care costs through prospective reimbursement and capitation programs, group purchasing, redesign of benefits, second opinions required prior to major surgery, careful review of bills and exploration of more cost-effective methods of delivering health care. These types of programs and legislative changes to reimbursement policies could potentially limit the amount which health care providers may be willing to pay for medical devices.

International Trade

The sale and shipment of our products and services across international borders, as well as the purchase of components and products from international sources, subject us to extensive governmental trade regulations. A variety of laws and regulations, both in the United States and in the countries in which we transact business, apply to the sale, shipment and provision of goods, services and technology across international borders, which include import and export laws and regulations, anti-boycott laws and anti-bribery laws. Because we are subject to extensive regulations in the countries in which we operate, we are subject to the risk that laws and regulations could change in a way that would expose us to additional costs, penalties or liabilities.

Environmental

We are subject to various environmental health and safety laws, directives and regulations both in the U.S. and abroad. Our operations, like those of other medical device companies, involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We do not expect that compliance with environmental protection laws will have a material impact on our capital expenditures, earnings or competitive position. Given the scope and nature of these laws, however, there can be no assurance that environmental laws will not have a material impact on our results of operations. Our leased Redwood City facility sits on property formerly occupied by Rohm & Haas and Occidental Chemical Company and contains residual contamination in soil and groundwater from these past industrial operations. Rohm & Haas and Occidental Chemical Company previously performed soil remediation on the property under the supervision of the California Regional Water Quality Control Board. Rohm & Haas has indemnified the owner of the facility and its tenants against costs associated with the residual contamination.

Competition

The markets in which we compete are highly competitive, subject to change and impacted by new product introductions and other activities of industry participants. We compete primarily on the basis of our ability to treat vascular diseases and disorders safely and effectively. Our success can be impacted by the ease and predictability of product use, adequate third-party reimbursement, brand name recognition and cost. We believe we compete favorably with respect to these factors, although there can be no assurance that we will be able to continue to do so in the future or that new products that perform better than those we offer will not be introduced. Because of the size of the peripheral vascular and neurovascular markets, competitors and potential competitors have historically dedicated and will continue to dedicate significant resources to aggressively promote their products and develop new and improved products.

Our competitors range from small start-up companies to much larger companies. The larger companies with which we compete include Abbott Laboratories, Boston Scientific Corporation, Cook Incorporated, Cordis Corporation (a Johnson & Johnson company), Covidien Public Limited Company, C.R Bard Inc., Medtronic, Inc., Terumo/MicroVention, Inc. and W.L. Gore & Associates, Inc. All of these larger companies 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 and have established

reputations and relationships with our target customers, as well as worldwide distribution channels that are more effective than ours. We also compete, however, and in some cases even more intensely, with smaller manufacturers. In the peripheral vascular market, we compete against, among others: MEDRAD, Inc., Cardiovascular Systems, Inc., Pathway Medical Technologies, Inc., Idev Technologies, Inc., Invatec s.r.l. (which recently agreed to be acquired by Medtronic) and Spectranetics Corporation. In the neurovascular market, we compete against, among others: Balt Extrusion, Inc. and Micrus Corporation. In addition, we compete with a number of drug therapy treatments manufactured by major pharmaceutical companies, including Otsuka Pharmaceutical, the manufacturer of Pletal, and Sanofi Aventis, the manufacturer of Plavix.

Many of our physician customers like to experiment with new technologies. Within the plaque excision market, although we believe our SilverHawk plaque excision products compete favorably against other competing technologies, surgical procedures and pharmaceutical products, recently introduced atherectomy products have adversely affected and may continue to adversely affect future sales of our plaque excision products, at least in the short term while physician customers experiment with such new products. Within the peripheral vascular stent market, we may experience increased competition from C. R. Bard Inc. which announced in 2009 that the FDA approved certain of its stents for use in the superficial femoral arteries and proximal popliteal arteries, if physicians decide to use C. R. Bard Inc.'s FDA cleared stents rather than our stents off-label.

We believe our continued success depends on our ability to:

- continue to innovate and maintain scientifically advanced technology, being responsive to the changing needs of our diverse customer base;
- apply our technology across disease states, product lines and markets;
- attract and retain skilled personnel;
- obtain and maintain regulatory approvals; and
- cost-effectively manufacture and successfully market our products.

Employees

As of December 31, 2009, we had approximately 1,350 employees worldwide. From time to time, we also employ independent contractors to support our operations.

Intellectual Property Rights

We believe that in order to maintain a competitive advantage in the marketplace, we must develop and maintain protection of the proprietary aspects of our technology. We rely on a combination of patent, trademark, trade secret, copyright and other intellectual property rights and measures to aggressively protect our intellectual property that we consider important to our business.

We have developed a patent portfolio internally, as well as through acquisitions, that cover many aspects of our product offerings. As of December 31, 2009, we had 498 issued patents and over 475 pending patent applications in the United States, Europe, Japan, Australia, Canada and other countries throughout the world. The expiration dates of our material patents range from 2010 to 2026. Additionally, we own or have rights to material trademarks or trade names that we use in conjunction with the sale of our products.

We continue to invest in internal research and development of concepts and product ideas for the peripheral vascular and neurovascular markets. This, combined with our patent program, has increased the number of patentable concepts we generate. We also continually evaluate the potential financial benefits and costs of the development of our products and maintenance of our intellectual property rights. If we determine that the costs associated with developing our products and/or maintaining our intellectual property rights exceed the potential financial benefits of

that product or right, or if the projected development timeline is inconsistent with our investment horizon, we may choose to stop development of a product and sell the underlying intellectual property rights.

We manufacture and market our products both under our own patents and under license agreements. While we believe that our patents are valuable, our knowledge and experience, our creative product development teams and marketing staff, and our confidential information regarding manufacturing processes, materials and product design have been equally important in maintaining our proprietary product offering. To protect that value, we have instituted policies and procedures, as well as a requirement that, as a condition of employment, all employees execute a confidentiality agreement relating to proprietary information and the assignment of intellectual property rights to us.

We also rely on unpatented proprietary technology. We seek to protect our trade secrets and proprietary know-how, in part, with confidentiality agreements with consultants, vendors and employees.

Despite measures we have taken to protect our intellectual property, we cannot be certain that such measures will be successful or that unauthorized parties will not copy aspects of our products or obtain and use information that we regard as proprietary. In such instances, we may not have adequate remedies for any such breach. These and other risks related to our intellectual property rights are described in more detail under "Item 1A. Risk Factors. We may be subject to intellectual property litigation and infringement claims, which could cause us to incur liabilities and costs, prevent us from selling our products, cause us to redesign our products, require us to enter into costly license agreements and result in other adverse consequences" and "Item 1A. Risk Factors—If our patents and other intellectual property rights do not adequately protect our products, we may lose market share to our competitors, which would harm our business."

Forward-Looking Statements

This annual report on Form 10-K contains and incorporates by reference not only historical information, but also forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the safe harbor created by those sections. In addition, we or others on our behalf may make forward-looking statements from time to time in oral presentations, including telephone conferences and/or web casts open to the public, in press releases or reports, on our Internet web site or otherwise. All statements other than statements of historical facts included in this report that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements including, in particular, the statements about our plans, objectives, strategies and prospects regarding, among other things, our financial condition, results of operations and business. We have identified some of these forward-looking statements with words like "believe," "may," "could," "would," "might," "forecast," "possible," "potential," "project," "will," "should," "expect," "intend," "plan," "predict," "anticipate," "estimate," "approximate" "outlook" or "continue" or the negative of these words or other words and terms of similar meaning or the use of future dates. These forward-looking statements may be contained in the notes to our consolidated financial statements and elsewhere in this report, including under the heading "Part II. Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations."

Forward-looking statements involve risks and uncertainties. These uncertainties include factors that affect all businesses as well as matters specific to us. Some of the factors known to us that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements are described under the heading "Item 1A. Risk Factors" below.

We wish to caution readers not to place undue reliance on any forward-looking statement that speaks only as of the date made and to recognize that forward-looking statements are predictions of future results, which may not occur as anticipated. Actual results could differ materially from those anticipated in the forward-looking statements and from historical results, due to the risks and uncertainties described under the heading "Item 1A. Risk Factors" below, as well as others that we may consider immaterial or do not anticipate at this time. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. Our expectations reflected in our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties, including those described below under the heading "Item 1A. Risk Factors." The risks and uncertainties described under the heading "Item 1A. Risk

Factors" below are not exclusive and further information concerning us and our business, including factors that potentially could materially affect our financial results or condition, may emerge from time to time. We assume no obligation to update forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements. We advise you, however, to consult any further disclosures we make on related subjects in our quarterly reports on Form 10-Q and current reports on Form 8-K that we file with or furnish to the Securities and Exchange Commission.

Available Information

ev3 LLC, our predecessor company prior to our initial public offering in June 2005, was formed in September 2003. Immediately prior to the consummation of our initial public offering in June 2005, ev3 LLC merged with and into ev3 Inc., at which time ev3 Inc. became the holding company for all of ev3 LLC's subsidiaries. Our principal executive offices are located at 3033 Campus Drive, Plymouth, Minnesota 55441. Our telephone number is (763) 398-7000, and our Internet web site address is *www.ev3.net*. We are a Delaware corporation. The information contained on our web site or connected to our website is not incorporated by reference into and should not be considered part of this report.

We make available, free of charge and through our Internet web site, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to any such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. We also make available, free of charge and through our Internet web site under the Investors—Corporate Governance section, to any stockholder who requests, the charters of our board committees and our Code of Business Conduct. Requests for copies can be directed to Investor Relations at (949) 680-1375.

ITEM 1A. RISK FACTORS

The following are significant factors known to us that could materially adversely affect our business, financial condition or operating results.

Risks Related to Our Business and Industry

Despite our recent profitability, we have a history of net losses and no assurance can be provided that we will continue to remain profitable.

We had net income of $41.9 million for the year ended December 31, 2009. We recognized net income in each of our last three quarters of 2009. Although we expect to be profitable for the year ending December 31, 2010, our quarterly results are subject to substantial fluctuations and no assurance can be provided that we will be profitable for each quarter of 2010 or achieve our goal of sustained profitability. Especially in light of the current economic conditions, it is difficult to predict our future financial performance and our failure to accurately predict future financial performance may lead to volatility in the price of our common stock. Our ability to achieve our goal of sustained profitable operations will be influenced by many factors, including the level and timing of future sales and expenditures, our ability to increase net sales and decrease costs, market acceptance of our products, the results and scope of ongoing research and development projects, the volatility of changes in contingent consideration, the effect of competing technologies, market and regulatory developments and the other risks described in this section. If we do not achieve sustained profitability within expected time frames, our business and stock price will be negatively impacted.

Adverse worldwide economic conditions may continue to result in reduced procedures using our products, which would adversely affect our net sales.

We believe the adverse worldwide economic conditions during the past 18 months or so have resulted and may continue to result in reduced procedures using our products. Many of the procedures that use our products are, to some extent, elective and therefore can be deferred by patients. In the face of adverse economic conditions, patients may not be as willing to take time off from work or spend their money on deductibles and co-payments often

required in connection with the procedures that use our products. In particular, patients that have high-deductible health plans and health savings accounts and thus require the patients to incur significant out-of-pocket costs are especially more apt to defer procedures at times when cash is tight. Although the specific impact of worldwide economic conditions is difficult to measure and although we believe such conditions did not have a material adverse effect on our net sales for 2009, we are unable to predict whether continuing adverse economic conditions will impact our sales in 2010 or beyond.

Adverse worldwide economic conditions may have other adverse implications on our business, operating results and financial condition.

Beyond patient demand, adverse worldwide economic conditions, including in particular continuing tight credit and capital markets, may have other adverse implications on our business. For example, our customers' and distributors' ability to borrow money from their existing lenders or to obtain credit from other sources to purchase our products may be impaired resulting in a decrease in sales. Although we review our customers' financial condition and ability to pay on an ongoing basis and we maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments and such losses have historically been within our expectations and the provisions established, we cannot guarantee that we will continue to experience the same loss rates that we have in the past. A significant change in the liquidity or financial condition of our customers or distributors could cause unfavorable trends in our receivable collections and additional allowances may be required, which could adversely affect our operating results. In addition, adverse worldwide economic conditions may adversely impact our suppliers' ability to provide us with materials and components, which could adversely affect our business and operating results.

Finally, we believe adverse worldwide economic conditions have caused many of our hospital customers to demand purchasing our products on a consignment basis and thus purchase our products as they use them as opposed to purchasing large stocking orders from time to time. Selling products on consignment involves other risks. For example, in these consignment locations, we do not have physical possession of our products. We therefore must rely on information from our customers as well as periodic inspections by our sales personnel to determine when our products have been used. Our efforts to strengthen our monitoring and management of consigned inventory may not be adequate to meaningfully reduce the risk of inventory loss. If we are not able to effectively manage appropriate consigned inventory levels, we may suffer inventory losses which will reduce our operating results.

Disruptions in the global financial markets could impact the ability of our counterparties and others to perform their obligations to us and our ability to obtain any additional future financing if needed or desired.

Disruptions in the global financial markets, including the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States and other governments and the related liquidity crisis, considerably disrupted the credit and capital markets at the end of 2008 and have not fully recovered since then. Our credit risk consists of cash and cash equivalents, trade receivables, lending commitments and insurance relationships in the ordinary course of business. We place cash and cash equivalents with high quality financial institutions, which we monitor regularly and take action where possible to mitigate risk. We do not hold investments in auction rate securities, mortgage backed securities, collateralized debt obligations, individual corporate bonds, special investment vehicles or any other investments which were directly impacted by the worldwide financial crisis. Our insurance programs are with carriers that remain highly rated and we have no significant pending claims. However, future disruptions in the credit and capital markets could cause our counterparties and others to breach their obligations or commitments to us under our contracts with them. To date, our credit arrangement with Silicon Valley Bank remains available to us. Although we do not anticipate requiring any additional financing in the near future, in the event we needed or desired such additional financing, we may be unable to obtain it by borrowing money in the credit markets and/or raising money in the capital markets.

Our business, financial condition, results of operations and cash flows could be significantly and adversely affected if certain types of healthcare reform programs are adopted in our key markets and other administration and legislative proposals are enacted into law.

Recently, President Obama and members of Congress have proposed significant reforms to the U.S. healthcare system. Both the U.S. Senate and House of Representatives have conducted hearings about healthcare reform. The

Obama administration's fiscal year 2010 budget included proposals to limit Medicare payments, reduce drug spending and increase taxes. In addition, members of Congress have proposed a single-payer healthcare system, a government health insurance option to compete with private plans and other expanded public healthcare measures, including an excise tax on all medical devices that could require the medical device industry to contribute over $2 billion to healthcare reform each year. Various healthcare reform proposals also have emerged at the state level. We cannot predict what healthcare initiatives, if any, will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. However, an expansion in government's role in the U.S. healthcare industry may lower reimbursements for our products, reduce medical procedure volumes and adversely affect our business and results of operations, possibly materially. In addition, if an excise tax on medical devices is enacted into law, our operating results could be materially and adversely affected.

Our marketing activities are subject to regulation regarding the promotion of "off-label" uses, which restrict our ability to market our products. If we are found to have improperly promoted off-label use of our products, we may become subject to enforcement action by the FDA or the U.S. Department of Justice and/or incur significant liabilities. Any off-label use of our products also may result in injuries that could lead to product liability claims against us.

We sell a number of our products to physicians who may elect to use the products in ways that are not within the scope of the approval or clearance given by the FDA or for other than FDA-approved indications, often referred to as "off-label" use. For example, although our SilverHawk Plaque Excision System received FDA clearance for the treatment of atherosclerosis in the peripheral vasculature, off-label use of our SilverHawk outside the peripheral vasculature, in coronary and carotid arteries, has occurred, as well as off-label use of the SilverHawk for treatment of in-stent restenosis. In addition, although most of our stents received FDA clearance for the palliative treatment of malignant neoplasms in the biliary tree, off-label use of our stents occurs regularly in the peripheral arteries for the treatment of peripheral artery disease. In fact, most of our U.S. stent sales are attributable to off-label use. While off-label uses of medical devices are common and the FDA does not regulate physicians' choice of treatments, the FDA does restrict a manufacturer's communications regarding such off-label use. Such laws and regulations prohibiting the promotion of products for off-label use restrict our ability to market our products. Although we have strict policies against the unlawful promotion of products for off-label use and we train our employees on these policies, it is possible that one or more of our employees will not follow the policies, or that regulations would change in a way that may hinder our ability to sell such products or make it more costly to do so, which could expose us to enforcement action by the FDA and the potential loss of approval to market and sell the affected products and/or significant financial and other penalties and liabilities.

The FDA and other regulatory agencies actively enforce regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained. During a March of 2007 meeting, the FDA warned device makers, including us, about promoting biliary stents for off-label uses. It is our understanding that certain biliary stent manufacturers, including some at the March 2007 FDA meeting, have since become involved in civil investigations by the U.S. Department of Justice alleging that they have improperly promoted their biliary stents for off-label uses. Although we have received no notice of any such investigation involving the sales practices of our biliary stents, no assurance can be provided that we will not become the subject of such an investigation, which could adversely affect our business, operating results and stock price. It is also possible that our company or board of directors could become subject to civil litigation or breach of fiduciary duty claims alleging that we improperly promoted off-label use of our products, which in turn improperly inflated our historical net sales.

Off-label use of our products may not be safe or effective and may result in unfavorable outcomes to patients, resulting in potential liability to us. For example, the use or misuse of the SilverHawk in the peripheral and coronary arteries has resulted in complications, including damage to the treated artery, internal bleeding, limb loss and death, potentially leading to a product liability claim. In addition, the use or misuse of our biliary stents in the peripheral arteries to treat peripheral artery disease has resulted in complications, potentially leading to a product liability claim. A third-party study published in 2008 found that off-label use of biliary stents was increasing and that the majority of adverse events and device malfunctions associated with the use of such stents occurs during off-label usage.

If we want to market any of our products in the U.S. for uses in ways for which they are not currently approved or cleared, we will need to obtain approval or clearance from the FDA and in most cases conduct additional clinical trials to support such approvals and clearances. Such trials are often time-consuming and costly. Although we continue to enroll patients for our DEFINITIVE Ca++ trial to support an FDA application to use our RockHawk/TurboHawk and SpiderFX in the treatment of lower extremity (SFA/Popliteal) calcified lesions and intend to conduct other clinical trials to expand the indication of use of our RockHawk/TurboHawk, no assurance can be provided that the results of these trials will adequately demonstrate the safety and efficacy of the SilverHawk for use in those expanded indications. In addition, although we continue to enroll patients for our DURABILITY II IDE trial to support an FDA application to use our EverFlex stent in long lesions in the superficial femoral artery, no assurance can be provided that the results of this trial will adequately demonstrate the safety and efficacy of our EverFlex stent for use in the peripheral arteries. In 2009, C. R. Bard Inc. announced that the FDA cleared certain of its stents for use in the superficial femoral arteries and proximal popliteal arteries. It is possible that physicians have decided to use and may continue to decide to use C. R. Bard Inc.'s FDA cleared stents rather than our stents off-label, which would harm sales of our stents. It is also possible that governmental or private health care payors could limit reimbursement for products used off-label, in which case, sales of our products and our business would be materially adversely affected.

Since a significant portion of our sales are derived from products that physicians in the past have elected to use and may continue to elect to use "off-label," ultimately, if physicians cease or lessen their use of our products for other than FDA-approved indications, sales of our products likely would decline, which could materially adversely affect our net sales and operating results. In addition, if we are perceived not to be in compliance with all of the restrictions limiting the promotion of our products for off-label use, we could be subject to various enforcement measures, including investigations, administrative proceedings and federal and state court litigation, which likely would be costly to defend and harmful to our business. If the FDA or another governmental authority ultimately concludes we are not in compliance with such restrictions, we could be subject to significant liability, including civil and administrative remedies, injunctions against sales for off-label uses, significant monetary and punitive penalties and criminal sanctions, any or all of which would be harmful to our business.

Our business strategy relies on assumptions about the market for our products, which, if incorrect, would adversely affect our business and operating results.

We are focused on the market for endovascular devices used to treat vascular diseases and disorders. We believe that the aging of the general population and inactive lifestyles will continue and that these trends will increase 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, would adversely affect our business and operating results.

If we fail to comply with laws prohibiting "kickbacks" and false or fraudulent claims and other similar laws, we could be subject to criminal and civil penalties and exclusion from governmental health care programs, which could have a material adverse effect on our business and operating results.

We are subject to various federal, state and foreign laws concerning health care fraud and abuse, including false claims laws, anti-kickback laws, physician self-referral laws and other similar laws. Many of these laws constrain the sales, marketing and other promotional activities of manufacturers of medical devices by limiting the kinds of financial arrangements, including sales programs, with physicians, hospitals, laboratories and other potential purchasers of medical devices. The scope of these laws and related regulations are very broad and many of their provisions have not been uniformly or definitively interpreted by existing case law or regulations, and thus are subject to evolving interpretations. There is very little precedent related to these laws and regulations. All of our financial relationships with health care providers and others who provide products or services to federal health care program beneficiaries are potentially governed by these laws. While we have established policies and procedures based on the AdvaMed Code of Ethics on Interactions with Health Care Professionals and implemented a broad-based corporate compliance program in order to inform our employees regarding these laws and maintain compliance with them, no assurance can be given that we will not be subject to investigations or litigation alleging violations of these laws. Increased funding for enforcement of these laws and regulations has resulted in greater scrutiny of financial relationships with physicians and marketing practices and resulted in several governmental

investigations by various governmental authorities, including investigations of the sales practices of several of our competitors. Any investigation or litigation against us, even if we were to successfully defend against it, would likely be time-consuming and costly for us to defend. It also would likely divert the attention of our management from the operation of our business, cause adverse publicity and damage our reputation. If our arrangements were found to have violated any of these laws, we and our officers and employees could be subject to severe criminal and/or civil penalties, including fines, imprisonment and exclusion from participation in government health care programs, which could have a material adverse effect on our reputation, business and operating results. Similarly, if the physicians or other providers or entities with which we do business are found to be non-compliant with such laws, they may be subject to sanctions, which also could have a negative impact on us.

Some of our products are emerging technologies or have only recently been introduced into the market. If physicians do not recommend and endorse them or if our working relationships with physicians deteriorate, our products may not be accepted in the marketplace, which would adversely affect our business and operating results.

In order for us to sell our products, physicians must recommend and endorse them. We may not obtain the necessary recommendations or endorsements from physicians. Acceptance of our products depends on educating the medical community as to the distinctive characteristics, perceived benefits, safety, clinical efficacy and cost-effectiveness of our products compared to products of our competitors, and on training physicians in the proper application of our products. We often need to invest in significant training and education of our sales representatives or our physician customers to achieve market acceptance of our products with no assurance of success. For example, the future success of our plaque excision products are dependent in part upon us educating first our sales representatives and second, physicians, and in particular interventional cardiologists, vascular surgeons, as well as general practitioners and other physicians, about screening for peripheral artery disease, or PAD, referral opportunities and the benefits of our plaque excision products in relating to competitive products and other treatment options. As another example, the future success of our Pipeline Embolization Device is also dependent in part upon us educating our sales organization and physician customers regarding the advantages of flow diversion and our Pipeline product in particular in treating wide-necked aneurysms. If we are not successful in obtaining the recommendations or endorsements of physicians for our products, if customers prefer our competitors' products or if our products otherwise do not gain market acceptance, our business could be adversely affected.

In addition, if we fail to maintain our working relationships with physicians, many of our products may not be developed and marketed consistent with the needs and expectations of professionals who use and support our products. We rely on these professionals to provide us with considerable knowledge and experience regarding our products and the marketing of our products. If we are unable to maintain these strong relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could adversely affect the acceptance of our products in the marketplace and our operating results. At the same time, we recognize and are careful to ensure that our relationships with physicians comply with applicable fraud and abuse and other laws and regulations and our Code of Ethics on Interactions with Health Care Professionals, which is based on the AdvaMed Code of Ethics on Interactions with Health Care Professionals.

We acquired Chestnut Medical Technologies, Inc. primarily for its Pipeline Embolization Device. If the Pipeline Embolization Device cannot be shown to be safe and effective in clinical trials, is not approvable or not commercially successful, or if we do not receive the pre-market approval letter from the FDA for any reason, then the benefits of our acquisition of Chestnut may never be fully realized.

In June of 2009, we acquired Chestnut primarily for its Pipeline Embolization Device, which is a new class of embolization device that is designed to divert blood flow away from an aneurysm in order to provide a complete and durable aneurysm embolization while maintaining patency of the parent vessel. The Pipeline Embolization Device has received CE Mark approval in Europe and we are currently conducting two clinical studies under FDA investigational device exemptions to gain approval for the Pipeline device in the United States. Under the terms of our agreement and plan of merger with Chestnut, we made an initial closing payment in the amount of approximately $75 million, approximately $26 million of which was paid in cash with the remaining approximately $49 million paid in shares of our common stock. In addition to the initial closing payment, we may be obligated to make an additional milestone payment of up to $75 million if the FDA issues a letter granting pre-market approval for the commercialization of the Pipeline Embolization Device in the United States pursuant to an indication to treat

intracranial aneurysms on or before December 31, 2012. If the Pipeline Embolization Device cannot be shown to be safe and effective in clinical trials, is not approvable or not commercially successful, or if we do not receive the pre-market approval letter from the FDA for any reason, then the benefits of our acquisition of Chestnut may never be fully realized.

Demand for our plaque excision products in the United States has suffered due in part, we believe, to the lack of long-term clinical data regarding their safety and efficacy. Future long-term data regarding the safety and efficacy of our plaque excision products may not be positive or consistent with data currently available, which would adversely affect their market acceptance and our operating results.

One of the primary reasons we completed our acquisition of FoxHollow Technologies, Inc. in October of 2007 was to add FoxHollow's SilverHawk and other products to our broad spectrum of technologically advanced products to treat vascular disease in the peripheral market to allow us to offer a more comprehensive and better integrated set of endovascular products to our customers. At the time of the acquisition, we expected SilverHawk sales to represent a significant portion of our future net sales. However, we experienced decreased demand and sales of the SilverHawk compared to levels experienced by FoxHollow prior to our acquisition due in part to sales force integration challenges, elevated inventory levels of the product at some of our customers and increased competition. We also believe the decreased demand and sales was due in part to a lack of definitive long-term clinical data regarding the safety and efficacy of the SilverHawk.

In 2008, we retained a third party research firm to help us examine our U.S. plaque excision business. The research firm conducted interviews with a significant number of physicians and sales force representatives and analyzed secondary data to understand factors driving the change in SilverHawk usage and plaque excision procedures. The results of this research confirmed our previously stated belief in the importance of investing in the necessary clinical trials to build the clinical foundation for the SilverHawk and capitalizing on our next generation technologies to expand clinical usage, particularly in treating calcified lesions, total occlusions and longer lesions.

Based on this third party research and our own due diligence, we believe that future demand for our plaque excision products will not increase if physicians are not presented with compelling data from long-term studies of the safety and efficacy of our products compared against alternative procedures, such as angioplasty, stenting or bypass grafting and alternative technologies. As a result, we have commenced our DEFINITIVE trial series, which we expect to consist of three trials using our plaque excision products. We are currently enrolling patients into our DEFINITIVE Ca++ trial to evaluate RockHawk/TurboHawk and SpiderFX in the treatment of lower extremity (SFA/Popliteal) calcified lesions and our DEFINITIVE LE trial, which is a post-market non-randomized study of SilverHawk/TurboHawk in the treatment of femoropopliteal and tibial arteries. We anticipate commencing enrollment in our DEFINITIVE AR trial in the second half of 2010 to evaluate SilverHawk/TurboHawk in the treatment of femoropopliteal arteries. These studies will be expensive and time consuming and there are no assurances that the results will prove favorable for our plaque excision products. If the results do not meet physicians' expectations, our plaque excision products may not become widely adopted and physicians may recommend alternative treatments for their patients.

Other significant factors that physicians will consider include acute safety data on complications that occur during the SilverHawk procedure. If the results obtained from any future clinical studies or clinical or commercial experience indicate that the SilverHawk is not as safe or effective as other treatment options or as prior short-term or long-term data would suggest, market acceptance of the product may suffer and the number of SilverHawk procedures may decrease, which would harm our business. Even if the data collected from clinical studies or clinical experience indicate positive results, each physician's actual experience with the SilverHawk may vary and may not be as favorable, which would also adversely affect the demand for our SilverHawk product. Other factors that may adversely affect the market acceptance of the SilverHawk include the time required to perform the procedure and the lack of on-board visualization capability. If we do not incorporate certain design improvements to the SilverHawk to respond to these and other physician preferences, we may be unable to generate new customers or retain our existing customers. However, we have limited funds dedicated to research and development; and therefore, we will not be able to pursue all of these suggested design changes. A decrease in SilverHawk procedures and any failure by us to generate additional demand for the SilverHawk will likely adversely affect our future net sales as well as our other operating results.

The demand for our products, the prices which customers and patients are willing to pay for our products and the number of procedures performed using our products depend upon the ability of our customers and patients to obtain sufficient third party reimbursement for their purchases of our products.

Sales of our products depend in part on sufficient reimbursement by governmental and private health care payors to our physician customers or their patients for the purchase and use of our products. In the United States, health care 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 endovascular procedures. Reimbursement systems in international markets vary significantly by country, and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis and can take up to 18 months or longer. Many international markets have government-managed health care 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 in a given period and therefore result in extended payment periods. Any delays in obtaining, or an inability to obtain, reimbursement approvals or sufficient reimbursement for our products could significantly affect the acceptance of our products and have a material adverse effect on our business. For example, international sales of our plaque excision products and Pipeline Embolization Device may be hampered by delay in obtaining reimbursement. In addition, if the reimbursement policies of domestic or foreign governmental or private health care payors were to change, our customers likely would change their purchasing patterns and/or the frequency of their purchases of the affected products. Additionally, payors continue to review their coverage policies carefully for existing and new therapies and can, without notice, deny coverage for treatments that include the use of our products. Our business would be negatively impacted to the extent any such changes reduce reimbursement for our products.

Healthcare costs have risen significantly over the past decade. There have been and may continue to be proposals by legislators, regulators and third-party payors to keep these costs down. The continuing efforts of governments, insurance companies and other payors of healthcare costs to contain or reduce these costs, combined with closer scrutiny of such costs, could lead to patients being unable to obtain approval for payment from these third-party payors. The cost containment measures that healthcare providers are instituting both in the United States and internationally could harm our business. Some health care providers in the United States have adopted or are considering a managed care system in which the providers contract to provide comprehensive health care for a fixed cost per person. Health care providers may attempt to control costs by authorizing fewer elective surgical procedures or by requiring the use of the least expensive devices possible, which could adversely affect the demand for our products or the price at which we can sell our products.

We also sell a number of our products to physician customers who may elect to use these products in ways that are not within the scope of the approval or clearance given by the FDA, often referred to as “off-label” use. In the event that governmental or private health care payors limit reimbursement for products used off-label, sales of our products and our business would be materially adversely affected.

Our stents and plaque excision products generate a significant portion of our product sales. Accordingly, if sales of these products were to decline, our operating results would be adversely affected.

Our stents and plaque excision products generate a significant portion of our net sales. During 2009, our stents and plaque excision products generated approximately 26% and 19% of our product sales, respectively. A decline in sales from these products as a result of increased competition, regulatory matters, intellectual property matters or any other reason would negatively impact our operating results.

Our products face the risk of technological obsolescence, which, if realized, could have a material adverse effect on our business and operating results.

The medical device industry is characterized by extensive research and development and rapid and significant technological change. The peripheral vascular and neurovascular markets in which we compete are in particular highly competitive and new technologies and products are often introduced. Therefore, product life cycles are relatively short. Developments by us and other companies of new or improved products, processes or technologies may make our products or proposed products obsolete or less competitive and may negatively impact our net sales or cause us to incur significant charges or write-offs. For example, new procedures and medications that are more

effective or less invasive or expensive could be developed that replace or reduce the importance of current procedures that use our products or our future products or may cause our customers to cease, delay or defer purchasing our products, which would adversely affect our business and operating results. As another example, it is possible that our recently acquired Pipeline Embolization Device could, over time, have an adverse effect on sales of our neurovascular coils.

Our future success depends in part on the introduction of new products. Failure to introduce and market new products in a timely fashion that are accepted by the marketplace could adversely affect our business and operating results.

Our success depends in part upon our ability to respond quickly to medical and technological changes through the development or acquisition and introduction of new products. If we do not introduce new products and technologies, or if our new products and technologies are not accepted by the physicians who use them or the payors who reimburse the costs of the procedures performed with them, or if there are any delays in our introduction of new products, we may not be successful and our business and operating results would suffer. Accordingly, we must devote substantial efforts and financial resources to develop or acquire scientifically advanced technologies and products, obtain patent and other protection for our technologies and products, obtain required regulatory and reimbursement approvals and successfully manufacture and market our products. For example, in June of 2009, we acquired Chestnut and paid $75.0 million up front and agreed to pay an additional $75.0 million milestone payment if the FDA issues a letter granting pre-market approval for the commercialization of the Pipeline Embolization Device in the United States pursuant to an indication to treat intracranial aneurysms on or before December 31, 2012. We cannot assure you that the Pipeline Embolization Device will obtain regulatory approval or will be accepted by the marketplace, which if not would adversely affect our business and operating results.

We plan to introduce additional products during 2010 which we expect to result in additional net sales. We may experience delays in any phase of a product launch, including during research and development, clinical trials, regulatory approvals, manufacturing, marketing and the education process. The relative speed with which we can develop or acquire products, complete clinical testing and regulatory clearance or approval processes, train physicians in the use of our products, gain reimbursement acceptance and supply commercial quantities of the products to the market are important competitive factors. Any delays could result in a loss of market acceptance and market share.

Product development involves a high degree of risk, and we cannot provide assurance that our product development efforts will result in any commercially successful products. Many of our clinical trials have durations of several years and it is possible that such trials may not be successful or that competing therapies, such as drug therapies, may be introduced while our products are still undergoing clinical trials. New products and technologies introduced by competitors may reach the market earlier, may be more effective or less invasive or expensive than our products or render our products obsolete, all of which would harm our business and operating results.

A number of our proposed products are in the early stages of development and some are in clinical trials. If the development of these products is not successfully completed or if these trials are unsuccessful, or if the FDA or other regulatory agencies require additional trials to be conducted, these products may not be commercialized and our business prospects may suffer.

Several of our products are in the early stages of development. Some only recently emerged from clinical trials and others have not yet reached the clinical trial stage. Our ability to market our products in the United States and abroad depends upon our ability to demonstrate the safety, and in the case of the United States, efficacy, of our products with clinical data to support our requests for regulatory approval. Our products may not be found to be safe and, where required, effective in clinical trials and may not ultimately be approved for marketing by U.S. or foreign regulatory authorities. Our failure to develop safe and effective products that are approved for sale on a timely basis would have a negative impact on our net sales.

Our current and anticipated trials for 2010 include the PROVE-IT (U.S.), CREATE Post Approval Study (U.S.), DURABILITY II Trial (U.S.), the DEFINITIVE Ca++ Trial (U.S.), the DEFINITIVE LE Trial (U.S), the DEFINITIVE AR Trial (Europe), the SWIFT Trial (U.S.) and the RACER Trial (U.S.). In addition, as a result of our acquisition of Chestnut, we are currently conducting two clinical studies in the U.S., PUFS and COCOA, under

Investigational Device Exemptions from the FDA investigating the use of Chestnut's Pipeline Embolization Device in the treatment of uncoilable aneurysms and coilable aneurysms, respectively. There is no assurance that we will be successful in achieving the endpoints in these trials or, if we do, that the FDA or other regulatory agencies will approve the devices for sale without the need for additional clinical trial data to demonstrate safety and efficacy. Some of the products for which we are currently conducting trials are already approved for sale outside of the United States. As a result, while our trials are ongoing, unfavorable data may arise in connection with usage of our products outside the United States which could adversely impact the approval of such products in the United States. Conversely, unfavorable data from clinical trials in the United States may adversely impact sales of our products outside of the United States.

We continually evaluate the potential financial benefits and costs of clinical trials 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 trial and/or the development of a product, which could result in a decrease in our stock price if investors are disappointed in our decision.

Our future success depends in part on our ability to sell our products internationally. There are risks inherent in operating internationally and selling and shipping our products and purchasing our components internationally, which may adversely impact our business, operating results and financial condition.

One of our strategic objectives is to leverage our strong international presence to increase sales of our products, including in particular the Pipeline Embolization Device that we recently acquired from Chestnut and our plaque excision products that we acquired from FoxHollow. For the year ended December 31, 2009 and 2008, 40% and 35%, respectively, of our net sales were derived from our international operations. We expect to continue to derive a significant portion of our net sales from operations in international markets. Our international distribution system consisted of 10 direct sales offices and 56 stocking distribution partners as of December 31, 2009. In addition, we purchase some of our components and products from international suppliers.

The sale and shipping of our products and services across international borders, as well as the purchase of components and products from international sources, subject us to extensive U.S. and foreign governmental trade regulations. Compliance with such regulations is costly and exposes us to penalties for non-compliance. Other laws and regulations that can significantly impact us include various anti-bribery laws, including the U.S. Foreign Corrupt Practices Act, laws restricting business with suspected terrorists and anti-boycott laws. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities, and exclusion or debarment from government contracting. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping and sales activities.

In addition, many of the countries in which we sell our products are, to some degree, subject to political, economic and/or social instability. 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;
- the imposition of costly and lengthy new export licensing requirements;
- 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 that possess proprietary knowledge, or who are otherwise important to our success in certain international markets;

- the imposition of different reimbursement requirements and changes in 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;

- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;

- the imposition of new trade restrictions;

- 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;

- significantly longer payment cycles;

- difficulties in maintaining consistency with our internal guidelines;

- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;

- difficulties in enforcing or defending intellectual property rights;

- exposure to different legal and political standards due to our conducting business in over 65 countries; and

- fluctuation in the rate of exchange between the U.S. dollar and foreign currencies which may make the effective price of our products more expensive to our distributors in foreign markets.

No assurance can be given that one or more of the factors will not harm our business. Any material decrease in our international sales would adversely impact our operating results and financial condition. Our international sales are predominately in Europe. In Europe, health care regulation and reimbursement for medical devices vary significantly from country to country. This changing environment could adversely affect our ability to sell our products in some European countries.

Fluctuations in the rate of exchange between the U.S. dollar and foreign currencies in which we transact business could adversely affect our financial results or cause our results to fluctuate.

We sell our products to customers in the United States, Europe and elsewhere throughout the world. Although most of our sales are made in U.S. dollars, a significant portion of our sales are denominated in foreign currencies, especially the Euro. Approximately 27% and 24% of our net sales were denominated in foreign currencies in 2009 and 2008, respectively. Our principal exposure to movements in foreign currency exchange rates relate to non-U.S. dollar denominated sales in Europe and throughout the world, as well as non-U.S. dollar denominated operating expenses incurred in Europe and throughout the world. Our reported net earnings may be significantly affected by fluctuations in currency exchange rates, with earnings generally decreasing with a strengthening U.S. dollar and increasing with a weaker U.S. dollar. For sales not denominated in U.S. dollars, if there is an increase in the rate at which a foreign currency is exchanged for U.S. dollars, it will require more of the foreign currency to equal a specified amount of U.S. dollars than before the rate increase. In such cases, we will receive less in U.S. dollars than we did before the exchange rate increase went into effect. Thus, a strengthening U.S. dollar relative to the foreign currencies in which we transact business will adversely affect the U.S. dollar value of our foreign currency-denominated sales and earnings. Although we may raise international pricing in such circumstances, such price increases may potentially reduce demand for our products, and thus in most circumstances, due to competition or

other reasons, we may decide not to raise local prices to the full extent of the U.S. dollar's strengthening or at all. A weakening of the U.S dollar relative to the foreign currencies in which we transact business is generally beneficial to our foreign currency-denominated sales and earnings. However, it may cause us to reduce our international pricing, thereby limiting the benefit. Additionally, strengthening of foreign currencies also may increase our operating costs or costs of product components denominated in those currencies, thus adversely affecting our gross margins. If we price our products in U.S. dollars and competitors price their products in local currency, an increase in the relative strength of the U.S. dollar could result in our price not being competitive in a market where business is transacted in the local currency.

We have hedged and may continue to hedge exposure to foreign currency exchange rates in the future. If we engage in hedging activities, such activities involve risk and may not limit our underlying exposure from currency fluctuations or minimize our net sales and earnings volatility associated with foreign currency exchange rate changes.

A substantial portion of our assets consist of goodwill and intangible assets and any impairment in the value of our goodwill and intangible assets would have the effect of decreasing our earnings or increasing our losses.

As of December 31, 2009, goodwill and intangible assets represented $621.8 million, or approximately 69%, of our total assets. During 2008, we recorded $288.8 million in goodwill and intangible asset impairment charges. The accounting standards require goodwill to be reviewed at least annually for impairment, and do not permit amortization. In the event that impairment is identified, a charge to earnings will be recorded and our stock price may decline as a result. We review our intangible assets for impairment when events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. An impairment loss on intangible assets is recognized when future undiscounted cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount. If we experience additional substantial declines in our market capitalization or if we experience other events or changes in circumstances that may indicate that the carrying amount of our goodwill and/or other intangible assets may not be recoverable, we may incur additional non-cash impairment charges to both our goodwill and intangible assets in future periods. For example, such other events or changes in circumstances may include a significant adverse change in the extent or manner in which an asset is being used or in the business climate that could affect the value of the asset, or significant reductions in operating cash flows, or a projection or forecast that demonstrates continuing losses associated with the use of the asset and a current expectation that, more likely than not, an asset will be sold or otherwise disposed of significantly before the end of its previously estimated useful life. If we are required to record an impairment charge to earnings relating to goodwill or intangible assets, it will have the effect of decreasing our earnings or increasing our losses.

Consolidation in the healthcare industry could lead to demands for price concessions or to the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, financial condition or operating results.

Because healthcare costs have risen significantly over the past decade, numerous initiatives and reforms initiated by legislators, regulators and third-party payors to curb these costs have resulted in a consolidation trend in the healthcare industry to create new companies with greater market power, including hospitals. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and will continue to become more intense. This in turn has resulted and will likely continue to result in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations, independent delivery networks and large single accounts continue to use their market power to consolidate purchasing decisions for some of our hospital customers. We expect that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances, which may increase competition, exert further downward pressure on the prices of their products and may adversely impact our business, financial condition or operating results.

Our group purchasing organization contracts are up for renewal during 2010 and if such contracts are not renewed, our net sales could suffer.

Our ability to sell our products to hospitals in the United States depends in part on our relationships with group purchasing organizations, or GPOs. Many existing and potential customers for our products are or become members of GPOs. GPOs negotiate pricing arrangements and contracts, sometimes on an exclusive basis, with medical supply manufacturers and distributors, and these negotiated prices are made available to a GPO's affiliated hospitals and other members. If we are not one of the providers selected by a GPO, affiliated hospitals and other members may be less likely to purchase our products, and if the GPO has negotiated a strict sole source, market share compliance or bundling contract for another manufacturer's products, we may be precluded from making sales to members of the GPO for the duration of the contractual arrangement.

We currently have contracts with multiple GPOs, several of which are subject to renewal during 2010. More than 50% of our total U.S. net sales in 2009 was derived from the GPO relationships that are subject to renewal this year. Our failure to renew one or more of these GPO contracts may cause us to lose market share and could have a material adverse effect on our net sales and operating results. We cannot assure you that we will be able to renew, renegotiate or replace these contracts at the current or substantially similar terms. If we are unable to maintain our current GPO relationships and/or develop new GPO relationships, our net sales and competitive position likely would suffer.

We may be subject to intellectual property litigation and infringement claims, which could cause us to incur liabilities and costs, prevent us from selling our products, cause us to redesign our products, require us to enter into costly license agreements and result in other adverse consequences.

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, including aggressively challenging the patent rights of other companies in order to prevent the marketing of new products. The fact that we have patents issued to us for our products does not mean that we will always be able to successfully defend our patents and proprietary rights against challenges or claims of infringement by our competitors. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. We have incurred in the past significant costs in connection with patent litigation, including in connection with our previous litigation with the Regents of the University of California and Boston Scientific Corporation. We continue to face the risk of claims that we have infringed on third parties' intellectual property rights.

From time to time, in the ordinary course of business, we receive notices from third parties alleging infringement or misappropriation of the patent, trademark or other intellectual property rights of third parties by us or our customers in connection with the use of our products or we otherwise may become aware of possible infringement claims against us. We routinely analyze such claims and determine how best to respond in light of the circumstances existing at the time, including the importance of the intellectual property right to us and the third party, the relative strength of our position of non-infringement or non-misappropriation and the product or products incorporating the intellectual property right at issue.

We also may be unaware of intellectual property rights of others that may cover some of our technology. Prior to launching major new products in our key markets, we normally evaluate existing intellectual property rights. However, our competitors may have filed for patent protection which 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;

- cause us to cease making or selling products that incorporate the challenged intellectual property;
- require us to redesign, reengineer or rebrand our products, if feasible;
- require us to enter into license agreements in order to obtain the right to use a third party's intellectual property, which agreements may require us to pay significant license fees, including royalties, or may not be available on terms acceptable to us or at all and which licenses may be non-exclusive, which could provide our competitors access to the same technologies;
- divert the attention of our management and other personnel from other business issues; or
- result in our customers or potential customers deferring or limiting their purchase or use of the affected products until resolution of the litigation.

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. Any of these adverse consequences could have a material adverse effect on our business, operating results and financial condition.

If our patents and other intellectual property rights do not adequately protect our products, we may lose market share to our competitors, which would harm our business.

Our future success depends significantly on our ability to protect our proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of copyright and trademark laws and nondisclosure, confidentiality and other contractual arrangements to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. In addition, we cannot be assured that any of our pending patent applications will result in the issuance of a patent to us. The United States Patent and Trademark Office, or PTO, may deny or require significant narrowing of claims in our pending patent applications, and patents issued as a result of the pending patent applications, if any, may not provide us with significant commercial protection or be issued in a form that is advantageous to us. We also could incur substantial costs in proceedings before the PTO. These proceedings could result in adverse decisions as to the priority of our inventions and the narrowing or invalidation of claims in issued patents. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products. Litigation also may be necessary to enforce patent rights we hold or to protect trade secrets or techniques we own. Intellectual property litigation is costly and may adversely affect our operating results. Although we have taken steps to protect our intellectual property and proprietary technology, there is no assurance that third parties will not be able to design around our patents. We also rely on unpatented proprietary technology. In addition, we rely on the use of registered trademarks with respect to the brand names of some of our products. We also rely on common law trademark protection for some brand names, which are not protected to the same extent as our rights in the use of our registered trademarks. We cannot assure you that we will be able to meaningfully protect all of our rights in our unpatented proprietary technology or that others will not independently develop substantially equivalent proprietary products or processes or otherwise gain access to our unpatented proprietary technology. We seek to protect our know-how and other unpatented proprietary technology, in part with confidentiality agreements and intellectual property assignment agreements with our employees, independent distributors and consultants. However, such agreements may not be enforceable or may not provide meaningful protection for our proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements or in the event that our competitors discover or independently develop similar or identical designs or other proprietary information. For example, we are currently involved in litigation with Cardiovascular Systems, Inc. in which we allege misappropriation and use of our confidential information by CSI and certain of CSI's employees who were formerly employees of our subsidiary, FoxHollow. The complaint also alleges that certain of CSI's employees violated their employment agreements with FoxHollow requiring them to refrain from soliciting FoxHollow employees.

Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. For example, foreign countries generally do not allow patents to cover methods for performing surgical procedures. If we cannot adequately protect our intellectual property rights in these foreign

countries, our competitors may be able to compete more directly with us, which could adversely affect our competitive position and business.

We also hold licenses from third parties that are necessary to use certain technologies used in the design and manufacturing of some of our products. The loss of such licenses would prevent us from manufacturing, marketing and selling these products, which could harm our business and operating results.

We manufacture our products at single locations. Any disruption in these manufacturing facilities, any patent infringement claims with respect to our manufacturing process or otherwise any inability to manufacture a sufficient number of our products to meet demand could adversely affect our business and operating results.

We rely on our manufacturing facilities in Plymouth, Minnesota, Irvine, California and Menlo Park, California. Any damage or destruction to our 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. The lease for our Plymouth manufacturing facility expires in 2010. If we are unable to renew this lease or find an alternative location on a timely basis, our manufacturing capabilities could be disrupted. Our facilities may be affected by natural or man-made disasters. In the event we are unable to renew our Plymouth manufacturing facility lease or if one of our facilities was affected by a disaster, we would be forced to rely on third-party manufacturers if we could not shift production to one of our other manufacturing facilities. In the case of a device with a premarket approval application, we might in such event be required to obtain prior FDA or notified body approval of an alternate manufacturing facility, which could delay or prevent our marketing of the affected product until such approval is obtained. Although we believe that we possess adequate 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 and may not continue to be available to us on acceptable terms, or at all. 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 might be forced to stop production at one of our manufacturing facilities in the United States and to seek alternative facilities. Even if we were able to identify such alternative facilities, we might incur additional costs and experience a disruption in the supply of our products until those facilities are available. Any disruption in our manufacturing capacity could have an adverse impact on our ability to produce sufficient inventory of our products or may require us to incur additional expenses in order to produce sufficient inventory, and therefore would adversely affect our net sales and operating results.

We have limited experience in manufacturing our products in commercial quantities and therefore may encounter unforeseen situations that could result in delays or shortfalls. Manufacturers often experience difficulties in increasing production, including problems with production yields and quality control and assurance. Any disruption or delay at our manufacturing facilities, any inability to accurately predict the number of products to manufacture or to expand our manufacturing capabilities if necessary could impair our ability to meet the demand of our customers and these customers may cancel orders or purchase products from our competitors, which could adversely affect our business and operating results.

Our dependence on key suppliers puts us at risk of interruptions in the availability of our products, which could reduce our net sales and adversely affect our operating results. In addition, increases in prices for raw materials and components used in our products could adversely affect our operating results.

We rely on a limited number of suppliers for certain raw materials and components used in our products. For reasons of quality assurance, cost effectiveness or availability, we procure certain raw materials and components from sole and limited source suppliers. We generally acquire such raw materials and components through purchase orders placed in the ordinary course of business, and as a result we do not have a significant inventory of these materials and components and do not have any guaranteed or contractual supply arrangements with many of these suppliers. In addition, we also rely on independent contract manufacturers for some of our products. Independent manufacturers have possession of, and in some cases hold title to, molds for certain manufactured components of our products. Our dependence on third-party suppliers involves several risks, including limited control over pricing, availability, quality and delivery schedules, as well as manufacturing yields and costs. Suppliers of raw materials and components may decide, or be required, for reasons beyond our control to cease supplying raw materials and components to us or to raise their prices.

Shortages of raw materials, quality control problems, production capacity constraints or delays by our contract manufacturers could negatively affect our ability to meet our production obligations and result in increased prices for affected parts. Any such shortage, constraint or delay may result in delays in shipments of our products or components, which could adversely affect our net sales and operating results. Increases in prices for raw materials and components used in our products could also adversely affect our operating results.

In addition, the FDA and foreign regulators may require additional testing of any raw materials or components from new suppliers prior to our use of these materials or components. In the case of a device with a premarket approval application, we may be required to obtain prior FDA approval of a new supplier, which could delay or prevent our access or use of such raw materials or components or our marketing of affected products until such approval is granted. In the case of a device with clearance under section 510(k) of the Federal Food, Drug and Cosmetic Act, referred to as a 510(k), we may be required to submit a new 510(k) if a change in a raw material or component supplier results in a change in a material or component supplied that is not within the 510(k) cleared device specifications. If we need to establish additional or replacement suppliers for some of these components, our access to the components might be delayed while we qualify such suppliers and obtain any necessary FDA approvals. Our suppliers of finished goods also are subject to regulatory inspection and scrutiny. Any adverse regulatory finding or action against those suppliers could impact their ability to supply us raw materials and components for our products.

Our inability to successfully grow through future acquisitions, our failure to integrate any acquired businesses successfully into our existing operations or our discovery of previously undisclosed liabilities could negatively affect our business and operating results.

In order to build our core technology platforms, we have acquired several businesses since our inception. For example, most recently, in June of 2009, we completed our acquisition of Chestnut. In October of 2007, we completed our acquisition of FoxHollow. In September of 2006, FoxHollow acquired Kerberos Proximal Solutions, Inc. In January of 2006, we acquired the outstanding shares of Micro Therapeutics, Inc. that we did not already own. We expect to continue to actively pursue additional targeted acquisitions of, investments in or alliances with, other companies and businesses in the future as a component of our business strategy. Our ability to grow through future acquisitions, investments and alliances will depend upon our ability to identify, negotiate, complete and integrate attractive candidates on favorable terms and to obtain any necessary financing. Our inability to complete one or more acquisitions, investments or alliances could impair our ability to develop our product lines and to compete against many industry participants, many of whom have product lines broader than ours. Acquisitions, investments and alliances involve risks, including:

- difficulties in integrating any acquired companies, personnel and products into our existing business;
- delays in realizing projected efficiencies, cost savings, revenue synergies and other benefits of the acquired company or products;
- inaccurate assessment of the future market size or market acceptance of any acquired products or technologies or the hurdles in obtaining regulatory approvals of such products;
- inaccurate assessment of undisclosed, contingent or other liabilities or problems;
- diversion of our management's time and attention from other business concerns;
- limited or no direct prior experience in new markets or countries we may enter;
- higher costs of integration than we anticipated;
- adverse accounting consequences; or
- difficulties in retaining key employees of the acquired business who are necessary to manage the acquired business.

In addition, an anticipated or completed acquisition, investment or alliance could materially impair our operating results and liquidity by causing us to use our cash resources to pay the purchase price, incur debt or reallocate amounts of capital from other operating initiatives or requiring us to expense incurred transaction and restructuring costs and amortize acquired assets, incur non-recurring charges as a result of incorrect estimates made in the accounting for such transactions or record asset impairment charges. For example, we incurred impairment charges to our goodwill and other intangible assets totaling $288.8 million in our fourth quarter of 2008 which charges related primarily to assets derived from previous acquisitions. We also may discover deficiencies in internal controls, data adequacy and integrity, product quality, regulatory compliance and product liabilities which we did not uncover prior to our acquisition of such businesses, which could result in us becoming subject to penalties or other liabilities. Any difficulties in the integration of acquired businesses or unexpected penalties or liabilities in connection with such businesses could have a material adverse effect on our operating results and financial condition. These risks could be heightened if we complete several acquisitions within a relatively short period of time. Finally, any acquisitions that involve the issuance of our common stock could be dilutive to our stockholders.

Our products and our product development and marketing activities are subject to extensive regulation as a result of which we may not be able to obtain required regulatory approvals for our products in a cost-effective manner or at all, which could adversely affect our business and operating results.

The production and marketing of our products and our ongoing research and development, preclinical testing 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 development, testing, marketing and premarket review of new medical devices, in addition to regulating manufacturing practices, reporting, advertising, exporting, labeling and record keeping procedures. We are required to obtain FDA approval or clearance before we can market our products in the United States and certain foreign countries. The regulatory process requires significant time, effort and expenditures to bring products to market, and it is possible that our products will not be approved for sale.

The FDA recently has requested that the Institute of Medicine perform a study on whether legislative, regulatory or administrative changes are needed to the FDA's 510(k) clearance process. The Institute of Medicine report is due in 2011. The FDA also announced an internal working group to evaluate and improve the consistency of FDA decision making in the clearance process, and recently released an internal report in which FDA officials questioned the 510(k) process in general. Various committees of the U.S. Congress also have indicated that they may consider investigating the FDA's 510(k) process. Under the current 510(k) rules, certain types of medical device can obtain FDA approval without lengthy and expensive clinical trials. Among our product offerings, those products that require FDA approval have received such approval under the 510(k) rules. Most of our research and development programs and new product programs contemplate obtaining any required FDA approvals under the current 510(k) rules. Any changes to the current 510(k) or related FDA rules that make such rules more stringent or require more clinical data, could significantly increase the time and costs associated with bringing new products to market. This likely would have a material adverse effect on our business, financial condition and operating results.

Even if regulatory approval or clearance of a product is granted, it may not be granted within the timeframe that we expect, which could have an adverse effect on our operating results and financial condition. In addition, even if regulatory approval or clearance of a product is granted, the approval or clearance could limit the uses for which the product may be labeled and promoted, which may limit the market for our products. Even after a product is approved or cleared by the FDA, we may have ongoing responsibilities under FDA regulations, non-compliance of which could result in the subsequent withdrawal of such approvals or clearances, or such approvals or clearances could be withdrawn due to the occurrence of unforeseen problems following initial approval. We also are subject to medical device reporting regulations that require us to report to the FDA if any of our products causes or contributes to a death or serious injury or if a malfunction were it to occur might cause or contribute to a death or serious injury. Any failure to obtain regulatory approvals or clearances on a timely basis or the subsequent withdrawal of such approvals or clearances could prevent us from successfully marketing our products, which could adversely affect our business and operating results.

Our failure to comply with applicable regulatory requirements could result in governmental agencies:

- imposing fines and penalties on us;
- 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;
- suspending any ongoing clinical trials;
- issuing an injunction preventing us from manufacturing or selling our products or imposing restrictions;
- recalling or seizing our products; or
- withdrawing or denying approvals or clearances for our products.

Our failure to comply with applicable regulatory requirements also may result in us not being able to meet the demands of our customers and our customers canceling orders or purchasing products from our competitors, which could adversely affect our business and operating results.

When required, with respect to the products we market in the United States, we have obtained premarket notification clearance under section 510(k), but do not believe certain modifications we have made to our products require us to submit new 510(k) notifications. However, if the FDA disagrees with us and requires us to submit a new 510(k) notification for modifications to our existing products, we may be subject to enforcement actions by the FDA and be required to stop marketing the products while the FDA reviews the 510(k) notification. If the FDA requires us to go through a lengthier, more rigorous examination than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline. In addition, the FDA may determine that future products will require the more costly, lengthy and uncertain premarket approval application process. Products that are approved through a premarket approval application generally need FDA approval before they can be modified. If we fail to submit changes to products developed under IDEs or premarket approval applications in a timely or adequate manner, we may become subject to regulatory actions.

In addition, we market our products in certain countries outside of the United States. In order to market our products abroad, we are required to obtain separate regulatory approvals and comply with numerous requirements. If additional regulatory requirements are implemented in the foreign countries in which we sell our products, the cost of developing or selling our products may increase. We depend on our distributors outside the United States in seeking regulatory approval to market our devices in certain other countries and we therefore are dependent on persons outside of our direct control to secure such approvals. For example, we are highly dependent on distributors in emerging markets such as China and Brazil for regulatory submissions and approvals and do not have direct access to health care agencies in those markets to ensure timely regulatory approvals or prompt resolution of regulatory or compliance matters. If our distributors fail to obtain the required approvals or do not do so in a timely manner, our sales from our international operations and our operating results may be adversely affected.

If we or others identify side effects after any of our products are on the market, we may be required to withdraw our products from the market, which would hinder or preclude our ability to generate sales.

As part of our post-market regulatory responsibilities for our products classified as medical devices, we are required to report all serious injuries or deaths involving our products, and any malfunctions where a serious injury or death would be likely if the malfunction were to recur. If we or others identify side effects after any of our products are on the market:

- regulatory authorities may withdraw their approvals;
- we may be required to redesign or reformulate our products;
- we may have to recall the affected products from the market and may not be able to reintroduce them onto the market;
- our reputation in the marketplace may suffer; and
- we may become the target of lawsuits, including class action suits.

Any of these events, some of which have happened to us in the recent past, could harm or prevent sales of the affected products or could substantially increase the costs and expenses of commercializing or marketing these products.

Our manufacturing facilities are subject to extensive governmental regulation with which compliance is costly and which expose us to penalties for non-compliance.

We and our third party manufacturers are required to register with the FDA as device manufacturers and as a result, we and our third party manufacturers are subject to periodic inspections by the FDA for compliance with the FDA's Quality System Regulation, or QSR, requirements, which require manufacturers of medical devices to adhere to certain regulations, including testing, quality control and documentation procedures. In addition, the federal Medical Device Reporting regulations require us and our third party manufacturers to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, could cause or contribute to a death or serious injury. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA. We also are subject to similar state requirements and licenses. In the European Community, we are required to maintain certain International Organization for Standardization, or ISO, certifications in order to sell products and we are required to undergo periodic inspections by notified bodies to obtain and maintain these certifications. If we or our manufacturers fail to adhere to QSR or ISO requirements, this could delay production of our products and lead to fines, difficulties and delays in obtaining regulatory approvals and clearances, the withdrawal of regulatory approvals and clearances, recalls or other consequences, which could in turn have a material adverse effect on our financial condition and operating results. In addition, regulatory agencies may not agree with the extent or speed of corrective actions relating to product or manufacturing problems.

Our operations are subject to environmental, health and safety, and other laws and regulations, with which compliance is costly and which expose us to penalties for non-compliance.

Our business, properties and products are subject to foreign, federal, state and local laws and regulations relating to the protection of the environment, natural resources and worker health and safety and the use, management, storage, and disposal of hazardous substances, wastes, and other regulated materials. Because we operate real property, various environmental laws also may impose liability on us for the costs of cleaning up and responding to hazardous substances that may have been released on our property, including releases unknown to us. These environmental laws and regulations also could require us to pay for environmental remediation and response costs at third-party locations where we disposed of or recycled hazardous substances. The costs of complying with these various environmental requirements, as they now exist or may be altered in the future, could adversely affect our financial condition and operating results.

We may require additional capital in the future, which may not be available or may be available only on unfavorable terms. In addition, any equity financings may be dilutive to our stockholders.

As of December 31, 2009, we had $98.1 million in cash and cash equivalents. We believe that our proposed operating plan can be accomplished without additional financing based on our cash and cash equivalent balance, current and projected net sales and expenses, working capital and current and anticipated financing arrangements. However, there can be no assurance that our anticipated net sales or expense projections will be realized. Furthermore, there may be delays in obtaining necessary governmental approvals of our products or introducing our products to market or other events that may cause our actual cash requirements to exceed those for which we have budgeted. Our capital requirements will depend on many factors, including our ability to sustain profitability, the amount and timing of any losses, our cash flows from operations, expenditures on intellectual property and technologies, the number of clinical trials which we will conduct, new product development and acquisitions. To the extent that our then existing capital, including amounts available under our current and anticipated financing arrangements, is insufficient to cover any losses and meet these requirements, we will need to raise additional funds through financings or borrowings or curtail our growth and reduce our assets. Any equity or debt financing, if available at all, may be on terms that are not favorable to us, especially in light of the difficult market conditions for raising additional financing. Equity or debt financing arrangements could result in dilution to our stockholders, and the securities issued in future financings as well as in any future acquisitions may have rights, preferences and privileges that are senior to those of our common stock. If we obtain debt financing, a portion of our operating cash flow would be dedicated to the payment of principal and interest on such indebtedness, thus limiting funds available for our business activities, and we could be subject to covenants that restrict our ability to operate our business and make distributions to our stockholders. If our need for capital arises because of continued losses, the occurrence of these losses may make it more difficult for us to raise the necessary capital.

Our quarterly operating results are subject to substantial fluctuations and you should not rely on them as an indication of our future results.

Our quarterly operating and financial results may fluctuate from period to period due to a combination of factors, many of which are beyond our control. These include:

- the seasonality of our product sales, which typically results in higher demand in our fourth quarter and lower sales volumes in our third quarter;
- the mix of our products sold;
- demand for, and pricing of, our products and the products of our competitors;
- timing of or failure to obtain regulatory approvals for products;
- costs, benefits and timing of new product introductions by us and our competitors;
- increased competition;
- the timing and extent of promotional pricing or volume discounts;
- the timing of larger orders by customers and the timing of shipment of such orders;
- field inventory levels;
- changes in average selling prices;
- the availability and cost of components and materials;
- the number of selling days;

- fluctuations in foreign currency exchange rates;
- the possible deferral of revenue under our revenue recognition policies;
- the timing of operating expenses in anticipation of sales;
- the timing of operating expenses for clinical and other product development activities;
- unanticipated expenses;
- the accounting treatment of the contingent consideration we agreed to pay in connection with our acquisition of Chestnut;
- the accounting treatment for income taxes, including the potential future reversal of our valuation allowance and the resulting impact on our future recorded effective tax rate;
- other costs related to acquisitions of technologies or businesses;
- restructuring, impairment and other special charges; and
- fluctuations in investment returns on invested cash balances.

Because of these and other factors, our quarterly sales and other operating results may vary significantly in the future and thus period to period comparisons may not be meaningful and should not be relied upon as indications of our future performance. Any shortfalls in sales or earnings from levels expected by securities analysts or investors could cause our stock price to decline significantly.

We may become obligated to make large milestone payments that are not reflected in our consolidated financial statements in certain circumstances, which would negatively impact our cash flows. In addition, due to changes in applicable generally accepted accounting principles, the milestone payment for our recent acquisition of Chestnut likely could negatively impact our future operating results.

Pursuant to the acquisition agreements relating to our purchases of Chestnut, MitraLife and Appriva and FoxHollow's purchase of Kerberos Proximal Solutions, Inc., we and/or our subsidiaries agreed to make additional payments to the sellers of these businesses in the event that we achieve contractually defined milestones. Generally, in each case, these milestone payments become due upon the completion of specific regulatory steps in the product commercialization process.

Under the terms of our acquisition agreement with Chestnut, we may be obligated to make an additional milestone payment of up to $75 million if the FDA issues a letter granting pre-market approval for the commercialization of the Pipeline Embolization Device in the United States pursuant to an indication to treat intracranial aneurysms on or before December 31, 2012. The milestone payment is to be made in cash and shares of our common stock and is subject to certain rights of set-off for permitted indemnification claims by us against Chestnut. If we are required to make an additional milestone payment of cash and common stock to the former Chestnut shareholders and if we do not have a sufficient amount of cash and cash equivalents to make this milestone payment, we will be required to raise additional financing, which may be difficult or impossible, depending upon our business and operating results and the market for such financings at that time.

With respect to the MitraLife acquisition, the maximum potential milestone payments totaled $25 million, and with respect to the Appriva acquisition, the maximum potential milestone payments totaled $175 million. Although we do not believe that it is likely that the milestone payment obligations to MitraLife or Appriva became due, the former stockholders of Appriva disagree with our position and have brought litigation against us making a claim for such payments and it is possible that the former stockholders of MitraLife also could disagree with our position and make a claim for such payments. Pursuant to the acquisition agreement relating to FoxHollow's purchase of Kerberos Proximal Solutions, Inc., FoxHollow agreed to pay certain earn-out payments which are capped at $117

million upon the achievement of contractually defined net sales milestones. We have received correspondence from counsel for the shareholder representatives of Kerberos alleging that FoxHollow has not used commercially reasonable efforts to market, promote, sell and distribute Kerberos's Rinspirator products, as required under the agreement and plan of merger. There can be no assurance that the stockholder representatives of Kerberos will not commence litigation on the alleged claims. The defense of the outstanding litigation related to our Appriva acquisition and the outstanding claims related to FoxHollow's Kerberos acquisition is, and any such additional dispute with MitraLife would likely be, costly and time-consuming and divert our management's time and attention away from our business. In the event any such milestone payments become due and/or any other damages become payable, our costs would increase correspondingly which would negatively impact our cash flow from operations.

We have accounted for our acquisition of Chestnut using the acquisition method. The fair value of the potential $75 million milestone payment in connection with our acquisition of Chestnut has been included as a component of consideration transferred at the acquisition date fair value and is classified as a liability on our consolidated balance sheet and is remeasured at fair value at each reporting date with changes in fair value recognized as income or expense. Therefore, any change in the fair value will impact our earnings in such reporting period thereby resulting in potential variability in our earnings until the contingent consideration is resolved. Assuming that we continue to expect to achieve the regulatory milestone, the accounting impact of the future milestone payment likely will negatively impact our future operating results.

We rely on independent sales distributors and sales associates to market and sell our products outside of the United States, Canada, Australia and Europe.

Our future success outside of the United States, Canada, Australia and Europe depends largely upon marketing arrangements with independent sales distributors and sales associates, in particular their sales and service expertise and relationships with the customers in the marketplace. Independent distributors and sales associates may terminate their relationship with us, or devote insufficient sales efforts to our products. We are not able to control our independent distributors, including their sales activities. Accordingly, although we require all of our independent sales distributors and sales associates to comply with all applicable laws and regulations, we cannot assure that they will do so. In addition, because we have no control over their sales activities, we cannot assure that they will be successful in implementing our marketing plans. Many of our independent distributors outside of the United States, Canada, Australia and Europe initially obtain and maintain foreign regulatory approval for sale of our products in their respective countries. Our failure to maintain our relationships with our independent distributors and sales associates outside of the United States, Canada, Australia and Europe, or our failure to recruit and retain additional skilled independent sales distributors and sales associates in these locations, could have an adverse effect on our operations. We have experienced turnover with some of our independent distributors in the past that has adversely affected our short-term financial results while we transitioned to new independent distributors. Similar occurrences could happen to us in the future. Fluctuations in foreign currency exchange rates, including in particular any strengthening of the U.S. dollar may cause our independent sales distributors to seek longer payment terms to offset the higher prices they are paying in local currency for our products. In addition, in light of adverse worldwide economic conditions, the ability of our distributors to borrow money from their existing lenders or to obtain credit from other sources to purchase our products may be impaired or our distributors could experience a significant change in their liquidity or financial condition, all of which could impair their ability to distribute our products and eventually lead to distributor turnover.

We are exposed to product liability claims that could have an adverse effect on our business and operating results.

The design, manufacture and sale of medical devices expose us to significant risk of product liability claims, some of which may have a negative impact on our business. Most of our products were developed relatively recently and defects or risks that we have not yet identified may give rise to product liability claims. Our product liability insurance coverage may be inadequate to protect us from any liabilities we may incur or we may not be able to maintain adequate product liability insurance at acceptable rates. If a product liability claim or series of claims is brought against us for uninsured liabilities or in excess of our insurance coverage and it is ultimately determined that we are liable, our business could suffer. Additionally, we could experience a material design defect or manufacturing failure in our products, a quality system failure, other safety issues or heightened regulatory scrutiny that would warrant a recall of some of our products. A recall of our products also could result in increased product

liability claims. Further, while we train our physician customers on the proper usage of our products, there can be no assurance that they will implement our instructions accurately. If our products are used incorrectly by our customers, injury may result and this could give rise to product liability claims against us. Even a meritless or unsuccessful product liability claim could harm our reputation in the industry, lead to significant legal fees and could result in the diversion of management's attention from managing our business and may have a negative impact on our business and our operating results. In addition, successful product liability claims against one of our competitors could cause claims to be made against us.

We face competition from other companies, which could adversely impact our business and operating results.

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. Because of the size of the peripheral vascular and neurovascular markets, competitors and potential competitors have historically dedicated and will continue to dedicate significant resources to aggressively promote their products, develop new and improved products and/or acquire smaller companies with established and/or promising product lines. Our competitors and potential competitors may develop or acquire technologies and products that are safer, more effective, easier to use, less expensive or more readily accepted than ours. Their products could make our technology and products obsolete or noncompetitive. None of our customers have long-term purchase agreements with us and at any time may switch to the use of our competitors' products. Many of our physician customers like to experiment with new technologies. Within the plaque excision market, although we believe our plaque excision products compete favorably against other competing technologies, surgical procedures and pharmaceutical products, recently introduced plaque excision products by our competitors have adversely affected and may continue to adversely affect future sales of our plaque excision products, at least in the short term while physician customers experiment with such new products. Within the peripheral vascular stent market, we have experienced and may continue to experience increased competition from C. R. Bard Inc. which announced in 2009 that the FDA cleared certain of its stents for use in the superficial femoral arteries and proximal popliteal arteries, if physicians decide to use C. R. Bard Inc.'s FDA cleared stents rather than our stents off-label.

Our competitors range from small start-up companies to much larger companies. The larger companies with which we compete include Abbott Laboratories, Boston Scientific Corporation, Cook Incorporated, Cordis Corporation (a Johnson & Johnson company), Covidien Public Limited Company, C.R. Bard Inc., Medtronic, Inc., Terumo/MicroVention, Inc. and W.L. Gore & Associates, Inc. All of these larger companies 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 and have established reputations and relationships with our target customers, as well as worldwide distribution channels that are more effective than ours. We also compete, however, and in some cases even more intensely, with smaller manufacturers. In the peripheral vascular market, we compete against, among others: MEDRAD, Inc., Cardiovascular Systems, Inc., Pathway Medical Technologies, Inc., Idev Technologies, Inc., Invatec s.r.l. (which recently agreed to be acquired by Medtronic) and Spectranetics Corporation. In the neurovascular market, we compete against, among others: Balt Extrusion, Inc. and Micrus Corporation. In addition, we compete with a number of drug therapy treatments manufactured by major pharmaceutical companies, including Otsuka Pharmaceutical, the manufacturer of Pletal, and Sanofi Aventis, the manufacturer of Plavix.

We also compete with other manufacturers of medical devices for clinical sites to conduct human trials. If we are not able to locate clinical sites on a timely or cost-effective basis, this could impede our ability to conduct trials of our products and, therefore, our ability to obtain required regulatory clearance or approval.

We rely on our management information systems for accounting and finance, 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 operating results could be adversely affected.

The efficient operation of our business is dependent on our management information systems, on which we rely to effectively manage accounting and financial functions; manage order entry, order fulfillment and inventory replenishment processes; and to maintain research and development and clinical data. The failure of our management information systems to perform as we anticipate could disrupt our business and product development and could result in decreased sales, increased overhead costs, excess inventory and product shortages, causing our business and operating results 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 computer systems, Internet, telecommunications or data network failure.

Any such interruption could adversely affect our business and operating results.

We face a risk of non-compliance with certain financial covenants in our loan agreement with Silicon Valley Bank. If we are unable to meet the financial or other covenants under the agreement or negotiate future waivers or amendments of the covenants, we could be in default under the agreement, which would give Silicon Valley Bank a range of remedies, including declaring all outstanding debt to be due and payable, foreclosing on the assets securing the loan agreement and/or ceasing to provide additional revolving loans or letters of credit, which could have a material adverse effect on us.

Our operating subsidiaries, ev3 Endovascular, Inc., ev3 International, Inc., Micro Therapeutics, Inc. and FoxHollow Technologies, Inc., are parties to a loan and security agreement with Silicon Valley Bank. The facility consists of a $50.0 million revolving line of credit and a $10.0 million term loan. As of December 31, 2009, we had approximately $6.5 million in outstanding borrowings under the term loan and no outstanding borrowings under the revolving line of credit; however, we had approximately $934,000 of outstanding letters of credit issued by Silicon Valley Bank. The loan agreement requires us to maintain a monthly specified liquidity ratio and a quarterly adjusted earnings before interest, taxes, depreciation and amortization, or EBITDA, level. The loan agreement contains customary events of default, including, among others, the failure to comply with certain covenants or other agreements. Upon the occurrence and during the continuation of an event of default, amounts due under the loan agreement may be accelerated by Silicon Valley Bank. If we are unable to meet the financial or other covenants under the loan agreement or negotiate future waivers or amendments of such covenants, an event of default could occur under the loan agreement. Upon the occurrence and during the continuance of an event of default under the loan agreement, Silicon Valley Bank has available a range of remedies customary in these circumstances, including declaring all outstanding debt, together with accrued and unpaid interest thereon, to be due and payable, foreclosing on the assets securing the loan agreement and/or ceasing to provide additional revolving loans or letters of credit, which could have a material adverse effect on us.

The restrictive covenants in our loan agreement could limit our ability to conduct our business and respond to changing economic and business conditions and may place us at a competitive disadvantage relative to other companies that are subject to fewer restrictions.

Our loan and security agreement with Silicon Valley Bank requires us to maintain a specified liquidity ratio and an adjusted EBITDA level. Our failure to comply with these financial covenants could adversely affect our financial condition. The loan agreement limits our ability and the ability of certain of our subsidiaries to, among other things:

- transfer all or any part of our business or properties;
- permit or suffer a change in control;
- merge or consolidate, or acquire any entity;
- engage in any material new line of business;
- incur additional indebtedness or liens with respect to any of their properties;
- pay dividends or make any other distribution on or purchase of, any of their capital stock;
- make investments in other companies; or
- engage in related party transactions,

subject in each case to certain exceptions and limitations. As of December 31, 2009, our cash and cash equivalents were $98.1 million. In light of the amount of our cash and cash equivalents and the amounts outstanding under the loan agreement, it is possible that if we needed to we could pay off the outstanding amounts under the loan agreement at this time. However, it is also possible that if we do not generate cash from operations as we anticipate or if we incur significant unanticipated costs that we may need the flexibility provided under our Silicon Valley Bank loan agreement. The restrictive covenants under the loan agreement could limit our ability, and that of certain of our subsidiaries, to obtain future financing, withstand a future downturn in our business or the economy in general or otherwise conduct necessary corporate activities. The financial and restrictive covenants contained in the loan agreement also could adversely affect our ability to respond to changing economic and business conditions and place us at a competitive disadvantage relative to other companies that may be subject to fewer restrictions. Transactions that we may view as important opportunities, such as acquisitions, may be subject to the consent of Silicon Valley Bank, which consent may be withheld or granted subject to conditions specified at the time that may affect the attractiveness or viability of the transaction.

If we remain profitable, we cannot assure you that our net operating losses will be available to reduce our tax liability.

Our ability to use, or the amount of, our net operating losses may be limited or reduced. Generally under section 382 of the Internal Revenue Code of 1986, in the event of an "ownership change" of a company, the company is only allowed to use a limited amount of its net operating losses arising prior to the ownership change for each taxable year thereafter. As a result of prior acquisitions, including Chestnut and FoxHollow, and potential future acquisitions, our ability to use existing net operating losses to offset U.S. federal taxable income, if we continue to generate taxable income, may be subject to substantial limitations. These limitations could potentially result in increased future tax liability for us.

Risks Related to our Common Stock

One of our principal stockholders and its affiliates are able to influence matters requiring stockholder approval and could discourage the purchase of our outstanding shares at a premium.

As of December 31, 2009, Warburg Pincus beneficially owned approximately 24.2% of our outstanding common stock. In addition, under a holders agreement, we are required to nominate and use our best efforts to have elected to our board of directors two persons designated by Warburg Pincus and certain of its affiliates, which we refer to collectively as the "Warburg Pincus Entities," and Vertical Fund I, L.P. and Vertical Fund II, L.P., which we refer to together as the "Vertical Funds," if the Warburg Pincus Entities, the Vertical Funds and their affiliates collectively beneficially own 20% or more of our common stock. As a result of Warburg Pincus's share ownership and representation on our board of directors, Warburg Pincus is able to influence our affairs and actions, including matters requiring stockholder approval, such as the election of directors and approval of significant corporate transactions. The interests of Warburg Pincus may differ from the interests of our other stockholders. For example, Warburg Pincus could oppose a third party offer to acquire us that the other stockholders might consider attractive, and the third party may not be able or willing to proceed unless Warburg Pincus, as one of our significant stockholders, supports the offer. Warburg Pincus's concentration of ownership may have the effect of delaying, preventing or deterring a change in control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale or merger of our company and may negatively affect the market price of our common stock. Transactions that could be affected by this concentration of ownership include proxy contests, tender offers, mergers or other purchases of common stock that could give our stockholders the opportunity to realize a premium over the then-prevailing market price for shares of our common stock. In such case and in similar situations, our other stockholders may disagree with Warburg Pincus as to whether the action opposed or supported by Warburg Pincus is in the best interest of our stockholders.

Certain of our principal stockholders may have conflicts of interests with our other stockholders or our company in the future.

Certain of our principal stockholders, including Warburg Pincus, may make investments in companies and from time to time acquire and hold interests in businesses that compete directly or indirectly with us. These other investments may:

- create competing financial demands on our principal stockholders;
- create potential conflicts of interest; and
- require efforts consistent with applicable law to keep the other businesses separate from our operations.

These principal stockholders also may pursue acquisition opportunities that may be complementary to our business and, as a result, those acquisition opportunities may not be available to us. Furthermore, these principal stockholders may have an interest in us pursuing acquisitions, divestitures, financings or other transactions that, in their judgment, could enhance their equity investment, even though such transactions might involve risks to our stockholders. In addition, these principal stockholders' rights to vote or dispose of equity interests in us are not subject to restrictions in favor of us other than as may be required by applicable law.

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

Provisions in our certificate of incorporation and bylaws may discourage, delay or prevent a merger or acquisition involving our company that our stockholders may consider favorable. For example, our certificate of incorporation authorizes our board of directors to issue up to 100 million 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 our company. In addition, our 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 our company that is not favored by our board of directors.

We also are 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 our company that owned 15% or more of our outstanding voting stock during the past three years, subject to certain exceptions as described in Section 203. Under one such exception, Warburg Pincus does not constitute an "interested stockholder."

A large percentage of our outstanding common stock is held by insiders, and, as a result, the trading market for our common stock may not be as liquid as the stock of other public companies, and our common stock price could be volatile.

As of December 31, 2009, we had 112.3 million shares of common stock outstanding and 27.1% of the shares were beneficially owned by directors, executive officers and their respective affiliates. Companies with a substantial amount of stock held by insiders can be subject to a more volatile stock price. Fluctuations in the price of our common stock could be significant and likely will be impacted by a number of factors, such as:

- the introduction of new products or product enhancements by us or our competitors;
- changes in our growth rate or our competitors' growth rates;
- strategic actions by us or our competitors, such as acquisitions or restructurings;
- our ability to develop, obtain regulatory clearance or approval for, and market new and enhanced products on a timely basis;
- loss of any of key management personnel;
- disputes or other developments with respect to intellectual property rights;
- product liability claims or other litigation;
- public concern as to the safety or efficacy of our products;
- the public's reaction to our press releases and other public announcements and our filings with the SEC;
- sales of common stock by us, our significant stockholders, executive officers or directors;
- changes in stock market analyst recommendations or earnings estimates regarding our common stock, other comparable companies or our industry generally;
- changes in expectations or future performance;

- new laws or regulations or new interpretations of existing laws or regulations applicable to our business; and

- changes in health care policy in the United States and internationally, including changes in the availability of third-party reimbursement.

A significant decline in the price of our common stock could result in substantial losses for individual stockholders and could lead to costly and disruptive securities litigation. Securities class action litigation is sometimes brought against a company following periods of volatility in the market price of its securities or for other reasons. We may become the target of similar litigation. Securities litigation, whether with or without merit, could result in substantial costs and divert management's attention and resources, which could harm our business and financial condition, as well as the market price of our common stock.

We do not intend to pay cash dividends for the foreseeable future.

We have never declared or paid any cash dividends on our common stock and we currently intend to retain all of our earnings for the foreseeable future to finance the operation and expansion of our business, and do not anticipate paying any cash dividends in the future. As a result, our stockholders will only receive a return on their investment in our common stock if the market price of our common stock increases.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our worldwide corporate headquarters is located in Plymouth, Minnesota. The sales, manufacturing and research and development activities of our peripheral vascular business are primarily located in Plymouth, and to a lesser extent, in Irvine, California. The sales, manufacturing and research and development activities of our neurovascular business are primarily located in Irvine and Menlo Park, California. Our U.S. distribution center is located in Plymouth. Outside the United States, our European headquarters is in Paris, France, and includes our sales and marketing, and administrative activities. Our European warehouse facilities are located in Maastricht, Netherlands. In addition to our sales office in Paris, we have European sales and marketing offices in Bonn, London, Madrid, Maastricht, Milan and Stockholm. Our total manufacturing space is approximately 160,000 square feet and our total warehouse space is approximately 39,000 square feet. All of our real properties are leased with terms ending at various times from 2010 to 2017. We believe that our premises are adequate for our needs for the foreseeable future.

We are subject to three leases associated with our former FoxHollow operations in Redwood City, California, which operations we relocated to our Irvine and Plymouth facilities in 2008. We have entered into an agreement to sublease one of the Redwood City leases until January 15, 2012. Although we plan to sublease the other two facilities, we have not yet entered into definitive agreements to do so.

ITEM 3. LEGAL PROCEEDINGS

We are from time to time subject to, and are presently involved in, various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of our business. Our significant legal proceedings are discussed in Note 18 to our consolidated financial statements and incorporated herein by reference. While it is not possible to predict the outcome for most of the legal proceedings discussed in Note 18, the costs associated with such proceedings could have a material adverse effect on our consolidated results of operations, financial position or cash flows of a future period.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matter was submitted to a vote of our security holders during the fourth quarter ended December 31, 2009.

ITEM 4A. EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers, their ages and positions held, as of February 19, 2010, are as follows:

Name	Age	Position
Robert J. Palmisano	65	President and Chief Executive Officer
Pascal E.R. Girin	50	Executive Vice President and Chief Operating Officer
Stacy Enxing Seng	45	Executive Vice President and President, Worldwide Peripheral Vascular
Kevin M. Klemz	48	Senior Vice President, Secretary and Chief Legal Officer
Shawn McCormick	45	Senior Vice President and Chief Financial Officer
Gregory Morrison	46	Senior Vice President, Human Resources
David H. Mowry	47	Senior Vice President and President, Worldwide Neurovascular
Julie D. Tracy	48	Senior Vice President, Chief Communications Officer
Brett A. Wall	44	Senior Vice President and President, International

Each of our executive officers serves at the discretion of our board of directors and holds office until his or her successor is elected and qualified or until his or her earlier resignation or removal. Information regarding the business experience of our executive officers is set forth below.

Robert J. Palmisano has served as our President and Chief Executive Officer and as one of our directors since April 2008. Mr. Palmisano served as President and Chief Executive Officer of IntraLase Corp., a company engaged in the design, development and manufacture of laser products for vision correction, from April 2003 to April 2007, when IntraLase was acquired by Advanced Medical Optics, Inc. From April 2001 to April 2003, Mr. Palmisano was the President, Chief Executive Officer and a director of MacroChem Corporation, a development stage pharmaceutical corporation. From April 1997 to January 2001, Mr. Palmisano served as President and Chief Executive Officer and a director of Summit Autonomous, Inc., a global medical products company that was acquired by Alcon, Inc. in October 2000. Prior to 1997, Mr. Palmisano held various executive positions with Bausch & Lomb Incorporated, a global eye care company. Mr. Palmisano earned his B.A. in Political Science from Providence College. Mr. Palmisano serves on the board of directors of Osteotech, Inc., a publicly held company, and Bausch & Lomb Incorporated and LenSX Lasers, Inc., both privately held companies and is a member of the Board of Trustees for Providence College in Providence, Rhode Island. During the past five years, Mr. Palmisano previously served on the board of directors of Abbott Medical Optics Inc.

Pascal E.R. Girin has served as our Executive Vice President and Chief Operating Officer since January 2010. Mr. Girin served as our Executive Vice President and President, Worldwide Neurovascular and International from July 2008 to December 2009. Mr. Girin served as our Senior Vice President from August 2007 to July 2008 and President, International from August 2005 to October 2009. Mr. Girin previously served as our General Manager, Europe from September 2003 to July 2005. From September 1998 to August 2003, Mr. Girin served in various capacities at BioScience Europe Baxter Healthcare Corporation, most recently as Vice President. Mr. Girin received an Engineering Education at the French Ecole des Mines.

Stacy Enxing Seng has served as our Executive Vice President and President, Worldwide Peripheral Vascular since January 2010. Prior to January 2010, Ms. Enxing Seng served as Executive Vice President and President, U.S. Peripheral Vascular since December 2008. Prior to December 2008, Ms. Enxing Seng served as President, FoxHollow Technologies Division since October 2007, Senior Vice President since August 2007 and President, Peripheral Vascular Division since March 2005. Ms. Enxing Seng also previously served as our Vice President, Marketing and New Business Development. Ms. Enxing Seng has served in various positions at our company since April 2001. Ms. Enxing Seng has been in the endovascular business since joining Scimed Life Systems, Inc. in 1993, and immediately prior to joining ev3, she served as Vice President of Global Marketing for the cardiology division at Boston Scientific/Scimed. Ms. Enxing Seng has a Bachelor of Arts in Public Policy from Michigan State University and a Master of Business Administration from Harvard University.

Kevin M. Klemz has served as our Senior Vice President since August 2007 and Secretary and Chief Legal Officer since January 2007. Prior to joining ev3, Mr. Klemz was a partner in the law firm Oppenheimer Wolff & Donnelly LLP where he was a corporate lawyer for over 20 years. Mr. Klemz has a Bachelor of Arts in Business Administration from Hamline University and a Juris Doctorate from William Mitchell College of Law.

Shawn McCormick has served as our Senior Vice President and Chief Financial Officer since January 2009. Prior to joining ev3, Mr. McCormick served as Vice President, Corporate Development at Medtronic, Inc., a global medical device company, where he was responsible for leading Medtronic's worldwide business development activities and previously had served in key corporate and divisional financial leadership roles within the Medtronic organization. Mr. McCormick joined Medtronic in July 1992 and held various finance positions during his tenure. From May 2008, he served as Vice President, Corporate Technology and New Ventures of Medtronic. From July 2002 to July 2007, he was Vice President, Finance for Medtronic's Spinal, Biologics and Navigation business. Prior to that, Mr. McCormick held various other positions with Medtronic, including Corporate Development Director, Principal Corporate Development Associate, Manager, Financial Analysis, Senior Financial Analyst and Senior Auditor. Prior to joining Medtronic, he spent almost four years with the public accounting firm KPMG Peat Marwick. Mr. McCormick earned his Master of Business Administration from the University of Minnesota's Carlson School of Management and his Bachelor of Science in Accounting from Arizona State University. He is a Certified Public Accountant.

Gregory Morrison has served as our Senior Vice President, Human Resources since August 2007 and from March 2002 to August 2007 as our Vice President, Human Resources. From March 1999 to February 2002, Mr. Morrison served as Vice President of Organizational Effectiveness for Thomson Legal & Regulatory, a division of The Thomson Corporation that provides integrated information solutions to legal, tax, accounting, intellectual property, compliance, business and government professionals. Mr. Morrison has a Bachelor of Arts in English and Communications from North Adams State College and a Master of Arts in Corporate Communications from Fairfield University.

David H. Mowry has served as our Senior Vice President and President, Worldwide Neurovascular since January 2010. From July 2008 to December 2009, Mr. Mowry served as Senior Vice President, Strategic and Corporate Operations and from October 2007 to July 2008, served as Senior Vice President, Corporate Manufacturing. Prior to October 2007, Mr. Mowry served as Vice President of Operations for ev3 Neurovascular since November 2006. From February 2004 to November 2006, Mr. Mowry served as Vice President of Operations and Logistics at the Zimmer Spine division of Zimmer Holdings Inc., a reconstructive and spinal implants, trauma and related orthopaedic surgical products company. Prior to Zimmer, Mr. Mowry was the President and Chief Operating Officer of HeartStent Corp., a medical device company. Mr. Mowry is a graduate of the United States Military Academy in West Point, New York with a degree in Engineering and Mathematics.

Julie D. Tracy has served as our Senior Vice President and Chief Communications Officer since January 2008. From March 2007 to November 2007, Ms. Tracy served as Vice President, Chief Communications Officer of Kyphon Inc., a medical device company that was purchased by Medtronic, Inc. in November 2007. From April 2005 to March 2007, Ms. Tracy served as Vice President, Investor Relations and Corporate Marketing of Kyphon Inc. From January 2003 to April 2005, Ms. Tracy served as Vice President of Marketing at Kyphon Inc. Prior to joining Kyphon Inc., Ms. Tracy held senior level positions in marketing, business development and reimbursement at Thoratec Corporation from January 1998 to January 2003. Ms. Tracy has a Bachelor of Science in Business Administration from the University of Southern California and a Master of Business Administration from Pepperdine University.

Brett A. Wall has served as our Senior Vice President and President, International since October 2009. From August 2008 to October 2009, Mr. Wall served as Vice President, Sales and Marketing for ev3 Neurovascular. Mr. Wall has served in various Vice President positions since April 2001. Mr. Wall served as Vice President of Marketing for ev3 Peripheral Vascular from January 2008 to August 2008, Vice President of Marketing for ev3 Neurovascular from April 2007 to January 2008, Vice President of Marketing for ev3 Peripheral Vascular from November 2005 to April 2007 and Vice President of Marketing for ev3 Neurovascular from April 2001 to November 2005. Mr. Wall was an early employee of MicroTherapeutics, Inc., serving in a variety of positions. We acquired MicroTherapeutics in 2006. From September 1995 to September 2000, Mr. Wall served in a variety of positions for Boston Scientific

including Director of Cardiovascular Marketing for the Asia Pacific region. Mr. Wall holds a Bachelor of Science Degree in Comprehensive Business Administration from the University of Nebraska at Kearney.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Price

Our common stock is listed for trading on the NASDAQ Global Select Market under the symbol "EVVV." Our common stock has traded on that market, which was formerly known as the NASDAQ National Market System, since the date of our initial public offering on June 16, 2005.

The following table sets forth the high and low daily sales prices for our common stock, as reported by the NASDAQ Global Select Market, for each quarter during 2009 and 2008.

	High	Low
2009		
First Quarter	$ 7.82	$ 4.40
Second Quarter	$11.19	$ 7.05
Third Quarter	$13.19	$ 9.60
Fourth Quarter	$13.93	$ 11.20

	High	Low
2008		
First Quarter	$12.72	$ 7.36
Second Quarter	$10.69	$ 7.32
Third Quarter	$12.58	$ 8.60
Fourth Quarter	$ 9.92	$ 3.37

Number of Record Holders; Dividends

As of February 18, 2010, there were 188 record holders of our common stock. To date, we have not declared or paid any cash dividends on our common stock. The restrictive covenants in our loan agreement with Silicon Valley Bank limit our ability to pay cash dividends.

Recent Sales of Unregistered Equity Securities

During the fourth quarter ended December 31, 2009, we did not issue or sell any shares of our common stock or other equity securities of our company without registration under the Securities Act of 1933, as amended.

Issuer Purchases of Equity Securities

The following table sets forth the information with respect to purchases made by or on behalf of us or any "affiliated purchaser" (as defined in Rule 10b-18(a)(3) under the Securities Exchange Act of 1934, as amended), of shares of our common stock during each month of our fourth quarter ended December 31, 2009.

Period	Total Number of Shares Purchased[1]	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs[2]	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs[2]
Month # 1				
(October 5, 2009 – November 8, 2009)	2,144	$ 12.18	N/A	N/A
Month # 2				
(November 9, 2009 – December 6, 2009)	34,600	12.57	N/A	N/A
Month # 3				
(December 7, 2009 - December 31, 2009). . . .	—	—	N/A	N/A
Total:	36,744	$ 12.55	N/A	N/A

(1) Consists of shares repurchased from employees in connection with the required payment of withholding or employment-related tax obligations due in connection with the vesting of restricted stock awards.

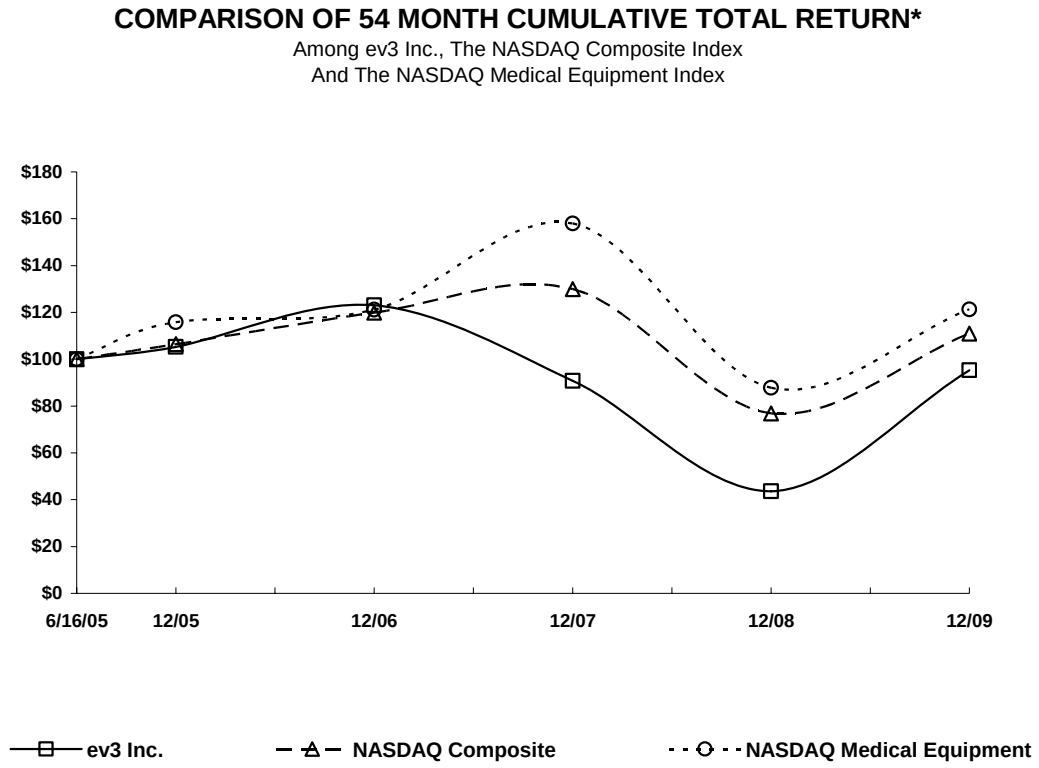
(2) Our board of directors has not authorized any repurchase plan or program for purchase of shares of our common stock or other equity securities on the open market or otherwise, other than an indefinite number of shares in connection with the cashless exercise of outstanding stock options and the surrender of shares of our common stock upon the issuance or vesting of stock grants to satisfy any required withholding or employment-related tax obligations.

Except as set forth in the table above, we did not purchase any shares of our common stock or other equity securities of our company registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended, during the fourth quarter ended December 31, 2009.

Stock Performance Graph

The following graph compares the annual cumulative total stockholder return on our common stock from June 16, 2005, the date of our initial public offering, until December 31, 2009, with the annual cumulative total return over the same period of The NASDAQ Stock Market (U.S.) Index and The NASDAQ Medical Equipment Index.

The comparison assumes the investment of $100 in each of our common stock, The NASDAQ Stock Market (U.S.) Index and The NASDAQ Medical Equipment Index on June 16, 2005, and the reinvestment of all dividends.



*$100 invested on 6/16/05 in stock & 5/31/05 in index-including reinvestment of dividends.
Fiscal year ending December 31.

The foregoing Stock Performance Graph shall not be deemed to be "filed" with the Securities and Exchange Commission or subject to the liabilities of Section 18 of the Securities Exchange Act of 1934, as amended. Notwithstanding anything to the contrary set forth in any of our previous filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, that might incorporate future filings, including this annual report on Form 10-K, in whole or in part, the foregoing Stock Performance Graph shall not be incorporated by reference into any such filings.

ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data set forth our results of operations and balance sheet data for the fiscal years and as of the dates indicated. Certain prior year items have been reclassified to conform to the current year presentation.

	For the Year Ended December 31,				
	2009[1]	2008	2007[2]	2006	2005
	(dollars in thousands, except per unit and per share amounts)				
Results of Operations:					
Sales:					
Net product sales	$ 449,072	$ 402,233	$ 278,226	$ 202,438	$133,696
Research collaboration	—	19,895	5,957	—	—
Net sales	449,072	422,128	284,183	202,438	133,696
Operating expenses:					
Product cost of goods sold	120,613	136,847	99,879	71,321	55,094
Research collaboration	—	6,051	1,065	—	—
Sales, general and administrative	225,023	232,200	194,289	141,941	130,627
Research and development	49,060	48,784	48,413	26,725	39,280
Amortization of intangible assets	25,143	31,072	20,306	17,223	10,673
Contingent consideration	4,876	—	—	—	—
Goodwill and intangible asset impairment[3]	—	299,263	—	—	—
Acquired in-process research and development	—	—	70,700	1,786	868
Special charges [4]	—	—	19,054	—	—
Total operating expenses	424,715	754,217	453,706	258,996	236,542
Income (loss) from operations	24,357	(332,089)	(169,523)	(56,558)	(102,846)
Other (income) expense:					
(Gain) loss on investments, net	(4,113)	(487)	116	(1,063)	(4,611)
Interest expense (income), net	788	(223)	(1,910)	(1,695)	9,916
Minority interest in loss of subsidiary	—	—	—	—	(2,013)
Other expense (income), net	1,588	2,427	(2,934)	(2,117)	3,360
Income (loss) before income taxes	26,094	(333,806)	(164,795)	(51,683)	(109,498)
Income tax (benefit) expense	(15,823)	1,816	949	688	526
Net income (loss)	41,917	(335,622)	(165,744)	(52,371)	(110,024)
Accretion of preferred membership units to redemption value[5]	—	—	—	—	12,061
Net income (loss) attributable to common unit/share holders	$ 41,917	$ (335,622)	$ (165,744)	$ (52,371)	$(122,085)
Net income (loss) per common unit/share[6]:					
Basic	$ 0.39	$ (3.22)	$(2.37)	$ (0.93)	$ (4.48)
Diluted	$ 0.38	$ (3.22)	$(2.37)	$ (0.93)	$ (4.48)
Weighted average units/shares outstanding:					
Basic	107,997,738	104,378,828	69,909,708	56,585,025	27,242,712
Diluted	108,998,528	104,378,828	69,909,708	56,585,025	27,242,712

(1) We acquired Chestnut Medical Technologies, Inc. on June 23, 2009. In connection with the acquisition, we recorded $4.9 million of contingent consideration and recognized a tax benefit of $19.0 million which resulted from the reversal of existing deferred tax valuation allowance. For a more complete description of these items and their impact on our consolidated financial results, see Note 3 to our consolidated financial statements.

(2) We acquired FoxHollow Technologies, Inc. on October 4, 2007. In connection with the acquisition, we recorded $14.9 million of integration costs associated with the acquisition and recognized $70.7 million for in-process research and development charges. For a more complete description of these items and their impact on our consolidated financial results, see Note 3 to our consolidated financial statements.

(3) We recorded $288.8 million in non-cash, asset impairment charges in our peripheral vascular segment to reduce the carrying values of goodwill and certain other intangible assets to their estimated fair values in 2008. In 2008, we also recorded an asset impairment charge of $10.5 million, as a result of the termination of our research collaboration with Merck & Co., Inc., to write-off the remaining carrying value of the related Merck intangible asset that was established at the time of our acquisition of FoxHollow. For a more complete description of these items and their impact on our consolidated financial results, see Note 9 to our consolidated financial statements.

(4) We recorded $19.1 million of special charges as a result of the settlement of the global coil patent litigation with The Regents of the University of California and Boston Scientific Corporation in 2007.

(5) The accretion of preferred membership units to redemption value presented above is based on the rights to which the Class A and Class B preferred membership unit holders of ev3 LLC were entitled related to a liquidation, dissolution or winding up of ev3 LLC. Notwithstanding this accretion right, in connection with the merger of ev3 LLC with and into ev3 Inc., each membership unit representing a preferred equity interest in ev3 LLC was converted into one share of our common stock and did not receive any additional rights with respect to the liquidation preference. Accretion was discontinued upon conversion of the preferred units to common equity at the time of our initial public offering on June 21, 2005.

(6) Net income (loss) per common unit/share and number of units/shares used in per unit/share calculations reflect our June 21, 2005 one-for-six reverse stock split for all periods presented.

	As of December 31,				
	2009	2008	2007	2006	2005
	(dollars in thousands)				
Balance Sheet Data:					
Cash and cash equivalents	$ 98,050	$ 59,652	$ 81,060	$ 24,053	$ 69,592
Short-term investments	—	—	9,744	14,700	12,000
Total current assets	240,460	187,123	228,370	135,845	151,675
Total assets	896,289	720,664	1,087,106	352,826	296,828
Total current liabilities	73,929	67,448	119,159	41,767	37,671
Long-term debt	3,958	6,458	6,429	5,357	—
Total liabilities	141,795	80,123	128,625	47,592	38,523
Total stockholders' equity	754,494	640,541	958,481	305,234	245,455

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Management's Discussion and Analysis provides material historical and prospective disclosures intended to enable investors and other users to assess our financial condition and results of operations. Statements that are not historical are forward-looking and involve risks and uncertainties discussed under the headings "Part I. Item 1. Business—Forward-Looking Statements" and "Part I. Item 1A. Risk Factors" of this report. The following discussion of our results of operations and financial condition should be read in conjunction with our consolidated financial statements and the related notes thereto included elsewhere in this report. This Management's Discussion and Analysis is organized in the following major sections:

- **Business Overview**. This section provides a brief overview description of our business, focusing in particular on developments during the most recent year.

- **Summary of 2009 Results and 2010 Outlook**. This section provides a brief summary of our financial results and financial condition for 2009 and our outlook for 2010.

- **Items Impacting Comparability**. This section provides a brief description of the significant items impacting comparability for 2009, 2008 and 2007.

- **Sales and Expense Components**. This section provides a brief description of the significant line items in our consolidated statements of operations.

- **Results of Operations**. This section provides our analysis of the significant line items in our consolidated statements of operations.

- **Seasonal and Quarterly Fluctuations**. This section describes the effects of seasonal and quarterly fluctuations in our business.

- **Liquidity and Capital Resources**. This section provides an analysis of our liquidity and cash flows and a discussion of our outstanding debt and commitments.

- **Critical Accounting Policies and Estimates**. This section discusses the accounting estimates that are considered important to our financial condition and results of operations and require us to exercise subjective or complex judgments in their application. All of our significant accounting policies, including our critical accounting estimates, are summarized in Note 2 to our consolidated financial statements.

- **Recently Issued Accounting Pronouncements**. This section discusses recently issued accounting pronouncements that have had or may affect our results of operations and financial condition.

Business Overview

We are a leading global endovascular company focused on identifying and treating peripheral vascular disease, including, in particular, lower extremity arterial disease, and neurovascular disease. Since our founding in 2000, we have been dedicated to developing innovative, breakthrough and clinically proven technologies and solutions for the treatment of peripheral vascular and neurovascular diseases, a strategy that we believe is uncommon in the medical device industry. We believe our unique approach of focusing on emerging and under-innovated opportunities, which treat peripheral vascular and neurovascular disease, allows us to compete with smaller companies that have narrow product lines and lack an international sales force and infrastructure, yet also compete with larger companies that do not have our focus and agility.

We believe the overall market for endovascular devices will grow as the demand for minimally invasive treatment of vascular diseases and disorders continues to increase. We intend to capitalize on this market opportunity through the continued introduction of new products. We expect to originate these new products primarily through our internal

research and development and clinical efforts, but we may supplement them with targeted acquisitions or other external collaborations. Most recently, in June 2009, we acquired Chestnut Medical Technologies, Inc., a then privately held, California-based company focused on developing minimally invasive therapies for interventional neuroradiology. This transaction broadened our neurovascular product portfolio by adding the Pipeline Embolization Device for the treatment of cerebral aneurysms and the Alligator Retrieval Device for foreign body retrieval to our existing embolic product and neuro access technologies. Additionally, our growth has been, and will continue to be, impacted by our expansion and penetration into new geographic markets, the expansion and penetration of our direct sales organization in existing geographic markets, and our continuing focus to increase the efficiency of our existing direct sales organization.

Our product portfolio includes a broad spectrum of over 100 products consisting of over 1,500 stock keeping units (SKUs), including plaque excision, stents, embolic protection and thrombectomy devices, carotid stenting solutions, percutaneous transluminal angioplasty (PTA) balloons and other procedural support products for the peripheral vascular market and embolic coils, flow diversion and flow restoration devices, flow directed and other micro catheters, liquid embolics, occlusion balloon systems, guidewires, neuro stents and retrieval devices for the neurovascular market. Our management, including our chief executive officer who is our chief operating decision maker, report and manage our operations in two reportable business segments based on similarities in the products sold, customer base and distribution system. We have corporate infrastructure and direct sales capabilities in the United States, Europe, Canada, Australia and other countries and have established distribution relationships in selected international markets. In order to drive sales growth, we have invested heavily throughout our history in not only the expansion of our global distribution system, but also new product development and clinical trials to obtain regulatory approvals. A significant portion of our net sales historically has been, and we expect to continue to be, attributable to new and enhanced products.

During 2009, our neurovascular net sales were benefited by continued market penetration of the Axium coil, Onyx Liquid Embolic System and the launch of our Pipeline Embolization Device in Europe and other international markets. Building on the success we have experienced to date with our Axium coils, we concluded our physician preference testing for two new versions of the Axium coil, the Axium PGLA and Axium Nylon microfilament coils in the U.S. and Europe during the fourth quarter of 2009 and are in the process of launching these products for broad commercial availability. We recently launched our new Marksman delivery catheter and Alligator Retrieval Device in the U.S. and Europe and introduced access product line extensions, including the HyperGlide 5.0 balloon in the U.S. and Europe and the HyperGlide 3.0 balloon in the U.S. Since receiving the CE Mark for our Solitaire FR, or flow restoration, device to treat ischemic stroke in July of 2009, we have completed our European physician preference testing, and the Solitaire FR device is now fully launched in Europe. We also expect to launch our new Apollo delivery catheter for our Onyx Liquid Embolic System in 2010.

Our peripheral vascular net sales for 2009 were benefited by increased market penetration of our EverFlex family of stents and our new PTA balloons. During fourth quarter of 2009, we launched our new TurboHawk Plaque Excision System, which we expect to positively affect our plaque excision sales in 2010, and our redesigned TrailBlazer Support Catheter. At the beginning of 2010, we also launched our PowerCross 0.018 PTA balloon platform and now have a variety of platform sizes available worldwide.

We expect to continue to further validate the clinical and competitive benefits of our technology platforms to drive utilization of our current products and the development of new and enhanced products. To accomplish this, we have a number of clinical trials underway and others that are currently in development, including our DURABILITY II trial in the U.S. with the objective of expanding our EverFlex stent's U.S. indication to include treatment of peripheral artery disease and our DEFINITIVE trial series designed to expand the clinical evidence supporting the value of our plaque excision systems to drive increased procedure adoption, expand clinical indications and support the use of atherectomy as a front-line therapy. In our neurovascular business, we anticipate commencing enrollment during the first quarter of 2010 of our Solitaire with Immediate Flow Restoration, or SWIFT, study under a U.S. investigational device exemption, or IDE, to obtain FDA clearance for our Solitaire neuro stent, and will continue with our PUFS and COCOA studies of our Pipeline Embolization Device.

It is our understanding that certain biliary stent manufacturers have received subpoenas from the U.S. Department of Justice. Based on publicly available information, we believe that these subpoenas requested information regarding the sales and marketing activities of these manufacturers' biliary stent products and that the Department of Justice is

seeking to determine whether any of these activities violated civil and/or criminal laws, including the Federal False Claims Act, the Food and Drug Cosmetic Act and the Anti-Kickback Statute in connection with Medicare and/or Medicaid reimbursement paid to third parties. As of the date of this report, we have not received a subpoena from the U.S. Department of Justice relating to this investigation. No assurance can be provided, however, that we will not receive such a subpoena or become the subject of such an investigation, which could adversely affect our business and stock price.

Summary of 2009 Financial Results and Outlook for 2010

During 2009, we achieved profitability and cash generation. Our operating results reflect sales growth in both our peripheral vascular and neurovascular segments, continued expansion of our international business, improvement in our gross margins and continued expense control. During 2010, we will continue to focus on growing our revenue at or above market rates, improving profitability and generating cash.

Our 2009 results and financial condition included the following items of significance, some of which we expect also may affect our results and financial condition in 2010:

- Net sales of our peripheral vascular products increased 4% to $279.5 million in 2009 compared to 2008 primarily as a result of continued market penetration of our embolic protection devices and EverFlex family of stents, partially offset by a decline in sales of our plaque excision products. We expect continued growth of our EverFlex family of stents during 2010, although we are prohibited from marketing and promoting these devices in the U.S. outside of their approved indication and, we remain cautious of the current regulatory environment regarding the off-label utilization of our stents and the increased competition we may experience. Although our plaque excision sales decreased in 2009 compared to 2008, we expect the recent launch of our new TurboHawk Plaque Excision System to have a positive impact on our plaque excision sales going forward.

- Net sales of our neurovascular products increased 28% to $169.5 million in 2009 compared to $132.3 million in 2008 primarily as a result of continued market penetration of our Axium coil and Onyx Liquid Embolic System and the launch of our Pipeline Embolization Device in Europe and other international markets. We believe our neurovascular business should benefit from the continued market penetration of the Axium coil and Onyx Liquid Embolic System in 2010, from new product introductions, including our Pipeline and Solitaire FR devices, and expanded geographic presence.

- On a geographic basis, 60% of our net sales for 2009 were generated in the United States and 40% were generated outside the United States. Our international net sales increased 21% to $178.1 million in 2009 compared to 2008 primarily driven by market penetration of the Axium coil and neuro stent, as well as the launch of our Pipeline Embolization Device. We expect our international business to continue to benefit from our ability to sell our EverCross, NanoCross and PowerCross PTA balloon catheters, the recent launch of our Pipeline Embolization Device in Europe and other international markets, the launch of our Axium PGLA and Nylon microfilament coils, Marksman delivery catheter and Alligator Retrieval Device, and expansion of sales of our plaque excision devices. Changes in foreign currency exchange rates had a negative impact on our 2009 net sales of $6.7 million compared to 2008, principally resulting from the relationship of the U.S. dollar as compared to the euro. At current exchange rates, we expect foreign currency exchange rates to have a negligible impact on our 2010 net sales compared to our 2009 net sales.

- Product gross margin increased to 73% in 2009 compared to 66% in 2008 primarily attributable to manufacturing efficiencies in our peripheral vascular segment, including synergies related to the consolidation of our FoxHollow manufacturing operations and manufacturing process improvements associated with our self-expanding stents. Product gross margin was also positively impacted by selling our own line of PTA balloons and the mix of neurovascular products sold. We expect to continue to increase our product gross margins through our focus on manufacturing efficiencies and opportunities to increase product pricing. Product gross margin for internal measurement purposes is defined as net

product sales less product cost of goods sold, excluding amortization of intangible assets, divided by net product sales.

- Our sales, general and administrative expenses decreased in absolute dollars in 2009 compared to 2008, and as a percentage of net sales, represented 50% of our net sales in 2009 compared to 55% of our net sales in 2008. We expect our sales, general and administrative expenses as a percentage of net sales to continue to decrease in 2010 compared to 2009 primarily as a result of our ability to improve our processes and leverage our infrastructure to grow expenses at a lesser rate than our anticipated revenue growth.

- Our net income for 2009 was $41.9 million, or $0.38 per diluted common share, compared to a net loss of $335.6 million, or $3.22 per diluted share, in 2008.

- We had $98.1 million of cash and cash equivalents at December 31, 2009, an increase of $38.4 million compared to December 31, 2008. This increase was primarily a result of cash provided by operating activities, totaling $69.3 million during 2009 driven primarily by our operating performance, offset by $24.7 million of net cash paid in conjunction with our acquisition of Chestnut. We plan to continue to focus on generating positive cash flow from operations during 2010.

Items Impacting Comparability

The following items impacted the comparability of our financial results for 2009, 2008 and 2007:

2009

- Charge of $3.4 million to increase reserves on our vacated FoxHollow lease facilities.
- Gain of $4.1 million attributed to the divestiture of non-strategic investments.
- Tax benefit of $19.0 million triggered by the purchase accounting for our acquisition of Chestnut.
- Charges relating to the estimated change in fair value of the contingent consideration of $4.9 million associated with the Chestnut acquisition.

2008

- Research collaboration revenue and expense of $19.9 million and $6.1 million, respectively, from our former collaboration and license agreement with Merck.
- An aggregate of $288.8 million in non-cash, asset impairment charges in our peripheral vascular segment to reduce the carrying amounts of goodwill and other intangible assets to their estimated fair values, which were driven primarily by the then substantial disruption in the general credit and equity markets and in particular the decline in our stock price and market capitalization and certain product discontinuations during our fourth quarter of 2008.
- Non-cash asset impairment charge of $10.5 million to write off the remaining carrying amount of the Merck intangible asset that was established at the time of our acquisition of FoxHollow.

2007

- Incremental net sales from FoxHollow products of $20.9 million.
- Research collaboration revenue and expense of $6.0 million and $1.1 million, respectively, from our former collaboration and license agreement with Merck.
- Charge of $70.7 million for acquired in-process research and development, integration costs of $14.9 million and a charge of $3.3 million for excess and obsolete inventory associated with our FoxHollow acquisition.
- Special charges of $19.1 million recorded as a result of entering into agreements in principle to settle certain patent infringement and other litigation with The Regents of the University of California and Boston Scientific Corporation.

Sales and Expense Components

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

Net product sales. We derive our net product sales from the sale of endovascular devices in two primary business segments: peripheral vascular and neurovascular devices. Sales are generated by our global, 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 generated by shipments to distributors who, in turn, sell to hospitals and clinics. In cases where our products are held in consignment at a customer's location, we generate sales at the time the product is used in a procedure and we are notified in writing by the hospital that the product was used, rather than at shipment. We charge our customers for shipping and record shipping income as part of net sales.

Research collaboration (revenue). Research collaboration revenue was derived from our former collaboration and license agreement with Merck, which we assumed as a result of our acquisition of FoxHollow. For additional discussion, see Note 2 to our consolidated financial statements included elsewhere in this report.

Product cost of goods sold. We manufacture a substantial majority of the products that we sell. Our product cost of goods sold consists primarily of direct labor, allocated manufacturing overhead, raw materials, components and royalties and excludes amortization of intangible assets, which is presented as a separate component of operating expenses.

Research collaboration (expense). Research collaboration expense consists primarily of costs associated with our former collaboration and license agreement with Merck.

Sales, general and administrative. Our selling and marketing expenses consist primarily of sales commissions and support costs for our global, direct distribution system, marketing costs and freight expense that we pay to ship products to customers. General and administrative expenses consist primarily of salaries and benefits, compliance systems, and other costs for our accounting, finance, legal, information technology and human resources functions.

Research and development. Research and development expense includes costs associated with the design, development, testing, deployment, enhancement and regulatory approval of our products. It also includes costs associated with the design and execution of our clinical trials and regulatory submissions.

Amortization of intangible assets. This caption includes amortization expense for intangible assets, such as purchased developed technology, distribution channels and intellectual property, including patents and trademarks.

Contingent consideration. Contingent consideration is recorded at the acquisition-date estimated fair value of the contingent payment for all acquisitions beginning in 2009. The fair value of the contingent consideration is remeasured at each reporting date with the change in fair value included in our consolidated statements of operations. For additional discussion, see Note 4 to our consolidated financial statements included elsewhere in this report.

Goodwill and other intangible asset impairment. Goodwill and other intangible asset impairment consists of non-cash charges to reduce the carrying amounts of goodwill and other intangible assets to their estimated fair values. For additional discussion, see Note 9 to our consolidated financial statements included elsewhere in this report.

Acquired in-process research and development. Acquired in-process research and development reflects amounts assigned to those projects acquired in business combinations prior to January 1, 2009 or the acquisition of assets for which the related products have not received regulatory approval and have no alternative future use. In-process research and development acquired in business combinations subsequent to December 31, 2008 have been recorded as indefinite-lived intangible assets on the consolidated balance sheets.

Special charges. Special charges relate to settlements of certain former patent infringement and other litigation between us, The Regents of the University of California and Boston Scientific Corporation. The special charges include amounts paid by us to the parties and legal fees and expenses associated with the litigation.

(Gain) loss on investments, net. (Gain) loss on investments, net includes the difference between the proceeds received from the sale of an investment and its carrying amount. In addition, this caption includes losses from other than temporary declines in investments accounted for on a cost basis.

Interest expense, net. Interest expense, net results primarily from interest associated with loans from Silicon Valley Bank. Interest income consists of interest earned on investments in investment-grade, interest-bearing securities and money market accounts.

Other expense (income), net. Other expense (income), net primarily includes foreign currency exchange gains and losses net of gains and losses incurred on forward exchange contracts intended to partially offset our exposure to foreign currency exchange rate fluctuations.

Income tax (benefit) expense. Income tax (benefit) expense includes federal income taxes (primarily alternative minimum tax), income tax in foreign jurisdictions, state income tax and changes to our deferred tax valuation allowance.

Results of Operations

The following table sets forth, for the periods indicated, our results of operations expressed as dollar amounts (in thousands), and the changes between the specified periods expressed as percent increases or decreases or "NM" if such increases or decreases are not material or applicable:

	For the Year Ended December 31,			For the Year Ended December 31,		
Results of Operations:	**2009[1]**	**2008**	**Percent Change**	**2008**	**2007[2]**	**Percent Change**
Sales:						
Net product sales	$449,072	$402,233	11.6%	$402,233	$278,226	44.6%
Research collaboration	—	19,895	-100.0%	19,895	5,957	234.0%
Net sales	449,072	422,128	6.4%	422,128	284,183	48.5%
Operating expenses:						
Product cost of goods sold	120,613	136,847	-11.9%	136,847	99,879	37.0%
Research collaboration	—	6,051	-100.0%	6,051	1,065	NM
Sales, general and administrative	225,023	232,200	-3.1%	232,200	194,289	19.5%
Research and development	49,060	48,784	0.6%	48,784	48,413	0.8%
Amortization of intangible assets	25,143	31,072	-19.1%	31,072	20,306	53.0%
Contingent consideration	4,876	—	NM	—	—	NM
Goodwill and intangible asset impairment[3]	—	299,263	-100.0%	299,263	—	NM
Acquired in-process research and development	—	—	NM	—	70,700	-100.0%
Special charges[4]	—	—	NM	—	19,054	-100.0%
Total operating expenses	424,715	754,217	-43.7%	754,217	453,706	66.2%
Income (loss) from operations	24,357	(332,089)	NM	(332,089)	(169,523)	-95.9%
Other (income) expense:						
(Gain) loss on investments, net	(4,113)	(487)	NM	(487)	116	NM
Interest expense (income), net	788	(223)	NM	(223)	(1,910)	88.3%
Other expense (income), net	1,588	2,427	-34.6%	2,427	(2,934)	NM
Income (loss) before income taxes	26,094	(333,806)	NM	(333,806)	(164,795)	-102.6%
Income tax (benefit) expense	(15,823)	1,816	NM	1,816	949	91.4%
Net income (loss)	$ 41,917	$(335,622)	NM	$(335,622)	$(165,744)	-102.5%

(1) In connection with the acquisition of Chestnut Medical Technologies, Inc. on June 23, 2009, we recorded $4.9 million of contingent consideration and recognized a tax benefit of $19.0 million which resulted from the reversal of existing deferred tax valuation allowance. For a more complete description of these items and their impact on our consolidated financial results, see Note 3 to our consolidated financial statements.

(2) In connection with the acquisition of FoxHollow Technologies, Inc. on October 4, 2007, we recorded $14.9 million of integration costs associated with the acquisition and recognized $70.7 million for in-process research and development charges. For a more complete description of these items and their impact on our consolidated financial results, see Note 3 to our consolidated financial statements.

(3) During 2008, we recorded $288.8 million in non-cash, asset impairment charges in our peripheral vascular segment to reduce the carrying amounts of goodwill and other intangible assets to their estimated fair values. Additionally, during 2008, as a result of the termination of our research collaboration with Merck, we recorded a non-cash asset impairment charge of $10.5 million to write off the remaining carrying amount of the related Merck intangible asset that was established at the time of our acquisition of FoxHollow. For a more complete description of these items and their impact on our consolidated financial results, see Note 9 to our consolidated financial statements.

(4) We recorded $19.1 million of special charges as a result of the settlement of the former litigation with The Regents of the University of California and Boston Scientific Corporation in 2007.

The following tables set forth, for the periods indicated, our net sales by segment and geography expressed as dollar amounts (in thousands) and the changes in net sales between the specified periods expressed as percentages:

NET SALES BY SEGMENT	For the Year Ended December 31, 2009	2008	Percent Change	For the Year Ended December 31, 2008	2007	Percent Change
Net sales						
Net product sales:						
Peripheral vascular:						
Plaque excision[1]	$ 84,072	$ 88,800	-5.3%	$ 88,800	$ 20,884	325.2%
Stents	114,900	107,146	7.2%	107,146	86,035	24.5%
Thrombectomy and embolic protection	31,513	27,779	13.4%	27,779	25,998	6.9%
Procedural support and other	49,046	46,204	6.2%	46,204	40,858	13.1%
Total peripheral vascular	$279,531	$269,929	3.6%	$269,929	$173,775	55.3%
Neurovascular:						
Embolic products	$103,081	$ 74,642	38.1%	$ 74,642	$ 56,003	33.3%
Neuro access and delivery products	66,460	57,662	15.3%	57,662	48,448	19.0%
Total neurovascular	$169,541	$132,304	28.1%	$132,304	$104,451	26.7%
Total net product sales	449,072	402,233	11.6%	402,233	278,226	44.6%
Research collaboration:	$ —	$ 19,895	-100.0%	$ 19,895	$ 5,957	234.0%
Total net sales	$449,072	$422,128	6.4%	$422,128	$284,183	48.5%

NET SALES BY GEOGRAPHY	For the Year Ended December 31, 2009	2008	Percent Change	For the Year Ended December 31, 2008	2007	Percent Change
United States	$270,961	$275,433	-1.6%	$275,433	$177,198	55.4%
International						
Before foreign exchange impact	184,803	146,695	26.0%	141,704	106,985	32.5%
Foreign exchange impact	(6,692)	—	NM	4,991	—	NM
Total	178,111	146,695	21.4%	146,695	106,985	37.1%
Total	$449,072	$422,128	6.4%	$422,128	$284,183	48.5%

(1) Formerly referred to as atherectomy

Comparison of the Year Ended December 31, 2009 to the Year Ended December 31, 2008

Net sales. Net sales increased 6% to $449.1 million in 2009 compared to $422.1 million in 2008. Our net sales in 2009 did not include any research collaboration revenue compared with $19.9 million of research collaboration revenue in 2008. Net product sales increased 12% to $449.1 million for 2009 compared to $402.2 million for 2008 driven by increased sales in all product categories, with the exception of our plaque excision (formerly referred to as atherectomy) products, which declined primarily as a result of increased competition.

Net sales of peripheral vascular products. Net sales of our peripheral vascular products increased 4% to $279.5 million in 2009 compared to $269.9 million in 2008. Net sales in our stent product line increased 7% to $114.9 million in 2009 compared to $107.1 million in 2008. This increase was attributable to increased market penetration of both our EverFlex family of stents and our balloon expandable stents. Net sales of our thrombectomy and embolic protection devices increased 13% to $31.5 million in 2009 compared to $27.8 million in 2008 largely due to increases in sales of our embolic protection devices. Net sales of our procedural support and other products, which include our PTA balloon devices, increased 6% to $49.0 million in 2009 compared to $46.2 million in 2008. Net

sales in our plaque excision product line decreased to $84.1 million in 2009 compared to $88.8 million in 2008 as a result of increased competition.

Net sales of neurovascular products. Net sales of our neurovascular products increased 28% to $169.5 million in 2009 compared to $132.3 million in 2008, driven by increases in all product categories. Net sales of our embolic products increased 38% to $103.1 million in 2009 compared to $74.6 million in 2008 primarily due to the continued market penetration of the Axium coil, Onyx Liquid Embolic System, neuro stents and launch of our Pipeline Embolization Device in Europe and other international markets. Net sales of our neuro access and delivery products increased 15% to $66.5 million in 2009 compared to $57.7 million in 2008 largely as a result of volume growth across multiple product lines including our catheters, neuro balloons and guidewires.

Net sales by geography. Net sales in the United States declined 2% to $271.0 million in 2009 compared to $275.4 million in 2008. Net sales in the U.S. in 2008 included $19.9 million of research collaboration revenue from Merck. Net product sales in the U.S. increased compared to 2008 primarily as a result of increased market penetration of our Onyx Liquid Embolic System, embolic protection devices and EverFlex family of stents.

International net sales increased 21% to $178.1 million in 2009 compared to $146.7 million in 2008 and represented 40% and 35% of our total net sales during 2009 and 2008, respectively. International growth was driven by an increase across all product categories including market penetration of the Axium coil and neuro stents and launch of our Pipeline Embolization Device and PTA balloons. Our international net sales in 2009 included the unfavorable impact of foreign currency of $6.7 million compared to a favorable impact of $5.0 million in 2008.

Research collaboration (revenue). Research collaboration revenue associated with our former collaboration agreement with Merck was $19.9 million in 2008. We did not recognize research collaboration revenue in 2009.

Product cost of goods sold. As a percentage of net product sales, product cost of goods sold declined to 27% of net product sales in 2009 compared to 34% in 2008. The improvement in our product costs of goods sold was mainly driven by cost improvements in our peripheral vascular division, as described in more detail below, and the mix of neurovascular products sold, which generally have lower product cost of goods sold.

In our peripheral vascular segment, product cost of goods sold as a percentage of product sales decreased to 29% in 2009 compared to 38% in 2008 as a result of improved manufacturing efficiencies including synergies related to the consolidation of our FoxHollow manufacturing operations, manufacturing process improvements associated with our self-expanding stents and selling our own line of PTA balloons, and volume growth. During 2008, we also incurred costs related to the consolidation of our FoxHollow manufacturing operations that did not recur in 2009.

In our neurovascular segment, product cost of goods sold as a percentage of product sales was 23% in 2009 compared to 26% in 2008 as a result of leverage due to volume growth and sales mix. Our product costs of goods sold in 2009 includes a $1.0 million impairment of an intellectual property asset.

Research collaboration (expense). Research collaboration expense incurred as a result of our former collaboration with Merck was $6.1 million in 2008. We did not incur research collaboration expense in 2009.

Sales, general and administrative. Sales, general and administrative expenses decreased 3% to $225.0 million in 2009 compared to $232.2 million in 2008 primarily as a result of synergies related to the consolidation of our FoxHollow facilities and cost management efforts. Sales, general and administrative expense as a percentage of net product sales declined to 50% of net product sales in 2009 compared to 58% of net product sales in 2008 primarily as a result of higher net product sales, improved sales productivity and continued expense leverage. During 2009 personnel and marketing costs decreased by $5.3 million compared to the prior year, slightly offset by $3.4 million of expense recorded in 2009 to increase accrued liabilities on our vacated FoxHollow leased facilities. In 2008, in connection with the resignation of our former chairman, president and chief executive officer, we recorded $2.8 million which consisted of a lump sum cash payment of $1.3 million and $1.5 million of non-cash stock-based compensation expense.

Research and development. Research and development expense increased slightly to $49.1 million in 2009 compared to $48.8 million in 2008. As a percentage of net sales, research and development expense decreased to 11% of net sales in 2009 compared to 12% of net sales in 2008.

Amortization of intangible assets. Amortization of intangible assets decreased 19% to $25.1 million in 2009 compared to $31.1 million in 2008 primarily as a result of lower gross intangible balances related to assets we impaired in 2008 and the full amortization of certain intangible assets, partially offset by the amortization of intangible assets purchased in connection with our acquisition of Chestnut. See Note 8 to our consolidated financial statements contained elsewhere in this report.

Contingent consideration. The change in the fair value of contingent consideration associated with our acquisition of Chestnut was $4.9 million in 2009. For additional discussion, see Note 3 and Note 4 of our consolidated financial statements.

Goodwill and intangible asset impairment. We did not incur goodwill and intangible asset impairment in 2009 compared to $299.3 million in 2008. We recorded $288.8 million in non-cash, impairment charges in our peripheral vascular segment to reduce the carrying amounts of goodwill and intangible assets to their estimated fair values. The impairment charges were driven primarily by the then substantial disruption in the general credit and equity markets and in particular the decline in our stock price and market capitalization and certain product discontinuations during our fourth quarter of 2008. As a result of the termination of our research collaboration with Merck in 2008, we also recorded a non-cash asset impairment charge of $10.5 million to write-off the remaining carrying amount of the Merck intangible asset that was established at the time of our acquisition of FoxHollow. See Note 9 to our consolidated financial statements contained elsewhere in this report.

(Gain) loss on investments, net. Gain on investments, net of $4.1 million in 2009 was for the realized gain on the sale of non-strategic investment assets. Gain on investments, net of $487,000 in 2008 was attributed to realized gains for various investments partly offset by other than temporary impairments.

Interest expense (income), net. Interest expense, net was $788,000 in 2009 compared to interest income, net of $223,000 in 2008. Interest expense for 2009 was $1.1 million and interest income was $278,000. Interest income for 2008 was $1.4 million and interest expense was $1.1 million. The change in interest income was due primarily to lower interest rates on invested cash balances in 2009 compared to 2008.

Other expense, net. Other expense, net was $1.6 million in 2009 compared to $2.4 million in 2008, and relates to net foreign currency exchange rate transaction gains and losses offset by gains and losses on forward foreign exchange contracts.

Income tax (benefit) expense. We recorded an income tax benefit of $15.8 million in 2009 and an expense of $1.8 million in 2008. In connection with our acquisition of Chestnut, we established net deferred tax liabilities which resulted in the reversal of $19.0 million of existing deferred tax valuation allowance. The reversal of our deferred tax valuation allowance is recorded as “Income tax (benefit) expense” on our consolidated statements of operations. This tax benefit amount is offset by $3.3 million of tax expense related primarily to estimated federal alternative minimum tax, income tax in foreign jurisdictions, and state income tax due in several states. The 2008 income tax expense related to certain foreign and U.S. state jurisdictions.

Comparison of the Year Ended December 31, 2008 to the Year Ended December 31, 2007

Net sales. Net sales increased 49% to $422.1 million in 2008 compared to $284.2 million in 2007, reflecting sales growth in each of our reportable business segments and geographic markets. In particular, our sales growth was positively affected by our FoxHollow acquisition, the launch of our Axium coil during the fourth quarter of 2007 and continued market penetration of the EverFlex family of stents and the Onyx Liquid Embolic System. Our net sales in 2008 included $88.8 million of net sales from our plaque excision products and $19.9 million of research collaboration revenue from our former collaboration arrangement with Merck.

Net sales of peripheral vascular products. Net sales of our peripheral vascular products increased 55% to $269.9 million in 2008 compared to $173.8 million in 2007. This sales growth was primarily the result of our FoxHollow acquisition and increased market penetration of our EverFlex family of stents.

Net sales in our plaque excision product line increased to $88.8 million in 2008 compared to $20.9 million in 2007 as a result of a full year of plaque excision sales in 2008. Net sales in our stent product line increased 25% to $107.1 million in 2008 compared to $86.0 million in 2007. This increase was attributable to increased market penetration of our EverFlex family of stents. Net sales of our thrombectomy and embolic protection devices increased 7% to $27.8 million in 2008 compared to $26.0 million in 2007. Net sales of our procedural support and other products increased 13% to $46.2 million in 2008 compared to $40.9 million in 2007 largely due to increased market penetration of Invatec's PTA balloon catheters in the United States.

Net sales of neurovascular products. Net sales of our neurovascular products increased 27% to $132.3 million in 2008 compared to $104.4 million in 2007 as a result of increased penetration of new and existing products and sales growth in virtually all of our neurovascular access and delivery products. Net sales of our embolic products increased 33% to $74.7 million in 2008 compared to $56.0 million in 2007 primarily due to the launch of the Axium coil and increased market penetration of the Onyx Liquid Embolic System, partially offset by sales declines in older generation products. Net sales of our neuro access and delivery products increased 19% to $57.6 million in 2008 compared to $48.4 million in 2007 largely as a result of volume increases across virtually all neuro access and delivery product lines.

Research collaboration (revenue). Research collaboration revenue was $19.9 million in 2008 compared to $6.0 million in 2007.

Net sales by geography. Net sales in the United States increased 55% to $275.4 million in 2008 compared to $177.2 million in 2007 and was driven mainly by the acquisition of FoxHollow, increased market penetration of our EverFlex family of stents, and the launch of the Axium coil. International net sales increased 37% to $146.7 million in 2008 compared to $107.0 million in 2007 and represented 35% and 38% of our total net sales during 2008 and 2007, respectively. International growth was primarily due to the launch of the Axium coil, further market penetration of the EverFlex family of stents and the Onyx Liquid Embolic System, and the continued penetration of our plaque excision products into international markets. Our international net sales in 2008 included a favorable foreign currency exchange rate impact of approximately $5.0 million compared to a favorable impact of $6.0 million in 2007, principally resulting from the relationship of the U.S. dollar to the euro.

Product cost of goods sold. As a percentage of product sales, product cost of goods sold was 34% in 2008 compared to 36% in 2007. In our peripheral vascular segment, product cost of goods sold as a percentage of net product sales decreased to 38% in 2008 compared to 42% in 2007 primarily attributable to manufacturing efficiencies and increased sales volumes, partially offset by costs associated with the consolidation of our Redwood City manufacturing operations into our Irvine and Plymouth facilities. In our neurovascular segment, product cost of goods sold as a percentage of net product sales was 26% in 2008 and 2007 and was attributable to manufacturing efficiencies and increased sales volumes, partially offset by additional excess and obsolete inventory reserves related to our planned product transitions to next generation devices.

Research collaboration (expense). Research collaboration expense incurred as a result of our former collaboration with Merck was $6.1 million in 2008 compared to $1.1 million incurred in 2007.

Sales, general and administrative. Sales, general and administrative expenses increased 20% to $232.2 million in 2008 compared to $194.3 million in 2007 primarily as a result of the acquisition of FoxHollow. Included in the increase were higher personnel costs of $30.8 million due to increases in overall staffing levels including the consolidated sales force as a result of our acquisition of FoxHollow, an increase of $7.1 million of additional marketing and selling costs, and a $3.6 million increase in non-cash stock-based compensation costs, offset by a decrease of $5.8 million in legal and litigation fees due to settlement of The Regents of the University of California and Boston Scientific Corporation litigation in 2007. Although sales, general and administrative expenses increased in absolute dollars, as a percentage of net sales, sales, general and administrative expenses decreased to 55% of net sales in 2008 compared to 68% of net sales in 2007 as a result of cost synergies implemented in the fourth quarter of 2007 and throughout 2008 and increased net sales.

Research and development. Research and development expense increased to $48.8 million in 2008 compared to $48.4 million in 2007. As a percentage of net sales, research and development expense decreased to 12% of net sales in 2008 compared to 17% of net sales in 2007 primarily as a result of increased net sales and cost saving efforts.

Amortization of intangible assets. Amortization of intangible assets increased 53% to $31.1 million in 2008 compared to $20.3 million in 2007 primarily as a result of the amortization of intangible assets purchased in connection with our acquisition of FoxHollow. See Note 8 to our consolidated financial statements contained elsewhere in this report.

Goodwill and other intangible asset impairment. Goodwill and other intangible asset impairment was $299.3 million in 2008. We recorded $288.8 million in non-cash, asset impairment charges in our peripheral vascular segment to reduce the carrying values of goodwill and other intangible assets to their estimated fair values. The impairment charges were driven primarily by the substantial disruption in the general credit and equity markets and in particular the decline in our stock price and market capitalization and certain product discontinuations during our fourth quarter of 2008. As a result of the termination of our research collaboration with Merck in 2008, we also recorded a non-cash asset impairment charge of $10.5 million to write-off the remaining carrying value of the related Merck intangible asset that was established at the time of our acquisition of FoxHollow. We did not incur goodwill and intangible asset impairment in 2007. See Note 9 to our consolidated financial statements contained elsewhere in this report.

Acquired in-process research and development. In 2007, we recorded $70.7 million in acquired in-process research and development projects that had not yet reached technological feasibility and had no future alternative use in connection with the FoxHollow acquisition. For further discussion, see Note 3 to our consolidated financial statements included elsewhere in this report.

Special charges. We recorded special charges of $19.1 million in 2007 as a result of us entering into agreements in principle to settle certain patent infringement and other litigation with The Regents of the University of California and Boston Scientific Corporation. The special charges consisted of amounts paid by us to the parties and our legal fees and expenses associated with the litigation.

(Gain) loss on investments, net. During 2008, we recorded a net realized gain of $487,000 related to various investments net of other than temporary impairments. During 2007, we recorded a loss of $116,000 realized on the sale of investments.

Interest expense (income), net. Interest income, net was $223,000 in 2008 compared to $1.9 million in 2007. Interest income for 2008 was $1.4 million and interest expense was $1.1 million. Interest income for 2007 was $3.3 million and interest expense was $1.4 million. The decrease in interest income was primarily due to lower average cash balances and decreased interest rates in 2008 compared to 2007.

Other expense (income), net. Other expense, net was an expense of $2.4 million in 2008 compared to other income, net of $2.9 million in 2007. The other expense (income), net in 2008 and 2007 was primarily due to foreign currency exchange rate transaction gains and losses. The stronger U.S. dollar compared to the euro negatively impacted our euro-designated accounts receivable in 2008.

Income tax expense. We incurred modest levels of income tax expense in 2008 related to certain foreign and U.S. state jurisdictions. In 2007, we incurred modest levels of income tax expense related to certain foreign jurisdictions. We did not record a provision for U.S. income taxes in 2007 due to our history of operating losses.

Seasonality and Quarterly Fluctuations

Our business is seasonal in nature. Historically, demand for our products has been the highest in our fourth quarter. We traditionally experience lower sales volumes in our third quarter than throughout the rest of the year as a result of the European holiday schedule during the summer months.

We have experienced and expect to continue to experience meaningful variability in our net sales and gross profit among quarters, as well as within each quarter, as a result of a number of factors, including, among other things, the number and mix of products sold in the quarter; the demand for, and pricing of, our products and the products of our competitors; the timing of or failure to obtain regulatory approvals for products; costs, benefits and timing of new product introductions; increased competition; the timing and extent of promotional pricing or volume discounts; the timing of larger orders by customers and the timing of shipment of such orders; changes in average selling prices; the availability and cost of components and materials; number of selling days; fluctuations in foreign currency exchange rates; and restructuring, impairment and other special charges. In addition, as a result of our recent acquisition of Chestnut, the potential $75 million milestone payment in connection with this acquisition is classified as a liability on our consolidated balance sheet, and remeasured at fair value at each reporting date, with changes in fair value recognized as income or expense. Therefore, any change in fair value impacts our earnings until the contingent consideration is resolved. Assuming that we continue to expect to achieve the regulatory milestone, the accounting impact of the future milestone payment will negatively impact our future quarterly operating results.

Liquidity and Capital Resources

The following table highlights several items from our consolidated balance sheet:

Balance Sheet Data	As of December 31, 2009	2008
	(dollars in thousands)	
Cash and cash equivalents	$ 98,050	$ 59,652
Total current assets	240,460	187,123
Total assets	896,289	720,664
Total current liabilities	73,929	67,448
Total liabilities	141,795	80,123
Total stockholders' equity	754,494	640,541

Working Capital

Cash and cash equivalents. Our cash and cash equivalents available to fund our current operations were $98.1 million and $59.7 million at December 31, 2009 and 2008, respectively. We expect to generate cash from operations in 2010, although no assurance can be provided that we will do so, especially if we incur significant unanticipated costs or do not achieve our anticipated net sales during 2010. We believe our cash and cash equivalents, anticipated cash from operations and current and anticipated financing arrangements will be sufficient to meet our liquidity requirements through at least the next 12 months.

Letters of credit and restricted cash. As of December 31, 2009, we had outstanding commitments of $4.2 million which are supported by irrevocable standby letters of credit and restricted cash. The letters of credit and restricted cash support various obligations, such as operating leases, tender arrangements with customers and automobile leases.

Financing history. Although we recognized net income during 2009, prior to such time, we generated significant operating losses including cumulative non-cash charges of $199.4 million for acquired in-process research and development and $299.3 million of non-cash asset impairment charges of goodwill and intangible assets that resulted in an accumulated deficit of $1.1 billion as of December 31, 2009.

Historically, our liquidity needs have been met primarily through equity issuances, our bank financing with Silicon Valley Bank and more recently cash generated from operations. In April of 2007, we completed a secondary public offering of our common stock in which we sold 2,500,000 shares of our common stock at $19.00 per share, resulting

in net proceeds to us of approximately $44.5 million. In October of 2007, we completed our acquisition of FoxHollow, which at the time had $166.9 million in cash, cash equivalents and short-term investments. We used $99.3 million to pay FoxHollow stockholders the cash portion of the merger consideration. In June of 2009, we completed our acquisition of Chestnut, and made a $26.2 million payment to the Chestnut stockholders for the cash portion of the acquisition consideration. For additional discussion, see Note 3 to our consolidated financial statements included elsewhere in this report.

Credit facility. Our operating subsidiaries, ev3 Endovascular, Inc., ev3 International, Inc., Micro Therapeutics, Inc. and FoxHollow Technologies, Inc., which we collectively refer to as the "borrowers," are parties to a loan and security agreement, with Silicon Valley Bank, which was amended most recently in December of 2008. The amended facility consists of a $50.0 million revolving line of credit and a $10.0 million term loan. The revolving line of credit expires on June 25, 2010 and the term loan matures on June 23, 2012. Pursuant to the terms of the loan agreement and subject to specified reserves, we may borrow under the revolving line of credit up to $12.0 million without any borrowing base limitations. Aggregate borrowings under the revolving line of credit that exceed $12.0 million will subject the revolving line to borrowing base limitations. These limitations allow us to borrow, subject to specified reserves, up to 80% of eligible domestic and foreign accounts receivables plus up to 30% of eligible inventory. Additionally, borrowings against the eligible inventory may not exceed the lesser of 33% of the amount advanced against eligible accounts receivable or $10.0 million. As of December 31, 2009, we had $6.5 million outstanding under the term loan and no outstanding borrowings under the revolving line of credit; however, we had approximately $934,000 of outstanding letters of credit issued by Silicon Valley Bank, which reduced the maximum amount available under our revolving line of credit to approximately $49.1 million.

Borrowings under the revolving line of credit bear interest at a variable annual rate equal to Silicon Valley Bank's prime rate plus 0.5%. Borrowings under the term loan bear interest at a variable annual rate equal to Silicon Valley Bank's prime rate plus 1.0%. Silicon Valley Bank's prime rate at December 31, 2009 was 4.0%. Accrued interest on any outstanding balance under the revolving line and the term loan is payable monthly in arrears. Principal amounts outstanding under the term loan are payable in 48 consecutive equal monthly installments on the last day of each month.

Both the revolving line of credit and term loan are secured by a first priority security interest in substantially all of our assets, excluding intellectual property, which is subject to a negative pledge, and are guaranteed by ev3 Inc. and all of our U.S. direct and indirect subsidiaries which are not borrowers. We are required to maintain a minimum adjusted quick ratio and a minimum consolidated earnings level. The loan agreement contains customary events of default, including the failure to make required payments, the failure to comply with certain covenants or other agreements, the occurrence of a material adverse change, failure to pay certain other indebtedness and certain events of bankruptcy or insolvency. Upon the occurrence and during the continuation of an event of default, amounts due under the loan agreement may be accelerated. We were in compliance with all of our financial and non-financial covenants at December 31, 2009.

Cash Flows

Operating activities. Net cash provided by operating activities was $69.3 million in 2009 compared to net cash used in operating activities of $13.9 million in 2008 and $49.2 million in 2007. We generated cash from operations during 2009 as a result of our improved operating results and working capital management. In 2009, our net income included a non-cash income tax benefit of $19.0 million recorded in connection with our acquisition of Chestnut (see Note 3 to our consolidated financial statements). Our net income in 2009 also included $50.9 million of non-cash charges for depreciation, amortization and stock-based compensation expense compared with $57.8 million during 2008. In 2008, our net loss also included $299.3 million of non-cash asset impairment charges of goodwill and other intangible assets. In 2007, our net loss included approximately $39.9 million of non-cash charges for depreciation, amortization and stock-based compensation expense, and $70.7 million of acquired in-process research and development expense.

Investing activities. Net cash used in investing activities was $32.4 million in 2009 compared to $9.6 million in 2008 and net cash provided by investing activities of $51.9 million in 2007. During 2009, in connection with the acquisition of Chestnut, we paid $24.7 million, net of cash received, for the cash portion of the acquisition consideration. During 2009, we also increased our restricted cash by $2.7 million and purchased $6.7 million of

property and equipment and $2.1 million of patents and licenses, offset by $4.1 million received in proceeds from the sale of non-strategic investment assets. Cash used in investing activities during 2008 was primarily due to purchases of $10.9 million of property and equipment, $7.5 million paid in connection with an earn-out contingency of a previous acquisition and $2.7 million of payments for patents and licenses, partially offset by $9.7 million in proceeds from the sale of short-term investments and $1.2 million in proceeds from the sale of assets. Net cash provided by investing activities in 2007 was primarily attributed to acquiring $166.9 million in cash as a result of our acquisition of FoxHollow and using $99.3 million of it to pay the cash portion of the merger consideration. During 2007, we also purchased $13.8 million of property and equipment, $6.5 million of distribution rights related to our former agreement with Invatec and $3.3 million of patents and licenses, partially offset by $6.9 million in proceeds from the sale of short-term investments and $2.0 million from the sale of assets. Historically, our capital expenditures have consisted of purchases of manufacturing equipment, research and testing equipment, computer systems and office furniture and equipment. We expect to continue to make investments in property and equipment and to incur approximately $10 million in capital expenditures during 2010.

Financing activities. Net cash provided by financing activities was $1.6 million in 2009, $1.6 million in 2008 and $54.0 million in 2007. During 2009, cash provided by financing activities was generated primarily from $2.8 million of proceeds from employee stock purchase plan purchases and $1.9 million of proceeds from stock option exercises, partially offset by payments on our term loan with Silicon Valley Bank. During 2008, we received $10.0 million in borrowings under our amended term loan with Silicon Valley Bank, $1.9 million in proceeds from our employee stock purchase plan purchases and $1.3 million in proceeds from stock option exercises, partially offset by $11.0 million in payments under our Silicon Valley Bank equipment financing. During 2007, we received $44.5 million in proceeds from the issuance of our common stock in our secondary public offering, $6.7 million in proceeds from stock option exercises and $5.0 million in borrowings under our equipment term loan with Silicon Valley Bank, partially offset by $2.5 million in payments under our equipment financing line with Silicon Valley Bank.

Contractual Cash Obligations

At December 31, 2009, we had contractual cash obligations and commercial commitments as follows (in thousands):

	Payments Due by Period					
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years	Other
	(dollars in thousand)					
Notes payable	$ 6,458	$ 2,500	$ 3,958	$ —	$ —	$ —
Interest obligations	409	258	151	—	—	—
Operating leases(1)	27,238	7,316	8,548	5,904	5,470	—
Uncertain income tax obligations, including interest and penalties(2)	1,588	216	—	—	—	1,372
Total	$35,693	$10,290	$12,657	$5,904	$5,470	$1,372

(1) The amounts reflected in the table above for operating leases represent future minimum lease payments under non-cancelable operating leases primarily for certain office space, warehouse space, computers and vehicles. Portions of these payments are denominated in foreign currencies and were translated in the tables above based on their respective U.S. dollar exchange rates at December 31, 2009. These future payments are subject to foreign currency exchange rate risk. In accordance with U.S. generally accepted accounting principles, our operating leases are not recognized on our consolidated balance sheet.

(2) The uncertain income tax obligations of $1.4 million included in the "other" column in the table above represent an amount of potential tax liabilities that we are uncertain as to if or when such amounts may be settled.

Not included in the table above is a payment for contingent consideration related to our acquisition of Chestnut. The milestone-based payment of up to $75 million, if due, will be paid in a combination of cash and shares of our common stock, the amount and form of which will be determined at the date of payment. This amount was not included in the table above due to our inability to predict the amount and timing of the cash portion of the payment. See Notes 3 and 4 to our consolidated financial statements contained elsewhere in this report.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined by the rules and regulations of the SEC, that have or are reasonably likely to have a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources. As a result, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these arrangements.

Other Liquidity Information

The acquisition agreement relating to our purchase of Chestnut Medical Technologies, Inc. requires us to make an additional milestone-based payment of up to $75.0 million to the sellers of the business upon the FDA pre-market approval of the Pipeline Embolization Device. This milestone-based contingent payment could range from: (1) $75.0 million upon FDA approval prior to October 1, 2011, (2) $75.0 million less $3.75 million per month upon FDA approval from October 1, 2011 through December 31, 2012 and (3) no payment required if FDA approval is not obtained by December 31, 2012. The milestone-based payment of up to $75.0 million will consist of cash and equity paid in the form of shares of our common stock ranging from 30% cash and 70% equity to 85% cash and 15% equity.

The acquisition agreement relating to our purchase of Appriva Medical, Inc. requires us to make additional payments of up to an aggregate of $175.0 million to the sellers of the business if certain milestones related to regulatory steps in the product commercialization process were achieved during the period of 2003 to 2009. We believe the first milestone was not achieved by the January 1, 2005 milestone date and that the first milestone was not payable. In September 2005, we announced that we had decided to discontinue the development and commercialization of the technology we acquired in the Appriva transaction. We are currently involved in litigation regarding this agreement as described in more detail in Note 18 to our consolidated financial statements included elsewhere in this report.

Pursuant to the acquisition agreement relating to FoxHollow's purchase of Kerberos Proximal Solutions, Inc., FoxHollow agreed to pay certain earn-out payments up to an aggregate of $117.0 million upon the achievement of contractually defined net sales milestones. Counsel for the shareholder representatives of Kerberos have alleged that FoxHollow has not used commercially reasonable efforts to market, promote, sell and distribute Kerberos's Rinspirator products, as required under the agreement. We discontinued the sale of the Rinspirator products in January 2009. Although no formal litigation has been commenced by the stockholder representatives of Kerberos regarding the alleged claims, there can be no assurance that the ultimate resolution of this matter will not result in a material adverse effect on our business, financial condition, results of operations or cash flows of a future period.

Our future liquidity and capital requirements will be influenced by numerous factors, including any future operating losses, the level and timing of future sales and expenditures, the results and scope of ongoing research and product development programs, working capital to support our sales growth, receipt of and time required to obtain regulatory clearances and approvals, sales and marketing programs, acceptance of our products in the marketplace, competing technologies, market and regulatory developments, acquisitions and the future course of pending and threatened litigation. We believe that our cash and cash equivalents, anticipated funds from operations and current and anticipated financing arrangements will be sufficient to meet our liquidity requirements through at least the next 12 months. However, there is no assurance that additional funding will not be needed or sought prior to such time. In the event that we require additional working capital to fund future operations and any future acquisitions, we may sell shares of our common stock or other equity securities, sell debt securities, or enter into additional credit and financing arrangements with one or more independent institutional lenders. There is no assurance that any financing transaction will be available on terms acceptable to us, or at all, or that any financing transaction will not be dilutive to our current stockholders. See Note 18 to our consolidated financial statements included elsewhere in this report.

Credit Risk

At December 31, 2009, our accounts receivable balance was $90.7 million, compared to $72.8 million at December 31, 2008. We monitor the creditworthiness of our customers to which we grant credit terms in the normal course of business. We believe that concentrations of credit risk with respect to our accounts receivable are limited due to the large number of customers and their dispersion across many geographic areas. However, a significant amount of our accounts receivable are with national healthcare systems in many countries. Although we do not currently foresee a credit risk associated with these receivables, repayment depends upon the financial stability of the economies of those countries. As of December 31, 2009, no customer represented more than 10% of our outstanding accounts receivable or sales. From time to time, we offer certain distributors in foreign markets who meet our credit standards extended payment terms, which may result in a longer collection period and reduce our cash flow from operations. We have not experienced significant losses with respect to the collection of accounts receivable from groups of customers or any particular geographic area nor experienced any material cash flow reductions as a result of offering extended payment terms.

Critical Accounting Policies and Estimates

Our consolidated financial statements and related financial information are based on the application of generally accepted accounting principles in the United States of America ("U.S. GAAP"). Our most significant accounting policies are described in Note 2 to our consolidated financial statements included elsewhere in this report. The preparation of our consolidated financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes.

Certain of our more critical accounting policies require the application of significant judgment by management in selecting the appropriate assumptions for calculating financial estimates. By their nature, these judgments are subject to an inherent degree of uncertainty. These judgments are based on our historical experience, terms of existing contracts, our observance of trends in the industry, information provided by our physician customers and information available from other outside sources, as appropriate. Changes in accounting estimates are reasonably likely to occur from period to period. Changes in these estimates and changes in our business could have a material impact on the presentation of our financial condition, changes in financial condition or results of operations.

We believe that the following financial estimates are both important to the portrayal of our financial condition and results of operations and require subjective or complex judgments. Further, we believe that the items discussed below are properly recognized in our consolidated financial statements for all periods presented. Management has discussed the development, selection and disclosure of our critical financial estimates with the audit committee and our board of directors. The judgments about those financial estimates are based on information available as of the date of our consolidated financial statements. Our critical financial policies and estimates are described below:

Revenue Recognition

We recognize revenue in accordance with four basic criteria that must be met before sales can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the price is fixed or determinable; and (4) collectibility is reasonably assured. These criteria are met at the time of shipment when risk of loss and title passes to the customer or distributor, unless a consignment arrangement exists. Sales from consignment arrangements are recognized upon written notification that the product has been used by the customer indicating that a sale is complete. Our normal terms of sale for regular sales are typically FOB shipping point, net 30 days. Regular sales include orders from customers for replacement of customer stock, replenishment of consignment product used by customers, orders for a scheduled case/surgery and stocking orders. We may agree to extended payment terms for certain international distributors based upon their payment history, financial condition and other general financial factors.

We allow customers to return defective or damaged products for credit. Our estimate for sales returns is based upon contractual commitments and historical return experience which we analyze by geography and is recorded as a reduction of sales for the period in which the related sales occurred. Historically, our return experience has been low with return rates of less than 4% of our net sales.

Stock-Based Compensation

We currently use the Black-Scholes option pricing model to determine the fair value of stock options and other equity incentive awards. The determination of the fair value of stock-based compensation awards on the date of grant using an option-pricing model is affected by our stock price, as well as assumptions regarding a number of complex and subjective variables which include the expected life of the award, the expected stock price volatility over the expected life of the awards, expected dividend yield, risk-free interest rate and the forfeiture rate.

We estimate the expected term of options based upon our historical experience. We estimate expected volatility and forfeiture rates based on a combination of historical factors related to our common stock. The risk-free interest rate is determined using U.S. Treasury rates appropriate for the expected term. Dividend yield is estimated to be zero as we have never paid dividends and have no plans to do so in the future.

We estimate forfeitures at the time of grant and revise those estimates in subsequent periods as necessary. We use historical data to estimate forfeitures and record stock-based compensation expense only for those awards that are expected to vest. Generally, all stock-based compensation is amortized on a straight-line basis over the respective requisite service periods, which are generally the vesting periods.

If factors change and we employ different assumptions for estimating stock-based compensation expense in future periods, the future periods may differ significantly from what we have recorded in the current period and could materially affect our results of operations. It may also result in a lack of comparability with other companies that use different models, methods and assumptions.

See Note 2 and Note 15 to our consolidated financial statements for further information regarding our stock-based compensation disclosures.

Assessment of Goodwill and Intangible Asset Impairment

Goodwill represents the excess of the aggregate purchase price over the fair value of net assets of acquired businesses. Intangible assets arise from the allocation of the purchase price of businesses acquired to identifiable assets. Our definite-lived intangible assets consist primarily of purchased developed technology, patents, customer relationships and trademarks and are amortized over their estimated useful lives, ranging from 2.5 to 11 years. Our indefinite-lived intangible assets consist of in-process research and development costs from the acquisition of Chestnut.

We assign goodwill to reporting units based on the allocation of purchase price to the assets acquired and the liabilities assumed. Goodwill is tested for impairment using a two-step approach at the reporting unit level--peripheral vascular and neurovascular. In the first step, the fair value of the reporting unit is compared to its carrying amount, including goodwill. If the carrying amount of a reporting unit exceeds its fair value, then the amount of the impairment loss must be measured. The impairment loss, if any, is calculated by comparing the implied fair value of reporting unit goodwill to its carrying amount.

We evaluate the carrying amount of goodwill and intangible assets during the fourth quarter of each year and between annual evaluations if events occur that indicate that the carrying amount of goodwill or intangible assets may be impaired. We use the income and market approaches to determine the fair value of reporting units in the goodwill valuation. Our valuation is weighted entirely using the income approach which is supported by a discounted cash flow analysis. We do not believe that there are any comparable companies to our reporting units, and therefore do not use the results of the market approach in our valuation.

The impairment evaluation related to goodwill and intangible assets with indefinite lives requires the use of considerable management judgment to determine discounted future cash flows, including estimates and assumptions regarding the amount and timing of cash flows, cost of capital and growth rates. Cash flow assumptions used in the assessment are estimated using assumptions in our annual operating plan as well as our five-year strategic plan. Our annual operating plan and strategic plan contain revenue assumptions that are derived from existing technology as well as future revenues attributed to in-process technologies and the associated launch, growth and decline

assumptions normal for the life cycle of those technologies. In addition, management considers relevant market information, peer company data and five years of historical financial information. In the goodwill analysis, the estimated fair value of the reporting units used in the impairment analysis is reconciled to our market capitalization at the measurement date to ensure the estimated enterprise fair values are consistent with those of a market participant.

For 2009, our goodwill impairment analysis indicated that the fair value of our reporting units exceeded the carrying amount by over 70%, substantiated by the increase in our stock price and market capitalization during the year. Had we increased the discount rate assumptions in our analysis by 500 basis points and decreased our terminal value multiplier by 10%, the fair value of our reporting units would have still exceeded the carrying amount and no impairment indicator would have existed. During 2008, we recognized a goodwill impairment charge of $281.9 million related to our peripheral vascular business. The impairment charge was driven primarily by the substantial disruption in the general credit and equity markets and, in particular, the decline in our stock price and market capitalization during our fourth quarter of 2008. The decline in our stock price and market capitalization were primarily a result of the then general market conditions and the associated increase in general market risk as well as changes in our future estimated cash flows which were significantly driven by the changes in the performance of our plaque excision (formerly atherectomy) business. The amount of goodwill was $367.5 million and $315.7 million at December 31, 2009 and 2008, respectively. See Note 9 to our consolidated financial statements for further information regarding our goodwill impairment disclosures.

We recorded impairment charges in 2008 of $6.9 million related to certain definite-lived intangible assets in our peripheral vascular business due to certain product discontinuations, and $10.5 million to write off the remaining carrying amount of the Merck intangible asset that was established at the time of our FoxHollow acquisition as a result of the termination of the Merck collaboration and license agreement. Definite-lived intangible assets, net of accumulated amortization, were $254.3 million and $185.3 million at December 31, 2009 and 2008, respectively. See Note 9 to our consolidated financial statements for further information regarding our intangible asset impairment disclosures.

Impairment of our indefinite-lived intangible assets is measured as the amount by which the carrying amount of the intangible asset exceeds its fair value. The estimated fair value is generally determined on the basis of discounted future cash flows. Based on our impairment analysis performed during the year ended December 31, 2009, the estimated fair value of our intangible assets with indefinite lives exceeded the carrying amount. The amount of indefinite-lived intangible assets was $27.4 million at December 31, 2009 with no amount recorded at December 31, 2008.

Contingent Consideration

Contingent consideration is recorded at the acquisition-date estimated fair value of the contingent milestone payment for all acquisitions beginning in 2009. Our 2009 acquisition of Chestnut included an agreement to pay a contingent milestone-based payment of cash and equity upon the FDA pre-market approval of the Pipeline Embolization Device. The acquisition-date fair value was measured based on the probability-adjusted present value of the amount expected to be paid. The probability-adjusted contingent consideration amounts were discounted at 26%, the weighted average cost of capital for the Chestnut transaction. We remeasure the fair value of the contingent milestone payment at each reporting period using Level 3 inputs. There were no changes in the assumptions utilized in the fair value of the contingent consideration at December 31, 2009. The change in fair value was $4.9 million for 2009 and is reflected as “Contingent consideration” in our consolidated statements of operations.

Excess and Obsolete Inventory

We calculate an inventory reserve for estimated obsolescence or excess inventory based on historical turnover and assumptions about future demand for our products and market conditions which includes estimates of the impact of the introduction of new or enhanced products on existing inventory. Our industry is characterized by regular new product development, and as such, our inventory is at risk of obsolescence following the introduction and development of new or enhanced products. Our estimates and assumptions for excess and obsolete inventory are reviewed and updated on a quarterly basis. The estimates we use for demand also are used for near-term capacity

planning and inventory purchasing and are consistent with our sales forecasts. Future product introductions and related inventories may require additional reserves based upon changes in market demand or introduction of competing technologies. Increases in the reserve for excess and obsolete inventory result in a corresponding expense to cost of goods sold. Our reserve for excess and obsolete inventory was $11.0 million and $10.3 million at December 31, 2009 and 2008, respectively.

Allowance for Doubtful Accounts

We maintain a large customer base that mitigates the risk of concentration with one customer. We make judgments as to our ability to collect outstanding receivables and provide allowance for a portion of receivables when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding account balances and the overall quality and age of those balances not specifically reviewed. In determining the provision for invoices not specifically reviewed, we analyze historical collection experience and current economic trends. If the historical data used to calculate the allowance provided for doubtful accounts does not reflect our future ability to collect outstanding receivables or if the financial condition of customers were to deteriorate, resulting in impairment of their ability to make payments, an increase in the provision for doubtful accounts may be required. We write off accounts receivable when we determine that the accounts receivable are uncollectible, typically upon customer bankruptcy or the customer's non-response to continuous collection efforts. Approximately 22% of our receivables outstanding as of December 31, 2009 were from foreign distributors, which carry a potentially higher degree of collection risk due to potential disruptions in the global financial markets and a potential inability for our distributors to obtain credit to continue to operate their businesses. In addition, if the overall condition of the health care industry were to deteriorate as a result of the recent financial and economic crisis or otherwise, resulting in an impairment of our customers' ability to make payments, significant additional allowances could be required.

Our accounts receivable balance was $90.7 million and $72.8 million, net of accounts receivable allowances, comprised of both allowances for doubtful accounts and sales returns, of $7.3 million and $8.1 million at December 31, 2009 and 2008, respectively.

Valuation of Acquired In-Process Research and Development

When we acquire another company, the purchase price is allocated, as applicable, between acquired in-process research and development, other identifiable intangible assets, tangible net assets and goodwill as required by U.S. GAAP. In-process research and development is defined as the value assigned to those projects for which the related products have not received regulatory approval and have no alternative future use. Determining the portion of the purchase price allocated to in-process research and development and other intangible assets requires us to make significant estimates that may change over time. During 2007, we recorded an in-process research and development charge of $70.7 million related to our October 2007 acquisition of FoxHollow. For acquisitions subsequent to December 31, 2008, acquired in-process research and development assets are capitalized as indefinite-lived intangible assets. In connection with the acquisition of Chestnut we capitalized $27.4 million of acquired in-process research and development. If development of a marketable product results, the asset will be amortized upon completion of development. Development costs incurred after the acquisition are charged to expense.

The income approach was used to determine the fair values of the acquired in-process research and development for both the FoxHollow and Chestnut acquisitions. This approach establishes fair value by estimating the after-tax cash flows attributable to the in-process project over its useful life and then discounting these after-tax cash flows back to the present value. Revenue estimates were based on relative market size, expected market growth rates and market share penetration. Gross margin estimates were based on the estimated cost of the product at the time of introduction and historical gross margins for similar products offered by us or by competitors in the marketplace. The estimated selling, general and administrative expenses were based on historical operating expenses of the acquired company as well as long-term expense levels based on industry comparables. The costs to complete each project were based on estimated direct project expenses as well as the remaining labor hours and related overhead costs. In arriving at the value of acquired in-process research and development projects, we considered each project's stage of completion, the complexity of the work to be completed, the costs already incurred, the remaining costs to complete the project, the contribution of core technologies, the expected introduction date and the estimated useful life of the technology. The discount rate used to arrive at the present value of acquired in-process research and development as of the

acquisition date was based on the time value of money and medical technology investment risk factors. We believe that the estimated acquired in-process research and development amounts determined represent the fair value at the date of acquisition and do not exceed the amount a third party would pay for the projects.

Accounting for Income Taxes

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

Management's judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. A portion of the valuation allowance was reversed in 2009 due to income earned in the current year and offsetting the deferred tax liability on the Chestnut acquisition. We will continue to monitor the realizability of our deferred tax assets and adjust the valuation allowance accordingly. For 2009, except for the deferred tax liability relating to an indefinite-lived intangible acquired in the Chestnut acquisition, we recorded a full valuation allowance on our net deferred tax asset.

Recently Issued Accounting Pronouncements

In the third quarter of 2009, we adopted the Financial Accounting Standards Board's ("FASB") Accounting Standards Codification ("ASC") Topic 105 as the single official source of authoritative, nongovernmental generally accepted accounting principles in the United States. On the effective date, all then-existing non-SEC accounting literature and reporting standards were superseded and deemed nonauthoritative. The adoption of this pronouncement did not have a material impact on our consolidated financial statements; however, the ASC affected the way we reference authoritative guidance in our consolidated financial statements.

In December 2007, the FASB issued additional guidance on business combinations contained in ASC Topic 805 and additional guidance on noncontrolling interests in consolidated financial statements contained in ASC Topic 810, which are effective for fiscal years beginning after December 15, 2008. These new standards represent the completion of the FASB's first major joint project with the International Accounting Standards Board and are intended to improve, simplify and converge internationally the accounting for business combinations and the reporting of noncontrolling interests (formerly minority interests) in consolidated financial statements.

ASC Topic 805 changes the application of the acquisition method in a number of significant respects, including the requirement to expense transaction fees and expected restructuring costs as incurred, rather than including these amounts in the allocated purchase price; the requirement to recognize the fair value of contingent consideration at the acquisition date, rather than the amount when the contingency is resolved; the requirement to recognize the fair value of acquired in-process research and development assets at the acquisition date, rather than immediately expensing; and the requirement to recognize a gain in relation to a bargain purchase price, rather than reducing the allocated basis of long-lived assets. We adopted these standards at the beginning of 2009. See Note 3 for further discussion of the impact the adoption of ASC Topic 805 had on our results of operations and financial conditions as a result of our Chestnut acquisition in 2009.

In May 2009, the FASB issued additional guidance on management's assessment of subsequent events. This guidance is contained in ASC Topic 855 and clarifies that management must evaluate, as of each reporting period, events or transactions that occur for potential recognition or disclosure in the financial statements and the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date through the date that the financial statements are issued or are available to be issued. ASC Topic 855 requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for that date. This disclosure alerts all users of financial statements that an entity has not evaluated subsequent events after that date in

the set of financial statements being presented. We adopted ASC Topic 855 in the second quarter of 2009. The implementation of ASC Topic 855 did not have a material impact on our consolidated financial statements.

In April 2008, the FASB issued guidance on the determination of the useful life of intangible assets, ("ASC Topic 350-30-35-1"), which amended the factors considered in developing renewal or extension assumptions used to determine the useful life of recognized intangible assets. ASC Topic 350-30-35-1 requires a consistent approach between the useful life of a recognized intangible asset and the period of expected cash flows used to measure the fair value of an asset. The ASC Topic 350-30-35-1 also requires enhanced disclosure when an intangible asset's expected future cash flows are affected by an entity's intent and/or ability to renew or extend the arrangement. We adopted ASC Topic 350-30-35-1 as of January 1, 2009. The adoption did not have a significant impact on our consolidated financial statements.

In 2006, the FASB issued an accounting pronouncement to provide enhanced guidance when using fair value to measure assets and liabilities. The pronouncement defines fair value, establishes a framework for measuring fair value in GAAP and expands disclosures about fair value measurements. The pronouncement applies whenever other pronouncements require or permit assets or liabilities to be measured by fair value. We adopted the pronouncement as of the beginning of 2008 as it relates to recurring measurements of financial assets and liabilities, and as of the beginning of 2009, as it relates to nonrecurring fair value measurement requirements for nonfinancial assets and liabilities. These assets and liabilities include goodwill and intangible assets not subject to amortization.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to various market risks, which are potential losses arising from adverse changes in market rates and prices, such as interest rates and foreign currency exchange rate fluctuations. We do not enter into derivatives or other financial instruments for trading or speculative purposes. We believe we are not exposed to a material market risk with respect to our invested cash and cash equivalents.

Interest Rate Risk

Borrowings under our revolving line of credit with Silicon Valley Bank bear interest at a variable annual rate equal to Silicon Valley Bank's prime rate plus 0.5%. Borrowings under the term loan bear interest at a variable annual rate equal to Silicon Valley Bank's prime rate plus 1.0%. We currently do not use interest rate swaps to mitigate the impact of fluctuations in interest rates. As of December 31, 2009, we had no borrowings under our revolving line of credit and had $6.5 million in borrowings under the term loan. Based upon this debt level, a 10% increase in the interest rate on such borrowings would cause us to incur an increase in interest expense of approximately $32,000 on an annual basis.

At December 31, 2009, our cash and cash equivalents were $98.1 million. Based on our annualized average interest rate, a 10% decrease in the interest rate on such balances would result in a reduction in interest income of approximately $15,000 on an annual basis.

Foreign Currency Exchange Rate Risk

Fluctuations in the rate of exchange between the U.S. dollar and foreign currencies in which we transact business could adversely affect our financial results. Approximately 27% and 24% of our net sales were denominated in foreign currencies in 2009 and 2008, respectively. Selling, marketing and administrative costs related to these sales are largely denominated in the same respective currency, thereby limiting our transaction risk exposure. If we price our products in U.S. dollars and competitors price their products in local currency, an increase in the relative strength of the U.S. dollar could result in our price not being competitive in a market where business is transacted in the local currency.

Our principal foreign currency exchange rate risks exist between the U.S. dollar and the euro. Approximately 74% and 76% of our net sales denominated in foreign currencies in 2009 and 2008, respectively, were derived from European Union countries and were denominated in the euro. Fluctuations during any given reporting period result in the remeasurement of our foreign currency-denominated cash, receivables and payables, generating currency transaction gains or losses and are reported in other expense (income), net in our consolidated financial statements. We recorded $1.6 million and $2.4 million of foreign currency exchange rate transaction losses in 2009 and 2008, respectively, net of activities from forward exchange contracts, primarily related to the translation of our foreign currency-denominated net receivables into U.S. dollars. Our 2009 forward contracts were settled prior to the end of 2009 and there were no outstanding forward exchange contracts as of December 31, 2009. We will continue to assess the use of forward contracts in the future and entered into three forward contracts at the beginning of the first quarter 2010 to economically hedge our risk of the euro, British pound and Canadian dollar. At December 31, 2009, we had euro-denominated accounts receivable and cash of €22.6 million and €924,000, respectively. A 10% increase in the foreign currency exchange rate between the U.S. dollar and the euro as a result of a weakening dollar would have the effect of approximately a $3.4 million foreign currency transaction gain. A 10% decrease in the foreign currency exchange rate between the U.S. dollar and the euro as a result of a strengthening dollar would have the effect of approximately a $3.4 million foreign currency transaction loss.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

As management of ev3 Inc., we are responsible for establishing and maintaining an adequate system of internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended, for ev3 Inc. and its subsidiaries. This system is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles.

ev3's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of ev3; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of ev3 are being made only in accordance with authorizations of management and directors of ev3; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of ev3's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements and even when determined to be effective, can only provide reasonable assurance with respect to financial statement preparation and presentation. Also, projection of any evaluation of the effectiveness of internal control over financial reporting to future periods is subject to the risk that controls may become inadequate because of changes in conditions, or that the degree or compliance with the policies or procedures may deteriorate.

With our participation, management evaluated the effectiveness of ev3's internal control over financial reporting as of December 31, 2009. In making this evaluation, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated Framework. Based on this assessment, management concluded that ev3's internal control over financial reporting was effective as of December 31, 2009.

Ernst & Young LLP, ev3's independent registered public accounting firm, audited the effectiveness of ev3's internal control over financial reporting as of December 31, 2009 and, based on that audit, issued the report which is included elsewhere in this report.

/s/ Robert J. Palmisano	/s/ Shawn McCormick
Robert J. Palmisano	Shawn McCormick
President and Chief Executive Officer	Senior Vice President and Chief Financial Officer

February 25, 2010

Further discussion of our internal controls and procedures is included under the heading "Part II. Item 9A. Controls and Procedures" of this report.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
ev3 Inc.

We have audited ev3 Inc.'s internal control over financial reporting as of December 31, 2009 based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). ev3 Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on ev3 Inc.'s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

In our opinion, ev3 Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on the COSO criteria**.**

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of ev3 Inc. as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2009 and our report dated February 25, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Minneapolis, Minnesota
February 25, 2010

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
ev3 Inc.

We have audited the accompanying consolidated balance sheets of ev3 Inc. as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2009. Our audits also included the financial statement schedule listed in the Index at Item 15. These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of ev3 Inc. at December 31, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly, in all material respects, the information set forth herein.

As discussed in Note 2, Summary of Significant Accounting Policies, to the consolidated financial statements, effective January 1, 2009 the Company adopted the provisions of the Financial Accounting Standards Board's Accounting Standards Codification Topic 805 and changed its method of accounting for business combinations.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), ev3 Inc.'s internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 25, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Minneapolis, Minnesota
February 25, 2010

ev3 Inc.

CONSOLIDATED BALANCE SHEETS

(Dollars in thousands, except per share amounts)

	December 31, 2009	December 31, 2008
Assets		
Current assets		
Cash and cash equivalents	$ 98,050	$ 59,652
Accounts receivable, less allowances of $7,260 and $8,098 respectively	90,711	72,814
Inventories, net	45,054	47,687
Prepaid expenses and other current assets	6,645	6,970
Total current assets	240,460	187,123
Restricted cash	4,346	1,531
Property and equipment, net	29,159	30,681
Goodwill	367,486	315,654
Intangible assets, net	254,288	185,292
Other assets	550	383
Total assets	$ 896,289	$ 720,664
Liabilities and stockholders' equity		
Current liabilities		
Current portion of long-term debt	$ 2,500	$ 2,500
Accounts payable	16,737	15,657
Accrued compensation and benefits	32,239	29,547
Accrued liabilities	22,453	19,744
Total current liabilities	73,929	67,448
Long-term debt	3,958	6,458
Other long-term liabilities	63,908	6,217
Total liabilities	141,795	80,123
Stockholders' equity		
Preferred stock, $0.01 par value, 100,000,000 shares authorized, none issued and outstanding as of December 31, 2009 and 2008	—	—
Common stock, $0.01 par value, 300,000,000 shares authorized, 112,345,500 and 105,822,444 shares issued and outstanding as of December 31, 2009 and 2008, respectively	1,123	1,058
Additional paid-in capital	1,828,655	1,756,832
Accumulated deficit	(1,074,744)	(1,116,661)
Accumulated other comprehensive loss	(540)	(688)
Total stockholders' equity	754,494	640,541
Total liabilities and stockholders' equity	$ 896,289	$ 720,664

The accompanying notes are an integral part of these consolidated financial statements.

ev3 Inc.

CONSOLIDATED STATEMENTS OF OPERATIONS

(Dollars in thousands, except per share amounts)

	For the years ended December 31,		
	2009	2008	2007
Sales:			
Net product sales	$ 449,072	$ 402,233	$ 278,226
Research collaboration	—	19,895	5,957
Net sales	449,072	422,128	284,183
Operating expenses:			
Product cost of goods sold	120,613	136,847	99,879
Research collaboration	—	6,051	1,065
Sales, general and administrative	225,023	232,200	194,289
Research and development	49,060	48,784	48,413
Amortization of intangible assets	25,143	31,072	20,306
Contingent consideration	4,876	—	—
Goodwill and intangible asset impairment	—	299,263	—
Acquired in-process research and development	—	—	70,700
Special charges	—	—	19,054
Total operating expenses	424,715	754,217	453,706
Income (loss) from operations	24,357	(332,089)	(169,523)
Other (income) expense:			
(Gain) loss on investments, net	(4,113)	(487)	116
Interest expense (income), net	788	(223)	(1,910)
Other expense (income), net	1,588	2,427	(2,934)
Income (loss) before income taxes	26,094	(333,806)	(164,795)
Income tax (benefit) expense	(15,823)	1,816	949
Net income (loss)	$ 41,917	$ (335,622)	$ (165,744)
Earnings per share:			
Net income (loss) per common share			
Basic	$ 0.39	$ (3.22)	$ (2.37)
Diluted	$ 0.38	$ (3.22)	$ (2.37)
Weighted average shares outstanding			
Basic	107,997,738	104,378,828	69,909,708
Diluted	108,998,528	104,378,828	69,909,708

The accompanying notes are an integral part of these consolidated financial statements.

ev3 Inc.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(Dollars in thousands, except per share amounts)

	Common Stock				Accumulated Other	Total
	Shares	Amount	APIC	Accumulated Deficit	Comprehensive Income (Loss)	Stockholders' Equity
Balance December 31, 2006	**57,594,742**	**$ 576**	**$919,221**	**$(614,578)**	**$ 15**	**$ 305,234**
Comprehensive loss:						
Net loss				(165,744)	—	(165,744)
Unrealized losses on investments, net.				—	(174)	(174)
Foreign currency translation adjustment				—	(436)	(436)
Comprehensive loss						(166,354)
Cumulative effect of adoption of ASC 740 (FASB Interpretation No. 48)	—	—	—	(717)	—	(717)
Common stock issued in secondary offering	2,500,000	25	44,517	—	—	44,542
Compensation expense on equity awards and stock purchase plan	—	—	11,127	—	—	11,127
Equity based compensation plans	1,867,775	19	7,068	—	—	7,087
Common stock issued in acquisition of FoxHollow	43,118,667	431	757,131	—	—	757,562
FoxHollow stock transactions, other	(2,415)	—	—	—	—	—
Balance December 31, 2007	**105,078,769**	**$1,051**	**$1,739,064**	**$(781,039)**	**$ (595)**	**$ 958,481**
Comprehensive loss:						
Net loss				(335,622)	—	(335,622)
Unrealized gains on investments, net				—	45	45
Foreign currency translation adjustment				—	(138)	(138)
Comprehensive loss						(335,715)
Compensation expense on equity awards and stock purchase plan	—	—	15,159	—	—	15,159
Equity based compensation plans	743,675	7	2,609	—	—	2,616
Balance December 31, 2008	**105,822,444**	**$1,058**	**$1,756,832**	**$(1,116,661)**	**$ (688)**	**$ 640,541**
Comprehensive income:						
Net income				41,917	—	41,917
Foreign currency translation adjustment				—	148	148
Comprehensive income						42,065
Compensation expense on equity awards and stock purchase plan	—	—	14,556	—	—	14,556
Equity based compensation plans	1,462,546	14	4,189	—	—	4,203
Common stock issued in acquisition of Chestnut	5,060,510	51	53,078	—	—	53,129
Balance December 31, 2009	**112,345,500**	**$1,123**	**$1,828,655**	**$(1,074,744)**	**$ (540)**	**$ 754,494**

The accompanying notes are an integral part of these consolidated financial statements.

ev3 Inc.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Dollars in thousands)

	For the years ended December 31,		
	2009	2008	2007
Operating activities			
Net income (loss)	$ 41,917	$(335,622)	$(165,744)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	36,340	42,595	28,726
Contingent consideration	4,876	—	—
Provision for bad debts and sales returns	(942)	2,538	2,024
Provision for inventory obsolescence	10,030	8,870	8,308
Acquired in-process research and development	—	—	70,700
Gain on sale or disposal of investments and assets, net	(4,055)	(244)	(978)
Stock-based compensation expense	14,556	15,159	11,127
Goodwill and intangible asset impairment	1,000	299,263	—
Deferred income taxes	(19,171)	—	—
Change in operating assets and liabilities, net of acquired:			
Accounts receivable	(15,998)	(8,281)	1,340
Inventories	(6,846)	6,169	(14,524)
Prepaid expenses and other assets	642	294	2,836
Accounts payable	(683)	(6,804)	3,060
Accrued expenses and other liabilities	7,683	(28,774)	(5,408)
Deferred revenue	—	(9,043)	9,347
Net cash provided by (used in) operating activities	69,349	(13,880)	(49,186)
Investing activities			
Proceeds from sale of investments	4,118	9,744	6,900
Purchase of investments	(300)	—	—
Purchase of property and equipment	(6,695)	(10,875)	(13,804)
Purchase of patents and licenses	(2,067)	(2,728)	(3,270)
Purchase of distribution rights	—	—	(6,500)
Proceeds from sale of assets	—	1,244	2,035
Acquisitions, net of cash acquired	(24,735)	(7,627)	65,556
Change in restricted cash	(2,731)	646	1,007
Net cash (used in) provided by investing activities	(32,410)	(9,596)	51,924

The accompanying notes are an integral part of these consolidated financial statements.

ev3 Inc.

CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)

(Dollars in thousands)

	For the years ended December 31,		
	2009	2008	2007
Financing activities			
Proceeds from issuance of common stock, net	$ —	$ —	$ 44,542
Proceeds from issuance of debt	—	10,000	5,000
Payments on long-term debt and capital lease obligations	(2,649)	(11,042)	(2,499)
Proceeds from exercise of stock options	1,850	1,275	6,726
Proceeds from employee stock purchase plan	2,823	1,903	868
Other	(470)	(541)	(646)
Net cash provided by financing activities	1,554	1,595	53,991
Effect of exchange rate changes on cash	(95)	473	278
Net increase (decrease) in cash and cash equivalents	38,398	(21,408)	57,007
Cash and cash equivalents, beginning of period	59,652	81,060	24,053
Cash and cash equivalents, end of period	$ 98,050	$ 59,652	$ 81,060
Supplemental cash flow information:			
Cash paid for interest	$ 588	$ 839	$ 1,400
Cash paid for income taxes	$ 3,303	$ 943	$ 610
Supplemental non-cash disclosure:			
Non-cash consideration in conjunction with the acquisition of Chestnut (see Note 3)	$ 90,461	$ —	$ —
Net assets acquired in conjunction with the acquisition of FoxHollow (see Note 3)	$ —	$ —	$757,562
Leasehold improvement tenant allowance	$ 2,606	$ —	$ —
Goodwill and intangible asset impairment (see Note 9)	$ —	$299,263	$ —
Earn-out payment accrued	$ —	$ —	$ 7,500

The accompanying notes are an integral part of these consolidated financial statements.

1. Description of Business

ev3 Inc. ("we," "our" or "us") is a global endovascular company focused on identifying and treating peripheral vascular disease, including, in particular, lower extremity arterial disease and neurovascular disease. We develop, manufacture and market a wide range of products that include plaque excision products, stents, embolic protection and thrombectomy devices, carotid stenting solutions, percutaneous transluminal angioplasty ("PTA") balloons and other procedural support products for the peripheral vascular market and embolic coils, flow diversion and flow restoration devices, liquid embolics, flow directed and other micro catheters, occlusion balloon systems, guidewires, neuro stents and retrieval devices for the neurovascular market. We market our products in the United States, Europe, Canada, Australia and other countries through a direct sales force and through distributors in certain other international markets.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include our accounts and the accounts of our wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated. On October 4, 2007, we acquired FoxHollow Technologies, Inc. ("FoxHollow") and on June 23, 2009, we acquired Chestnut Medical Technologies, Inc. ("Chestnut"). In connection with those acquisitions, FoxHollow and Chestnut became our wholly-owned subsidiaries (see Note 3).

We have evaluated all subsequent events through February 25, 2010, the date the financial statements were issued.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts and disclosures in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

Cash Equivalents

We consider highly liquid investments with maturities of three months or less from the date of purchase to be cash equivalents. These investments are stated at cost, which approximates fair value.

Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. We make judgments as to our ability to collect outstanding receivables and provide an allowance for credit losses when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding account balances and the overall quality and age of those balances not specifically reviewed. Outstanding receivables are considered past due based upon invoice due dates. In determining the allowance required, we analyze historical collection experience and current economic trends. If the historical data used to calculate the allowance for doubtful accounts does not reflect our future ability to collect outstanding receivables or if the financial condition of customers were to deteriorate, an increase in the provision for doubtful accounts may be required. We write-off accounts receivable when we determine that the accounts receivable are uncollectible, typically upon customer bankruptcy or the customer's non-response to continuous collection efforts.

Inventories

Inventories include material, labor and overhead and are stated at the lower of cost or net realizable value, determined on a first-in, first-out basis.

We calculate a reserve for estimated obsolete or excess inventory based on historical turnover and assumptions about future demand for our products and market conditions. This includes estimates of the impact of the introduction of new or enhanced products on existing inventory. Our industry is characterized by continuous product development, and as such, our inventory is at risk of obsolescence following the introduction and development of new or enhanced products. Our estimate and assumptions for excess and obsolete inventory are reviewed and updated on a quarterly basis. The estimates we use for demand are also used for near-term capacity planning and inventory purchasing and are consistent with our sales forecasts. Future product introductions and related inventories may require additional reserves based upon changes in market demand or introduction of competing technologies. Adjustments for excess and obsolete inventory are recorded in product cost of goods sold.

Restricted Cash

Restricted cash consists of various deposits supporting credit arrangements and security deposits for our building leases.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Additions and improvements that extend the lives of assets are capitalized, while expenditures for repairs and maintenance are expensed as incurred. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Amortization of capital leases and leasehold improvements is provided on a straight-line basis over the estimated lives of the related assets or the life of the lease, whichever is shorter, and generally ranges from three to seven years. Machinery and other equipment are depreciated over three to ten years, computer hardware and software are depreciated over three to five years, furniture and fixtures over seven years. Property and equipment classified as construction in process are not depreciated until the related asset is placed in service.

Goodwill and Indefinite-Lived Intangible Assets

Goodwill represents the excess of the aggregate purchase price over the fair value of net assets of acquired businesses. Intangible assets arise from the allocation of the purchase price of businesses acquired to identifiable assets. Our indefinite-lived intangible assets consist of in-process research and development costs.

We assign goodwill to reporting units based on the allocation of purchase price to the assets acquired and the liabilities assumed. Goodwill is tested for impairment using a two-step approach at the reporting unit level--peripheral vascular and neurovascular. In the first step, the fair value of the reporting unit is compared to its carrying amount, including goodwill. If the carrying amount of a reporting unit exceeds its fair value, then the goodwill of the reporting unit is potentially impaired and we complete step two. In the second step, the amount of the potential impairment loss is measured. The impairment loss, if any, is calculated by comparing the implied fair value of reporting unit goodwill to its carrying amount.

We evaluate the carrying amount of goodwill and indefinite-lived intangible assets as of the first day of our fourth quarter of each year and between annual evaluations if events occur that indicate that the carrying amount of goodwill or intangible assets may be impaired. We use the income and market approaches to determine the fair value of reporting units in the goodwill valuation. We also use the income method to measure the fair value of indefinite-lived intangible assets.

The impairment evaluation for goodwill and intangible assets with indefinite lives requires the use of considerable management judgment to determine discounted future cash flows, including estimates and assumptions regarding the amount and timing of cash flows, cost of capital and growth rates. Cash flow assumptions used in the assessment are estimated using our annual operating plan as well as our five-year strategic plan. The annual operating plan and strategic plan contain assumptions for revenue derived from existing technology as well as future revenues attributed to in-process technologies and the associated launch, growth and decline assumptions normal for the life cycle of those technologies. In addition, management considers relevant market information, peer company data and five years of historical financial information. In the goodwill analysis, the estimated fair value of the reporting units used in the impairment analysis is reconciled to the company's market capitalization at the measurement date to ensure the estimated enterprise fair values are consistent with those of a market participant.

Impairment of Long-Lived Assets and Amortizable Intangible Assets

Long-lived assets such as property, equipment, and definite-lived intangible assets are reviewed for impairment when events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. An impairment loss is recognized when estimated future undiscounted cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount. Where available, quoted market prices are used to determine fair value. When quoted market prices are not available, various valuation techniques, including the discounted value of estimated future cash flows, are utilized.

Investments

We have made certain strategic investments in companies of less than 20% of their outstanding equity interests and in various stages of development. These investments were accounted for under the cost method of accounting. The valuation of investments accounted for under the cost method is based on all available financial information related to the investee, including valuations based on recent third party equity investments in the investee. If an unrealized loss on any investment is considered to be other-than-temporary, the loss is recognized in the period the determination is made. All investments are reviewed for changes in circumstances or occurrence of events that suggest our investment may not be recoverable.

Revenue Recognition

We sell the majority of our products via direct shipment to hospitals or clinics. Sales are made through our direct sales force, distributors or through consignment arrangements with hospitals and clinics. We recognize revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred; the sales price is fixed or determinable; and collectibility is reasonably assured. These criteria are met at the time of shipment when the risk of loss and title passes to the customer or distributor, unless a consignment arrangement exists. Revenue from consignment arrangements is recognized when we receive written notification from the hospital or clinic that the product has been used. We record estimated sales returns, discounts and rebates as a reduction of net sales in the same period revenue is recognized.

Sales to distributors are recognized at the time of shipment, provided that we have received an order, the price is fixed or determinable, collectibility of the resulting receivable is reasonably assured and we can reasonably estimate returns.

In conjunction with our acquisition of FoxHollow on October 4, 2007, we assumed all rights and obligations associated with an Amended and Restated Collaboration and License Agreement ("Collaboration and License Agreement") with Merck & Co., Inc. ("Merck"), which was terminated by Merck effective July 22, 2008. Under the former Collaboration and License Agreement, we were obligated to grant Merck certain exclusive rights and to perform certain research activities under Merck's direction, including removal of atherosclerotic plaque from patient arteries for analysis, conduct clinical trials and drug profiling by Merck. The revenue streams for the Collaboration and License Agreement included a minimum of $60.0 million in aggregate for collaboration for three years beginning November 2006 and a total of $40.0 million in license/exclusivity payments for four years beginning on the same date. Both the collaboration and license components were accounted for as a single unit of accounting. The revenue was being recognized on a straight-line basis over the four-year term of the license/exclusivity portion

of the Collaboration and License Agreement until the termination at which time the remaining amount of deferred revenue was recognized.

During 2008, we also recognized revenue related to our arrangement with Merck to accomplish an orderly wind-down of our research and collaboration activities. We concluded that our arrangement regarding wind-down activities was separate from our former Collaboration and License Agreement with Merck as the substance, manner and terms of the arrangement substantially differed from the original agreement. Pursuant to the arrangement, Merck agreed to reimburse us for costs incurred subject to a mark-up. Under the new arrangement we recognized revenue using the proportional performance method and recognized revenue as services were performed. As of December 31, 2008, we had completed all services under the our former Collaboration and License Agreement and arrangement regarding wind-down activities with Merck.

Costs related to products delivered are recognized in the period revenue is recognized. Cost of goods sold consists primarily of direct labor, allocated manufacturing overhead, raw materials and components and excludes the amortization of intangible assets.

Contingent Consideration

Contingent consideration is recorded at the acquisition-date estimated fair value of the contingent milestone payment for all acquisitions subsequent to December 31, 2008. The fair value of the contingent milestone consideration is remeasured at the estimated fair value at each reporting period with the change in fair value included as "Contingent consideration" in our consolidated statements of operations.

Shipping and Handling Costs

All shipping and handling costs are expensed as incurred and recorded as a component of sales, general and administrative expense in the consolidated statements of operations. Shipping and handling costs included in sales, general and administrative expenses were $2.9 million, $3.5 million, and $2.9 million in 2009, 2008 and 2007, respectively. Shipping and handling amounts, if any, billed to customers are included in net product sales.

Advertising Costs

All advertising costs are expensed as incurred. We market our products primarily through a direct sales force and advertising expenditures are not material.

Research and Development

Research and development costs are expensed as incurred and include the costs to design, develop, test, deploy and enhance our products. It also includes costs related to the execution of clinical trials and costs incurred to obtain regulatory approval for our products.

Acquired In-process Research and Development ("IPR&D")

When we acquire another company or group of assets, the purchase price is allocated, as applicable, between IPR&D, net tangible assets, goodwill and intangible assets. We define IPR&D as the value assigned to those projects for which the related products have not received regulatory approval and have no alternative future use. Determining the portion of the purchase price allocated to IPR&D requires us to make significant estimates. The amount of the purchase price allocated to IPR&D is determined by discounting estimated future cash flows of each project or technology. The discount rate used is determined at the time of the acquisition and includes consideration of the assessed risk of the project not being successfully developed to a stage of commercial feasibility. For acquisitions prior to January 1, 2009, amounts allocated to IPR&D were expensed at the time of acquisition. For acquisitions subsequent to December 31, 2008, acquired in-process research and development assets are capitalized as indefinite-lived intangible assets until the completion of or abandonment of the associated research and development efforts. During the development period, these assets are assessed for impairment at least annually. Upon completion of the development process for the acquired IPR&D, the associated asset is considered definite-

lived and amortized over the estimated useful life of the asset. Development costs incurred after the acquisition date are charged to research and development.

Special Charges

During 2007, we recorded a charge of $19.1 million as a result of the settlement of the litigation with The Regents of the University of California and Boston Scientific Corporation.

Foreign Currency Translation/Forward Foreign Currency Contracts

The local currency is generally designated as the functional currency for our international operations. Accordingly, assets and liabilities are translated from the local currency into U.S. dollars at period-end exchange rates and currency translation adjustments resulting from fluctuations in exchange rates are recorded in "Accumulated other comprehensive loss" in the consolidated balance sheets. Revenues and expenses are translated at weighted average exchange rates for the year. Gains and losses on foreign currency transactions are included in "Other expense (income), net" in the consolidated statements of operations. Foreign currency transactions, net of gains and losses on forward foreign currency contracts, resulted in losses of $1.6 million and $2.4 million for 2009 and 2008, respectively, and transaction gains of $2.9 million for 2007.

We use forward foreign currency contracts to economically hedge the volatility of foreign currency rates for foreign cash balances and accounts receivable for which payment is settled in a currency other than our local operations' functional currency. We did not have any forward foreign currency contracts outstanding at the end of 2009 and 2008. During the years ended December 31, 2009 and December 31, 2008, we recorded $2.3 million and $941,000 of losses, respectively, as "Other expense (income), net" in our consolidated statements of operations associated with the settlement of our foreign currency contracts.

Income Taxes

Deferred income taxes are recognized for the tax consequences in future years of differences between the tax basis of assets and liabilities and their financial reporting amounts at each year end, based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable earnings. Valuation allowances are established when necessary to reduce deferred tax assets to the amount that is more likely than not to be realized. The effect of changes in tax rates is recognized in the period in which the rate change occurs.

On January 1, 2007, we adopted the provisions which require certain disclosures of uncertain tax matters and indicate how any tax reserves should be classified in a balance sheet. As a result, we recorded a charge of $717,000, which was accounted for as an increase to the January 1, 2007 balance of accumulated deficit.

Net Income (Loss) per Common Share

Basic net earnings (loss) per share is computed based on the weighted average number of common shares outstanding. Diluted earnings (loss) per share is computed based on the weighted average number of common shares outstanding adjusted, to the extent dilutive, by the number of additional shares that would have been outstanding had the potentially dilutive common shares been issued and reduced by the number of shares we could have repurchased with the proceeds from the potentially dilutive shares. Potentially dilutive shares include stock options and other share-based awards granted under share-based compensation plans.

Comprehensive Income (Loss)

Comprehensive income (loss) consists of net income (loss), the effects of foreign currency translation and unrealized (losses) gains on available-for-sale investments.

Concentrations of Credit Risk

Financial instruments that potentially subject us to credit risk consist principally of cash and cash equivalents and accounts receivable.

We maintain cash and cash equivalents with various major financial institutions; however, we are exposed to credit risk in the event of default by these financial institutions for amounts in excess of Federal Deposit Insurance Corporation insured limits. We perform periodic evaluations of the relative credit standings of these financial institutions and attempt to limit the amount of credit exposure with any one institution by maintaining accounts at multiple institutions. Management believes that our investments in cash and cash equivalents are financially sound and have minimal credit risk.

We have a credit policy and perform ongoing credit evaluations of our customers. We do not generally require collateral or other security and maintain an allowance for potential credit losses. Management believes this risk is limited due to the large number and diversity of hospitals and distributors who comprise our customer base.

Accounting for Stock-Based Compensation

We measure and recognize the cost of employee services received in exchange for awards of equity instruments based on the grant date fair value of those awards. Compensation cost is recognized ratably using the straight-line attribution method over the expected vesting period, which is considered to be the requisite service period. In addition, we estimate the amount of expected forfeitures when calculating the compensation costs.

The fair value of options are estimated at the date of grant using the Black-Scholes option pricing model. Risk free interest rate is based on U.S. Treasury rates appropriate for the expected term. Expected volatility and forfeiture rates are based on historical factors related to our common stock. The assumed dividend yield is zero as we do not expect to declare any dividends in the foreseeable future. The expected term is based on the weighted average time between grant and employee exercise. The fair value of stock granted to employees is based upon the closing market value of our common stock on the date of grant. The key assumptions used in estimating the fair value of our stock-based compensation awards were as follows:

	Year Ended December 31,		
	2009	2008	2007
Risk free interest rate	1.6%	2.6%	4.4%
Expected dividend yield	0.0%	0.0%	0.0%
Expected volatility	53.5%	44.8%	43.6%
Expected option term	3.85 years	3.85 years	3.85 years

Non-employee equity-based awards, in which goods or services are the consideration received for the equity instruments issued, are classified as liability awards and are recorded at fair value.

The following table summarizes the stock-based compensation expense (in thousands) for employees and non-employees recognized in our consolidated statements of operations for each period:

	Year Ended December 31,		
	2009	2008	2007
Product cost of goods sold	$ 1,007	$ 834	$ 926
Sales, general and administrative	11,985	12,438	8,832
Research and development	1,564	1,887	1,369
Total stock-based compensation expense	$14,556	$15,159	$11,127

The resignation of our former chairman, president and chief executive officer on April 6, 2008, resulted in the recognition of approximately $1.5 million of non-cash stock-based compensation in “Sales, general and administrative” expenses which we recorded in the second quarter of 2008 as a result of accelerated vesting of certain stock options and restricted stock awards and the extension of the exercise period on certain stock options.

Fiscal Year

We operate on a manufacturing calendar with our fiscal year always ending on December 31. Each quarter is 13 weeks, consisting of one five-week and two four-week periods.

Reclassifications

Certain amounts reported in our consolidated financial statements for the previous reporting periods have been reclassified to conform to the current period presentation.

New Accounting Pronouncements

In the third quarter of 2009, we adopted the Financial Accounting Standards Board's ("FASB") Accounting Standards Codification ("ASC") Topic 105 as the single official source of authoritative, nongovernmental generally accepted accounting principles in the United States. On the effective date, all then-existing non-SEC accounting literature and reporting standards were superseded and deemed nonauthoritative. The adoption of this pronouncement did not have a material impact on our consolidated financial statements; however, the ASC affected the way we reference authoritative guidance in our consolidated financial statements.

In December 2007, the FASB issued additional guidance on business combinations contained in ASC Topic 805 and additional guidance on noncontrolling interests in consolidated financial statements contained in ASC Topic 810, which are effective for fiscal years beginning after December 15, 2008. These new standards represent the completion of the FASB's first major joint project with the International Accounting Standards Board and are intended to improve, simplify and converge internationally the accounting for business combinations and the reporting of noncontrolling interests (formerly minority interests) in consolidated financial statements.

ASC Topic 805 changes the application of the acquisition method in a number of significant respects, including the requirement to expense transaction fees and expected restructuring costs as incurred, rather than including these amounts in the allocated purchase price; the requirement to recognize the fair value of contingent consideration at the acquisition date, rather than the amount when the contingency is resolved; the requirement to recognize the fair value of acquired in-process research and development assets at the acquisition date, rather than immediately expensing; and the requirement to recognize a gain in relation to a bargain purchase price, rather than reducing the allocated basis of long-lived assets. We adopted these standards at the beginning of 2009. See Note 3 for further discussion of the impact the adoption of ASC Topic 805 had on our results of operations and financial conditions as a result of our Chestnut acquisition in 2009.

In May 2009, the FASB issued additional guidance on management's assessment of subsequent events. This guidance is contained in ASC Topic 855 and clarifies that management must evaluate, as of each reporting period, events or transactions that occur for potential recognition or disclosure in the financial statements and the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date through the date that the financial statements are issued or are available to be issued. ASC Topic 855 requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for that date. This disclosure alerts all users of financial statements that an entity has not evaluated subsequent events after that date in the set of financial statements being presented. We adopted ASC Topic 855 in the second quarter of 2009. The implementation of ASC Topic 855 did not have a material impact on our consolidated financial statements.

In April 2008, the FASB issued guidance on the determination of the useful life of intangible assets, ("ASC Topic 350-30-35-1"), which amended the factors considered in developing renewal or extension assumptions used to determine the useful life of recognized intangible assets. ASC Topic 350-30-35-1 requires a consistent approach between the useful life of a recognized intangible asset and the period of expected cash flows used to measure the fair value of an asset. The ASC Topic 350-30-35-1 also requires enhanced disclosure when an intangible asset's expected future cash flows are affected by an entity's intent and/or ability to renew or extend the arrangement. We adopted ASC Topic 350-30-35-1 as of January 1, 2009. The adoption did not have a significant impact on our consolidated financial statements.

In 2006, the FASB issued an accounting pronouncement to provide enhanced guidance when using fair value to measure assets and liabilities. The pronouncement defines fair value, establishes a framework for measuring fair value in GAAP and expands disclosures about fair value measurements. The pronouncement applies whenever other pronouncements require or permit assets or liabilities to be measured by fair value. We adopted the pronouncement as of the beginning of 2008 as it relates to recurring measurements of financial assets and liabilities, and as of the

beginning of 2009, as it relates to nonrecurring fair value measurement requirements for nonfinancial assets and liabilities. These assets and liabilities include goodwill and intangible assets not subject to amortization.

3. Acquisitions

Chestnut Acquisition

On June 23, 2009, we acquired Chestnut Medical Technologies, Inc., a then privately held, California-based company focused on developing minimally invasive therapies for interventional neuroradiology. The transaction broadens our neurovascular product portfolio by adding the Pipeline Embolization Device for the treatment of cerebral aneurysms and the Alligator Retrieval Device for foreign body retrieval to our existing neurovascular embolic products and neuro access technologies.

We acquired 100 percent of the equity interests of Chestnut for total consideration valued at $116.7 million, consisting of upfront consideration of common stock and cash valued at $79.4 million, as well as an additional milestone-based contingent payment of up to $75.0 million, payable in a combination of common stock and equity, upon FDA pre-market approval of the Pipeline Embolization Device.

The transaction has been accounted for under the acquisition method. Our consolidated financial statements include the financial results of Chestnut subsequent to the acquisition date of June 23, 2009.

The following table presents the purchase price consideration (in thousands) for the acquisition:

Equity consideration	$	53,186
Cash consideration		26,240
Total cash and equity	$	79,426
Contingent consideration		37,275
Total purchase price consideration	$	116,701

We issued 5,060,510 shares of our common stock, with an estimated fair value of $53.2 million. The estimated fair value per share of common stock of $10.51 was based on the closing price of our common stock on June 23, 2009, the date of the acquisition. The cash consideration, net of cash acquired, was approximately $24.7 million. We have also incurred $1.0 million in direct acquisition costs which were expensed as incurred.

In addition, we have agreed to pay an additional milestone-based payment of cash and equity upon the FDA pre-market approval of the Pipeline Embolization Device. This milestone-based contingent payment could range from: (1) $75.0 million upon FDA approval prior to October 1, 2011, (2) $75.0 million less $3.75 million per month upon FDA approval from October 1, 2011 through December 31, 2012 and (3) no payment required if FDA approval is not obtained by December 31, 2012. The milestone-based payment of up to $75.0 million will consist of cash and equity paid in the form of shares of our common stock ranging from 30% cash and 70% equity to 85% cash and 15% equity. We have recorded the acquisition-date estimated fair value of the contingent milestone payment of $37.3 million as a component of the consideration transferred in exchange for the equity interests of Chestnut. The acquisition-date fair value was measured based on the probability-adjusted present value of the consideration expected to be transferred, discounted at 26%, the weighted average cost of capital for the Chestnut transaction. The fair value of the contingent milestone payment was remeasured as of December 31, 2009 at $42.2 million and is reflected in “Other long-term liabilities” in our consolidated balance sheets. The change in fair value of $4.9 million for the year ended December 31, 2009 is reflected as “Contingent consideration” in our consolidated statements of operations.

The assets acquired and liabilities assumed in the Chestnut acquisition were measured and recognized at their fair values, with limited exceptions, at the date of the acquisition. The excess of the purchase price over the net identifiable assets acquired and liabilities assumed was recognized as goodwill, and reflect the future benefit we expect from leveraging our commercial operations to market the acquired products. None of the goodwill or intangible assets resulting from our acquisition of Chestnut are deductible for tax purposes.

The following table summarizes the preliminary amounts (in thousands) recognized on the acquisition date as part of the acquisition of Chestnut:

Intangible assets	$ 93,070
Tangible assets acquired, net of liabilities assumed	822
Deferred tax liabilities acquired, net	(29,323)
Goodwill	52,132
Estimated fair value of net assets acquired	$ 116,701

In connection with the Chestnut acquisition, we recorded deferred tax liabilities of $29.3 million, which includes $19.0 million related to amortizable intangible assets and $10.3 million related to indefinite-lived acquired in-process research and development. For additional discussion regarding deferred tax liabilities, see Note 17.

The following table presents the preliminary allocation of the purchase consideration to identifiable intangible assets acquired, excluding goodwill and the weighted average amortization period in total and by major intangible asset class (in thousands):

Intangible Asset Description	**Fair Value Assigned**	**Weighted Average Amortization Period (in years)**
Developed and core technology	$ 64,130	12
Customer and distributor relationships	220	3
Trademarks and tradenames	960	5
Non-compete agreements	360	3
Total amortizable intangible assets acquired	$ 65,670	11
Acquired in-process research and development	27,400	Indefinite
Total intangible assets acquired (excluding goodwill)	$ 93,070	

The acquired in-process research and development asset relates primarily to the Pipeline Embolization Device, which is a new class of embolization device that is designed to divert blood flow away from an aneurysm in order to provide a complete and durable aneurysm embolization while maintaining patency of the parent vessel. This asset is recognized and measured at the estimated fair value at the date of acquisition. As of the date of the acquisition, the in-process project had not yet reached technological feasibility in the United States and had no alternative use. The primary basis for determining technological feasibility of the project in the United States is obtaining FDA regulatory approval to market the device.

The income approach was used to determine the fair value of the acquired in-process research and development asset. This approach measures fair value by estimating the after-tax cash flows attributable to the in-process project over its useful life on a discounted basis. The costs to complete each project were based on estimated direct project expenses as well as the remaining labor hours and related overhead costs. In arriving at the value of the acquired in-process research and development project, we considered the project's stage of completion, the complexity of the work to be completed, the costs already incurred, the remaining costs to complete the project, the contribution of core technologies, the expected introduction date and the estimated useful life of the technology. We expect to incur approximately $8.0 million of development expense to obtain the regulatory approval required to commercialize the Pipeline Embolization Device in the United States. The discount rate used to arrive at the present value of acquired in-process research and development as of the date of the acquisition was approximately 27% and was based on the time value of money and medical technology investment risk factors.

The value attributable to this project, which had not yet obtained regulatory approval in the United States, has been capitalized as an indefinite-lived intangible asset. Development costs incurred on this project after the acquisition are charged to expense as incurred. If the project is not successful, or completed in a timely manner, we may not realize the financial benefit expected from this project. Upon completion of development and the obtaining of regulatory approval in the United States, this asset will become an amortizable intangible asset.

Tangible assets acquired, net of liabilities assumed, were stated at fair value at the date of the acquisition based on management's assessment.

FoxHollow Acquisition

On October 4, 2007, we acquired FoxHollow Technologies, Inc., a medical device company that designs, develops, manufactures and sells medical devices primarily for the treatment of peripheral artery disease. With this acquisition, we expanded our product portfolio to include technologically advanced products to treat vascular disease in the peripheral vascular market. At the time of the acquisition, FoxHollow was also engaged in a research collaboration with Merck & Co., Inc. for the analysis of atherosclerotic plaque removed from patient arteries with the goal of identifying new biomarkers for atherosclerotic disease progression and new therapies for atherosclerotic disease.

We paid $857.0 million to acquire FoxHollow through a combination of common stock, cash and fully vested and partially vested stock options and stock awards. In the transaction, we acquired all of the outstanding shares of FoxHollow in exchange for 43,118,667 shares of our common stock, which represented approximately 41% of the outstanding common stock of the combined company at that time, with an estimated fair value of $725.7 million. At the effective date and as a result of the acquisition, each share of common stock of FoxHollow issued and outstanding immediately prior to the effective date of the acquisition was converted into the right to receive 1.45 shares of our common stock and $2.75 in cash. Alternatively, FoxHollow stockholders could have elected to receive either 1.62 shares of our common stock or $25.92 in cash for each share of FoxHollow common stock by making an all-stock or an all-cash election, respectively. Stock and cash elections were subject to pro-ration to preserve an overall mix of 1.45 shares of our common stock and $2.75 in cash for all of the outstanding shares of FoxHollow common stock in the aggregate.

The fair value of the shares of our common stock issued as a result of the acquisition was $16.83 per share based on the average trading price of our common stock for the two full trading days prior to and subsequent to the date of the announcement, July 22, 2007.

We paid $81.8 million in cash and approximately $17.7 million in direct acquisition costs, including a payment of $8.8 million to Merck. The purchase price net of cash acquired was approximately $690.0 million and cash acquired was comprised of $81.5 million of cash on hand and $85.4 million of short-term investments.

At the effective time of the acquisition, each outstanding option to purchase shares of FoxHollow common stock and other awards based on FoxHollow common stock were converted into and became respectively an option to purchase 1.618 shares of our common stock or an award based on shares of our common stock. The number of shares of our common stock exchanged for FoxHollow options and stock awards was 6,605,663 shares, with an estimated fair value of $45.9 million, of which $31.9 million related to the vested portion of the options and therefore represented additional purchase price consideration and $14.0 million related to the unvested portion of the options which will be recognized as compensation cost over the remaining service periods.

We determined the estimated fair value of the ev3 stock options and awards exchanged for FoxHollow options and awards was $6.34 per share. We used a Black-Scholes option pricing model to determine the fair value of the exchanged options and awards. The determination of the fair value for the exchanged options and awards requires the use of significant estimates and assumptions which include the expected life of the award, the expected stock price volatility over the expected life of the awards and the risk-free interest rate. A change in any of the estimates or assumptions used could significantly change the valuation and fair value of the options and awards. Our estimates and assumptions were based upon information that we believed to be reasonable as of the date of the acquisition.

The following table presents the assumptions used to determine the fair value of the options and awards assuming no expected dividends:

Expected term (in years)	2.7
Expected volatility	45.00%
Risk-free interest rate	4.60%
Stock price on date of grant	$ 16.83
Weighted-average exercise price	$ 14.99

There were no contingent payments, options or commitments specified in our merger agreement with FoxHollow.

The following table presents the purchase price consideration (in thousands) for the acquisition:

FoxHollow common shares converted	$ 725,687
Cash consideration	81,811
FoxHollow options converted	31,875
Total cash and equity	$ 839,373
Merck consideration	8,824
Deal costs	8,846
Total purchase price consideration	$ 857,043

The acquisition has been accounted for under the purchase method. Our consolidated financial statements include the financial results of FoxHollow subsequent to the acquisition date of October 4, 2007.

The aggregate FoxHollow purchase price was allocated to the assets acquired and liabilities assumed based on their fair values at the date of the acquisition. The excess of purchase price over the fair value of net tangible assets acquired was allocated to identifiable intangible assets and goodwill. The following table summarizes the estimate of fair value (in thousands) of net assets that were acquired as part of the acquisition:

Intangible assets	$ 199,500
Acquired in-process research and development	70,700
Tangible assets acquired, net of liabilities assumed	145,854
Goodwill	440,989
Estimated fair value of net assets acquired	$ 857,043

The following table presents the identifiable intangible assets acquired, excluding goodwill and the weighted average amortization period in total and by major intangible asset class:

Intangible Asset Description	Fair Value Assigned	Weighted Average Amortization Period (in years)
Developed and core technology	$ 138,800	12
Customer relationships	40,000	12
Merck exclusivity	13,600	3.25
Trademarks and tradenames	7,100	10
Total intangible assets acquired (excluding goodwill)	$ 199,500	11

The acquired in-process research and development charges represented the estimated fair value of the in-process projects at the date of the acquisition. As of the date of the acquisition, the in-process projects had not yet reached technological feasibility and had no alternative use. The primary basis for determining technological feasibility of these projects was obtaining regulatory approval to market the products. Accordingly, the value attributable to these projects, which had yet to obtain regulatory approval, was expensed in conjunction with the acquisition. If the projects are not successful, or completed in a timely manner, we may not realize the financial benefits expected from these projects.

The income approach was used to determine the fair value of the acquired in-process research and development. This approach establishes fair value by estimating the after-tax cash flows attributable to any in-process project over its useful life and then discounting these after-tax cash flows back to the present value. The costs to complete each project were based on estimated direct project expenses as well as the remaining labor hours and related overhead costs. In arriving at the value of acquired in-process research and development projects, we considered the project's stage of completion, the complexity of the work to be completed, the costs already incurred, and the remaining costs to complete the project, the contribution of core technologies, the expected introduction date and the estimated useful life of the technology. The discount rate used to arrive at the present value of acquired in-process research and development as of the date of the acquisition was based on the time value of money and medical technology investment risk factors. The discount rate used was approximately 14%.

The most significant acquired research and development projects were the RockHawk and Next Generation SilverHawk (TurboHawk) projects which represents 92% of the acquired research and development projects. We attributed approximately $64.9 million of fair value to the RockHawk and TurboHawk projects.

The RockHawk is designed to treat calcified lesions with an improved cutting blade. In February 2008, we received FDA clearance for surgical use of the RockHawk device in the United States. The TurboHawk is designed to improve the procedure time, cutting efficiency and ease of use of the SilverHawk system. The TurboHawk was cleared by the FDA for endovascular use in soft lesions as well as mild to moderate calcified lesions in November 2009. It is also FDA cleared for surgical use in heavily calcified lesions. We incurred approximately $3.2 million to bring the TurboHawk device to commercial viability.

The TurboHawk device has been approved by the FDA for inclusion in our Investigational Device Exemption trial for treatment of moderate to severe calcified lesions using an endovascular surgical approach. The realization of increased cash flow relating to the TurboHawk endovascular use in severe calcified lesions is contingent on the timing of FDA clearance for this expanded indication.

Tangible assets acquired, net of liabilities assumed, were stated at fair value at the date of the acquisition based on management's assessment or third party appraisals and included a $1.8 million inventory step-up which was fully amortized at December 31, 2007. The amortization for the inventory step-up is included in product cost of goods sold in the consolidated statements of operations for the year ended December 31, 2007 as the acquired inventory was sold subsequent to the merger.

None of the goodwill resulting from the FoxHollow acquisition is deductible for tax purposes.

Pro Forma Results of Operations

The unaudited pro forma combined consolidated statements of operations for the year ended December 31, 2007 combines the historical results of ev3 and the unaudited pro forma combined results of FoxHollow for the year ended December 31, 2007 and gives effect to the acquisition as if it occurred on January 1, 2007. Pro forma adjustments have been made related to amortization of identified intangible assets. Pro forma net earnings for 2007 include the $70.7 million IPR&D charge that was a direct result of the acquisition. The pro forma consolidated results do not purport to be indicative of results that would have occurred had the acquisition been in effect for the periods presented, nor do they claim to be indicative of the results that will be obtained in the future, and do not include any adjustments for cost savings or other synergies. The pro forma financial results include the results of continuing operations of FoxHollow in its entirety during this period.

The following table contains unaudited pro forma results (in thousands except per share data) for the year ended December 31, 2007, as if the acquisition had occurred at January 1, 2007:

	Reported	Pro Forma
Net revenues	$ 284,183	$ 439,893
Net loss	$ (165,744)	$ (202,337)
Net loss per share:		
Basic and diluted	$ (2.37)	$ (1.98)

4. Fair Value Measurements

The fair value of assets and liabilities is determined on the exchange price which would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants. The determination of fair value is based upon a three-tier fair value hierarchy, which prioritizes the inputs used in fair value measurements. The three-tier hierarchy for inputs used in measuring fair value is as follows:

- *Level 1*. Observable inputs such as quoted prices in active markets;
- *Level 2*. Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and
- *Level 3*. Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

As of December 31, 2009 and 2008, we held approximately $55.4 million and $45.6 million, respectively, in money market accounts measured at fair value on a recurring basis using Level 1 inputs. Our money market accounts are reflected as "Cash and cash equivalents" in our consolidated balance sheets.

In connection with our 2009 acquisition of Chestnut, we entered into an agreement to pay a contingent milestone-based payment of cash and equity upon the U.S. Food and Drug Administration ("FDA") pre-market approval of the Pipeline Embolization Device ("Pipeline"). We recorded the acquisition-date estimated fair value of the contingent milestone payment of $37.3 million as a component of the consideration transferred in exchange for the equity interests of Chestnut. We measured the initial amount and remeasure the liability each reporting period using Level 3 inputs. For additional discussion regarding the valuation of contingent consideration, see Note 3.

The following table presents a summary of the contingent consideration long-term liability and activity (in thousands) for the periods presented:

Balance as of December 31, 2008	$ —
Purchase price contingent consideration	37,275
Change in fair value of contingent consideration	4,876
Balance as of December 31, 2009	$ 42,151

5. Restructuring

In conjunction with our acquisition of FoxHollow, our management began to assess and formulate a plan to restructure certain activities of FoxHollow and to terminate certain contractual agreements assumed in the acquisition. A significant portion of these costs were related to management's plan to reduce the workforce and included costs for severance and change of control provisions provided for under certain FoxHollow employment contracts. The workforce reductions began during the fourth quarter of 2007 and were completed as of the end of the third quarter of 2008. The unpaid portion of the workforce reductions represents salary continuance, which was paid over subsequent periods. We finalized our restructuring costs in conjunction with our plans to consolidate our manufacturing and other operations including the closure of our facilities located in Redwood City, California,

which we acquired in connection with our acquisition of FoxHollow. We have completed the relocation of the sales, manufacturing and research and development activities performed in FoxHollow's former Redwood City facilities to our existing facilities located in Irvine, California and Plymouth, Minnesota.

During 2009, it was determined the estimated salary continuance costs to be incurred were $300,000 less than the amount previously estimated. An adjustment to the purchase price allocation was made to reduce the restructuring accrual and the amount allocated to goodwill. In addition, in light of the current economic environment and continued downward pressures in the California real estate markets, we revised certain sub-lease rental assumptions related to our vacated leased FoxHollow facilities, which resulted in an increase in the estimated liability related to future lease payments of $3.4 million in 2009. The changes in assumptions relate to the additional time it will likely take to find a sub-lessor and the rental rate of the sub-lessor. Since this adjustment was made as a result of changes in market conditions subsequent to the acquisition and was made outside of the purchase price allocation period, the adjustment was included in the determination of net income (loss) for the year ended December 31, 2009 and is reflected in "Sales, general, and administrative" expenses on the consolidated statement of operations.

The following table represents a summary of activity (in thousands) associated with the FoxHollow restructuring accruals that occurred during 2008 and 2009. The unpaid portions of these costs are included in "Accrued compensation and benefits," "Accrued liabilities," and "Other long-term liabilities" on the consolidated balance sheets for the periods presented:

	Balance at December 31, 2007	Adjustments to Purchase Price Allocation	Adjustments Reflected in Consolidated Statements of Operations	Amounts Paid	Balance at December 31, 2008
Workforce reductions	$ 7,605	$ 848	$ —	$ (7,783)	$ 670
Termination of contractual commitments	2,476	6,294	—	(1,275)	7,495
Total	$ 10,081	$ 7,142	$ —	$ (9,058)	$ 8,165

	Balance at December 31, 2008	Adjustments to Purchase Price Allocation	Adjustments Reflected in Consolidated Statements of Operations	Amounts Paid	Balance at December 31, 2009
Workforce reductions	$ 670	$ (300)	$ (49)	$ (321)	$ —
Termination of contractual commitments	7,495	—	3,421	(3,211)	7,705
Total	$ 8,165	$ (300)	$ 3,372	$ (3,532)	$ 7,705

As part of our restructuring plan, we also incurred costs related to workforce reductions of the ev3 pre-acquisition workforce of approximately 40 employees in 2007, which were recognized when the amounts became probable and estimable. All amounts were paid prior to December 31, 2008.

6. Inventories, Net

Inventories, net consists of the following (in thousands):

	December 31, 2009	December 31, 2008
Raw materials	$10,927	$10,472
Work-in-progress	4,849	4,144
Finished goods	40,252	43,408
	56,028	58,024
Inventory reserve	(10,974)	(10,337)
Inventories, net	$45,054	$47,687

Consigned inventories as of December 31, 2009 and 2008 were $21.7 million and $20.9 million, respectively.

7. Property and Equipment

Property and equipment consists of the following (in thousands):

	December 31, 2009	December 31, 2008
Machinery and equipment	$ 32,126	$ 29,550
Office furniture and equipment	21,508	18,466
Leasehold improvements	16,846	14,131
Construction in progress	3,567	5,670
	74,047	67,817
Less:		
Accumulated depreciation and amortization	(44,888)	(37,136)
Property and equipment, net	$ 29,159	$ 30,681

Depreciation and amortization expense for property and equipment for the years ended December 31, 2009, 2008 and 2007 was $11.2 million, $11.5 million and $8.4 million, respectively.

8. Goodwill and Intangible Assets

The changes in the carrying amount of goodwill by operating segment for the years ended December 31, 2009 and 2008 were as follows (in thousands):

	Peripheral Vascular	Neuro-vascular	Total
Balance as of January 1, 2008	$ 501,394	$85,254	$586,648
Adjustments to finalize purchase accounting	10,902	—	10,902
Goodwill impairment (see Note 9)	(281,896)	—	(281,896)
Balance as of December 31, 2008	230,400	85,254	315,654
Adjustments to goodwill related to acquisition of FoxHollow (see Note 3)	(300)	—	(300)
Goodwill related to acquisition of Chestnut (see Note 3)	—	52,132	52,132
Balance as of December 31, 2009	$ 230,100	$137,386	$367,486

Intangible assets, net consist of the following (dollars in thousands):

	Weighted average useful life (in years)	December 31, 2009 Gross Carrying Amount	2009 Accumulated Amortization	2009 Net Carrying Amount	2008 Gross Carrying Amount	2008 Accumulated Amortization	2008 Net Carrying Amount
Patents and licenses	5.0	$16,016	$ (7,743)	$ 8,273	$15,413	$ (6,264)	$ 9,149
Developed technology	11.0	260,147	(83,242)	176,905	196,016	(66,312)	129,704
Trademarks and tradenames	8.0	13,182	(5,562)	7,620	12,222	(4,457)	7,765
Customer relationships	10.0	56,314	(22,520)	33,794	56,094	(17,967)	38,127
Acquired in-process research and development	—	27,400	—	27,400	—	—	—
Distribution rights	2.5	—	—	—	7,966	(7,419)	547
Other intangible assets	3.0	360	(64)	296	—	—	—
Intangible assets, net		$373,419	$(119,131)	$254,288	$287,711	$(102,419)	$185,292

Intangible assets are amortized using methods which approximate the benefit provided by the utilization of the assets. Patents and licenses, developed technology and trademarks and tradenames are amortized on a straight-line basis. Customer relationships are amortized using both straight-line and accelerated methods that approximate the pattern of economic benefit. Acquired in-process research and development is an indefinite-lived intangible asset until it reaches technological feasibility, at which time it would become a finite-lived asset and be amortized over its estimated useful life.

Total amortization of intangible assets was $25.1 million, $31.1 million and $20.3 million for the years ended December 31, 2009, 2008 and 2007, respectively.

Based on the intangible assets in service as of December 31, 2009, estimated amortization expense, excluding any possible future amortization associated with acquired in-process research and development which has not reached technological feasibility, for the next five years ending December 31 is as follows (in thousands):

2010	$25,383
2011	23,860
2012	23,652
2013	23,285
2014	20,799

9. Goodwill and Intangible Asset Impairment

During 2008, we performed our annual goodwill impairment test as of October 1, 2008 in accordance with our accounting policy. We performed our tests using our 2009 Annual Operating Plan ("AOP") as well as forecasts for 2010 through 2012. The AOP and three-year forecast were based upon our strategic plan for those years which included a detailed revenue build-up by technology. The AOP and strategic plan contain revenue assumptions that were derived from existing technology as well as future revenues attributed to in-process technologies and the associated launch, growth and decline assumptions normal for the life cycle of those technologies. In addition, we considered relevant market information, peer company data and five years of historical financial information. Finally, as part of the step 1 test, we performed a market capitalization reconciliation to ensure the resulting outputs of the test and the total enterprise fair value were consistent with those of a market participant. Based upon the step 1 test results, both our neurovascular and peripheral vascular reporting units passed the test and there was no goodwill impairment indicated.

Subsequent to our annual impairment test in 2008, there was a substantial disruption in the general credit and equity markets and in particular a substantial decline in our stock price and market capitalization during our fourth quarter of 2008. The decline in our stock price and market capitalization were primarily a result of the then general market conditions and the associated increase in general market risk as well as changes in our future estimated cash flows which were significantly driven by the changes in the performance of our plaque excision (formerly atherectomy) business. A substantial decline in market capitalization is an indicator of impairment, and we were required to reassess the carrying value of our goodwill. We re-performed the step 1 test. There was no indication of impairment for our neurovascular reporting unit, but the carrying amount of our peripheral vascular reporting unit was less than the estimated fair value. Therefore, we performed a step 2 valuation of impairment for the peripheral vascular reporting unit.

We performed a hypothetical valuation of the peripheral vascular reporting unit to determine the implied fair value of goodwill. The amount of impairment was determined by comparing the fair value of the goodwill to its carrying amount. In order to determine the fair value of goodwill, the fair value of the reporting unit was allocated to the assets and liabilities of that unit. The unallocated amount represented the fair value of goodwill. All of the data and key assumptions used to derive the fair value were consistent with those used in step 1 testing.

We used the income and the market approaches to determine the fair value of goodwill. After consideration of both approaches, the concluded fair values were weighted entirely on the income approach. We determined that the market approach was not appropriate to use for this valuation as there was no direct comparability between the reporting units and companies that were included in the market valuation. As part of our step 2 valuation, we identified and valued all of our recorded and unrecorded tangible and intangible assets. The most significant assumptions used in the valuation of our assets included a weighted average cost of capital ("WACC") of 19% and a terminal value of 2.0 times 2012 estimated revenues. The estimated proportion of debt and equity financing is an important component of the WACC calculation. In our analysis, the capital structure was based on the median equity-to-capital structure for comparable companies and the proportion of debt to equity was 0% and 100%, respectively. Based upon the results of our step 2 test, we recorded a $281.9 million impairment charge associated

with our peripheral vascular business which we recognized in "Goodwill and intangible asset impairment" in our consolidated statements of operations.

During 2008, we made the decision to discontinue selling a developed technology acquired in our FoxHollow acquisition. Prior to this decision, we had discussions with various third parties to ascertain whether or not the technology had any perceived market value. We concluded there was no viable interest to acquire the technology and estimated there was no market value for the asset. As a result, we impaired the remaining carrying amount of this developed technology and recognized a $5.6 million intangible asset impairment charge reflected in "Goodwill and intangible asset impairment" in our consolidated statements of operations.

Additionally, during 2008, we assessed the distribution rights intangible asset associated with our former agreement with Invatec S.r.l. ("Invatec") to distribute their PTA balloons. We had entered into a distribution agreement with Invatec that gave us non-exclusive rights to distribute Invatec's products, which expired on December 31, 2008, but allowed us to sell our remaining inventory of Invatec products through June 30, 2009. We estimated the undiscounted cash flows for the six month period following the December 31, 2008 termination date and recorded a $1.3 million intangible asset impairment charge to write-down the carrying amount of the asset to its estimated fair value. We adjusted the amortization period of the asset to correspond with the period we expected to generate future cash flows. We recognized the intangible asset impairment in "Goodwill and intangible asset impairment" in our consolidated statements of operations.

Merck exercised its right to terminate the amended and restated collaboration and license agreement, dated September 26, 2006, between Merck and FoxHollow, effective July 22, 2008. As a result of the termination of the agreement, we recorded an intangible asset impairment charge of $10.5 million during 2008 to write-off the Merck intangible asset that was established at the time of our acquisition of FoxHollow, as no further cash flows were expected to be generated from the agreement.

10. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31, 2009	December 31, 2008
Accrued clinical studies	$ 3,085	$ 2,714
Accrued royalties	3,062	2,527
Deferred rent and lease liabilities	2,885	3,607
Tax liabilities	2,144	1,865
Accrued legal and professional services	1,899	1,971
Accrued sales rebates	1,530	852
Accrued other	7,848	6,208
Total accrued liabilities	$22,453	$19,744

11. Long-Term Debt

Long-term debt consists of the following (in thousands):

	December 31, 2009	December 31, 2008
Equipment term loan	$ 6,458	$ 8,958
Less: current portion	(2,500)	(2,500)
Total long-term debt	$ 3,958	$ 6,458

Our operating subsidiaries, ev3 Endovascular, Inc., ev3 International, Inc., Micro Therapeutics, Inc. and FoxHollow Technologies, Inc. which we collectively refer to as the "borrowers," are parties to a loan and security agreement with Silicon Valley Bank, which was amended most recently in December 2008. The amended facility consists of a $50.0 million revolving line of credit and $10.0 million term loan. The revolving line of credit expires June 25, 2010 and the term loan matures on June 23, 2012. Pursuant to the terms of the loan agreement, and subject to

specified reserves, we may borrow under the revolving line of credit up to $12.0 million without any borrowing base limitations. Aggregate borrowings under the revolving line of credit that exceed $12.0 million will subject the revolving line to borrowing base limitations. These limitations allow us to borrow, subject to specified reserves, up to 80% of eligible domestic and foreign accounts receivables plus up to 30% of eligible inventory. Additionally, borrowings against the eligible inventory may not exceed the lesser of 33% of the amount advanced against accounts receivable or $10.0 million. As of December 31, 2009, we had $6.5 million of outstanding borrowings under the term loan and no outstanding borrowings under the revolving line of credit; however, we had $934,000 of outstanding letters of credit issued by Silicon Valley Bank, which reduced the maximum amount available under our revolving line of credit to $49.1 million.

Borrowings under the revolving line of credit bear interest at a variable annual rate equal to Silicon Valley Bank's prime rate plus 0.5%. Borrowings under the term loan bear interest at a variable annual rate equal to Silicon Valley Bank's prime rate plus 1.0%. Silicon Valley Bank's prime rate at December 31, 2009 was 4.0%. Accrued interest on any outstanding balance under the revolving line and the term loan is payable monthly in arrears. Principal amounts outstanding under the term loan are payable in 48 consecutive equal monthly installments on the last day of each month. We incurred $150,000 of debt issuance costs which are being amortized over the term of the revolving line of credit.

Both the revolving line of credit and term loan are secured by a first priority security interest in substantially all of our assets, excluding intellectual property, which is subject to a negative pledge, and are guaranteed by ev3 Inc. and all of our U.S. direct and indirect subsidiaries which are not borrowers. We are required to maintain a minimum adjusted quick ratio and a minimum consolidated earnings level. The loan agreement contains customary events of default, including the failure to make required payments, the failure to comply with certain covenants or other agreements, the occurrence of a material adverse change, failure to pay certain other indebtedness and certain events of bankruptcy or insolvency. Upon the occurrence and during the continuation of an event of default, amounts due under the loan agreement may be accelerated. We were in compliance with all of our financial and non-financial covenants at December 31, 2009.

Annual maturities of our long-term debt at December 31, 2009 are as follows (in thousands):

2010	$2,500
2011	2,500
2012	1,458
Total	$6,458

12. Other Long-Term Liabilities

Other long-term liabilities consist of the following (in thousands):

	Year Ended December 31,	
	2009	2008
Contingent consideration (see Notes 3 and 4)	$ 42,151	$ —
Deferred tax liability (see Notes 3 and 17)	10,360	—
Other long-term liabilities	11,397	6,217
Total other long-term liabilities	$ 63,908	$ 6,217

13. (Gain) Loss on Investments, Net

On June 15, 2007, we entered into an intellectual property transfer agreement pursuant to which we sold and licensed, on a royalty-free perpetual basis, certain intellectual property. In exchange for the assets and license, we received $2.0 million in cash, shares of common stock and an unsecured, subordinated, non-interest-bearing promissory note, and recognized a gain of $1.0 million in "Sales, general and administrative" expenses in our consolidated statements of operations. In 2009, we recognized a gain of $4.1 million in connection with the sale of

the common stock and promissory note, which is recognized as "Gain (loss) on investments, net" on our 2009 consolidated statement of operations.

14. Interest Expense (Income), Net

Interest expense (income), net for the years ended December 31, 2009, 2008 and 2007 are as follows (in thousands):

	Year Ended December 31,		
	2009	2008	2007
Interest income	$ (278)	$(1,369)	$(3,284)
Interest expense	1,066	1,146	1,374
Interest expense (income), net	$ 788	$ (223)	$(1,910)

15. Equity-Based Compensation Plans

We have several stock-based compensation plans under which stock options and other equity-based incentive awards have been granted. Under the ev3 Inc. Second Amended and Restated 2005 Incentive Stock Plan, eligible employees, outside directors and consultants may be awarded options, stock grants, stock units or stock appreciation rights. The terms and conditions of an option, stock grant, stock unit or stock appreciation right (including any vesting or forfeiture conditions) are set forth in the certificate evidencing the grant. Subject to adjustment as provided in the plan, 11.3 million shares of our common stock are authorized for issuance under the plan, including 3.3 million shares that were unallocated and available for grant under stock plans assumed by ev3 in connection with our acquisition of FoxHollow and became available for issuance under the 2005 plan. As of December 31, 2009, 7.9 million shares of our common stock had been issued under the 2005 plan or were subject to outstanding awards and options granted under the 2005 plan and 2.0 million shares remained available for future grants. As of December 31, 2009, 2.3 million shares of our common stock were issuable pursuant to outstanding stock options and other awards granted under predecessor and/or assumed plans, including the ev3 LLC plan, Micro Therapeutics, Inc. stock plans and FoxHollow plans.

We granted non-plan options to purchase 754,000 shares of our common stock outside of the terms of our existing stockholder-approved equity incentive plans to Robert J. Palmisano, our President and Chief Executive Officer, as an inducement grant in April 2008.

Options, other than those granted to outside consultants and our board of directors, generally vest over a four-year period and expire within a period of not more than ten years from the date of grant. Vested options generally expire 90 days after termination of employment. Options granted to outside consultants generally vest over the term of their consulting contract and generally expire 90 days after termination of the consulting relationship. The exercise price per share for each option is set by the board of directors or the compensation committee at the time of grant and pursuant to the terms of the plan may not be less than the fair market value per share on the grant date.

In addition to our 2005 Incentive Stock Plan, we maintain the ev3 Inc. Employee Stock Purchase Plan ("ESPP"). The ESPP was amended and restated by our Board of Directors in December 2009 to increase the number of shares of our common stock available for sale under the plan and make other minor revisions. The amended and restated ESPP is subject to the approval of our stockholders at our next annual meeting of stockholders anticipated to be held in May 2010. The maximum number of shares of our common stock available for issuance under the amended and restated ESPP is 1.75 million shares, subject to adjustment as provided in the ESPP. The ESPP provides for six-month offering periods beginning on January 1 and July 1 of each year. The purchase price of the shares is 85% of the lower of the fair market value of our common stock at the beginning or end of the offering period. This discount does not exceed the maximum discount rate permitted for plans of this type under Section 423 of the Internal Revenue Code of 1986, as amended. The ESPP is compensatory for financial reporting purposes.

A summary of option activity for all plans (dollars in thousands, except per share amounts) during the year is as follows:

	Awarded Shares Outstanding	Weighted-Average Exercise Price Per Share	Aggregate Intrinsic Value
Balance at January 1, 2009	9,747,532	$ 12.98	$ 721
Granted	2,108,446	$ 7.07	
Exercised	(254,461)	$ 7.27	
Forfeited	(305,354)	$ 13.82	
Expired	(1,772,160)	$ 14.94	
Balance at December 31, 2009	9,524,003	$ 11.44	$28,252
Options exercisable at December 31, 2009	5,728,621	$ 13.01	$10,235

The weighted average grant date fair value of options issued under all plans for 2009, 2008 and 2007 was $2.96, $3.37 and $6.55, respectively.

As of December 31, 2009, the total compensation cost for nonvested options not yet recognized in our statements of operations was $14.3 million, net of estimated forfeitures. This amount is expected to be recognized over a weighted average period of 2.58 years.

The intrinsic value of a stock option award is the amount by which the fair market value of the underlying stock exceeds the exercise price of the award. The total intrinsic value of options exercised was $789,000, $1.1 million, and $4.8 million during 2009, 2008 and 2007, respectively.

For options outstanding and exercisable at December 31, 2009, the exercise price ranges and average remaining lives were as follows:

	Options Outstanding			Options Exercisable	
Exercise Price Per Share	Number Outstanding	Weighted-Average Per Share Exercise Price	Weighted-Average Remaining Contractual Life	Number Exercisable	Weighted-Average Exercise Price Per Share
$0.20 - $8.06	2,051,063	$ 6.01	8.3 years	307,388	$ 5.23
$8.07 - $8.82	1,999,201	$ 8.71	5.6 years	1,367,800	$ 8.74
$8.84 - $13.26	1,914,111	$11.28	7.8 years	983,360	$11.86
$13.41 - $16.64	2,435,239	$15.08	4.6 years	2,145,488	$14.91
$16.66 - $96.06	1,124,389	$18.56	6.1 years	924,585	$18.73
	9,524,003	$11.44	6.4 years	5,728,621	$13.01

A summary of restricted stock awards activity for all plans during 2009 is as follows:

	Awarded Shares Outstanding	Weighted-Average Grant Date Fair Value
Nonvested balance at January 1, 2009	1,241,830	$12.04
Granted	921,965	$ 7.21
Vested	(572,721)	$10.62
Forfeited	(161,037)	$12.06
Nonvested balance at December 31, 2009	1,430,037	$ 9.26

The value of these shares of restricted stock was measured at the closing market price of our common stock on the grant date. The unamortized compensation expense for these awards was $14.4 million as of December 31, 2009, which will be recognized over the remaining weighted average vesting period of approximately 2.25 years.

16. Defined Contribution Plans

We offer substantially all of our employees the opportunity to participate in defined contribution retirement plans qualifying under the provisions of Section 401(k) of the Internal Revenue Code of 1986, as amended ("IRC"). The plans provide for a match of 50% of the employees' pre-tax contribution, up to a maximum of 3% of eligible earnings. The employee is immediately vested in the matching contribution. Compensation expense related to this plan was $2.5 million, $2.7 million and $1.9 million for the years ended December 31, 2009, 2008 and 2007, respectively.

17. Income Taxes

The components of our income tax (benefit) expense are as follows (in thousands):

	For the Years Ended December 31,		
	2009	2008	2007
Current:			
U.S.	$ 1,906	$ 245	$ —
Foreign	1,442	1,571	949
Total current	3,348	1,816	949
Deferred:	(19,171)	—	—
Total income tax (benefit) expense	$(15,823)	$1,816	$949

Following is a reconciliation of the U.S. federal statutory rate to our effective tax rate:

	For the Years Ended December 31,		
	2009	2008	2007
U.S. federal statutory tax rate	35.0 %	(35.0) %	(35.0) %
Goodwill and intangible asset impairment	—	29.6 %	—
Change in valuation allowance	(39.5) %	5.7 %	20.2 %
Change in valuation allowance – Chestnut acquisition	(72.8) %	—	—
Alternative minimum tax	3.9 %	—	—
Stock options	1.5 %	0.9 %	—
State income taxes	2.3 %	(0.4) %	(0.1) %
Research and development tax credits	(3.8) %	(0.3) %	—
Meals and entertainment	2.5 %	0.2 %	0.3 %
Foreign income taxes	1.8 %	0.1 %	0.6 %
Acquired in-process research and development	—	—	15.1 %
Contingent consideration	6.6 %	—	—
Other, net	1.7 %	(0.3) %	(0.5) %
Effective tax rate	(60.8) %	0.5 %	0.6 %

Deferred tax assets and liabilities were attributed to the following items (in thousands):

	December 31, 2009	December 31, 2008
Deferred Tax Assets:		
Net operating loss carryforwards	$ 199,741	$ 212,443
Capitalized research & development costs	30,226	35,878
Other reserves and accruals	13,520	11,576
Stock options	8,854	6,453
Tax credit carryforwards	7,366	5,439
Inventories	3,994	4,677
Unrealized losses on investments	—	3,362
Capital loss carryforward	1,905	—
Property and equipment	6,161	2,764
Other	484	609
Valuation allowance	(190,253)	(220,077)
Total deferred tax assets	$ 81,998	$ 63,124
Deferred Tax Liabilities:		
Intangible assets	(92,358)	(63,124)
Net deferred tax liability	$ (10,360)	$ —

In connection with the Chestnut acquisition, we recorded deferred tax liabilities of $29.3 million, which included $19.0 million related to amortizable intangible assets and $10.3 million related to indefinite-lived acquired in-process research and development. The deferred tax liabilities of $19.0 million related to the amortizable intangibles reduces our net deferred tax assets by a like amount and in a manner that provides predictable future taxable income over the asset amortization period. As a result, we reduced our pre-acquisition deferred tax asset valuation allowance in 2009 by $19.0 million, which has been reflected as an “Income tax benefit” in our consolidated statements of operations. Although the deferred tax liability of $10.3 million related to acquired in-process research and development also reduces our net deferred tax assets by a like amount, it does so in a manner that does not provide predictable future taxable income because the related asset is indefinite-lived. Therefore, the deferred tax asset valuation allowance was not reduced as a result of this item, and we have reported the net $10.3 million deferred tax liability under the caption “Other long-term liabilities” in our consolidated balance sheet.

We have assessed all available evidence to determine the necessity of maintaining a valuation allowance for our deferred tax assets. A valuation allowance has been recorded against our remaining net deferred tax assets as we have concluded that it is more likely than not that the deferred tax assets will not be utilized. If it is determined in a future period that it is more likely than not that the deferred tax assets will be utilized, we will reverse all or part of the valuation allowance for our deferred tax assets.

In December 2007, the FASB issued additional guidance on business combinations contained in ASC Topic 805 (“ASC Topic 805”), which was effective beginning in 2009 and where acquired income tax contingencies and reversals of valuation allowances related to previous acquisitions will impact income tax expense in the period of reversal.

A reconciliation of the beginning and ending balances of the total amounts of gross unrecognized tax benefits is as follows (in thousands):

Gross unrecognized tax benefits at December 31, 2007	$ 9,430
Increase for tax positions in prior years	1,260
Decrease for tax positions in prior years	(334)
Settlements	(80)
Increase for tax positions in current years	415
Gross unrecognized tax benefits at December 31, 2008	$ 10,691
Increase for tax positions in prior years	67
Purchase accounting	225
Increase for tax positions in current years	208
Gross unrecognized tax benefits at December 31, 2009	$ 11,191

The total amount of net unrecognized tax benefits that, if recognized, would affect tax expense was $1.2 million at December 31, 2009. We accrue interest and penalties related to unrecognized tax benefits and recognized the expense in our provision for income taxes. At December 31, 2009, we had accrued interest and penalties related to unrecognized tax benefits of $88,000 and $317,000, respectively.

We do not believe within the next twelve months there will be a significant change in the total amount of unrecognized tax benefits as of December 31, 2009.

We, or one of our subsidiaries, file income tax returns in the U.S. federal jurisdiction and in various U.S. state and foreign jurisdictions. With few exceptions, as a result of net operating loss carryforwards generated, we are subject to U.S. federal and state income tax examinations by tax authorities for years after 1994, and for years after 2002 in foreign jurisdictions.

At December 31, 2009, we had U.S. net operating loss carryforwards of $484.8 million (net of $35.6 million expected to expire before utilization due to the IRC Section 382 limitation) and foreign net operating loss carryforwards of $36.2 million (net of uncertain tax positions recorded). The general time frame of the net operating loss carryforwards expiration is as follows (in thousands):

U. S.	Foreign	Total	Carryforward Expiration Period
$ 27,826	$21,852	$ 49,678	2010 - 2019
206,991	—	206,991	2020 - 2023
250,002	—	250,002	2024 - 2029
—	14,313	14,313	No expiration date
$484,819	$36,165	$520,984	

In addition, we currently have approximately $303.1 million in state net operating loss carryforwards. These net operating loss carryforwards will expire in varying amounts between 2010 and 2029.

We have research and experimentation credit carryforwards for U.S. and California purposes of approximately $4.4 million and $1.4 million, respectively (collectively net of $5.9 million expected to expire before utilization due to the IRC Section 382 limitation and net of uncertain tax positions recorded) which will expire between 2010 and 2023. In addition, we have business loss carryforwards in the state of Texas in the amount of $300,000 to be utilized between 2010 and 2017.

As of December 31, 2009, our deferred tax assets also included $1.1 million of alternative minimum tax credits carryforwards which may be carried forward indefinitely.

Certain acquisitions made since 2001 have resulted in ownership changes which limit our ability to utilize our net operating loss and credit carryforwards pursuant to IRC Section 382. Additionally, a number of our subsidiaries, including Chestnut acquired in June 2009, have more than one IRC Section 382 limitation associated with their net

operating loss carryovers as a result of multiple past ownership changes. Subsequent changes in equity could further limit the utilization of our federal and state net operating loss and credit carryforwards. Such limitations could result in expiration of carryforward periods prior to utilization of the net operating loss and credit carryforwards. The net operating losses of certain subsidiaries acquired in prior years are subject to the separate return limitation year provisions of the Treasury Regulations. Net operating loss carryforwards from these acquisitions may only be used to offset future taxable income generated by these subsidiaries.

18. Commitments and Contingencies

Operating Leases

We lease various manufacturing and office facilities and certain equipment under operating leases, which include standard terms of renewal and rent escalation clauses which we account for on a straight-line basis over the term of the operating lease.

Total future non-cancelable minimum lease commitments are as follows (in thousands):

Years ending December 31:	
2010	$ 7,316
2011	5,069
2012	3,479
2013	2,952
2014	2,952
Thereafter	5,470
	$27,238

Rent expense related to non-cancelable operating leases for the years ended December 31, 2009, 2008 and 2007 was $5.8 million, $6.3 million and $5.1 million, respectively.

We recorded a lease termination reserve associated with three FoxHollow leased facilities which we effectively abandoned during 2008 as part of our consolidation strategy. During 2009, we recorded a $3.4 million adjustment to our lease termination reserve. For additional discussion regarding the termination of these contractual commitments see Note 5.

Letters of Credit

As of December 31, 2009, we had outstanding commitments of $4.2 million which are supported by irrevocable standby letters of credit and restricted cash. The letters of credit and restricted cash support various obligations, such as operating leases, tender arrangements with customers and automobile leases.

Royalties

We have various licensing agreements with third parties for the use of certain technologies for which we are required to pay royalties ranging from 0.5% to 6.0% of net sales. We incurred costs of $11.7 million, $10.1 million and $8.1 million in connection with these agreements in 2009, 2008 and 2007, respectively.

Contingent Consideration

Under the terms of our Chestnut acquisition agreement, we may be obligated to make an additional milestone-based payment of cash and equity totaling up to $75 million upon the FDA pre-market approval of the Pipeline device. For additional discussion regarding the contingent consideration, see Notes 3 and 4.

Other Contingencies

We are from time to time subject to, and are presently involved in, various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of our business. Such matters are subject to many uncertainties and to outcomes that are not predictable with assurance and that may not be known for extended periods of time. We record a liability in our consolidated financial statements for costs related to claims, including future legal costs, settlements and judgments, where we have assessed that a loss is probable and an amount can be reasonably estimated. Our significant legal proceedings are discussed below. While it is not possible to predict the outcome for most of the legal proceedings discussed below, the costs associated with such proceedings could have a material adverse effect on our consolidated results of operations, financial position or cash flows of a future period.

The acquisition agreement relating to our acquisition of Appriva Medical, Inc. contains four milestones to which payments relate totaling $125 million. We believe that the milestones were not achieved by the applicable dates and that none of the milestones are payable. On May 20, 2005, Michael Lesh, as an individual seller of Appriva stock and purporting to represent certain other sellers of Appriva stock, filed a complaint in the Superior Court of the State of Delaware with individually specified damages aggregating $70 million and other unspecified damages. On or about November 21, 2005, a second lawsuit was filed in Delaware Superior Court relating to the acquisition of Appriva Medical, Inc. The named plaintiff of that action was Appriva Shareholder Litigation Company, LLC, which according to the complaint was formed for the purpose of pursuing claims against us. That complaint alleged specified damages in the form of the second milestone payment ($25 million), which was claimed to be due and payable, and further alleged unspecified damages. On November 26, 2008, in a consolidated proceeding, the trial court granted our motion for summary judgment on the issue of standing and dismissed both complaints without prejudice. On April 7, 2009, Michael Lesh and Erik Van Der Burg, acting jointly as the Shareholder Representatives for the former shareholders of Appriva Medical, Inc., filed a motion to amend their complaints in Superior Court of the State of Delaware. The proposed amended complaint seeks the recovery of all of the milestone payments and punitive damages. The plaintiffs assert several claims, including breach of contract, fraudulent inducement and violation of California securities law. We filed a motion to dismiss the entire amended complaint, but the trial court has yet to rule on the motion. Because this matter is in the early stages, we cannot estimate the possible loss or range of loss, if any, associated with its resolution. However, there can be no assurance that the ultimate resolution of this matter will not result in a material adverse effect on our business, financial condition, results of operations or cash flows of a future period.

In July 2006, August 2006 and February 2007, three separate shareholder class action complaints were filed against FoxHollow and two of its officers in the U.S. District Court for the Northern District of California. These cases were subsequently consolidated into a single matter. On May 27, 2008, the U.S. District Court dismissed the consolidated case without leave to amend the complaint and judgment was enforced that day against the plaintiffs. The plaintiffs subsequently filed a notice of appeal to the United States Court of Appeals for the Ninth Circuit. On December 4, 2009, the Court of Appeals affirmed the U.S. District Court's dismissal of the consolidated cases.

In February 2007, David Martin, FoxHollow's former chief operating officer, filed a wrongful termination and defamation suit against FoxHollow and one of its officers in the Superior Court of the State of California, San Mateo County. During 2009, the parties settled this dispute. We have made the appropriate provision in our consolidated financial statements, which did not have a material adverse effect on our business, financial condition, results of operations or cash flows.

Pursuant to the acquisition agreement relating to FoxHollow's purchase of Kerberos Proximal Solutions, Inc., FoxHollow agreed to pay certain earn-out payments up to an aggregate of $117.0 million upon the achievement of contractually defined net sales milestones. Counsel for the shareholder representatives of Kerberos have alleged that FoxHollow has not used commercially reasonable efforts to market, promote, sell and distribute Kerberos's Rinspirator products, as required under the agreement. We discontinued the sale of the Rinspirator products in January 2009. Although no formal litigation has been commenced by the stockholder representatives of Kerberos regarding the alleged claims, there can be no assurance that the ultimate resolution of this matter will not result in a material adverse effect on our business, financial condition, results of operations or cash flows of a future period.

19. Segment and Geographic Information

Our management, including our chief executive officer who is our chief operating decision maker, report and manage our operations in two reportable business segments based on similarities in the products sold, customer base and distribution system. Our peripheral vascular segment contains products that are used primarily in peripheral vascular procedures by radiologists, vascular surgeons and cardiologists. Our neurovascular operating segment contains products that are used primarily by neuroradiologists, interventional neurosurgeons and neurosurgeons.

Management measures segment profitability on the basis of gross profit calculated as net sales less cost of goods sold excluding amortization of intangible assets. Other operating expenses are not allocated to individual operating segments for internal decision making activities.

We sell our products through a direct sales force in the United States, Europe, Canada, Australia and other countries as well as through distributors in other international markets. Our customers include a broad physician base consisting of vascular surgeons, neurosurgeons, other endovascular specialists, radiologists, neuroradiologists and cardiologists.

Selected financial information related to our segments is presented below (in thousands):

	For the Years Ended December 31,		
	2009	2008	2007
Net sales			
Net product sales:			
Peripheral vascular			
Plaque excision	$ 84,072	$ 88,800	$ 20,884
Stents	114,900	107,146	86,035
Thrombectomy and embolic protection	31,513	27,779	25,998
Procedural support and other	49,046	46,204	40,858
Total peripheral vascular	279,531	269,929	173,775
Neurovascular			
Embolic products	103,081	74,642	56,003
Neuro access and delivery products and other	66,460	57,662	48,448
Total neurovascular	169,541	132,304	104,451
Total net product sales	$ 449,072	$402,233	$278,226
Research collaboration:	—	19,895	5,957
Total net sales	$ 449,072	$ 422,128	$ 284,183
Gross profit			
Peripheral vascular	$ 198,704	$ 167,505	$ 100,693
Neurovascular	129,755	97,881	77,654
Research collaboration	—	13,844	4,892
Total gross profit (1)	$ 328,459	$ 279,230	$ 183,239
Operating expense	304,102	611,319	352,762
Income (loss) from operations	$ 24,357	$ (332,089)	$(169,523)
Total assets			
Peripheral vascular	$ 548,641	$ 545,588	
Neurovascular	347,648	175,076	
Total	$ 896,289	$ 720,664	

(1) Gross profit for internal measurement purposes is defined as net sales less cost of goods sold which excludes amortization of intangible assets.

For the years ended December 31, 2009, 2008 and 2007, no single customer represented more than 10% of our consolidated net sales.

The following table presents net sales and long-lived assets by geographic area (in thousands):

	December 31,		
Geographic Data	**2009**	**2008**	**2007**
Net Sales			
United States	$270,961	$275,433	$177,198
International	178,111	146,695	106,985
Total net sales	$449,072	$422,128	$284,183
Long-lived Assets			
United States	$ 27,823	$ 29,603	
International	1,336	1,078	
Total long-lived assets	$ 29,159	$ 30,681	

20. Related Party Transactions

During the second quarter of 2007, we entered into a distribution agreement with Beijing Lepu Medical Device, Inc. ("Lepu"), a Chinese domiciled manufacturer and distributor of interventional cardiology and peripheral products. The agreement was amended in the fourth quarter of 2009 allowing Lepu to sell certain of our embolic protection devices and stents in China, through the expiration date of the amendment, December 31, 2010. We believe that having access to Lepu and their sub-distributor network is a strategic way for us to quickly gain access and market share in these strategic markets. Warburg Pincus Equity Partners, L.P. ("Warburg Pincus"), who owned approximately 24% of our outstanding common stock as of December 31, 2009, and who together with Vertical Group, L.P. ("Vertical") has two designees on our board of directors, has approximately 18% ownership interest in Lepu and has a designee on Lepu's board of directors. Lepu purchased peripheral vascular products from us that we have recognized as net product sales totaling $2.7 million, $2.3 million and $1.5 million for the years ended December 31, 2009, 2008, and 2007, respectively. As of December 31, 2009, 2008 and 2007, Lepu owed us approximately $70,000, $364,000 and $306,000, respectively, that is recorded as "Accounts receivable".

During the third quarter of 2007, we entered into a distribution agreement with Bacchus Vascular, Inc. ("Bacchus"), a provider of medical devices used by interventional radiologists and vascular surgeons for the minimally invasive treatment of deep vein thrombosis and other peripheral vascular disease. The six-year agreement allowed Bacchus to sell certain of our products. We also entered into an option agreement with Bacchus, which granted us a call option and Bacchus a put option to cause us to acquire Bacchus at a formula price in 2010. The call and put options were terminable by either party prior to December 31, 2009. Warburg Pincus and Vertical and certain of their affiliates, who collectively owned over 56% of our outstanding common stock at that time and who have two designees on our board of directors, owned an interest of approximately 64% in Bacchus and had designees on Bacchus' board of directors at the time we entered into the agreements. During the year ended December 31, 2007, Bacchus purchased peripheral vascular products from us totaling $486,000 that we recognized as net product sales, and as of December 31, 2007, owed us $182,000 that was recorded as "Accounts receivable" and was paid prior to the end of the first quarter of 2008. Bacchus did not purchase products from us in either 2009 or 2008. The distribution agreement and option agreement were both terminated prior to the end of the first quarter of 2009.

As a result of our acquisition of FoxHollow, we assumed the obligations of FoxHollow under a time-sharing agreement, effective as of September 1, 2005, between FoxHollow and JBS Consulting, LLC, an entity affiliated with John B. Simpson, Ph.D., M.D., who served as our vice chairman, chief scientist and a director from October 4, 2007 through February 7, 2008, and a reimbursement agreement, also effective as of September 1, 2005, among FoxHollow, JBS Consulting and Dr. Simpson. Under the terms of the time-sharing agreement, FoxHollow leased an airplane owned by JBS Consulting and a flight crew in exchange for FoxHollow's payment of the aggregate incremental cost of each flight conducted at the request of FoxHollow. We terminated the time-sharing agreement and reimbursement agreement after Dr. Simpson's resignation in February 2008.

21. Net Income (Loss) Per Common Share

Basic net earnings (loss) per share is computed based on the weighted average number of common shares outstanding. Diluted net earnings (loss) per share is computed based on the weighted average number of common shares outstanding adjusted, to the extent dilutive, by the number of additional shares that would have been outstanding had the potentially dilutive common shares been issued and reduced by the number of shares we could have repurchased with the proceeds from the potentially dilutive shares. Potentially dilutive shares include options to purchase shares of our common stock and other share-based awards granted under our share-based compensation plans.

The weighted average number of common shares outstanding for basic and diluted earnings per share purposes is as follows:

	Year Ended December 31,		
	2009	2008	2007
Weighted average number of shares outstanding, basic	107,997,738	104,378,828	69,909,708
Incremental effect of stock options and awards	1,000,790	—	—
Weighted average number of shares outstanding, diluted	108,998,528	104,378,828	69,909,708

There were 7,471,704, 10,304,801 and 7,709,924 stock options and awards at the end of 2009, 2008 and 2007, respectively, that were excluded from the incremental effect of stock options and awards in the table above as their effect would have been anti-dilutive.

In connection with our Chestnut acquisition, we may be obligated to make an additional milestone-based payment of cash and equity totaling up to $75 million upon the FDA pre-market approval of the Pipeline Embolization Device. The contingently issuable shares of common stock associated with the equity portion of the milestone-based contingent payment are not included in our basic or diluted shares outstanding. For additional discussion regarding our potential milestone-based contingent payment, see Notes 3 and 4.

22. Quarterly Financial Data (Unaudited)

	Net Sales	Cost of Sales	Income (Loss) from Operations	Net Income (Loss)	Net Income (Loss) Per Basic and Diluted Share
2009					
First Quarter	$100,395	$30,988	$ (3,647) (1)	$ (1,809) (1)	$ (0.02)
Second Quarter	109,086	30,478	5,327 (2)	23,989 (2)	0.23
Third Quarter	112,838	28,608	7,582	6,736	0.06
Fourth Quarter	126,753	30,539	15,095	13,001	0.12
2008					
First Quarter	$101,257	$33,618	$(12,158)	$ (9,770)	$ (0.09)
Second Quarter	107,717	36,189	(26,862) (3)	(27,422) (3)	(0.26)
Third Quarter	107,029	38,282	(4,608)	(7,310)	(0.07)
Fourth Quarter	106,125	34,809	(288,461) (4)	(291,120) (4)	(2.78)

(1) During the first quarter of 2009, in light of the current economic environment and continued downward pressures in the California real estate markets, we recorded a $3.4 million adjustment to increase our liability related to our vacated leased FoxHollow facilities. For additional discussion, see Note 5 above. During the first quarter of 2009, we also recorded a gain of $4.1 million attributed to the divestiture of non-strategic investment assets. For additional discussion, see Note 13 above.

(2) As a result of the acquisition of Chestnut, we recorded a one-time non-cash tax benefit of $19.0 million in the second quarter of 2009. For additional discussion, see Note 3 above.

(3) During the second quarter of 2008, as a result of the termination of our research and collaboration with Merck, we recorded an asset impairment charge of $10.5 million to write-off the remaining carrying value of the related Merck intangible asset that was established at the time of our acquisition of FoxHollow. For additional discussion, see Note 9 above.

(4) During the fourth quarter of 2008, we recorded $288.8 million non-cash, asset impairment charges in our peripheral vascular segment to reduce the carrying values of goodwill and other intangible assets to their estimated fair values. For additional discussion, see Note 9 above.

ev3 Inc.

Schedule II

Valuation and Qualifying Accounts

Description	Balance at Beginning of Period	Charged to Revenue, Costs or Expenses	Other Additions	Deductions	Balance at End of Period
Reserves deducted from assets to which it applies:					
Year ended December 31, 2009					
Reserve for deferred income tax asset	$220,077	$(29,275)	$ —	$ (549)	$190,253
Accounts receivable allowances	8,098	(942)	104	—	7,260
Reserve for inventory obsolescence	10,337	8,582	25	(7,970)	10,974
Year ended December 31, 2008					
Reserve for deferred income tax asset	$199,040	$19,418	$ 1,619	$ —	$220,077
Accounts receivable allowances	6,783	2,538	—	(1,223)	8,098
Reserve for inventory obsolescence	10,968	9,235	—	(9,866)	10,337
Year ended December 31, 2007					
Reserve for deferred income tax asset	$191,960	$34,273	$ —	$(27,193) (b)	$199,040
Accounts receivable allowances	3,924	2,024	1,661 (a)	(826)	6,783
Reserve for inventory obsolescence	4,725	9,018	1,513 (a)	(4,288)	10,968

(a) Other additions primarily related to acquisitions.

(b) Other deductions primarily related to acquisitions.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) that are designed to reasonably ensure that information required to be disclosed by us in the reports we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated can provide only reasonable assurance of achieving the desired control objectives.

Our management evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered in this annual report on Form 10-K. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of the end of such period to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that material information relating to our company and our consolidated subsidiaries is made known to management, including our Chief Executive Officer and Chief Financial Officer, particularly during the period when our periodic reports are being prepared.

Management's Report on Internal Control Over Financial Reporting

Our management report on internal control over financial reporting is included in this report in "Part II. Item 8. Financial Statements and Supplementary Data" under "Management's Report on Internal Control over Financial Reporting."

The report of Ernst & Young LLP, our independent registered public accounting firm, regarding the effectiveness of our internal control over financial reporting is included in this report in "Part II. Item 8. Financial Statements and Supplementary Data" under "Report of Independent Registered Public Accounting Firm."

Change in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting that occurred during our fourth quarter ended December 31, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors

The information in the “Proposal One – Election of Directors” section of our proxy statement in connection with our 2010 annual meeting of stockholders to be filed with the Securities and Exchange Commission is incorporated in this annual report on Form 10-K by reference.

Executive Officers

Information about our executive officers is included in this annual report on Form 10-K under Part I. Item 4A, “Executive Officers of the Registrant.”

Section 16(a) Beneficial Ownership Reporting Compliance

The information in the “Stock Ownership - Section 16(a) Beneficial Ownership Reporting Compliance” section of our proxy statement in connection with our 2010 annual meeting of stockholders to be filed with the Securities and Exchange Commission is incorporated in this annual report on Form 10-K by reference.

Code of Ethics

The information in the “Corporate Governance – Code of Business Conduct” section of our proxy statement in connection with our 2010 annual meeting of stockholders to be filed with the Securities and Exchange Commission is incorporated in this annual report on Form 10-K by reference.

Changes to Nomination Procedures

We have made no material changes to the procedures by which stockholders may recommend nominees to our board of directors, as described in our most recent proxy statement.

Audit Committee Matters

The information under the heading “Corporate Governance – Audit Committee” section of our proxy statement in connection with our 2010 annual meeting of stockholders to be filed with the Securities and Exchange Commission is incorporated in this annual report on Form 10-K by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information in the "Compensation Discussion and Analysis," "Executive Compensation" and "Director Compensation" sections of our proxy statement in connection with our 2010 annual meeting of stockholders to be filed with the Securities and Exchange Commission is incorporated in this annual report on Form 10-K by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Securities Authorized for Issuance Under Equity Compensation Plans

The following table and notes provide information about shares of our common stock that may be issued under all of our equity compensation plans as of December 31, 2009.

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	8,839,309[1][2][5][6]	$ 9.60[3]	3,010,110[4]
Equity compensation plans not approved by security holders	754,000[7]	8.64	0
Total	9,593,309	$ 9.53	3,010,110

(1) Amount includes shares of our common stock issuable upon the exercise of stock options outstanding as of December 31, 2009 under the ev3 Inc. Second Amended and Restated 2005 Incentive Stock Plan and the ev3 LLC Amended and Restated 2003 Incentive Plan and shares of our common stock issuable upon the vesting of restricted stock units outstanding as of December 31, 2009 under the ev3 Inc. Second Amended and Restated 2005 Incentive Stock Plan.

(2) Excludes employee stock purchase rights under the ev3 Inc. Employee Stock Purchase Plan. Under such plan, each eligible employee may purchase up to 2,500 shares of our common stock at semi-annual intervals on June 30th and December 31st each year at a purchase price per share equal to 85% of the lower of (i) the closing sales price per share of our common stock on the first day of the offering period or (ii) the closing sales price per share of our common stock on the last day of the offering period.

(3) Included in the weighted-average exercise price calculation are 1,429,795 restricted stock units with an exercise price of $0.00. The weighted-average exercise price of all outstanding stock options as of December 31, 2009 and reflected in column (a) was $11.19.

(4) Amount includes 2,009,924 shares remaining available at December 31, 2009 for future issuance under the ev3 Inc. Second Amended and Restated 2005 Incentive Stock Plan and 1,000,186 shares remaining available at December 31, 2009 for future issuance under the ev3 Inc. Employee Stock Purchase Plan, of which 1,000,000 shares remaining available under the ev3 Inc. Employee Stock Purchase Plan are subject to approval by ev3's stockholders at the next annual meeting of stockholders. No shares remain available for grant under the ev3 LLC Amended and Restated 2003 Incentive Plan since such plan was terminated with respect to future grants in June 2005.

(5) Excludes options assumed by us in connection with our acquisitions of Micro Therapeutics, Inc. and FoxHollow Technologies, Inc. As of December 31, 2009, a total of 1,360,489 shares of our common stock were issuable upon exercise of the assumed options. The weighted average exercise price of the outstanding assumed options as of such date was $12.86 per share and they have an average weighted life remaining of 5.18 years. All of the 520,087 options outstanding in connection with our acquisition of Micro Therapeutics, Inc. were exercisable as of December 31, 2009. 798,618 of the 840,644 options assumed and outstanding in connection with our acquisition of FoxHollow Technologies, Inc. were exercisable as of December 31, 2009. No additional options, restricted stock units or other

equity incentive awards may be granted under the assumed Micro Therapeutics, Inc. and FoxHollow Technologies, Inc. plans.

(6) Excludes shares issuable upon the vesting of restricted stock units assumed by us in connection with our acquisition of FoxHollow Technologies, Inc. As of December 31, 2009, a total of 242 shares of our common stock were issuable upon the vesting of the assumed restricted stock units.

(7) Consists of a non-plan option to purchase 754,000 shares of our common stock granted outside of the terms of our existing stockholder-approved equity incentive plans to Robert J. Palmisano, our President and Chief Executive Officer, as an inducement grant in April 2008 pursuant to an exemption from NASDAQ's shareholder approval requirements under former NASDAQ Marketplace Rule Section 4350(i)(1)(A)(iv).

Stock Ownership

The information in the "Stock Ownership" section of our proxy statement in connection with our 2010 annual meeting of stockholders to be filed with the Securities and Exchange Commission is incorporated in this annual report on Form 10-K by reference.

ITEM 13. CERTAIN RELATIONSHIPS, RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information in the "Related Person Relationships and Transactions," the "Proposal One - Election of Directors – Board Designation Rights," and "Corporate Governance – Director Independence" section of our proxy statement in connection with our 2010 annual meeting of stockholders to be filed with the Securities and Exchange Commission is incorporated in this annual report on Form 10-K by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information in the "Proposal Four – Ratification of Selection of Independent Registered Public Accounting Firm - Audit, Audit-Related, Tax and Other Fees" and the "Proposal Four – Ratification of Selection of Independent Registered Public Accounting Firm – Pre-Approval Policies and Procedures" sections of our proxy statement in connection with our 2010 annual meeting of stockholders to be filed with the Securities and Exchange Commission is incorporated in this annual report on Form 10-K by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Our consolidated financial statements are included in Item 8 of Part II of this report.

The following financial statement schedule is included in Item 8 of Part II of this report: Schedule II—Valuation and Qualifying Accounts. All other schedules are omitted because the required information is inapplicable or the information is presented in the consolidated financial statements or related notes.

The exhibits to this report are listed on the Exhibit Index to this report. A copy of any of the exhibits will be furnished at a reasonable cost, upon receipt from any such person of a written request for any such exhibit. Such request should be sent to ev3 Inc., 3033 Campus Drive, Plymouth, Minnesota 55441, Attn: Stockholder Information.

The following is a list of each management contract or compensatory plan or arrangement required to be filed as an exhibit to this annual report on Form 10-K pursuant to Item 13(a):

1. ev3 Inc. Second Amended and Restated 2005 Incentive Stock Plan (incorporated by reference to Exhibit 10.1 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 17, 2007 (File No. 000-51348)).

2. Form of Option Certificate under the ev3 Inc. Second Amended and Restated 2005 Incentive Stock Plan (incorporated by reference to Exhibit 10.5 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended September 28, 2008 (File No. 000-51348)).

3. Form of Restricted Stock Grant Certificate under the ev3 Inc. Second Amended and Restated 2005 Incentive Stock Plan (incorporated by reference to Exhibit 10.6 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended September 28, 2008 (File No. 000-51348)).

4. Form of Stock Grant Certificate applicable to French Participants under the ev3 Inc. Amended and Restated 2005 Incentive Stock Plan (incorporated by reference to Exhibit 10.7 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended September 28, 2008 (File No. 000-51348)).

5. ev3 LLC Amended and Restated 2003 Incentive Plan, as amended (incorporated by reference to Exhibit 10.2 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended July 2, 2006 (File No. 000-51348)).

6. Micro Therapeutics, Inc. 1996 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.7.1 to Micro Therapeutics, Inc.'s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002 (File No. 000-06523)).

7. FoxHollow Technologies, Inc. 2004 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to FoxHollow's Amendment No. 2 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on October 13, 2004 (Registration No. 333-118191)).

8. ev3 Inc. Employee Stock Purchase Plan (As Amended and Restated and Subject to Stockholder Approval) (incorporated by reference to Exhibit 10.1 to ev3's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on December 15, 2009 (File No. 333-163742)).

9. ev3 Inc. Employee Performance Incentive Compensation Plan Effective January 1, 2010 (filed herewith).

10. Form of Indemnification Agreement between ev3 Inc. and each of its directors and officers (incorporated by reference to Exhibit 10.11 to ev3's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 (File No. 000-51348)).

11. Form of Change in Control Agreement among ev3 Inc., ev3 Endovascular, Inc., Micro Therapeutics, Inc. or FoxHollow Technologies, Inc. and each executive officer of ev3 Inc. (incorporated by reference to Exhibit 10.12 to ev3's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 (File No. 000-51348)).

12. Employment and Change in Control Agreement dated as of April 6, 2008 between ev3 Inc. and Robert J. Palmisano (incorporated by reference to Exhibit 10.1 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on April 7, 2008 (File No. 000-51348)).

13. Confidentiality, Non-Competition and Non-Solicitation Agreement dated as of April 6, 2008 between ev3 Inc. and Robert J. Palmisano (incorporated by reference to Exhibit 10.2 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on April 7, 2008 (File No. 000-51348)).

14. Robert J. Palmisano Inducement Grant Option Agreement (incorporated by reference to Exhibit 10.4 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on April 7, 2008 (File No. 000-51348)).

15. Offer Letter dated January 5, 2009 between ev3 Inc. and Shawn McCormick (incorporated by reference to Exhibit 10.1 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 9, 2009 (File No. 000-51348)).

16. Employment Agreement effective as of January 19, 2009 between ev3 Endovascular, Inc. and Shawn McCormick (incorporated by reference to Exhibit 10.2 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 9, 2009 (File No. 000-51348)).

17. Separation Agreement and Release of Claims effective as of January 19, 2009 between ev3 Endovascular, Inc. and Patrick D. Spangler (incorporated by reference to Exhibit 10.5 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 9, 2009 (File No. 000-51348)).

18. Consulting Agreement effective as of January 20, 2009 between ev3 Endovascular, Inc. and Patrick D. Spangler (incorporated by reference to Exhibit 10.6 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 9, 2009 (File No. 000-51348)).

19. Employment Agreement, dated as of September 17, 2009, between ev3 Europe SAS and Pascal E.R. Girin (incorporated by reference to Exhibit 10.1 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended October 4, 2009 (File No. 000 51348)).

20. Offer Letter effective December 5, 2008 between ev3 Endovascular, Inc. and Stacy Enxing Seng (incorporated by reference to Exhibit 10.27 to ev3's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 (File No. 000-51348)).

21. Letter Agreement Regarding Foreign Assignment dated January 20, 2010 between ev3 Inc. and Brett Wall (filed herewith).

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: February 25, 2010

ev3 INC.

By /s/ ROBERT J. PALMISANO
Robert J. Palmisano
President and Chief Executive Officer
(principal executive officer)

By /s/ SHAWN MCCORMICK
Shawn McCormick
Senior Vice President and Chief Financial Officer
(principal financial and accounting officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name and Signature	Title	Date
/s/ ROBERT J. PALMISANO Robert J. Palmisano	President and Chief Executive Officer	February 25, 2010
/s/ DANIEL J. LEVANGIE Daniel J. Levangie	Chairman of the Board	February 25, 2010
/s/ JOHN K. BAKEWELL John K. Bakewell	Director	February 25, 2010
/s/ JEFFREY B. CHILD Jeffrey B. Child	Director	February 25, 2010
/s/ RICHARD B. EMMITT Richard B. Emmitt	Director	February 25, 2010
/s/ DOUGLAS W. KOHRS Douglas W. Kohrs	Director	February 25, 2010
/s/ JOHN L. MICLOT John L. Miclot	Director	February 25, 2010
/s/ THOMAS E. TIMBIE Thomas E. Timbie	Director	February 25, 2010
/s/ ELIZABETH H. WEATHERMAN Elizabeth H. Weatherman	Director	February 25, 2010

ev3 INC.

EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2009

Exhibit No.	Exhibit	Method of Filing
2.1	Agreement and Plan of Merger, dated as of April 4, 2005, by and between ev3 LLC and ev3 Inc.	Incorporated by reference to Exhibit 2.1 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)
2.2	Contribution and Exchange Agreement, dated as of April 4, 2005, by and among the institutional stockholders listed on Schedule I thereto, ev3 LLC, ev3 Inc. and Micro Therapeutics, Inc.	Incorporated by reference to Exhibit 2.2 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)
2.3	Note Contribution and Exchange Agreement, dated as of April 4, 2005, by and among the noteholders listed on Schedule I thereto and ev3 Inc.	Incorporated by reference to Exhibit 2.3 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)
2.4	Agreement and Plan of Merger, dated as of July 15, 2002, by and among Microvena Corporation, Appriva Acquisition Corp. and Appriva Medical, Inc.	Incorporated by reference to Exhibit 2.4 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)
2.5	Agreement and Plan of Merger, dated November 14, 2005, by and between ev3 Inc., Micro Investment, LLC and Micro Therapeutics, Inc.	Incorporated by reference to Exhibit 2.1 to ev3's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 14, 2005 (File No. 000-51348)
2.6	Agreement and Plan of Merger dated as of July 21, 2007 by and among ev3 Inc., Foreigner Merger Sub, Inc. and FoxHollow Technologies, Inc.(1)	Incorporated by reference to Exhibit 2.1 to ev3's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 23, 2007 (File No. 000-51348)
2.7	Agreement and Plan of Merger, dated as of August 26, 2006, by and between FoxHollow Technologies, Inc. and Kerberos Proximal Solutions, Inc.	Incorporated by reference to Exhibit 2.1 to FoxHollow's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 28, 2006 (File No. 000-50998)
2.8	Agreement and Plan of Merger, dated as of June 2, 2009, by and among ev3 Inc., Starsky Merger Sub, Inc., Starsky Acquisition Sub, Inc., Chestnut Medical Technologies, Inc. and CMT SR, Inc. (1)	Incorporated by reference to Exhibit 2.1 to ev3's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 3, 2009 (File No. 000-51348)
3.1	Amended and Restated Certificate of Incorporation of ev3 Inc.	Incorporated by reference to Exhibit 3.1 to ev3's Amendment No. 5 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on June 14, 2005 (File No. 333-123851)
3.2	Amendment to Amended and Restated Certificate of Incorporation of ev3 Inc.	Incorporated by reference to Exhibit 99.1 to ev3's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 27, 2005 (File No. 000-51348)

Exhibit No.	Exhibit	Method of Filing
3.3	Amendment to Amended and Restated Certificate of Incorporation of ev3 Inc.	Incorporated by reference to Exhibit 3.1 to ev3's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 23, 2007 (File No. 000-51348)
3.4	Amended and Restated Bylaws of ev3 Inc.	Incorporated by reference to Exhibit 3.1 to ev3's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 3, 2008 (File No. 000-51348)
4.1	Form of Stock Certificate	Incorporated by reference to Exhibit 4.1 to ev3's Amendment No. 4 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on June 2, 2005 (File No. 333-123851)
4.2	Holders Agreement dated as of August 29, 2003 among the institutional investors listed on Schedule I thereto, Dale A. Spencer, Paul Buckman, the individuals whose names and addresses appear from time to time on Schedule II thereto, the individuals whose names and addresses appear from time to time on Schedule III thereto and ev3 LLC	Incorporated by reference to Exhibit 4.2 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)
4.3	Operating Agreement of ev3 LLC dated as of August 29, 2003 by and among ev3 LLC, Warburg, Pincus Equity Partners, L.P., Warburg, Pincus Netherlands Equity Partners I, C.V., Warburg, Pincus Netherlands Equity Partners II, C.V., Warburg, Pincus Netherlands Equity Partners III, C.V., Vertical Fund I, L.P., Vertical Fund II, L.P. and certain other persons party thereto	Incorporated by reference to Exhibit 4.3 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)
4.4	Amendment No. 1 to Operating Agreement of ev3 LLC dated as of March 1, 2005 by and among ev3 LLC, Warburg, Pincus Equity Partners, L.P., Warburg, Pincus Netherlands Equity Partners I, C.V., Warburg, Pincus Netherlands Equity Partners II, C.V., Warburg, Pincus Netherlands Equity Partners III, C.V., Vertical Fund I, L.P., Vertical Fund II, L.P. and certain other persons party thereto	Incorporated by reference to Exhibit 4.4 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)
4.5	Registration Rights Agreement dated as of June 21, 2005 by and among ev3 Inc., Warburg, Pincus Equity Partners, L.P., Warburg, Pincus Netherlands Equity Partners I, C.V., Warburg, Pincus Netherlands Equity Partners II, C.V., Warburg, Pincus Netherlands Equity Partners III, C.V., Vertical Fund I, L.P., Vertical Fund II, L.P. and certain other investors party thereto	Incorporated by reference to Exhibit 4.2 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended July 3, 2005 (File No. 000-51348)

Exhibit No.	Exhibit	Method of Filing
10.1	ev3 Inc. Second Amended and Restated 2005 Incentive Stock Plan	Incorporated by reference to Exhibit 10.1 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 17, 2007 (File No. 000-51348)
10.2	Form of Option Certificate under the ev3 Inc. Second Amended and Restated 2005 Incentive Stock Plan	Incorporated by reference to Exhibit 10.5 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended September 28, 2008 (File No. 000-51348)
10.3	Form of Restricted Stock Grant Certificate under the ev3 Inc. Second Amended and Restated 2005 Incentive Stock Plan	Incorporated by reference to Exhibit 10.6 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended September 28, 2008 (File No. 000-51348)
10.4	Form of Stock Grant Certificate applicable to French Participants under the ev3 Inc. Amended and Restated 2005 Incentive Stock Plan	Incorporated by reference to Exhibit 10.7 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended September 28, 2008 (File No. 000-51348)
10.5	ev3 LLC Amended and Restated 2003 Incentive Plan, as amended	Incorporated by reference to Exhibit 10.2 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended July 2, 2006 (File No. 000-51348)
10.6	Micro Therapeutics, Inc. 1996 Stock Incentive Plan, as amended	Incorporated by reference to Exhibit 10.7.1 to Micro Therapeutics, Inc.'s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002 (File No. 000-06523)
10.7	FoxHollow Technologies, Inc. 2004 Equity Incentive Plan	Incorporated by reference to Exhibit 10.3 to FoxHollow Technologies, Inc.'s Amendment No. 2 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on October 13, 2004 (Registration No. 333-118191)
10.8	ev3 Inc. Employee Stock Purchase Plan (As Amended and Restated and Subject to Stockholder Approval)	Incorporated by reference to Exhibit 10.1 to ev3's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on December 15, 2009 (File No. 333-163742)
10.9	ev3 Inc. Employee Performance Incentive Compensation Plan Effective January 1, 2010	Filed herewith
10.10	Form of Indemnification Agreement between ev3 Inc. and each of its directors and officers	Incorporated by reference to Exhibit 10.11 to ev3's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 (File No. 000 51348)
10.11	Form of Change in Control Agreement among ev3 Inc., ev3 Endovascular, Inc., Micro Therapeutics, Inc. or FoxHollow Technologies, Inc. and each of executive officer of ev3 Inc.	Incorporated by reference to Exhibit 10.12 to ev3's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 (File No. 000-51348)
10.12	Employment and Change in Control Agreement dated as of April 6, 2008 between ev3 Inc. and Robert J. Palmisano	Incorporated by reference to Exhibit 10.1 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on April 7, 2008 (File No. 000-51348)

Exhibit No.	Exhibit	Method of Filing
10.13	Confidentiality, Non-Competition and Non-Solicitation Agreement dated as of April 6, 2008 between ev3 Inc. and Robert J. Palmisano	Incorporated by reference to Exhibit 10.2 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on April 7, 2008 (File No. 000-51348)
10.14	Robert J. Palmisano Inducement Grant Option Agreement	Incorporated by reference to Exhibit 10.4 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on April 7, 2008 (File No. 000-51348)
10.15	Offer Letter dated January 5, 2009 between ev3 Inc. and Shawn McCormick	Incorporated by reference to Exhibit 10.1 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 9, 2009 (File No. 000-51348)
10.16	Employment Agreement effective as of January 19, 2009 between ev3 Endovascular, Inc. and Shawn McCormick	Incorporated by reference to Exhibit 10.2 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 9, 2009 (File No. 000-51348)
10.17	Separation Agreement and Release of Claims effective as of January 19, 2009 between ev3 Endovascular, Inc. and Patrick D. Spangler	Incorporated by reference to Exhibit 10.5 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 9, 2009 (File No. 000-51348)
10.18	Consulting Agreement effective as of January 20, 2009 between ev3 Endovascular, Inc. and Patrick D. Spangler	Incorporated by reference to Exhibit 10.6 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 9, 2009 (File No. 000-51348)
10.19	Employment Agreement, dated as of September 17, 2009, between ev3 Europe SAS and Pascal E.R. Girin	Incorporated by reference to Exhibit 10.1 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended October 4, 2009 (File No. 000-51348)
10.20	Offer Letter effective as of December 5, 2008 between ev3 Endovascular, Inc. and Stacy Enxing Seng	Incorporated by reference to Exhibit 10.27 to ev3's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 (File No. 000-51348)
10.21	Letter Agreement Regarding Foreign Assignment dated January 20, 2010 between ev3 Inc. and Brett Wall	Filed herewith
10.22	Form of Subscription Agreement between ev3 Endovascular, Inc. (formerly known as ev3 Inc.) and Warburg, Pincus Equity Partners, L.P., Warburg, Pincus Netherlands Equity Partners I, C.V., Warburg, Pincus Netherlands Equity Partners II, C.V., Warburg, Pincus Netherlands Equity Partners III, C.V., Vertical Fund I, L.P., Vertical Fund II, L.P.	Incorporated by reference to Exhibit 10.33 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)
10.23	Loan and Security Agreement dated as of June 28, 2006 among Silicon Valley Bank, ev3 Endovascular, Inc., ev3 International, Inc. and Micro Therapeutics, Inc.	Incorporated by reference to Exhibit 10.8 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended July 2, 2006 (File No. 000-51348)

Exhibit No.	Exhibit	Method of Filing
10.24	First Amendment to Loan and Security Agreement dated March 15, 2007 between Silicon Valley Bank and ev3 Endovascular, Inc., ev3 International, Inc. and Micro Therapeutics, Inc.	Incorporated by reference to Exhibit 10.1 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 21, 2007 (File No. 000-51348)
10.25	Consent and Second Amendment to Loan and Security Agreement dated October 4, 2007 between Silicon Valley Bank and ev3 Endovascular, Inc., ev3 International, Inc. and Micro Therapeutics, Inc.	Incorporated by reference to Exhibit 10.38 to ev3's Annual Report on Form 10-K for the fiscal year ended December 31, 2007 (File No. 000-51348)
10.26	Third Amendment to Loan and Security Agreement dated November 2, 2007 between Silicon Valley Bank and ev3 Endovascular, Inc., ev3 International, Inc. and Micro Therapeutics, Inc.	Incorporated by reference to Exhibit 10.39 to ev3's Annual Report on Form 10-K for the fiscal year ended December 31, 2007 (File No. 000-51348)
10.27	Assumption Agreement and Fourth Amendment to Loan and Security Agreement dated December 14, 2007 between Silicon Valley Bank and ev3 Endovascular, Inc., ev3 International, Inc., Micro Therapeutics, Inc., and FoxHollow Technologies, Inc.	Incorporated by reference to Exhibit 10.40 to ev3's Annual Report on Form 10-K for the fiscal year ended December 31, 2007 (File No. 000-51348)
10.28	Fifth Amendment to Loan and Security Agreement dated June 24, 2008 between Silicon Valley Bank and ev3 Endovascular, Inc., ev3 International, Inc., Micro Therapeutics, Inc. and FoxHollow Technologies, Inc.	Incorporated by reference to Exhibit 10.1 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 25, 2008 (File No. 000-51348)
10.29	Sixth Amendment to Loan and Security Agreement dated December 22, 2008 between Silicon Valley Bank and ev3 Endovascular, Inc., ev3 International, Inc. , Micro Therapeutics, Inc. and FoxHollow Technologies, Inc.	Incorporated by reference to Exhibit 10.1 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 24, 2008 (File No. 000-51348)
10.30	Consent Regarding Loan and Security Agreement, dated June 19, 2009, between Silicon Valley Bank and ev3 Endovascular, Inc., ev3 International, Inc. , Micro Therapeutics, Inc. and FoxHollow Technologies, Inc.	Incorporated by reference to Exhibit 10.2 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended July 5, 2009 (File No. 000-51348)
10.31	Lease Agreement dated May 3, 2002 by and between Liberty Property Limited Partnership and ev3 Endovascular, Inc. (formerly known as ev3 Inc.)	Incorporated by reference to Exhibit 10.1 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)
10.32	First Amendment to the May 3, 2002 Lease Agreement between Liberty Property Limited Partnership and ev3 Endovascular, Inc. (formerly known as ev3 Inc.) effective as of October 17, 2005	Incorporated by reference to Exhibit 10.2 to ev3's Annual Report on Form 10-K for the fiscal year ended December 31, 2006 (File No. 000-51348)

Exhibit No.	Exhibit	Method of Filing
10.33	Second Amendment to the May 3, 2002 Lease Agreement between Liberty Property Limited Partnership and ev3 Endovascular, Inc. (formerly known as ev3 Inc.) effective as of October 1, 2005	Incorporated by reference to Exhibit 10.3 to ev3's Annual Report on Form 10-K for the fiscal year ended December 31, 2006 (File No. 000-51348)
10.34	Lease dated October 13, 2005 by and between Micro Therapeutics, Inc. and The Irvine Company	Incorporated by reference to Exhibit 10.53 to Micro Therapeutics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on October 18, 2005 (File No. 000-06523)
10.35	Office Lease for Atria Corporate Center, dated April 2, 2009, by and between Talcott III Atria, LLC and ev3 Inc.	Incorporated by reference to Exhibit 10.1 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on April 2, 2009 (File No. 000 51348)
10.36	Corporate Opportunity Agreement dated as of April 4, 2005 by and between the institutional stockholders listed on Schedule I thereto and ev3 Inc.	Incorporated by reference to Exhibit 10.32 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)
21.1	Subsidiaries of ev3 Inc.	Filed herewith
23.1	Consent of Ernst & Young LLP	Filed herewith
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)	Filed herewith
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)	Filed herewith
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith

(1) All exhibits and schedules to the Agreement and Plan of Merger have been omitted pursuant to Item 601(b)(2) of Regulation S-K. ev3 will furnish the omitted exhibits and schedules to the Securities and Exchange Commission upon request by the Commission.