UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 [NO FEE REQUIRED]**

For the year ended December 31, 2012

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 [NO FEE REQUIRED]**

For the transition period from to

Commission file number 0-19711

THE SPECTRANETICS CORPORATION

(Exact name of Registrant as specified in its charter)

Delaware	**84-0997049**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

9965 Federal Drive
Colorado Springs, Colorado 80921
(Address of principal executive offices and zip code)

Registrant's Telephone Number, Including Area Code:
(719) 633-8333

Securities registered pursuant to Section 12(b) of the Act:
None

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $.001 par value
(Title of class)

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 (§232.405 of this chapter) 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 is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (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 the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes ☐ No ☒

The aggregate market value of the voting stock of the Registrant, as of June 30, 2012, the last business day of the registrant's most recently completed second fiscal quarter was 381,103,843, as computed by reference to the closing sale price of the voting stock held by non-affiliates on such date. As of March 6, 2013, there were outstanding 35,066,954 shares of Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement for its 2013 Annual Meeting of Stockholders, to be filed with the Securities and Exchange Commission not later than April 30, 2013, are incorporated by reference into Part III as specified herein.

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PART I

The information set forth in this annual report on Form 10-K includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934 (the Exchange Act), as amended, and the Private Securities Litigation Reform Act of 1995, and is subject to the safe harbor created by that section. Forward-looking statements contained in this report or incorporated herein by reference constitute our expectations or forecasts of future events as of the date this report was filed with the Securities and Exchange Commission (SEC) and are not statements of historical fact. You can identify these statements by the fact that they do not relate strictly to historical or current facts. Such statements may include words such as "anticipate," "will," "estimate," "seek," "expect," "project," "intend," "should," "plan," "believe," "hope," and other words and terms of similar meaning in connection with any discussion of, among other things, future operating or financial performance, strategic initiatives and business strategies, regulatory or competitive environments, our intellectual property and product development. You are cautioned not to place undue reliance on these forward-looking statements and to note that they speak only as of the date hereof. Factors that could cause actual results to differ materially from those set forth in the forward-looking statements are set forth in the risk factors listed from time to time in our filings with the SEC as well as those set forth in Item 1A, "Risk Factors." We disclaim any intention or obligation to update or revise any financial projections or forward-looking statements due to new information or other events. Some of the industry and market data contained in this Annual Report on Form 10-K are based on independent industry publications, including those generated by the Millennium Research Group, or other publicly available information. This information involves a number of assumptions and limitations. Although we believe that each source is reliable as of its respective date, we have not independently verified the accuracy or completeness of this information.

A glossary of terms relevant to our products begins on page 65 of this annual report.

ITEM 1. *Business*

General

We develop, manufacture, market and distribute single-use medical devices used in minimally invasive procedures within the cardiovascular system. Our products are used to access and treat arterial blockages in the legs and heart and to remove pacemaker and defibrillator cardiac leads. We believe that the diversified nature of our business allows us to respond to a wide range of physician and patient needs. During the year ended December 31, 2012, approximately 66% of our disposable product revenue was from products used in connection with our proprietary excimer laser system, the CVX-300 ®. Our single-use laser catheters contain up to 250 small diameter, flexible optical fibers that can access difficult to reach peripheral and coronary anatomy and produce evenly distributed laser energy at the tip of the catheter. Our excimer laser system is the only laser system approved in the United States, Europe, Japan and Canada for use in multiple minimally invasive cardiovascular procedures.

Our disposable devices include Vascular Intervention and Lead Management products. For the year ended December 31, 2012, our disposable products generated 87% of our revenue, of which Vascular Intervention accounted for 55% and Lead Management accounted for 45%. The remainder of our revenue is derived from sales and rental of our laser system and related services.

Our business strategy emphasizes:

- organic growth through new product development;
- new clinical indications for our existing products;
- continued execution of our commercial and educational programs;
- acquisitions that leverage our current customer base and extend our existing product lines; and
- continued international expansion.

We seek to increase the market share of our Vascular Intervention products by:

- adding to our product portfolio;
- expanding into in-stent restenosis with our current laser atherectomy devices and in combination with drug-coated balloons;
- executing on new products currently in development;
- increasing awareness of peripheral artery disease (PAD);
- driving adoption in office-based lab settings; and
- the commercial launch of the recently acquired Quick-Access™ and Quick-Cross Capture™ devices.

We intend to continue to increase sales of our Lead Management products by:

- building on the ongoing commercial launch of our new GlideLight™ product;
- expanding our product portfolio to include mechanical lead extraction tools;
- continuing to focus on training physicians and fellows through our simulation systems and other training programs; and
- further penetrating the market to treat infected leads.

Internationally, we are focused on:

- increasing our sales presence in our current top markets;
- rapidly growing in Japan; and
- further unlocking our opportunity in the BRICK (Brazil, Russia, India, China and South Korea) countries, with the registration of our products already underway in China and India.

Our Vascular Intervention products include:

- a range of laser catheters for ablation of blockages in arteries above and below the knee (peripheral atherectomy);
- support catheters to facilitate crossing of peripheral and coronary arterial blockages, and retrograde access and guidewire retrieval devices used in the treatment of peripheral arterial blockages, including chronic total occlusions (crossing solutions);
- aspiration and cardiac laser catheters for the treatment of blockages in the heart (coronary atherectomy and thrombectomy); and
- drug delivery catheters for vascular delivery of drugs and diagnostic agents.

Our Lead Management products include:

- excimer laser sheaths;
- non-laser sheaths; and
- cardiac lead management accessories for the removal of pacemaker and defibrillator cardiac leads.

We also sell, rent and service our CVX-300 laser systems.

Our two operating segments are United States Medical and International Medical. United States Medical includes direct sales operations in the United States and Canada. International Medical includes our sales presence in more than 40 countries outside of the U.S. and Canada, including our direct sales operations in certain countries in Europe and Puerto Rico and a network of approximately 45 distributors. Total international revenue in 2012 (including Asia Pacific and Latin American countries) was 16% of our consolidated revenue.

Vascular Intervention Products

Peripheral Atherectomy

PAD is characterized by clogged or obstructed arteries in the legs. The resulting lack of blood flow can cause leg pain and lead to tissue loss or amputation. According to a 2011 industry report, an estimated 17.6 million people in the United States suffer from PAD, and according to a 2012 Millennium Research Group (MRG) Report, only approximately 800,000 of these people are treated. Symptoms of PAD include pain, cramping and weakness in the leg or hip muscles. In the case of intermittent claudication, the symptoms may appear while walking. For individuals with critical limb ischemia, the most severe form of PAD, symptoms may appear while resting. According to the 2012 MRG Report, approximately 550,000 endovascular procedures were performed in 2012 in the U.S. to treat PAD in the leg; of these procedures, nearly 80,000 were atherectomy procedures. Endovascular treatment options include balloon angioplasty, stenting and atherectomy, and more invasive approaches include bypass surgery and amputation. According to industry sources, there were approximately 170,000 femoropopliteal bypass procedures performed in the U.S. in 2011. We believe, based on data from multiple sources, that there are approximately 160,000 PAD-related amputations performed each year in the U.S. According to internal estimates, reducing amputations by 25% could save $3 billion in treatment and follow-up costs in the U.S. alone.

Peripheral atherectomy is our largest product line and represented approximately 54% of our VI revenue and 26% of our total revenue in 2012. It represented 25% of total revenue in 2011 and 26% of total revenue in 2010. In the periphery, laser catheters are often used as an alternative to stents and other atherectomy or thrombectomy devices. Our laser catheters are offered in sizes ranging from 0.9 to 2.5 millimeters in diameter. Our laser catheter is inserted into an artery through a small incision and then guided to the site of the blockage or lesion under x-ray guidance using conventional angioplasty tools. When the tip of the laser catheter has been placed at the site of the blockage or lesion, the physician activates the laser to ablate the lesion. Our laser generates minimal heat and is a contact ablation laser that only ablates materials within 50 microns (approximately the width of a human hair) ahead of the laser tip. It is able to break down the molecular bonds of plaque, moderate calcium and thrombus into particles, the majority of which are smaller than red blood cells, without significant thermal damage to surrounding tissue.

We have an indication cleared by the Food and Drug Administration (FDA) for the treatment of stenoses and occlusions within the arteries of the leg. Because our technology can be utilized to treat multiple lesion morphologies, including plaque, moderate calcium and thrombus, we believe our system enables physicians to expand the number of minimally invasive procedures they can perform. For example, our system can be used to cross chronic total occlusions (CTO) in the heart or the leg. We believe our 0.9 mm catheters are smaller than any approved balloon angioplasty catheter or any other approved mechanical atherectomy device, which enables the treatment of smaller arteries in the lower leg.

We believe that physicians, including interventional cardiologists, vascular surgeons, and interventional radiologists, are looking for effective minimally invasive solutions to treat PAD. We believe that balloons and stents, although commonly used to treat PAD, have not been proven to have a long-lasting clinical benefit in the legs, and surgical bypass and amputation carry significant patient risk and cost. Laser atherectomy has emerged as a viable treatment option for PAD, both as a stand-alone treatment and as an adjunctive treatment with other therapies, such as balloons and stents. We offer our Turbo Elite® atherectomy catheters in a broad range of sizes, enabling physicians to treat both smaller and larger diameter arteries. In addition, we believe our laser system and Turbo Elite

catheter technology each offer a number of patient benefits, including a minimally invasive alternative to bypass surgery and amputation, predictable outcomes in addressing PAD, short procedure time and a robust safety profile.

We believe there is the potential for as many as 250,000 procedures worldwide each year to treat in-stent restenosis (ISR), more than twice the number of atherectomy procedures. ISR occurs when a previously placed stent becomes occluded, or blocked, and is considered to be a challenging condition to treat. We believe no directional or orbital atherectomy device is capable of providing an effective solution, and no medical device currently has an FDA indication for the treatment of ISR. Through three on-going clinical studies, PATENT, EXCITE ISR and PHOTOPAC, which are discussed below under "Clinical Trials," we are accumulating data on the potential safety and efficacy of excimer laser in the treatment of ISR. We have recently initiated discussions with the FDA to explore achievement of an ISR indication prior to full enrollment of the EXCITE ISR study. This may involve use of the PATENT registry in combination with patients enrolled in the EXCITE ISR study. We believe through these studies we will be able to prove our clinical superiority over standard of care and become the only company to achieve an indication for ISR from the FDA. Discussions with the FDA are ongoing. There is no assurance that the ISR indication will be cleared by the FDA without full enrollment of the EXCITE ISR study.

We also offer, through a distribution agreement with the manufacturer, the TAPAS™ (Targeted Adjustable Pharmaceutical Application System) drug delivery catheter that enables targeted local delivery of any physician-specified drug or diagnostic agent. We believe a significant portion of approximately 550,000 U.S. peripheral interventions do not have an effective method of delivering local drug therapy.

The TAPAS catheter features two compliant occlusion balloons and an adjustable treatment zone that expands up to 300mm, allowing for the treatment of long vessels and multiple blockages with only one device. The therapeutic drug or diagnostic agent can also be extracted from the treatment zone following treatment, providing localized intravascular treatment with an improvement around mitigating systemic run-off. The TAPAS catheter can be used in conjunction with our laser atherectomy catheters or other interventional devices.

Our primary products for peripheral atherectomy include the Turbo Elite ® and Turbo-Tandem® laser catheters and the TAPAS drug delivery catheters.

Crossing Solutions

Our crossing solutions products support vascular access in the arterial system to enable various types of interventions. Gaining access to the lesion and fully crossing the blockage with the guidewire is essential. The interventional procedure, whether atherectomy, balloon dilation, or stent placement, cannot occur without lesion access. Our crossing support catheters are designed to provide directional support and force transfer to the guidewire, either columnar straightline strength to progress through an occluded artery or angled support to gain access into difficult branched anatomy. We believe we are the leader in the support catheter market, which we estimate to be approximately $35 million in the U.S. annually.

Crossing solutions represented 31% of our VI revenue and 15% of our total revenue in 2012. It represented 16% of total revenue in 2011 and 17% of total revenue in 2010. All of our crossing catheters offer a low profile tapered distal tip, slick, low-friction outer coating, and three radiopaque markers to aid in assessing lesion geometry. Our primary products include the Quick-Cross ®, Quick-Cross Select, and Quick-Cross Extreme.

At the beginning of 2013, we announced the acquisition of products from Upstream Peripheral Technologies Ltd. that complement our portfolio of crossing solutions devices. Two devices we acquired were developed to minimize radiation exposure in peripheral vascular procedures generally and decrease procedure time specifically in retrograde access procedures. The Quick-Access™ Needle Holder helps physicians access vessels safely and efficiently. The Quick-Cross Capture™ Guidewire Retriever enables physicians to easily, reliably and safely capture and exchange guidewires in retrograde procedures.

Coronary Atherectomy and Thrombectomy

In the coronary market, our disposable catheters are used to treat complex coronary artery disease as an adjunctive treatment to traditional percutaneous coronary interventions, or PCI, using balloons and stents. Coronary atherectomy represented 8% of our VI revenue and 4% of our total revenue in 2012. It represented 4% of total revenue in 2011 and 3% of total revenue in 2010. The coronary atherectomy product line consists of a broad selection of proprietary laser catheters that can be used in many different types of coronary artery disease (CAD). Approved indications include occluded saphenous vein bypass grafts, ostial lesions, long lesions, moderately calcified stenoses, total occlusions traversable by guidewire, lesions with previously failed balloon angioplasty, and restenosis in 316L stainless steel stents, prior to brachytherapy. In this market, our laser catheters are frequently used with other devices such as balloons and drug-eluting stents. Our primary product for coronary atherectomy is the ELCA ® Laser Ablation Catheter.

In the thrombus management market, we offer aspiration catheters to address thrombus-laden lesions. Thrombus, or clot, is an accumulation of blood coagulation large enough to block blood flow in the coronary, peripheral, or cerebral arteries. Thrombosis is a natural response to vascular damage, commonly arising as a result of a lesion in the vessel wall, or atherosclerosis. The thrombus may block the artery at the lesion location and can potentially dislodge and travel further downstream in the arterial system. Depending on the location of the thrombus, arterial complications such as myocardial infarction in the coronary arteries, stroke in the brain, or acute limb ischemia in the extremities may occur.

Thrombus management represented 7% of our VI revenue and 3% of our total revenue in 2012. It represented 4% of total revenue in 2011 and 5% of total revenue in 2010. The thrombus management product line consists of the QuickCat™ aspiration catheter, designed for quick deliverability and efficient thrombus removal from vessels in the arterial system. In this market, these devices are often used with other devices such as balloons and stents.

Lead Management Products

We are a global leader in devices for the removal of pacemaker and defibrillation cardiac leads. We believe that approximately 400,000 patients worldwide are indicated every year for a potential lead extraction due to infection, malfunction, system upgrade, venous occlusion and other less common reasons. We also believe that the majority of the non-infected portion of these leads are presently capped and left in the body as a predominant mode of practice, based on physician perception of risk associated with removal and perception that abandoned leads are benign. We believe the long-term consequences associated with abandoned leads are more significant than generally believed, and that clinical data, strongly supporting the safety of laser-assisted lead removal, will be instrumental in reshaping perceptions around this procedure as a mainstream treatment option for device patients.

We believe that removal of non-functional leads in many cases, especially in relatively younger patients, serves to avoid future complicating scenarios that may occur over the course of the patient's life with their implanted leads. Consistent with our view, the Heart Rhythm Society updated its recommendations for lead extraction in 2009 and expanded the list of indications for lead extraction to include several well-defined scenarios involving non-functional leads, functional leads and venous occlusion. In addition, the Heart Rhythm Society strengthened recommendations on extraction of infected leads. The ongoing management of the Medtronic Sprint Fidelis lead recall, initially announced in 2007 to affect 265,000 leads worldwide, has elevated physician awareness of the need to employ a comprehensive lead management strategy for their patients, to include appropriate use of laser-assisted lead removal. In 2011, a recall of St. Jude's Riata Silicone ICD leads, with 227,000 implanted worldwide, also increased the awareness of the need for lead management strategies and tools. The Heart Rhythm Society guidelines from 2009 also identified specific clinical indications related to device patients requiring magnetic resonance imaging (MRI), because nearly 200,000 device patients each year cannot have an MRI performed due to the potential for serious adverse events of exposing a traditional pacemaker and pacing leads to a strong magnetic field.

Multiple manufacturers now offer pacing systems specifically designed to operate in an MRI environment internationally, and Medtronic offers this technology in the U.S. When these MRI-compatible pacemakers and leads are implanted in a patient with an existing pacemaker, the previously implanted leads need to be removed. We believe there will be a growing opportunity for lead extraction for thousands of device patients who may replace their pacemakers to have access to an MRI.

According to clinical research conducted by the cardiac rhythm management industry, patients suffering from congestive heart failure, as well as patients who have had prior heart attacks, may have reduced mortality risk as a result of the implant of an implantable cardioverter defibrillator (ICD). Because the most advanced ICD systems, known as cardiac resynchronization therapy defibrillators or CRT-Ds, have more leads per device than standard pacemakers, and because defibrillation leads are typically larger in diameter than pacemaker leads, the potential for venous obstruction is increased. This is especially true where an existing pacing system is upgraded to an ICD system resulting in a redundant ventricular pacing lead. As a result, we believe these situations lend themselves to an increased likelihood of redundant leads being removed.

Lead Management represented approximately 39% of our total revenue in 2012, 37% of total revenue in 2011 and 35% of total revenue in 2010. Our primary Lead Management products include the following:

Spectranetics Laser Sheath (SLS® II). The Spectranetics Laser Sheath is a laser-assisted lead removal device designed to be used with our CVX-300 excimer laser system to remove implanted leads with minimal force. The SLS II laser sheath uses excimer laser energy with a repetition rate from 25 - 40 Hz focused through the tip of the sheath to facilitate lead removal by ablating through scar tissue surrounding the lead with low-temperature ultraviolet light. We believe that the advantages of this approach include low trauma to the surrounding veins, low occurrence of complication, effectiveness and time efficiency.

GlideLight™. To enhance the ability of physicians to treat the wide variety of indicated patients, in 2012 we launched the GlideLight Laser Sheath, our third generation laser sheath technology, which delivers a repetition rate of up to 80 Hz. We believe physicians appreciate the clinical versatility and control with GlideLight.

Lead Locking Device (LLD®). Our Lead Locking Device product complements our laser sheath product line as an adjunctive mechanical tool. The LLD is a mechanical device that assists in the removal of leads by providing traction on the inner aspect of the leads, which are typically constructed of wire coils covered by insulating material.

Laser equipment and services

Laser equipment and services revenue represented 13% of total revenue in 2012, 15% of total revenue in 2011 and 14% of total revenue in 2010. We sell or rent our CVX-300 excimer laser systems to hospitals and physicians' offices, and our field service engineers service the laser systems on a periodic basis.

Corporate Information

Spectranetics is a Delaware corporation formed in 1984. Our principal executive offices are located at 9965 Federal Drive, Colorado Springs, Colorado 80921. Our telephone number is (719) 633-8333.

Our corporate website is located at www.spnc.com. A link to a third-party website is provided at our corporate website to access our SEC filings free of charge promptly after such material is electronically filed with, or furnished to, the SEC. We do not intend for information found on our website to be part of this document.

Corporate Compliance and Corporate Integrity Agreement

We have processes, policies and procedures designed to maintain compliance with applicable federal, state and foreign laws and regulations governing our operations.

In December 2009, in connection with the resolution of a federal investigation, we entered a five-year Corporate Integrity Agreement with the Office of Inspector General of the United States Department of Health and Human Services (OIG). The Corporate Integrity Agreement acknowledges the existence of our corporate compliance program and provides for certain other compliance-related activities during the five-year term of the agreement. Those activities include specific written standards, training, education, review, disclosure and reporting requirements related to our governmental reporting functions, sales and promotional activities, and clinical studies. We have enhanced our compliance systems to address the provisions of the Corporate Integrity Agreement. We filed an Initial Implementation Report in May 2010 and our first three Annual Reports in February 2011, 2012 and 2013, respectively.

While we believe that our compliance program is sufficient to meet our Corporate Integrity Agreement obligations and other legal requirements, we, our employees, our consultants or our contractors may not be in compliance with all potentially applicable U.S. federal and state regulations or laws or all potentially applicable foreign regulations or laws.

Research and Development

We believe research and development investments are critical to increasing our revenue growth rate. Our product development and technology teams are focused on the development of additional disposable devices addressing the Vascular Intervention and Lead Management markets, as well as the development of our laser system. Our team of research scientists, engineers and technicians, supported by third-party research and engineering organizations, performs substantially all of our research and development activities. Our research and development expense, which also includes clinical studies and regulatory costs, totaled $15.2 million in 2012, $14.6 million in 2011, and $12.1 million in 2010.

Clinical Trials

We support many of our new product initiatives with clinical studies in order to obtain regulatory approval. Our clinical and regulatory departments are focused on developing the necessary clinical data to achieve initial regulatory approval or clearance, and expanded indications for our existing and emerging products around the world. The goal of a clinical trial is to meet the primary endpoint, which measures the clinical effectiveness and may also provide information about performance and safety of a device, which are the bases for FDA approval. 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.

The following is a summary of selected current clinical trials. We have also provided a summary of our historical pivotal trials that led to PMA approval or 510(k) clearance of our coronary, peripheral and lead extraction products. The trials listed below are intended to represent the significant trials we have commenced and, as such, are not a complete listing of every trial conducted or underway. Furthermore, some or all of the trials underway may not be completed, and the clinical results of these trials may not be favorable.

Current Clinical Trials

During the second quarter of 2011, the FDA granted approval for an investigational device exemption (IDE) related to a multi-center, randomized trial to treat in-stent restenosis (ISR) in the legs under the study name

EXCITE ISR. The study compares laser ablation using our Turbo-Tandem and Turbo Elite laser ablation devices followed by adjunctive balloon angioplasty with balloon angioplasty alone. The first enrollment in the study occurred in June 2011. The planned enrollment is 318 subjects in the randomized control trial arm of the study at up to 35 active sites in the U.S. Subjects enrolled will be followed at one, six and 12 months after the procedure. The primary endpoint is freedom from Target Lesion Revascularization (TLR) through six months following the procedure. The primary safety endpoint is freedom from major adverse events, such as death, major amputation or TLR, at 30 days following the procedure. If the data merit it, we plan to submit a new 510(k) to the FDA based on the six month follow-up data. To date, our primary focus has been increasing enrollment in the study. As of March 7, 2013, 35 sites are approved to enroll in the study and 138 subjects have been enrolled. We have recently initiated discussions with the FDA to explore achievement of an ISR indication prior to full enrollment of the EXCITE ISR study. This may involve use of the PATENT registry, which is discussed below, in combination with patients enrolled in the EXCITE ISR study and clinical data from other sources. Discussions with the FDA are ongoing. There is no assurance that the ISR indication will be cleared by the FDA without full enrollment of the EXCITE ISR study.

In January 2013, we announced final results from the Photo Ablation Using the Turbo-Booster ® and Excimer Laser for In-Stent Restenosis Treatment, or PATENT, registry. A total of 90 patients were included by December 2011 at five centers in Germany. Seventy-three patients were followed through 12 months. The registry results presented at the Leipzig Interventional Course 2013 in Leipzig, Germany indicated 82% and 52% freedom from TLR at six and 12 months, respectively.

In the results of the PATENT registry, the procedural success rate, defined as achievement of ≤ 30% final residual restenosis from procedure through 30 days following the procedure, was 98.9%, and Cumulative Major Adverse Events (MAEs) were 2.2% . The study population included patients with PAD ranging from intermittent claudication to critical limb ischemia (Rutherford class 2-5). Lesions ranged from 1cm to 25cm with average total lesion length of 12.3cm, and 93% were in the superficial femoral artery (SFA).

The PATENT registry serves as a feasibility study for the EXCITE ISR trial. Although we believe the interim PATENT registry results are favorable, these results may not predict the results of the EXCITE ISR trial, a controlled clinical trial. Because there is no control group in a registry, registry results are not as reliable as the results of a controlled clinical trial.

We are supporting a physician-sponsored pilot study evaluating the use of laser ablation followed by a paclitaxel-coated angioplasty balloon (PTX PTA) compared with the use of PTX PTA alone in the treatment of in-stent restenosis in above-the-knee arteries. This pilot study, Photoablation Followed by a Paclitaxel-Coated Balloon to Inhibit Restenosis in Instent Femoro-popliteal Obstructions, or PHOTOPAC, is not intended to be used to gain an indication in the U.S. for the use of PTX PTA with laser, but to determine whether the use of laser with PTX PTA potentially provides a benefit over PTX PTA alone and to provide data for potential future studies. The planned enrollment for the PHOTOPAC trial is 50 subjects, who will be followed at one, six and 12 months after the procedure. Our support of the PHOTOPAC trial is in the form of an unrestricted research grant. The pilot study is being conducted at up to four sites in Germany. As of March 7, 2013, two sites are approved to enroll in the study and 41 subjects have been enrolled.

Pivotal Clinical Trials

The Lead Extraction in Contemporary Settings, or LExICon, trial was an observational, multi-center retrospective data collection study of consecutive laser lead extractions using the SLS II lead management system, evaluating factors affecting success and complications. The study was published in the February 9, 2010 issue of the *Journal of the American College of Cardiology*. The study examined laser-assisted lead removal of 2,405 leads in 1,449 patients at 13 centers between January 2004 and December 2007, using the SLS II laser sheath. Resulting key data points included: (i) 97.7% clinical success rate, (ii) 96.5% complete lead removal success rate, (iii) 1.4% major

adverse event rate—a 26% relative reduction (compared to a previous multi-center study evaluating the original SLS laser sheath), and (iv) 0.28% procedural mortality rate—more than a 50% relative reduction (compared to a previous multi-center study evaluating the original SLS laser sheath).

The CLiRpath Excimer Laser System to Enlarge Lumen Openings, or CELLO, trial was a pivotal IDE clinical trial for our Turbo-Booster catheter in the treatment of larger diameter arteries within the legs. We enrolled 65 patients in the trial at 17 sites in the United States and Europe. The trial included patients with stenoses and occlusions that were greater than or equal to 70% and less than or equal to 100% of the vessel lumen within arteries four to seven millimeters in diameter. Three independent core labs analyzed the angiographic, intravascular ultrasound, and duplex ultrasound data from the trial. The primary endpoints of the trial were the achievement of a minimum 20% reduction in the percent diameter stenosis post-laser compared to pre-intervention and major adverse events. The reduction in percent diameter stenosis following the use of the Turbo-Booster was 35% and there were no major adverse events reported through six months following the procedure. As a result, the primary endpoints were met. Further, the durability of the procedure was demonstrated through freedom from target lesion revascularization in 77% of the patients through 12 months following enrollment. Significant improvements in all clinical outcomes measured at twelve months following the procedure were noted, including Rutherford category, ankle-brachial index and walking impairment. Based on a review of the data, in June 2007, we received clearance from the FDA to market our Turbo-Booster product for the treatment of arterial stenoses and occlusions in the leg. The Turbo-Booster functions as a guiding catheter facilitating directed ablation of blockages in the main arteries at or above the knee. The CELLO trial data through the 12 month follow-up was published in *The Journal of Endovascular Therapy* in December 2009.

FDA clearance for use of our CVX-300 excimer laser system for the treatment of CTOs in the leg that are not crossable with a guidewire was based on the Laser Angioplasty for Critical Limb Ischemia, or LACI, trial, which dealt with multi-vessel PAD in patients presenting with critical limb ischemia (CLI) who are not eligible for bypass surgery. The LACI trial enrolled 145 patients at 15 domestic and several European sites. The purpose of the study was to evaluate the effectiveness of laser-assisted PCI for CLI patients who were poor candidates for surgical revascularization, and, as a result, at a higher risk for amputation. The primary endpoint was limb salvage for a six month follow-up period. Data from the trial indicated a 93% success rate as compared with 87% in the historical control group of 789 patients treated with a variety of standard therapies, including bypass surgery. There were no statistical differences in serious adverse events between the LACI group and the historical control group. Although the clinical trial endpoints were achieved, the advisory panel to the FDA recommended non-approval in October 2003, citing concerns over the non-randomized nature of the trial, use of a historical control group, and the inability to distinguish the specific benefit of laser treatment, since it was used adjunctively with balloons and stents. The FDA, which generally follows the advisory panel's recommendation, issued a non-approval letter following the panel meeting. Based on input at the advisory panel meeting and subsequent discussions with the FDA, we elected to pursue 510(k) clearance to market our products to patients who have total occlusions that are not crossable with a guidewire, which is a subset of the LACI data. On January 14, 2004, we submitted data on 47 patients that showed an overall procedural success rate of 72%. The data consisted of 28 patients from the LACI trial supplemented with an additional 19 patients treated at two other sites that were not part of the original LACI trial, but followed the LACI trial protocol. There was no difference in serious adverse events as compared with the entire set of patients treated in the LACI trial. We received 510(k) clearance from the FDA on April 29, 2004.

With respect to our cardiac lead removal products, the Pacemaker Lead Extraction with the Excimer Sheath, or PLEXES, trial was completed in October 1996 and demonstrated that use of our SLS increased the complete lead removal success rate to 94% as compared with 64% for mechanical lead removal techniques. This was a randomized trial that enrolled more than 750 patients. Another study completed in 1999 and published in December 2000 in the *Journal of Interventional Cardiac Electrophysiology* reported that using both our SLS and LLD increased our success rate to 98%.

Initial FDA approval for use of our excimer laser for coronary indications was based on the results of the Percutaneous Excimer Laser Coronary Angioplasty, or PELCA**,** trial which evaluated a registry of laser usage in blocked coronary arteries and served as the basis for the FDA approval for our technology in 1993.

Sales and Marketing

Our sales goals are to increase the use of laser catheters and other disposable devices in new and existing accounts. We seek to educate and train physicians and institutions regarding the safety, efficacy, ease of use and growing number of applications addressed by our excimer laser technology through published studies of clinical applications and our various training initiatives. By leveraging the success of existing product applications, we hope to expand the use of our technology in new applications.

Providing customers with answers about the cost of acquisition, use of the laser and types of lesions addressable by our excimer laser system is critical to the education process. Through our marketing and distribution strategy, both in the United States and internationally, we believe that we are well positioned to capitalize not only on our excimer laser technology in peripheral and coronary atherectomy, but also in lead extraction and in other new areas of development for excimer laser technology in the cardiovascular system. We are also continuing to expand sales of our non-laser disposable products, including crossing solutions, a drug-delivery system and thrombectomy devices.

North America Sales and Marketing

U.S. Sales Organization. We divide our U.S. sales organization into two separate groups, one focusing on Vascular Intervention and the other focusing on Lead Management, as there are different selling strategies and physician specialties for these applications. Our Vascular Intervention sales team members primarily work with interventional cardiologists, vascular surgeons and interventional radiologists who perform vascular procedures on a more regular basis and with a wider range of treatment options, compared with Lead Management. Our Lead Management sales team members primarily work with electrophysiologists and cardiac surgeons who perform lead extraction procedures.

We conduct education sessions with our simulation system, which is intended to augment traditional procedural training for physicians on the use of laser in peripheral interventions and laser-assisted lead extraction procedures by permitting hands-on practice with extraction tools and techniques in multiple case scenarios in a virtual operating environment.

Our field team in the United States also includes field service engineers who are responsible for the installation of each laser and participation in the training program at each site. We provide a one-year warranty on laser sales, which includes parts, labor and replacement gas. Upon expiration of the warranty period, we offer service to our customers under annual service contracts or on a fee-for-service basis. The field service engineers also perform ongoing service on the lasers placed under our various rental programs.

We currently have a global marketing team that supports our two U.S. sales organizations and global product development. Our team includes marketing and product managers who are responsible for all marketing activities for each of our target markets. Our marketing activities are designed to support our direct sales teams and include advertising and product publicity in trade journals, newsletters, continuing education programs, and attendance at trade shows and professional association meetings.

International Sales and Marketing

We have a sales presence in more than 40 countries outside of the U.S., including our direct sales operations in certain countries in Europe and Puerto Rico and a network of approximately 45 distributors. Total

international revenue in 2012 (including Asia Pacific and Latin American countries) was $ 22.8 million, or 16% of our consolidated revenue. This represents an increase of 7% over 2011 international revenue of $21.4 million, or 13% on a constant currency basis (see the "Non-GAAP Financial Measures" section in "Management's Discussion and Analysis of Financial Condition and Results of Operations" for a discussion of our use of the constant currency financial measure).

We market and sell our products in Europe, the Middle East and Russia through Spectranetics International, B.V., a wholly-owned subsidiary; Spectranetics Deutschland GmbH and Spectranetics Austria GmbH, two wholly-owned subsidiaries of Spectranetics International, B.V.; as well as through distributors.

In addition to the operations of Spectranetics International, B.V., Spectranetics Deutschland GmbH and Spectranetics Austria GmbH, we conduct international business in Japan and other select countries in the Pacific Rim and Latin America through distributors. We also have a direct sales presence in Puerto Rico, which falls under our international operations.

Our distributor in Japan, DVx Inc., is our Japanese Market Authorization Holder (MAH). In conjunction with DVx, we have regulatory and reimbursement approval from the Japanese Ministry of Health, Labor and Welfare (MHLW) to market our laser and various models of our coronary catheters, along with our SLS lead extraction catheters and LLD lead locking device in Japan. In January 2013, we received regulatory and reimbursement approval for the Quick-Cross Support Catheter, the first of our peripheral intervention products to receive such approval in Japan. In addition, we are in various stages of the submission process to obtain regulatory approval in Japan for some of our newer products and certain of our peripheral atherectomy and additional crossing solutions products.

Foreign sales may be subject to certain risks, including export/import licenses, tariffs, foreign exchange rate fluctuations, other trade regulations and foreign medical regulations and reimbursement. Tariff and trade policies, domestic and foreign tax and economic policies, exchange rate fluctuations and international monetary conditions have not significantly affected our business to date.

Competition

The medical device industry is highly competitive, subject to rapid change and significantly affected by new product introductions and other activities of industry participants. Our primary competitors are manufacturers of products used in competing therapies within the peripheral and coronary atherectomy markets, such as: atherectomy using mechanical methods to remove arterial blockages (peripheral and coronary), balloon angioplasty and stents (peripheral), specialty balloon angioplasty, bypass surgery (peripheral and coronary) and amputation (peripheral). Many of our competitors have substantially greater financial, manufacturing, marketing and technical resources than we do.

Although balloon angioplasty and stents are used extensively in the vascular system, we do not compete directly with these products. Rather, our laser technology is used as an adjunctive treatment to balloon angioplasty and stents in complex peripheral and coronary procedures.

Competitive methods available to remove implanted leads include open-chest surgery and transvenous removal with other mechanical sheaths or devices using radiofrequency energy, each having particular drawbacks or limitations. For example, open-chest surgery is costly and traumatic to the patient, while mechanical sheaths rely on tearing of scar tissue to liberate a lead targeted for removal.

Manufacturers of peripheral atherectomy devices include ev3 Inc. (acquired by Covidien in 2010), Cardiovascular Systems, Inc., and Pathway Medical Technologies, Inc. (acquired by MEDRAD in 2011, a business of Bayer HealthCare). In the coronary atherectomy market, we compete primarily with Boston Scientific

Corporation. Manufacturers of aspiration devices include Medtronic, Inc., Vascular Solutions, Inc., Covidien, Atrium Medical, Terumo Interventional Systems, Volcano Corporation, Straub Medical AG and Bayer HealthCare. In crossing solutions, we compete primarily with Vascular Solutions, Inc., Covidien, Cook Vascular Inc., Bard Peripheral Vascular (a division of C.R. Bard, Inc.), Boston Scientific, and Terumo Interventional Systems. In the drug delivery market, we may compete with Bacchus Vascular (acquired by Covidien in 2009), Ekos, and Atrium Medical.

We also compete with a narrow set of companies marketing non-laser lead extraction devices. In the lead removal market, the primary other supplier is Cook Vascular Inc., while internationally VascoMed also offers lead extraction devices.

Manufacturing

We manufacture substantially all of our products with the exception of the TAPAS catheter, the Quick-Access Needle Holder and the Quick-Cross Capture Guidewire Retriever, which are currently manufactured for us by third-party manufacturers. The transition of the manufacture of the Quick-Access Needle Holder and the Quick-Cross Capture Guidewire Retriever is underway and we expect it to be completed by the end of 2013. We have vertically integrated a number of manufacturing processes in an effort to provide increased quality and reliability of the components used in the production process. Many of our manufacturing processes are proprietary. We believe that our level of manufacturing integration allows us to better control lead time, costs, quality and process advancements, to accelerate new product development cycle time, to provide greater design flexibility and to scale manufacturing, should market demand increase.

Our manufacturing facilities are subject to periodic inspections by federal, state, international and other regulatory authorities, including the Quality System Regulation (QSR) compliance inspections by the FDA and International Organization for Standardization (ISO 13485:2003) compliance inspections by the British Standards Institution (BSi), which is a private company authorized by European medical agencies to assess and certify compliance with regulatory requirements (Notified Body). In addition, we are subject to inspections by the Japanese regulatory agency, the Pharmaceutical and Medical Device Agency (PMDA). During the past year we have undergone the following quality system inspections: a BSi Microbiology Assessment; a BSi Surveillance Assessment for ISO 13485:2003; and two TÜV (another European Notified Body) Factory Safety Inspections. These inspections resulted in zero non-conformances.

We purchase some components of our CVX-300 excimer laser system and some disposable products from sole source suppliers. Most raw materials, components and subassemblies used in our products are purchased from outside suppliers and are generally readily available from multiple sources. While we believe we could obtain replacement components from alternative suppliers, we may be unable to do so. The loss of any of these suppliers could result in a disruption in our production and adversely affect us.

In recent years, we have moved the manufacturing of our disposable products and our CVX-300 laser system to our corporate headquarters in Colorado Springs, Colorado. In 2012, we successfully completed the transfer of manufacturing of the ELCA coronary atherectomy product line and the SLS II laser-assisted lead extraction product line, to this facility.

Patents and Proprietary Rights

We hold numerous issued U.S. patents and have rights to additional U.S. patents under license agreements. We also hold issued patents in various countries, including the United Kingdom, France, Germany, Italy and Japan. We also have numerous pending U.S. and international patent applications that cover numerous inventions, including general features of the laser system, features of our catheters and other technologies.

Any patents for which we have applied may not be granted. Our patents may not be sufficiently broad to protect our technology or to provide us with any competitive advantage. Our patents could be challenged as invalid, unenforceable, or circumvented by competitors. In addition, the laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States. We could be adversely affected if any of our licensors terminate our license agreements.

It is our policy to require our employees and consultants to execute confidentiality agreements upon the commencement of an employment or consulting relationship with us. Each agreement provides that all confidential information developed or made known to the individual during the course of the relationship will be kept confidential and not disclosed to third parties except in specified circumstances. In the case of employees, the agreements provide that all inventions developed by the individual pursuant to their employment are our exclusive property. These agreements may not provide meaningful protection in the event of unauthorized use or disclosure of such information.

We also rely on trade secrets and unpatented know-how to protect our proprietary technology and may be vulnerable to competitors who attempt to copy our products or gain access to our trade secrets and know-how.

We are party to license agreements pursuant to which we license patents covering certain aspects of our products.

In January 2012, we entered into a Termination and Mutual Release with Medtronic, Inc. The Termination Agreement terminates a License Agreement between us and Medtronic dated February 28, 1997 (the License Agreement). The parties disputed whether royalties were owed under the License Agreement. Under the Termination Agreement, we paid to Medtronic $3.0 million in January 2012 in settlement of all obligations under the License Agreement, and neither party has any further rights or obligations under the License Agreement. Royalty expenses to Medtronic have not been incurred subsequent to the effective date of the Termination Agreement.

We are party to an amended vascular laser angioplasty catheter license agreement with SurModics pursuant to which SurModics has granted us a worldwide non-exclusive license to use a lubricious coating that is applied to our products using certain SurModics patents. We pay SurModics royalties as a specified percentage of net sales of products using its patents, subject to a quarterly minimum royalty. The license agreement expires on the later of the date of expiration of the last licensed patent or the fifteenth anniversary of the date a licensed product is first sold unless terminated earlier (1) by either party if the other party is involved with insolvency, dissolution or bankruptcy proceedings, (2) by us upon 90 days' advance written notice, or (3) by SurModics upon 60 days' advance written notice if we have failed to perform our obligations under the agreement and have not cured such breach during such 60-day period, or if the amount of royalties we pay SurModics is not greater than specified levels. In 2012, we incurred royalties of approximately $0.8 million to SurModics under this license agreement.

In 2004, we purchased certain intellectual property assets related to our Turbo-Booster product from Peripheral Solutions, Inc. (PSI). Pursuant to our agreement with PSI, we have made payments to PSI upon the completion of certain sales and FDA approval milestones. In 2009, we paid an additional milestone payment of $0.1 million, based on the issuance of the first U.S. patent relating to the intellectual property assets. The next contingent milestone payment would be $1.0 million upon the sale of the first 100,000 units of the Turbo-Booster product or other products that incorporate the licensed technology, which would include the Turbo-Tandem.

In December 2009, we entered into a license agreement with Peter Rentrop, M.D. As part of the agreement, we received a worldwide, exclusive license to certain patents and patent applications owned by Dr. Rentrop, which, in general, apply to laser catheters with a tip diameter less than 1 millimeter. We pay Dr. Rentrop royalties of a specified percentage of net sales of products using his patents subject to a quarterly minimum royalty. The license agreement expires in January 2020, unless terminated earlier in accordance with its terms. In 2012, we incurred royalties of approximately $0.9 million to Dr. Rentrop under this license agreement.

Litigation concerning patents and proprietary rights is time-consuming, expensive, unpredictable and could divert the efforts of our management. An adverse ruling could subject us to significant liability, require us to seek licenses and restrict our ability to manufacture and sell our products. We are, and in the past have been a party to legal proceedings involving our intellectual property and may be a party to future proceedings. See Item 1A, "Risk Factors" for additional discussion regarding the risks associated with our intellectual property.

Third-Party Reimbursement

Our CVX-300 excimer laser system and related disposable devices are generally purchased by hospitals, which then bill various third-party payers for the healthcare services provided to their patients. These payers include Medicare, Medicaid and private insurance payers. Private payers are influenced by Medicare coverage and payment methodologies. The Centers for Medicare and Medicaid Services (CMS) administers the federal Medicare program. Medicare policies and payment rates depend on the setting in which the services are performed.

Hospitals are reimbursed for inpatient services by Medicare under the Inpatient Prospective Payment System (IPPS). Payment is made to the hospital through the Medicare Severity Diagnosis Related Group (MS-DRG) methodology. MS-DRGs classify discharges into groups with similar clinical characteristics that are expected to require similar resource utilization. MS-DRG assignment for a patient's hospitalization is based on the patient's reason for admission, discharge diagnoses, and procedures performed during the inpatient stay. Hospitals are paid a fixed payment that is designed to be inclusive of all supplies, devices, and overhead associated with the stay. IPPS does not separately reimburse for the actual cost of the medical device used or for the services provided. Hospitals performing inpatient procedures using our technology are paid the applicable MS-DRG payment rate for the inpatient stay.

For outpatient hospital services, payments are also made under a prospective payment system, the Outpatient Prospective Payment System (OPPS). Payments are based on Ambulatory Payment Classifications(APCs), under which each procedure is categorized. Most procedures are assigned to APCs with other procedures that are clinically and resource comparable.

An Ambulatory Surgery Center (ASC) is typically defined as a center that is not attached to a hospital and surgical procedures are performed where the patient has a recovery of less than 24 hours. The payment methodology uses relative weights based on the OPPS. Medicare makes a single payment to ASCs for covered surgical procedures, which includes ASC facility services that are furnished in connection with the covered procedure. Beginning in 2013, lower extremity revascularization procedures have been designated by Medicare as covered procedures in this setting.

In addition to payments made to hospitals and ASCs for procedures using our technology, Medicare makes separate payments to physicians for their professional services. Payments to physicians are made under the national Medicare Physician Fee Schedule (MPFS). National payment rates are assigned based on the Resource Based Relative Value System (RBRVS). Payment is adjusted for geographic location as well as place of service. Lower extremity revascularization procedures have been designated by Medicare as covered procedures in the physician's office setting since 2011.

Hospital outpatient and physician services are reported with the Healthcare Common Procedure Coding System (HCPCS), which includes the AMA Current Procedural Terminology (CPT). Cardiac lead extraction procedures using the SLS, GlideLight and LLD are typically reported with the current code sets describing lead removal. Percutaneous coronary and peripheral vascular laser atherectomy procedures are reported with the current code sets that describe coronary atherectomy and percutaneous endovascular revascularization.

Most third-party payers currently cover and reimburse for procedures using our products. However, in the past, certain private payers had limited coverage for laser atherectomy procedures. While we believe that a laser

atherectomy procedure offers a less costly alternative for the treatment of certain types of cardiovascular disease, the procedure may not receive adequate coverage and reimbursement and may not be viewed as cost-effective under future coverage and reimbursement guidelines or other healthcare payment systems.

Reimbursement rates are unpredictable, and we cannot project how our business may be affected by future legislative and regulatory developments. Future legislation or regulation, or changing payment methodologies, may have a material adverse effect on our business, and reimbursement may not be adequate for all customers.

Government Regulation

Overview of Medical Device Regulation

Our products are medical devices subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act, or FDCA. FDA regulations govern, among other things, the following activities that we perform:

- product design, development, manufacture and testing;
- product labeling;
- product storage;
- premarket clearance or approval;
- advertising and promotion;
- product sales and distribution; and
- post-market safety reporting.

To be commercially distributed in the United States, non-exempt medical devices must receive either approval through a Premarket Approval (PMA) or be found to be substantially equivalent to an already marketed device through a Premarket Notification 510(k) from the FDA prior to marketing and distribution pursuant to the FDCA. Using the FDA's classification system, devices deemed to pose relatively less risk are placed into either Class I or II, which requires the manufacturer to submit a Premarket Notification 510(k) requesting permission for commercial distribution. In some cases, the FDA has determined that devices in this relatively lower risk classification may be exempt from requiring premarket notification through the 510(k) process. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously 510(k) cleared device or a pre-amendment Class III device for which the FDA has not yet called for submission of PMA applications, are placed in Class III requiring a PMA.

510(k) Clearance Premarket Notification Pathway. To obtain 510(k) clearance, a manufacturer must submit a Premarket Notification 510(k) application demonstrating that the proposed device is substantially equivalent in intended use and in safety and effectiveness to a previously 510(k) cleared device or a device that was in commercial distribution before May 28, 1976. The FDA's 510(k) premarket notification pathway usually takes from three to six months, but it can last longer.

After a device is found to be substantially equivalent through the 510(k) process, which is also referred to as a marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a PMA. The FDA requires each manufacturer to determine whether a new 510(k) is required for product modifications in the first

instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) or PMA approval. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) or PMA approval is obtained.

PMA Pathway. A high risk device not eligible for 510(k) clearance must follow the PMA pathway, which requires data demonstrating the safety and effectiveness of the device to the FDA's satisfaction. The PMA pathway is much more costly, lengthy and uncertain than the 510(k) process. It generally takes from one to three years, but may take longer.

A PMA application must provide extensive preclinical and clinical trial data and also information about the device and its components regarding, among other things, device design, manufacturing and labeling. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with accepted Quality System Regulations (QSR), which impose elaborate testing, control, documentation and other quality assurance procedures.

Upon submission, the FDA determines if the PMA application is sufficiently complete to permit a substantive review, and, if so, the application is accepted for filing. The FDA then commences an in-depth review of the PMA application, which can take one to three years, but may take longer. The review time is often significantly extended as a result of the FDA asking for more information or clarification of information already provided. The FDA also may respond with a "not approvable" determination based on deficiencies in the application and require additional clinical trials that are often expensive and time consuming and can delay approval for months or even years. During the review period, an FDA advisory committee, typically a panel of clinicians, likely will be convened to review the application and recommend to the FDA whether, or upon what conditions, the device should be approved. Although the FDA is not bound by the advisory panel decision, the panel's recommendation is important to the FDA's overall decision making process.

If the FDA's evaluation of the PMA application is favorable, the FDA typically issues an "approvable letter" requiring the applicant's agreement to specific conditions (e.g., changes in labeling) or specific additional information (e.g., submission of final labeling) in order to secure final approval of the PMA application. Once the approvable letter is satisfied, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the manufacturer. The PMA can include postapproval conditions that the FDA believes are necessary to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution. Failure to comply with the conditions of approval can result in an enforcement action, which could have material adverse consequences, including the loss or withdrawal of the approval.

Even after a PMA, a new PMA or PMA supplement is required in the event of a modification to the device, its labeling or its manufacturing process, as in the recent relocation of manufacturing of our products to our newer facility in Colorado Springs. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA.

Clinical Trials. A clinical trial is often required to support a PMA application and is sometimes required for a Premarket Notification 510(k) application. In some cases, one or more relatively smaller studies may precede a pivotal clinical trial intended to demonstrate the safety and efficacy of the investigational device.

All clinical studies of investigational devices must be conducted in compliance with the FDA's requirements. If an investigational device could pose a significant risk to subjects (as defined in the regulations), the FDA must approve an IDE application prior to initiation of investigational use. An Investigational Device Exemption (IDE) application must be supported by appropriate data, such as animal and laboratory test results,

showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The FDA typically grants IDE approval for a specified number of subjects to be enrolled at specified study centers. A clinical trial of a non-significant risk device is governed by several of the IDE application requirements (e.g. clinical trial monitoring and record keeping) and does not require FDA approval of an IDE application before the trial is started. Both significant risk and non-significant risk investigational devices require ethical approval from institutional review boards, or IRBs, at the study centers where the device will be used.

During the study, the sponsor must comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting, and record keeping. The investigators must obtain subject informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with all reporting and record keeping requirements. Many IDE requirements apply to all investigational devices, whether considered significant or non-significant risk. Prior to approving a PMA, the FDA typically inspects the records relating to the conduct of the study and the clinical data supporting the PMA application for compliance with IDE requirements.

The FDA Quality System Regulations do not fully apply to investigational devices, but the requirement for controls on design and development does apply. The sponsor also must manufacture the investigational device in conformity with the quality controls described in the IDE application and any conditions of IDE approval that the FDA may impose with respect to manufacturing.

Postmarket. After a device is placed on the market, numerous regulatory requirements apply. These include: FDA labeling regulations that prohibit manufacturers from promoting products for unapproved or "off-label" uses, the Medical Device Reporting regulation, which requires 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 the Reports of Corrections and Removals regulation, which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA.

The FDA enforces these requirements by inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as:

- fines, injunctions, and civil penalties;
- recall or seizure of products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing requests for 510(k) clearance or PMA of new products;
- withdrawing 510(k) clearance or PMAs already granted; and
- criminal prosecution.

The FDA may not approve our current or future PMA applications or supplements or clear our Premarket Notification 510(k) applications on a timely basis or at all. The absence of such approvals or clearance could have a material adverse impact on our ability to generate future revenue.

Labeling and promotional activities are also subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission (FTC). The FDA and FTC actively enforce regulations prohibiting marketing of products for unapproved uses.

International Regulations. International sales of our products are subject to foreign regulations, including health and medical safety regulations. The regulatory review process varies from country to country. Many countries also impose product standards, packaging and labeling requirements, and import restrictions on devices. Exports of products that have been approved by the FDA do not require FDA authorization for export. However, foreign countries often require an FDA Certificate to Foreign Government verifying that the product complies with FDCA requirements. To obtain a Certificate to Foreign Government, the device manufacturer must certify to the FDA that the product has been granted approval in the United States and that the manufacturer and the exported products are in substantial compliance with the FDCA and all applicable or pertinent regulations. The FDA may refuse to issue a Certificate to Foreign Government if significant outstanding Quality System Regulations violations exist.

The Medical Device Directive (MDD) is a directive that covers the regulatory requirements for medical devices in the European Union. The MDD was amended and compliance with the new regulations became mandatory in March 2010. This amendment was the first significant modification to the MDD since 1993 and there were multiple changes that affected our products. Specifically, clinical data is now required for all devices regardless of classification, the definition of "central circulatory system" has been expanded which may affect the classification of devices, and the definition of "continuous use" has been expanded and may affect the classification of devices.

With respect to our international operations, in November 1994, we received ISO 9001 certification from TÜV, which allows us to manufacture products for use in the European Community within compliance of the manufacturing quality regulations. In addition, we received CMDCAS (Canadian) certification by TÜV in January 2002. We have received CE (Communauté Européene) mark registration for substantially all of our current products. The CE mark indicates that a product is certified for sale throughout the European Union and that the manufacturer of the product complies with applicable safety and quality standards. We have also received approval to market certain coronary atherectomy products, certain lead removal products and our Quick-Cross support catheter in Japan, and are seeking additional approvals there for our other coronary, peripheral and lead removal products with the assistance of our distributor, DVx. In Australia, we have approvals to market certain peripheral atherectomy, coronary atherectomy, crossing and lead removal products. We also have approvals to market certain products in several Asia Pacific and Latin American countries.

We are also subject to certain federal, state and local regulations regarding environmental protection and hazardous substance controls, among others. To date, compliance with such environmental regulations has not had a material effect on our capital expenditures or competitive position.

Product Liability Insurance

Our business entails the risk of product liability claims. We maintain product liability insurance in the amount of $20 million per occurrence with an annual aggregate maximum of $20 million. Product liability claims may exceed such insurance coverage limits, and such insurance coverage limits may not continue to be available on acceptable terms, or at all.

Employees

As of December 31, 2012, we had 548 full time employees worldwide. None of our employees are covered by collective bargaining agreements. We believe that the success of our business will depend, in part, on our ability to attract and retain qualified personnel. We believe that our relationship with our employees is good.

ITEM 1A. *Risk Factors*

We may be unable to compete successfully with larger companies in our highly competitive industry.

The medical device industry is highly competitive. Our primary competitors are manufacturers of products used in competing therapies within the peripheral and coronary atherectomy markets, such as:

- atherectomy and thrombectomy, using mechanical methods to remove arterial blockages (peripheral and coronary);
- balloon angioplasty and stents (peripheral);
- specialty balloon angioplasty, such as cutting balloons and drug-eluting balloons;
- bypass surgery (peripheral and coronary); and
- amputation (peripheral).

Many of our competitors have substantially greater financial, manufacturing, marketing and technical resources than we do. Larger competitors have substantially larger sales and marketing operations than we do. This allows those competitors to spend more time with potential customers and to focus on a larger number of potential customers, which gives them a significant advantage over our sales and marketing team and our international distributors in making sales. At times, we have experienced periods of higher sales personnel turnover, particularly in our VI sales organization. Sales turnover could be an issue in the future.

Larger competitors also have broader product lines, which enables them to offer customers bundled purchase contracts and quantity discounts, and more experience than we have in research and development, marketing, manufacturing, preclinical testing, conducting clinical trials, obtaining FDA and foreign regulatory approvals and marketing approved products. Our competitors may discover technologies and techniques, or enter into partnerships and collaborations, in order to develop competing products that are more effective or less costly than the products we develop. This may render our technology or products obsolete or noncompetitive. Academic institutions, government agencies, and other public and private research organizations may seek patent protection with respect to potentially competitive products or technologies and may establish exclusive collaborative or licensing relationships with our competitors. As a result, our competitors may be better equipped than we are to develop, manufacture, market and sell competing products. We expect competition to intensify.

We believe that the primary competitive factors in the interventional cardiology market include:

- the ability to treat a variety of lesions safely and effectively as demonstrated by credible clinical data;
- ease of use;
- the impact of managed care practices, related reimbursement to the healthcare provider, and procedure costs;
- size and effectiveness of sales forces; and
- research and development capabilities.

Our ability to increase our revenue is largely dependent on our ability to successfully penetrate our target markets and develop new products for those markets.

Our ability to increase our revenue depends largely on our ability to increase sales in the PAD market and in the lead management market. In order to increase future revenue, we must increase sales of these and other products. New products will also need to be developed and approved by the FDA and foreign regulatory agencies to sustain revenue growth in our markets. Additional clinical data and new products to treat coronary artery disease may be necessary to grow revenue within the coronary market, and we are not investing in these areas at this time.

Our products may not achieve or maintain market acceptance.

Market acceptance in the healthcare community, including physicians, patients and third-party payers, of our laser system and other products depends on many factors, including:

- our ability to provide incremental clinical and economic data that shows the safety and clinical efficacy and cost effectiveness of, and patient benefits from, laser atherectomy and pacemaker and ICD lead removal;
- the availability of alternative treatments;
- the inclusion of our products on insurance company formularies;
- the willingness and ability of patients and the healthcare community to adopt new technologies;
- the convenience and ease of use of our products relative to existing treatment methods;
- the pricing and reimbursement of our products relative to existing treatment methods; and
- marketing and distribution support for our products.

Generally, any of our products may fail to achieve market acceptance. More specifically, if we do not educate physicians about PAD in general and the existence of our products in particular, these products may not gain market acceptance, as many physicians do not routinely screen for PAD while screening for coronary artery disease. In addition, if any of our products achieves market acceptance, we may not be able to maintain that market acceptance over time if competing products or technologies are introduced that are received more favorably or are more cost effective. Failure to achieve or maintain market acceptance would limit our ability to generate revenue and would have a material adverse effect on our business, financial condition and results of operations.

If we do not achieve our projected development and commercialization goals, our business may be harmed.

For planning purposes, we estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development and commercialization goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. From time to time, we publicly announce the expected timing of some of these milestones. All of these milestones are based on a variety of assumptions and are subject to numerous risks and uncertainties. There is a risk that we will not achieve these milestones on a timely basis or at all. For example, if we are unable to get agreement for an adjunctive data analysis from the FDA for an ISR indication prior to full enrollment of the EXCITE ISR study, or if we are unable to complete subject enrollments required by the FDA in a timely manner, the commercialization of our products for an ISR indication could be delayed beyond our anticipated date of mid-2014. Moreover, even if we are successful in achieving these milestones, the actual timing of the

achievement of these milestones can vary dramatically compared to our estimates—in many cases for reasons beyond our control—depending on numerous factors, including:

- the rate of progress, costs and results of our clinical trials and research and development activities;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- the extent of scheduling conflicts with participating physicians and clinical institutions;
- adverse reactions reported during clinical trials or commercialization;
- the receipt of marketing approvals and clearances by our competitors and by us from the FDA and other regulatory agencies;
- other actions by regulators, including actions related to a class of products; and
- actions of our development partners in supporting product development programs.

If we do not meet these milestones for our products or if we are delayed in achieving any of these milestones, the development and commercialization of new products, modifications of existing products or sales of existing products for new approved indications may be prevented or delayed, which could damage our reputation or materially adversely affect our business.

We have a history of losses and may not be able to maintain profitability.

We incurred net losses from our inception in 1984 until 2000, and again in 2002, 2006 and from 2008 to 2010. At December 31, 2012, we had accumulated $93.9 million in net losses since inception. Our net losses have decreased significantly, we were profitable in 2011 and 2012 and we intend to stay profitable; however, we may not remain profitable in the future.

If we make acquisitions, we could encounter difficulties that harm our business.

We may acquire companies, products or technologies that we believe to be complementary to our business. If we engage in such acquisitions, we may have difficulty integrating the acquired personnel, operations, products or technologies. Acquisitions may dilute our earnings per share, disrupt our ongoing business, distract our management and employees, increase our expenses, subject us to liabilities, and increase our risk of litigation, all of which could harm our business. If we use cash to acquire companies, products or technologies, it may divert resources otherwise available for other purposes or increase our debt. If we use our common stock to acquire companies, products or technologies, we may experience a change of control or our stockholders may experience substantial dilution or both.

If we are unable to obtain additional funding, we may be unable to make desirable acquisitions.

We may require additional funds to make acquisitions of desirable companies, products, or technologies. There can be no assurance that financing will be available in amounts or on terms acceptable to us, if at all. The inability to obtain additional capital may restrict our ability to grow and may reduce our ability to make desirable acquisitions. Any equity or convertible debt financing may involve substantial dilution to our existing stockholders.

If we do not effectively manage our growth or control costs related to growth, our results of operations will suffer.

We intend to grow our business by expanding our customer base and product offerings, including through business combinations. Growth could place significant strain on our management, employees, operations, operating and financial systems, and other resources. To accommodate significant growth we could be required to open additional facilities, expand and improve our information systems and procedures, and hire, train, motivate, and manage a growing workforce, all of which would increase our costs. Our systems, facilities, procedures, and personnel may not be adequate to support our future operations. Further, we may not be able to maintain or accelerate our current growth, effectively manage our expanding operations, or achieve planned growth on a timely and profitable basis.

Our business may be adversely affected by litigation and other legal proceedings.

From time to time we are involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee claims, tort or contract claims, federal regulatory investigations, security class action and shareholder derivative lawsuits, and other legal proceedings or investigations, any of which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts and/or injunctive relief that affect how we operate our business. Consequently, it is possible that we could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, any of which could have a material adverse impact on us. Moreover, adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers' confidence and reduce long-term demand for our products, even if the regulatory or legal action is unfounded or not material to our operations.

We are generally obligated to indemnify officers and directors, including, in certain circumstances, former employees, against all losses, including expenses, incurred by them in legal proceedings and to advance their reasonable legal defense expenses, unless certain conditions apply. We maintain insurance for claims of this nature which does not apply in all such circumstances, may be denied or may not be adequate to cover all legal or other costs related to the investigation. A prolonged uninsured expense and indemnification obligation could have a material adverse impact on us. For example, from 2009 through 2012, we incurred more than $6 million in indemnification costs not covered by insurance for former employees who were charged in connection with a previously disclosed federal investigation.

Our business, financial condition, results of operations and cash flows could be adversely affected by certain healthcare reform initiatives and other administrative and legislative proposals that may be adopted in the future in our key markets.

In March 2010, the President of the United States signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (together, the "PPACA"), which makes significant changes to the way healthcare is financed by both federal and state governments and private insurers; and directly impacts the medical device and pharmaceutical industries. The PPACA includes, among other things, with limited exceptions, a deductible excise tax of 2.3% on sales of products by entities that manufacture or import certain medical devices offered for sale in the United States, effective January 1, 2013. Revenues from many of our products are now subject to that excise tax. It is unclear whether we will be able to offset the cost of the tax through higher sales volumes resulting from the expansion of health insurance coverage. Various healthcare reform proposals also have emerged at the state level. We expect that the PPACA, as well as other federal and state healthcare initiatives that may be adopted in the future, could have a material adverse effect on our industry generally and our results of operations.

Regulatory compliance is expensive and complex, and approvals can often be denied or significantly delayed.

Our products are regulated as medical devices, which are subject to extensive regulation by the FDA and similar state and foreign agencies. Complying with these regulations is costly, time consuming and complex. FDA regulations and regulations of similar state and foreign agencies are wide-ranging and govern, among other things:

- product design, development, manufacture and testing;
- product safety and efficacy;
- product labeling;
- product storage and shipping;
- record keeping;
- pre-market clearance or approval;
- advertising and promotion;
- product sales and distribution; and
- post-market surveillance and reporting of deaths or serious injuries.

All of our potential products and improvements of our current products are subject to extensive regulation and will require clearance or approval from the FDA and other regulatory agencies prior to commercial sale and distribution. Pursuant to FDA regulations, unless exempt, the FDA permits commercial distribution of a new medical device only after the device has received 510(k) clearance or is the subject of an approved PMA. The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to other 510(k)-cleared products. In some cases, a 510(k) clearance must be supported by preclinical and clinical data. The PMA process is more costly, lengthy and uncertain than the 510(k) process, and must be supported by extensive data, including data from preclinical studies and human clinical trials. Therefore, in order to obtain regulatory clearance or approvals, we typically must, among other requirements, provide the FDA and similar foreign regulatory authorities with preclinical and clinical data that demonstrate to the satisfaction of the FDA and such other authorities that our products satisfy the criteria for clearance or approval. Preclinical testing and clinical trials must comply with the regulations of the FDA and other government authorities in the United States and similar agencies in other countries.

Additionally, we may be required to obtain PMAs, PMA supplements or additional 510(k) premarket clearances to market modifications to our existing products. The FDA requires device manufacturers to make and document a determination of whether a modification requires an approval, supplement or clearance; however, the FDA can review a manufacturer’s decision. The FDA may not agree with our decisions not to seek approvals, supplements or clearances for particular device modifications. If the FDA requires us to obtain PMAs, PMA supplements or pre-market clearances for any modification to a previously cleared or approved device, we will likely be required to cease manufacturing and marketing the modified device or perhaps also to recall such modified device until we obtain FDA clearance or approval and we may be subject to significant regulatory fines or penalties. In addition, there can be no assurance that the FDA will clear or approve such submissions in a timely manner, if at all.

International regulatory approval processes may take longer than the FDA approval process. If we fail to comply with applicable FDA and foreign regulatory requirements, we may not receive regulatory approvals or may be subject to fines, suspensions or revocations of approvals, seizures or recalls of products, operating restrictions, criminal prosecutions and other penalties. We may be unable to obtain future regulatory approval in a timely manner, or at all, especially if existing regulations are changed or new regulations are adopted. For example, the FDA clearance process for the use of excimer laser technology in clearing blocked arteries in the leg took longer than we anticipated due to requests for additional clinical data and changes in regulatory requirements. A failure or delay in obtaining necessary regulatory approvals would materially adversely affect our business.

If our clinical trials are unsuccessful or significantly delayed, or if we do not complete our clinical trials, our business may be harmed.

Clinical development is a long, expensive, and uncertain process and is subject to delays and to the risk that products may ultimately prove ineffective in treating the indications for which they are designed. Completion of the necessary clinical trials usually takes several years or more. We cannot assure you that we will successfully complete clinical testing of our products within the time frame we have planned, or at all. Even if we achieve positive interim results in clinical trials, these results do not necessarily predict final results, and positive results in early trials may not be indicative of success in later trials. A number of companies in the medical device industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials.

We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent us from receiving regulatory approval for new products, modification of existing products, or new approved indications for existing products including the following:

- delays in enlisting an adequate number of subjects in clinical trials when competing with other companies;
- enrollment in our clinical trials may be slower than we anticipate, or we may experience high drop-out rates of subjects from our clinical trials, resulting in significant delays;
- the FDA or similar foreign regulatory authorities may find that the product is not sufficiently safe for investigational use in humans;
- officials at the FDA or similar foreign regulatory authorities may interpret data from preclinical testing and clinical trials in different ways than we do;
- there may be delays or failure in obtaining approval of our clinical trial protocols from the FDA or other regulatory authorities;
- there may be delays in obtaining institutional review board approvals or government approvals to conduct clinical trials at prospective sites;
- the FDA or similar foreign regulatory authorities may find our or our suppliers' manufacturing processes or facilities unsatisfactory;
- the FDA or similar foreign regulatory authorities may change their approval policies or adopt new regulations that may negatively affect or delay our ability to bring a product to market or receive approvals or clearances for the treatment of new indications;
- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing or to abandon programs;

- we may experience difficulties in managing multiple clinical sites;
- trial results may not meet the level of statistical significance required by the FDA or other regulatory authorities;
- we may experience delays in reaching agreement on acceptable terms with third party research organizations and trial sites that will conduct the clinical trials; and
- we, or regulators, may suspend or terminate our clinical trials because the participating patients are being exposed to unacceptable health risks.

Failures or perceived failures in our clinical trials will delay and may prevent our product development and regulatory approval process, damage our business prospects and negatively affect our reputation and competitive position.

From time to time we engage outside parties to perform services related to certain of our clinical studies and trials, and any failure of those parties to fulfill their obligations could result in costs and delays.

From time to time we engage consultants and contract research organizations to help design, monitor and analyze the results of certain of our clinical studies and trials. The consultants and contract research organizations we engage interact with clinical investigators to enroll patients in our clinical trials. As a result, we depend on these consultants, contract research organizations and clinical investigators to perform the clinical studies and trials and monitor and analyze data from these studies and trials in accordance with the investigational plan and protocol for the study or trial and in compliance with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting results of clinical studies or trials to assure that the data and results are credible and accurate and the trial participants are adequately protected, as required by the FDA and foreign regulatory authorities. The consultants and contract research organizations are responsible for protecting confidential patient data and complying with U.S. and foreign laws and regulations related to data privacy, including the Health Insurance Portability and Accountability Act. We may face delays in our regulatory approval process if these parties do not perform their obligations in a timely or competent fashion or if we are forced to change service providers. This risk is heightened for our clinical studies and trials conducted outside of the United States, where it may be more difficult to ensure that our studies and trials are conducted in compliance with FDA requirements. Any third parties that we hire to design or monitor and analyze results of our clinical studies and trials may also provide services to our competitors, which could compromise the performance of their obligations to us. If these third parties do not successfully carry out their duties or meet expected deadlines, or if the quality, completeness or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical trial protocols or for other reasons, our clinical studies or trials may be extended, delayed or terminated or may otherwise prove to be unsuccessful, and our development costs will increase. In addition, we may not be able to establish or maintain relationships with these third parties on favorable terms, or at all. If we need to enter into replacement arrangements because a third party is not performing in accordance with our expectations, we may not be able to do so without undue delays or considerable expenditures or at all.

Our regulatory compliance program cannot guarantee that we are in compliance with all potentially applicable U.S. federal and state regulations and all potentially applicable foreign regulations.

The development, manufacturing, distribution, pricing, sales, marketing, import, export and reimbursement of our products, together with our general operations, are subject to extensive federal and state regulation in the United States and in foreign countries, including the new National Physician Payment Transparency Program in the U.S. which requires reporting of payments to physicians beginning in 2013. Congress and certain governmental entities, such as the FDA and Department of Justice, have been increasing their scrutiny of our industry. Although

we have a regulatory compliance program, our employees, our consultants, or our contractors may not be in compliance with all potentially applicable U.S. federal and state laws and regulations or all potentially applicable foreign laws and regulations. If we fail to comply with any of these laws or regulations a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, including withdrawal of our products from the market, significant fines, penalties and/or damages, exclusion from government healthcare programs or other sanctions or litigation.

Compliance with the terms and conditions of our Corporate Integrity Agreement with the Office of Inspector General of the United States Department of Health and Human Services requires significant resources and management time and, if we fail to comply, we could be subject to penalties or, under certain circumstances, excluded from government healthcare programs, which would materially adversely affect our business.

In December 2009, as part of the settlement of a federal investigation of our company, we entered into a five-year corporate integrity agreement (CIA) with the OIG. The CIA provides criteria for establishing and maintaining compliance with various federal laws and regulations governing our clinical investigation related functions, reporting related functions and certain of our promotional and product services related functions. It applies to all of our U.S. subsidiaries and employees and certain of our employees based outside the U.S. Under the CIA, we are required, among other things, to keep in place our current compliance program, to provide specified training to employees, and to retain an independent review organization to perform reviews to assist us in assessing and evaluating our various functions discussed above.

Maintaining the broad array of processes, policies and procedures necessary to comply with the CIA is expected to continue to require a significant portion of management's attention and the application of significant resources. Failure to meet the CIA obligations could have serious consequences for us including stipulated monetary penalties for each instance of noncompliance. In addition, material breaches of the CIA could result in our being excluded from participating in federal healthcare programs, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our products are subject to recalls after receiving FDA or foreign approval or clearance, which would divert managerial and financial resources, harm our reputation, and could adversely affect our business.

We are subject to medical device reporting regulations that require us to report to the FDA or similar foreign governmental authorities if our products cause or contribute to death or serious injury or malfunction in a way that would be reasonably likely to contribute to death or serious injury if the malfunction were to occur. The FDA and similar foreign governmental authorities have the authority to require the recall of our products in the event of any failure to comply with applicable laws and regulations or defects in design or manufacture. A government mandated or voluntary product recall by us could occur as a result of, among other things, component failures, device malfunctions, or other adverse events, such as serious injuries or deaths, or quality-related issues such as manufacturing errors or design or labeling defects. For example, in 2010 our QuickCat product was subject to a voluntary recall that resulted in a $0.3 million charge. Any recalls of any of our products could divert managerial and financial resources, harm our reputation, and could adversely affect our business.

The continuing development of many of our products depends upon us maintaining strong working relationships with physicians.

If we fail to maintain our working relationships with physicians, many of our products may not be developed and marketed in line with the needs and expectations of the professionals who use and support our products, which could cause a decline in our earnings and profitability. The research, development, marketing, and sale of many of our new and improved products is dependent upon our maintaining working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the

development, marketing, and sale of our products. Physicians assist us as researchers, marketing and product consultants, inventors, and public speakers. If we are unable to maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our consolidated earnings, financial condition, and/or cash flows.

Some of our patents have expired and our patents and proprietary rights may be proved invalid or unenforceable, which would enable competitors to copy our products.

We hold patents and licenses to use patented technology, and have pending patent applications. Our patents cover numerous inventions, including general features of the laser system, features of our catheters and other technologies. Our patents periodically expire, including patents that will expire in 2013 and 2014. Our competitors may seek to produce products that include these technologies, which are no longer subject to patent protection, and this increase in competition may negatively affect our business.

The patents we own and license may not be sufficiently broad to protect our technology or to give us any competitive advantage. Our patents could be challenged as invalid, unenforceable, or circumvented by competitors. The issuance of a patent is not conclusive as to its validity or enforceability. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which our products are marketed. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our products or technologies may infringe. Challenges raised in patent infringement litigation may result in determinations that our patents or licensed patents are invalid, unenforceable or otherwise subject to limitations. In such events, third parties may be able to use the discoveries or technologies without paying damages, licensing fees or royalties to us, which could significantly diminish the value of our intellectual property. We could also be adversely affected if any of our licensors terminates our licenses to use patented technology. In addition, the laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States. Any of the foregoing could have a material adverse effect on our business.

We have important sole source suppliers and may be unable to replace them if they stop supplying us.

We purchase certain components of our CVX-300 laser system and select disposable products from several sole source suppliers. We do not have guaranteed commitments from these suppliers, as we order products through purchase orders placed with these suppliers from time to time. While we believe that we could obtain replacement components from alternative suppliers, we may be unable to do so. The loss of any of these suppliers could result in a disruption in our production. Our suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction and environmental factors. In addition, establishing additional or replacement suppliers for these materials may take a substantial period of time, as certain of these suppliers must be approved by regulatory authorities. If we are unable to secure on a timely basis sufficient quantities of the materials we depend on to manufacture our CVX-300 laser systems and disposable products, if we encounter delays or contractual or other difficulties in our relationships with these suppliers, or if we cannot find replacement suppliers at an acceptable cost, then the manufacture of our CVX-300 laser system and disposable products may be disrupted, which could increase our costs and have a material adverse effect on our business.

The amount of our net operating loss carryovers may be limited.

We have net operating loss carryovers (NOLs) that may be used by us to offset against taxable income, if any, for U.S. federal income tax purposes. However, the amount of NOLs that we may use in any year in the U.S. could be limited by Section 382 of the Internal Revenue Code of 1986, as amended, in addition to certain limitations to which we are subject. In general, Section 382 would limit our ability to use NOLs for U.S. federal income tax

purposes in the event of certain changes in ownership of our company. Any limitation of our use of NOLs could (depending on the extent of such limitation and the amount of NOLs previously used) result in us retaining less cash after payment of U.S. federal income taxes during any year in which we have taxable income (rather than losses) than we would be entitled to retain if such NOLs were available as an offset against such income for U.S. federal income tax reporting purposes.

The FDA requires the use of adjunctive balloon angioplasty in coronary procedures performed using our products, which increases the cost of performing these procedures.

The FDA has required that the label for the CVX-300 excimer laser system state that adjunctive balloon angioplasty was performed together with laser atherectomy in the coronary procedures we submitted to the FDA for PMA. This means that our laser system cannot be used alone to treat coronary conditions. Adjunctive balloon angioplasty requires the purchase of a balloon catheter in addition to the laser catheter. The requirement that our coronary procedures be performed together with balloon angioplasty increases the aggregate cost of performing these procedures. As a result, third-party payers may attempt to deny or limit reimbursement, including if they determine that a device used in a procedure was experimental, was used for a non-approved indication or was not used in accordance with established pay protocols regarding cost effective treatment methods. Hospitals that have experienced reimbursement problems or expect to experience reimbursement problems may not acquire or may cease using our laser system and disposable products.

Technological change may result in our products becoming obsolete.

The medical device market is characterized by extensive research and development and rapid technological change. We derive most of our revenue from the sale of our disposable catheters. Technological progress or new developments in our industry could adversely affect sales of our products. Our products could be rendered obsolete as a result of future innovations in the treatment of cardiovascular disease.

We and our component suppliers may not meet regulatory quality standards applicable to our manufacturing processes, which could have an adverse effect on our business, financial condition and results of operations.

As a device manufacturer, we are required to register with the FDA and are subject to periodic inspection by the FDA for compliance with the FDA's Quality System Regulation (QSR) requirements, which require manufacturers of medical devices to adhere to certain good manufacturing practice regulations, including testing, quality control and documentation procedures. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA. Our component suppliers are also required to meet certain standards applicable to their manufacturing processes.

We cannot assure you that we or any of our component suppliers is in compliance or will be able to maintain compliance with all regulatory requirements. The failure by us or one of our component suppliers to achieve or maintain compliance with these requirements or quality standards may disrupt our ability to supply products sufficient to meet demand until compliance is achieved or, in the case of a component supplier, until a new supplier has been identified and evaluated. In addition, our failure to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could harm our business. Furthermore, we cannot assure you that if we find it necessary to engage new suppliers to satisfy our business requirements, then we will be able to locate new suppliers who are in compliance with regulatory requirements. Our failure to do so could have a material adverse effect on our business.

In the European Union, we are required to maintain certain International Organization for Standardization (ISO) certifications in order to sell our products and must undergo periodic inspections by notified bodies, including

the BSi, to obtain and maintain these certifications. If we fail these inspections or fail to meet these regulatory standards, our business could be materially adversely affected.

We do not manufacture the TAPAS catheter, the Quick-Access Needle Holder, or the Quick-Cross Capture Guidewire Retriever, and any interruption in the supply of these products could have an adverse effect on our business, financial condition, and results of operations.

We distribute the TAPAS catheter under a distribution agreement with the manufacturer. The Quick-Access Needle Holder and the Quick-Cross Capture Guidewire Retriever are manufactured for us by a third-party manufacturer. The manufacturers may be unable to deliver an adequate supply of these products in a timely manner, or at all. Such inability by the manufacturers would likely disrupt our ability to supply these products to our customers because we currently do not have a replacement manufacturer. Any interruption in the supply of these products could have an adverse effect on our business, financial condition, and results of operations.

Healthcare cost containment pressures and legislative or administrative reforms resulting in restrictive coverage and reimbursement practices of third-party payers could decrease the demand for our products, the prices that customers are willing to pay for those products and the number of procedures performed using our devices, which could have an adverse effect on our business.

Our products are purchased principally by hospitals and stand-alone peripheral intervention practices, which typically bill various third-party payers, including governmental programs (e.g., Medicare and Medicaid), private insurance plans and managed care plans, for the healthcare services provided to their patients. The ability of our customers to obtain appropriate coverage and reimbursement for our products and services from government and private third-party payers is critical to our success. The availability of coverage and reimbursement affects which products customers purchase and the prices they are willing to pay.

Reimbursement varies from country to country, state to state and plan to plan and can significantly impact the acceptance of new products and services. Certain private third-party payers may view some of the procedures using our products as experimental and may not provide coverage. Third-party payers may not cover and reimburse the procedures using our products in whole or in part in the future or payment rates may not be adequate, or both. Further, the adequacy of coverage and reimbursement by third-party payers is also related to the existence of billing codes to describe procedures that are performed using our products. There are currently a number of billing codes that are used by hospitals and physicians to bill for such procedures. The billing codes currently available may not continue to be recognized by third-party payers for use by our customers.

After we develop new products or seek to market our products for new approved indications, we may find limited demand for the product unless adequate coverage and reimbursement is obtained from government and private third-party payers. Even with reimbursement approval and coverage by government and private payers, providers submitting reimbursement claims may face delay in payment if there is confusion on the part of providers regarding the appropriate codes to use in seeking reimbursement. Such delays may create an unfavorable impression within the marketplace regarding the level of reimbursement or coverage available for our products.

Demand for our products or new approved indications for our existing products may fluctuate over time if federal or state legislative or administrative policy changes affect coverage or reimbursement levels for our products or the services related to our products. In the United States, there have been and we expect there will continue to be a number of legislative and regulatory proposals to change the healthcare system, some of which could significantly affect our business. Legislative or administrative reforms to the U.S. or international reimbursement systems in a manner that significantly reduces reimbursement for procedures using our medical devices or denies coverage for those procedures could have a material adverse effect on our business.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and regulations and, if we are unable to fully comply with such laws, could face substantial penalties.

Our operations may be directly or indirectly affected by various broad federal and state healthcare fraud and abuse laws. Such laws include the federal Anti-Kickback Statute and related state anti-kickback laws, which prohibit any person from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, to induce or reward either the referral of an individual, or the furnishing, purchasing, leasing or ordering of, or arranging for or recommending the furnishing, purchasing, leasing or ordering of an item or service, for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. The federal Stark law and self-referral prohibitions under analogous state laws restrict referrals by physicians and, in some instances, other healthcare providers, practitioners and professionals, to entities with which they have indirect or direct financial relationships for furnishing of designated health services. These healthcare fraud and abuse laws are subject to evolving interpretations by various federal and state enforcement and regulatory authorities. Under current interpretations of the Federal False Claims Act and certain similar state laws, some of these laws also may be subject to enforcement in a qui tam lawsuit brought by a private party "whistleblower," with or without the intervention of the government.

If our operations, including our laser system placement and disposable sales and marketing programs, clinical research and consulting arrangements with physicians are found to be in violation of these laws and not protected under a statutory exception or regulatory safe harbor provision, we, our officers or our employees may be subject to civil or criminal penalties, including large monetary penalties, damages, fines, imprisonment and exclusion from Medicare and other federal healthcare program participation, including the exclusion of our products from use in treatment of Medicare or other federal healthcare program patients. If federal or state investigations or enforcement actions were to occur, our business and financial condition would be harmed.

If we fail to obtain regulatory approvals in other countries for our products, we will not be able to market our products in such countries, which could harm our business.

The requirements governing the conduct of clinical trials and manufacturing and marketing of our products, new products or additional indications for our existing products outside the United States vary widely from country to country. Foreign approvals may take longer to obtain than FDA approvals and can require, among other things, additional testing and different clinical trial designs. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval processes. Some foreign regulatory agencies also must approve the reimbursement policies related to specific products. We have experienced difficulties in the past in obtaining reimbursement approvals for our products in Europe and are currently seeking regulatory and reimbursement approval for certain of our products in Japan. We cannot assure you that this approval will be obtained or that revenue in Japan will increase if this approval is received. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. We may not be able to file for regulatory approvals and may not receive necessary approvals to market our existing products in any foreign country. If we fail to comply with these regulatory requirements or obtain and maintain required approvals in any foreign country, we will not be able to sell our products in that country and our ability to generate revenue could be materially adversely affected.

We are exposed to the risks that come from having international operations.

For the year ended December 31, 2012, our revenue from international operations represented 16% of consolidated revenue, of which 13% of consolidated revenue was generated in Europe, the Middle East and Russia. Changes in overseas political or economic conditions, war or other conflicts, currency exchange rates, foreign laws regulating the approval and sales of medical devices, foreign tax laws or tariffs, other trade regulations or intellectual property protection could adversely affect our ability to market our products outside the United States. In addition, our international operations subject us to the extraterritorial effects of U.S. laws such as the Foreign

Corrupt Practices Act. Any significant changes in the competitive, political, legal, regulatory, reimbursement or economic environment where we will conduct international operations may have a material adverse impact on our business. To the extent we expand our international operations, we expect our sales and expenses denominated in foreign currencies to expand, therefore increasing the risk that we will be adversely affected by fluctuations in currency exchange rates. We currently do not hedge against foreign currency fluctuations, which could result in reduced consolidated revenue or increased operating expenses.

We use both a direct sales organization and distributors for sales of our products throughout most of Europe, the Middle East, the Pacific Rim and Latin America. The sales and marketing efforts on our behalf by international distributors could fail to attain long-term success.

If our manufacturing operations are interrupted for any reason, our results may be adversely affected.

Our ability to manufacture our products may be adversely affected by factors such as a failure to follow specific internal protocols and procedures, equipment malfunction, environmental factors or damage to our facility. In the event of an interruption in manufacturing, we may be unable to quickly move to alternate means of producing affected products or to meet customer demand. In some instances, for example, if the interruption is a result of a failure to follow regulatory protocols and procedures, we may experience delays in resuming production of affected products due primarily to needs for regulatory approvals. As a result, we may suffer loss of market share, which we may be unable to recapture, and harm to our reputation, which could adversely affect our results of operations and financial condition.

Product liability and other claims against us may reduce demand for our products or result in substantial damages.

Our business exposes us to potential liability for risks that may arise from the clinical testing of our unapproved or cleared new products, the clinical testing of expanded indications for existing products, the use of our products by physicians and the manufacture and sale of any approved products. An individual may bring a product liability claim against us, including frivolous lawsuits, if one of our products causes, or merely appears to have caused, an injury. We maintain product liability insurance in the amount of $20 million per occurrence with an annual aggregate maximum of $20 million. We cannot assure, however, that product liability claims will not exceed our insurance coverage limits or that such insurance coverage limits will continue to be available on acceptable terms, or at all. Our insurers may also claim that certain claims are not within the scope of our product liability insurance. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business. Any product liability claim or series of claims or class actions brought against us, with or without merit, could result in:

- liabilities that substantially exceed our insurance levels, which we would then be required to pay from other sources, if available;
- an increase of our product liability insurance rates or the inability to renew or obtain product liability insurance coverage in the future on acceptable terms, or at all;
- withdrawal of clinical trial volunteers or subjects;
- damage to our reputation and the reputation of our products;
- regulatory investigations that could require costly recalls or product modifications;
- litigation costs; and
- diversion of management’s attention from managing our business.

Patients treated with our products often are seriously ill or have pacemaker or ICD leads embedded and surrounded by scar tissue within their chest. Patients treated with our products may suffer from severe infection, peripheral artery disease, coronary artery disease, diabetes, high blood pressure, high cholesterol and other problematic conditions. During procedures or the clinical follow-up subsequent to procedures involving the use of our products, serious adverse events may occur and some patients may die. Serious adverse events or patient deaths involving the use of our products may subject us to product liability litigation, product recalls or limit our ability to grow our revenue, which could have a material adverse impact on our business.

Claims may be made by consumers, healthcare providers or others selling our products. We may be subject to claims against us even if an alleged injury is due to the actions of others. For example, we rely on the expertise of physicians, nurses and other associated medical personnel to perform the medical procedures and related processes relating to our products. If these medical personnel are not properly trained or are negligent in using our products, the therapeutic effect of our products may be diminished or the patient may suffer injury or death, which may subject us to liability. In addition, an injury or death resulting from the activities of our suppliers may serve as a basis for a claim against us. We maintain policies and procedures and require training designed to educate our employees that off-label promotion is illegal. However, we cannot prevent a physician from using our products for any off-label applications. If injury to a patient results from such use, we may become involved in a product liability suit, which may be expensive to defend. Even if we do not become involved in a suit, quality or safety issues could result in reputational harm, warning letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of devices, civil or criminal sanctions, or withdrawal of existing approvals.

Although there is federal preemption for medical devices approved by the FDA under a pre-market approval application that in some situations provides a shield against state tort product liability claims, Supreme Court decisions or federal legislation could reverse the exemption. If this preemption is removed, product liability claims may increase. Moreover, federal preemption for medical devices cleared through the 510(k) process is limited, if it exists at all.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, which could result in substantial costs and liability.

There may be patents and patent applications owned by others relating to laser and fiber-optic or other technologies, which, if determined to be valid and enforceable, may be infringed by us. Holders of certain patents, including holders of patents involving the use of lasers in the body, may contact us and request that we enter into license agreements for the underlying technology and pay them royalties, which could be substantial. We cannot guarantee that other patent holders will not file a lawsuit against us and prevail. If we decide that we need to obtain a license to use any intellectual property, we may be unable to obtain these licenses on favorable terms or at all or we may be required to make substantial royalty or other payments to use this intellectual property. Litigation concerning patents and proprietary rights is time-consuming, expensive, unpredictable and could divert the attention of our management from our business operations. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. An unfavorable outcome in an interference proceeding or patent infringement suit could require us to pay substantial damages, cease using the technology or to license rights, potentially at a substantial cost, from prevailing third parties. There is no guarantee that any prevailing party would offer us a license or that we could acquire any license made available to us on commercially acceptable terms. Even if we are able to obtain rights to a third party's patented intellectual property, those rights may be non-exclusive and therefore our competitors may obtain access to the same intellectual property. Ultimately, we may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business. To the extent we are found to be infringing on the intellectual property of others, we may not be able to develop or otherwise obtain alternative technology. If we need to redesign our products to avoid third party patents, we may suffer significant regulatory delays associated with conducting additional studies or submitting technical, manufacturing or other information related to any

redesigned product and, ultimately, in obtaining regulatory approval. Further, any such redesigns may result in less effective and/or less commercially desirable products.

If we are not able to protect and control unpatented trade secrets, know-how and other proprietary technology, we may suffer competitive harm.

In addition to patented intellectual property, we also rely on trade secrets, unpatented proprietary technology, confidential information and know-how to protect our technology and maintain our competitive position, particularly when we do not believe patent protection is appropriate or obtainable. However, trade secrets and unpatented proprietary technology are difficult to protect. In order to protect proprietary technology and processes, we rely in part on confidentiality and intellectual property assignment agreements with our employees, consultants and others. These agreements may not effectively prevent disclosure of confidential information nor result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements. In addition, others may independently discover trade secrets and proprietary information that have been licensed to us or that we own, and in such case, we could not assert any trade secret rights against such party. Enforcing a claim that a party illegally obtained and is using trade secrets that have been licensed to us or that we own is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets or unpatented proprietary technology. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Environmental and health safety laws may result in liabilities, expenses and restrictions on our operations.

Federal, state, local and foreign laws regarding environmental protection, hazardous substances and human health and safety may adversely affect our business. The use of hazardous substances in our operations exposes us to the risk of accidental injury, contamination or other liability from the use, storage, importation, handling or disposal of hazardous materials. If our or our suppliers' operations result in the contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and fines, and any liability could significantly exceed our insurance coverage and have a material adverse effect on our financial condition. We maintain insurance for certain environmental risks, subject to substantial deductibles; however, we cannot assure you that we will be able to continue to maintain this insurance in the future at an acceptable cost or at all. Future changes to environmental and health and safety laws could cause us to incur additional expenses or restrict our operations.

We depend on attracting, retaining and developing key management, clinical, scientific and sales and marketing personnel, and the loss of these personnel could impair the development and sales of our products.

Our success depends on our continued ability to attract, retain, develop and motivate highly qualified management, clinical, scientific and sales and marketing personnel. We do not have employment agreements with any of our employees, other than our chief executive officer. Their employment with us is "at will," and each employee, other than our chief executive officer, can terminate his or her employment with us at any time. As a condition of employment, our employees sign a confidentiality and trade secrets agreement that precludes them, upon termination of their employment, from recruiting our employees or working for a direct competitor. We also have agreements with several of our officers that provide for the payment of either one year's salary plus bonus or six months' salary plus bonus in the event of separation of the officer's employment in certain circumstances. The agreements also prohibit the officer from competing with us and soliciting our employees and customers in the case of termination of employment. The enforceability of these agreements depends on the circumstances at the time of separation, and the agreements may be difficult to enforce. We do not carry key person insurance covering members of senior management. The competition for qualified personnel in the medical device industry is intense. We will need to hire additional personnel as we continue to expand our development activities and drive sales of our

products. We may not be able to attract, retain and develop quality personnel on acceptable terms given the competition for such personnel.

Consolidation in the healthcare industry could have an adverse effect on our revenues and results of operations.

Many healthcare industry companies, including healthcare systems, are consolidating to create new companies with greater market power. As the healthcare industry consolidates, competition to provide goods and services to industry participants will become more intense. These industry participants may try to use their market power to negotiate price concessions or reductions for medical devices that incorporate components produced by us. If we are forced to reduce our prices because of consolidation in the healthcare industry, our revenues would decrease and our consolidated earnings, financial condition, and/or cash flows would suffer.

An interruption in or breach of security of our information or manufacturing systems, including the occurrence of a cyber incident or a deficiency in our cybersecurity, may result in a loss of business or damage to our reputation.

We rely on communications, information and manufacturing systems to conduct our business. Any failure, interruption or cyber incident of these systems could result in failures or disruptions in our customer relationship management or product manufacturing. A cyber incident is an intentional attack or an unintentional event that can include gaining unauthorized access to information systems to disrupt operations, corrupt data, or steal confidential information. The occurrence of any failures, interruptions or cyber incidents could result in a loss of customer business or reputation and have a material effect on our business, financial condition, results of operations and cash flows.

A U.S. and global economic downturn could adversely affect our operating results, financial condition, or liquidity.

We are subject to risks arising from adverse changes in general domestic and global economic conditions, including recession or economic slowdown and disruption of credit markets. The European sovereign debt crisis has increased concerns about global economic recovery. Over the past several years, the credit and capital markets have experienced extreme volatility and disruption. The strength of the United States and global economy is uncertain, and the United States may experience slowed growth or another recession. Turbulence in the financial markets and general economic uncertainties may make it more difficult and more expensive for hospitals and health systems to obtain credit, which would contribute to pressures on our operating margin, resulting from rising supply costs, reduced investment income and philanthropic giving, increased interest expense, reimbursement pressure, reduced elective healthcare spending and uncompensated care. In such circumstances, we expect many of our customers would continue to scrutinize costs, trim budgets and look for opportunities to further reduce or slow capital spending.

In addition, the potential decline in federal and state revenues that may result from such conditions may create additional pressures to contain or reduce reimbursements for our products from Medicare, Medicaid and other government sponsored programs. Increasing job losses or slow improvement in the unemployment rate in the U.S. has and may continue to result in a smaller percentage of patients being covered by an employer group health plan and a larger percentage being covered by lower paying Medicare and Medicaid programs.

Further, a strengthening of the United States dollar in conjunction with the European sovereign debt crisis or other negative economic event may adversely affect the results of our international operations when those results are translated into United States dollars. Additionally, disruptions in the credit markets could impede our access to capital, which could be further adversely affected if we are unable to maintain our current credit ratings. If we cannot obtain financing, we may need to defer capital expenditures or seek other sources of liquidity, which may not be available to us on acceptable terms if at all. All of these factors related to the global economic situation, which

are beyond our control, could negatively impact our business, results of operations, financial condition, and liquidity.

Our stock price may continue to be volatile.

The market price of our common stock, similar to other medical device companies, has been, and is likely to continue to be, highly volatile. The trading price of our stock varied from a low of $7.04 to a high of $15.45 during 2012. The following factors, among other things, may significantly affect the market price of our common stock:

- actual or anticipated fluctuations in our operating results and the operating results of competitors;
- announcements of technological innovations or new products by us or our competitors;
- results of clinical trials or studies by us or our competitors;
- governmental regulation;
- developments with respect to patents or proprietary rights, including assertions that our products infringe the intellectual property rights of others;
- public concern regarding the safety of products developed by us or others;
- the initiation or cessation in coverage of our common stock, or changes in estimates or recommendations concerning us or our common stock, by securities analysts;
- changes in accounting principles;
- past or future management changes;
- litigation;
- adverse developments in any government inquiry or investigation;
- changes in general market and economic conditions; and
- the possibility of our financing future operations through additional issuances of equity securities, which may result in dilution to existing stockholders.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Following the decrease in our stock price in September 2008 and following the execution of a search warrant related to a government investigation of us and certain of our employees, we became the target of securities litigation. Due to the potential volatility of our stock price, we may be the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business and could require us to make substantial payments to settle those proceedings or satisfy any judgments that may be reached against us.

Protections against unsolicited takeovers in our charter and bylaws may reduce or eliminate our stockholders' ability to resell their shares at a premium over market price.

Our charter and bylaws contain provisions relating to issuance of preferred stock, special meetings of stockholders and advance notification procedures for stockholder proposals that could have the effect of discouraging, delaying or preventing an unsolicited change in the control of Spectranetics. Our board of directors is elected for staggered three-year terms, which prevents stockholders from electing all directors at each annual meeting and may have the effect of discouraging, delaying or preventing a change in control.

We are subject to Section 203 of the Delaware General Corporation law, which in general and subject to exceptions, prohibits a publicly held Delaware corporation from engaging in a "business combination" (as defined in Section 203) with an "interested stockholder" (as defined in Section 203) for a period of three years after the date of the transaction in which the person became an interested stockholder, unless certain conditions are met. Section 203 may discourage, delay or prevent an acquisition of our company even at a price our stockholders may find attractive.

ITEM 1B. *Unresolved Staff Comments*

None.

ITEM 2. *Properties*

All of our domestic operations are currently located in an 80,000 square foot building in Colorado Springs, Colorado. The facility has approximately 17,000 square feet of manufacturing space which contains our manufacturing operations. In 2012, we transferred the manufacturing of the ELCA and SLS product lines to this facility, and expanded the facility by 5,000 square feet. In October 2012, we amended our existing lease and simultaneously entered into a new building lease for 20,000 square feet adjacent to the current headquarters in order to expand our facilities. We anticipate occupying the new facility in the third quarter of 2013. In addition, we are currently expanding the main building for an additional 2,700 square feet. The term of both leases is through September 2023.

In addition to the leased facilities described above, we continue to occupy a building in Colorado Springs, Colorado. This facility, which we purchased in 2005, contains approximately 24,000 square feet of usable space, and currently houses our finished goods inventory and shipping functions.

Spectranetics International B.V. leases 3,337 square feet in Leusden, The Netherlands. The facility houses our operations for the marketing and distribution of products in Europe, and the lease expires June 30, 2014. Spectranetics Deutschland GmbH leases a small office in Germany through July 2015.

With the expansions taking place in 2013, we believe these facilities are adequate to meet our requirements for the foreseeable future.

ITEM 3. *Legal Proceedings*

For a discussion of our legal proceedings, please refer to Note 14, "Commitments and Contingencies," to our consolidated financial statements included in Part IV, Item 15, "Exhibits and Financial Statement Schedules."

ITEM 4. *Mine Safety Disclosures*

Not applicable.

PART II

ITEM 5. *Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities*

Our common stock is traded on the NASDAQ Global Select Market under the symbol "SPNC." The table below sets forth the high and low sales prices for our common stock as reported on the NASDAQ Global Select Market for each calendar quarter in 2012 and 2011. These quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions, and may not necessarily represent the sales prices in actual transactions.

	High	Low
Year Ended December 31, 2011		
1st Quarter	$ 5.37	$ 4.12
2nd Quarter	6.39	4.61
3rd Quarter	7.72	5.16
4th Quarter	8.31	6.30
Year Ended December 31, 2012		
1st Quarter	$ 10.95	$ 7.04
2nd Quarter	11.58	9.25
3rd Quarter	14.76	9.93
4th Quarter	15.45	13.12

Number of Record Holders; Dividends

We have not paid cash dividends on our common stock in the past and do not expect to do so in the foreseeable future. The payment of dividends in the future will be at the discretion of the Board of Directors and will be dependent upon our financial condition, results of operations, capital requirements and such other factors as the Board of Directors deems relevant. Our line of credit with Wells Fargo Bank limits our ability to pay dividends in some circumstances.

The closing sales price of our common stock on March 6, 2013 was $18.56. On March 6, 2013, we had 472 stockholders of record. This number was derived from our stockholder records and does not include beneficial owners of our common stock whose shares are held in the names of various dealers, clearing agencies, banks, brokers, nominees and other fiduciaries.

Recent Sales of Unregistered Equity Securities

During the fourth quarter ended December 31, 2012, 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

We did not repurchase any of our equity securities during the quarter ended December 31, 2012.

Securities Issuable Under Equity Compensation Plans

For a discussion of the securities authorized under our equity compensation plans, see Item 12, "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters," which incorporates by reference the information to be disclosed in our definitive proxy statement for our 2013 Annual Meeting of Stockholders.

ITEM 6. ***Selected Financial Data***

The following selected consolidated financial data, as of and for each year in the five-year period ended December 31, 2012, is derived from our consolidated financial statements. The information set forth below should be read in conjunction with the Management's Discussion and Analysis of Financial Condition and Results of Operations, and the consolidated financial statements and notes thereto included in Part IV, Item 15 in this annual report.

	Year Ended December 31,				
	2012	**2011**	**2010**	**2009**	**2008**
	(in thousands, except per share data)				
STATEMENT OF OPERATIONS DATA:					
Revenue	$ 140,285	$ 127,287	$ 117,917	$ 114,837	$ 104,010
Cost of products sold	37,927	35,723	34,031	33,140	29,389
Selling, general and administrative	82,254	70,502	66,665	68,478	61,150
Research, development and other technology	16,846	17,729	14,900	15,060	13,449
Acquisition-related costs(1)	311	—	—	—	—
Federal investigation legal and accrued indemnification costs(2)	—	(370)	6,798	2,362	2,450
Federal investigation settlement(3)	—	—	—	5,000	—
Settlement costs—license agreement dispute(4)	—	1,821	—	—	—
Litigation charges(5)	—	596	—	1,166	—
Employee termination and lease abandonment costs(6)	—	—	1,630	536	—
Asset impairment charge(7)	—	—	939	—	—
Discontinuation costs-Safe-Cross product line(8)	—	—	—	1,075	—
Purchased in-process research and development(9)	—	—	—	—	3,849
Operating income (loss)	2,947	1,286	(7,046)	(11,980)	(6,277)
Interest income (expense), net(5)	8	(149)	223	410	1,668
Loss on sale of auction rate securities(10)	—	—	—	(540)	—
Other-than-temporary impairment of auction rate securities(11)	—	—	—	(1,100)	—
Other, net	5	(12)	(8)	(37)	(52)
Income (loss) before income taxes	2,960	1,125	(6,831)	(13,247)	(4,661)
Income tax expense (benefit)(12)	734	231	6,232	126	(706)
Net income (loss)	$ 2,226	$ 894	$ (13,063)	$ (13,373)	$ (3,955)
Income (loss) from continuing operations per share:					
Basic	$ 0.06	$ 0.03	$ (0.39)	$ (0.41)	$ (0.12)
Diluted	$ 0.06	$ 0.03	$ (0.39)	$ (0.41)	$ (0.12)
Weighted average common shares outstanding:					
Basic	34,377	33,458	33,091	32,529	31,826
Diluted	35,767	34,370	33,091	32,529	31,826

	As of December 31,				
	2012	2011	2010	2009	2008
	(In thousands)				
BALANCE SHEET DATA:					
Working capital	$ 49,634	$ 41,374	$ 40,512	$ 32,958	$ 32,668
Cash, cash equivalents, and current investment securities available for sale(13)	37,775	39,638	33,662	19,053	20,478
Non-current investment securities(13)	—	—	—	9,800	15,570
Restricted cash	—	—	—	817	1,350
Property and equipment, net	27,006	27,249	28,669	31,475	32,345
Total assets	110,769	109,036	93,695	100,683	107,096
Long-term liabilities	1,879	1,566	598	593	422
Stockholders' equity	88,697	79,510	74,498	84,928	90,984

(1) In the fourth quarter of 2012, we incurred $0.3 million in legal and other costs related to our acquisition of certain products from Upstream Peripheral Technologies Ltd. on January 7, 2013. See Note 15, "Subsequent Event—Acquisition," to our consolidated financial statements included in Part IV, Item 15 of this annual report.

(2) See further discussion of these costs in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in Note 14, "Commitments and Contingencies," to our consolidated financial statements included in Part IV, Item 15 of this annual report.

(3) In 2009, we reached a resolution with the federal government regarding a federal investigation. We entered into a non-prosecution agreement and a civil settlement agreement under which we made a payment of $5.0 million to the federal government, without any admission of wrongdoing.

(4) In the fourth quarter of 2011, we recorded $1.8 million related to the termination of a license agreement with Medtronic, Inc. See further discussion of these costs in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in Note 13, "Settlement costs —license agreement dispute," to our consolidated financial statements included in Part IV, Item 15 of this annual report.

(5) In the third quarter of 2011, the Dutch Court of Appeals issued a ruling in favor of Cardiomedica S.p.A., requiring us to pay to Cardiomedica $0.6 million in damages plus $0.2 million in interest. See further discussion of these costs in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in Note 14, "Commitments and Contingencies," to our consolidated financial statements included in Part IV, Item 15 of this annual report.

For 2009, the $1.2 million included in this line item represent royalties related to a patent license agreement, which was executed and paid in December 2009.

(6) In 2010, we terminated 14 employees, primarily within the Vascular Intervention sales organization, as a result of a strategic re-alignment of certain sales territories designed to improve sales productivity. As a result, we recorded severance obligations totaling $0.7 million in the third quarter of 2010. In addition, in the fourth quarter of 2010, we recorded a charge of $1.0 million related to the retirement of an executive from his positions as chairman, president, and chief executive officer. See further discussion of these costs in "Management's Discussion and Analysis of Financial Condition and Results of Operations."

During 2009, we eliminated certain positions in order to streamline operations. As a result, we recorded severance obligations totaling $0.4 million for year ended December 31, 2009. In addition, we recorded a charge for remaining lease obligations in the amount of $0.1 million for a portion of a leased facility that we no longer utilized.

(7) In the third quarter of 2010, we wrote off a capital project in process that was no longer expected to be completed and utilized due to an EPA ruling which effectively limited the useful life of the asset. See Note 3, “Property and Equipment,” to our consolidated financial statements included in Part IV, Item 15 of this annual report.

(8) In the third quarter of 2009, we discontinued the marketing and sales of the Safe-Cross product line, which we acquired in May 2008. The $1.1 million charge included a patent impairment charge, impairment of long-lived assets, inventory write-offs and remaining contractual obligations to the seller primarily related to inventory purchases.

(9) In-process research and development expense of $3.8 million in 2008 represented amounts related to a development project we acquired as part of an endovascular product line acquisition.

(10) In the fourth quarter of 2009, we sold two of our auction rate securities at 90% and 92% of par, respectively. The amounts recorded represent the realized loss on the sale of these securities, which were recorded on our balance sheet at 90% of par at the date of sale.

(11) In the fourth quarter of 2009, we determined that our remaining auction rate securities were other-than-temporarily impaired, due to a change in our intent to hold such investments until a full recovery of their par value, resulting in an impairment charge of $1.1 million.

(12) Income tax expense for the year ended December 31, 2011 included a tax benefit of $0.5 million resulting from a reduction in the valuation allowance against our deferred tax asset in the Netherlands related to a foreign strategic tax transaction enacted in 2011.

Income tax expense for the year ended December 31, 2010 included an increase in the valuation allowance against our deferred tax asset of $6.1 million, which was recorded in the third quarter of 2010 as a result of management’s assessment of the recoverability of the asset.

(13) We had no investment securities at December 31, 2012 or 2011. Current investment securities at December 31, 2010 included $3.6 million of auction rate securities, which we liquidated in the first quarter of 2011. Non-current investment securities at December 31, 2009 and 2008 included $9.8 million and $15.6 million of auction rate securities, respectively, which were deemed to be illiquid at their respective balance sheet dates.

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

The following discussion should be read in conjunction with our consolidated financial statements and the related notes contained elsewhere in this annual report on Form 10-K and in our other SEC filings. The following discussion may contain forward-looking statements that constitute our expectations or forecasts of future events as of the date this report was filed with the SEC and are not statements of historical fact. You are cautioned not to place undue reliance on these forward-looking statements and to note that they speak only as of the date hereof. Factors that could cause actual results to differ materially from those set forth in the forward-looking statements are set forth in the risk factors listed from time to time in our filings with the SEC as well as those set forth in Item 1A, "Risk Factors." See the introduction to Part I of this annual report.

Corporate Overview

We develop, manufacture, market and distribute single-use medical devices used in minimally invasive procedures within the cardiovascular system. Our products are used to access and treat arterial blockages in the legs and heart and to remove pacemaker and defibrillator cardiac leads. During the year ended December 31, 2012, approximately 66% of our disposable product revenue was from products used in connection with our proprietary excimer laser system, the CVX-300®. Our single-use laser catheters contain up to 250 small diameter, flexible optical fibers that can access difficult to reach peripheral and coronary anatomy and produce evenly distributed laser energy at the tip of the catheter for more uniform ablation. Our excimer laser system is the only laser system approved in the United States, Europe, Japan and Canada for use in multiple minimally invasive cardiovascular procedures.

For an overview of our business, market opportunities, products and clinical trials, please see Part I, Item I, "Business" to this annual report on Form 10-K.

Results of Operations

Revenue by Product Line

	2012		2011		2010	
	(in thousands)					
Disposable products:						
Vascular Intervention	$ 67,336	48%	$ 62,264	49%	$ 60,224	51%
Lead Management	55,186	39	46,480	37	41,162	35
Total disposable products	122,522	87	108,744	85	101,386	86
Service and other revenue	10,439	7	10,122	8	9,380	8
Laser equipment	7,324	5	8,421	7	7,151	6
Total revenue	$ 140,285	100%	$ 127,287	100%	$ 117,917	100%

Percentage amounts may not add due to rounding.

Financial Results by Geographical Segment

Our two operating segments consist of United States Medical, which includes the United States and Canada, and International Medical, which includes Europe, the Middle East, Asia Pacific, Latin America and Puerto Rico. United States Medical also includes all costs for our corporate headquarters, research and development, and corporate administrative functions. The International Medical segment is engaged primarily in distribution activities, with no local manufacturing or product development functions. For the years ended December 31, 2012, 2011 and 2010, a portion of research and development and general and administrative costs incurred in the U.S. has been allocated to International Medical based on a percentage of revenue, because these costs support our ability to generate revenue in the international segment.

	Year Ended December 31,					
	2012		2011		2010	
	(in thousands)					
Revenue						
United States	$ 117,436	84%	$ 105,933	83%	$ 101,008	86%
International	22,849	16	21,354	17	16,909	14
Total revenue	$ 140,285	100%	$ 127,287	100%	$ 117,917	100%

	Year Ended December 31,		
	2012	2011	2010
	(in thousands)		
Operating income (loss)			
United States	$ 1,037	$ 647	$ (7,006)
International	1,910	639	(40)
Total operating income (loss)	$ 2,947	$ 1,286	$ (7,046)

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Year Ended December 31, 2012 Compared with Year Ended December 31, 2011

Selected Consolidated Statements of Comprehensive Income Data

The following tables present Consolidated Statements of Comprehensive Income data for the years ended December 31, 2012 and December 31, 2011 based on the percentage of revenue for each line item, as well as the dollar and percentage change of each of the items.

	For the year ended December 31,					
(in thousands, except for percentages)	2012	% of revenue (1)	2011	% of revenue (1)	$ change	% change
Revenue						
Disposable products revenue:						
Vascular intervention	$ 67,336	48%	$ 62,264	49 %	$ 5,072	8 %
Lead management	55,186	39	46,480	37	8,706	19
Total disposable products revenue	122,522	87	108,744	85	13,778	13
Service and other revenue	10,439	7	10,122	8	317	3
Laser revenue:						
Equipment sales	2,682	2	3,269	3	(587)	(18)
Rental fees	4,642	3	5,152	4	(510)	(10)
Total laser revenue	7,324	5	8,421	7	(1,097)	(13)
Total revenue	**140,285**	100	**127,287**	100	**12,998**	10
Gross profit	102,358	73	91,564	72	10,794	12
Operating expenses						
Selling, general and administrative	82,254	59	70,502	55	11,752	17
Research, development and other technology	16,846	12	17,729	14	(883)	(5)
Acquisition-related costs	311	—	—	—	311	nm
Federal investigation legal and accrued indemnification costs	—	—	(370)	—	370	nm
Settlement costs—license agreement dispute	—	—	1,821	1	(1,821)	nm
Litigation charge	—	—	596	—	(596)	nm
Total operating expenses	**99,411**	71	**90,278**	71	**9,133**	10
Operating income	**2,947**	2	**1,286**	1	**1,661**	129
Other income (expense)	13	—	(161)	—	174	(108)
Income before income taxes	**2,960**	2	**1,125**	1	**1,835**	163
Income tax expense	734	1	231	—	503	218
Net income	**$ 2,226**	2%	**$ 894**	1 %	**$ 1,332**	149 %

(1) Percentage amounts may not add due to rounding.
nm = not meaningful.

Revenue and gross margin

Revenue for the year ended December 31, 2012 was $140.3 million, an increase of 10% as compared with $127.3 million for the year ended December 31, 2011. On a constant currency basis, total revenue increased 11% compared with the previous year (see the "Non-GAAP Financial Measures" section below for a discussion of our use of the constant currency financial measure). All of the $13.0 million revenue increase was in disposables product revenue, partially offset by a 4% decrease in laser and service revenue. This resulted in a slight change in our product mix year-over-year, with disposable products generating 87% of revenue in 2012 compared with 85% in 2011. Service and other revenue decreased to 7% of total revenue in 2012 compared with 8% in 2011. Revenue from laser equipment sales and rentals decreased to 5% of total revenue in 2012 compared with 7% in 2011.

Vascular Intervention (VI) revenue, which includes products used in both the peripheral and coronary vascular systems, increased 8% (9% on a constant currency basis) in 2012 compared with 2011.

VI sales include three product categories: peripheral atherectomy, which increased 15%; crossing solutions, which increased 2%; and coronary atherectomy and thrombus management, which decreased 12%, all compared with 2011. Increased peripheral atherectomy product sales were primarily related to higher sales to office based physician clinics in the U.S., which provide increased access for patients at a potentially lower cost to the healthcare system. In addition, we believe that our peripheral artery disease (PAD) awareness program contributed to the 18% increase in U.S. peripheral atherectomy sales. The growth in crossing solutions product sales was due to increased unit volumes despite a larger number of competitors. Coronary atherectomy and thrombus management are not currently a strategic priority for us, which is reflected in the decrease in revenue. In addition, our QuickCat™ product faced pricing pressures due to increased competition, and we have made the decision to discontinue sale of our ThromCat ® product, which totaled $0.5 million for the year ended December 31, 2012.

Lead Management (LM) revenue, which includes excimer laser sheaths and cardiac lead management accessories for the removal of pacemaker and defibrillator cardiac leads, grew 19% (20% on a constant currency basis) in 2012 as compared with 2011. In the second quarter of 2012, we initiated a launch of GlideLight, our next generation lead extraction tool, and by year-end approximately 50% of our customers had been converted from its predecessor, the SLS II. Approximately two-thirds of the increase in LM revenue related to the SLS II/GlideLight lead extraction laser sheaths was attributable to increased volumes; the remaining one-third was due to the higher average selling price of GlideLight compared to the SLS II. We believe the volume increases are primarily a result of an expanding market for lead extractions due to increasing infection rates and increased indications for lead extraction set forth by the Heart Rhythm Society. We believe clinical data, including results from the four-year Lead Extraction in Contemporary Settings (LExICon) study published in February 2010, supports the safety and efficacy of removing pacemaker and defibrillator leads. In addition, we received reimbursement approval in Japan for the LLD ® lead locking device in April 2011, which allowed us to make available our complete lead management system in Japan.

Service and other revenue increased 3%, to $10.4 million in 2012 from $10.1 million in 2011, due primarily to our increased installed base of laser systems.

Laser equipment revenue decreased to $7.3 million in 2012 from $8.4 million in 2011. Equipment sales revenue, which is included in laser equipment revenue, decreased 18% as compared with 2011. We sold 19 laser systems in 2012 compared with 29 in 2011. Rental revenue decreased 10% in 2012 as compared with the prior year, primarily because higher disposables purchases by certain customers under volume-based rental agreements led to lower rent due.

We placed 125 laser systems with new customers during 2012 compared with 129 during the prior year. Of those new laser placements in 2012, 70 laser systems were direct transfers from the existing installed base or were deployments of remanufactured lasers from our factory compared with 60 transfers/remanufactured systems in 2011.

The new placements brought our worldwide installed base of laser systems to 1,066 (799 in the U.S.) at December 31, 2012, compared to 1,011 (770 in the U.S.) at December 31, 2011.

On a geographic basis, revenue in the U.S. was $117.4 million in 2012, an increase of 11% from the prior year. International revenue was $22.8 million, an increase of 7% from 2011 and an increase of 13% on a constant currency basis. The increase in international revenue was primarily due to an increase in international LM revenue and crossing solutions revenue, primarily in Europe and Japan.

Gross margin in 2012 was 73% compared with 72% in 2011 and 71% in 2010. The increase was due to a combination of changes in product mix, improved pricing from our GlideLight product, improved manufacturing efficiencies and higher production volumes. Our net revenue increase over the prior year was due to increased disposable product revenue, which carries a significantly higher gross margin percentage than laser equipment or service revenue.

Operating expenses

Operating expenses were $99.4 million in 2012, an increase of 10% from $90.3 million in 2011. Operating expenses represented 71% of total revenue in both 2012 and 2011. Operating expenses in 2012 included $0.3 million of acquisition-related costs and in 2011 included $2.0 million of litigation and settlement costs which are separately disclosed components within operating expenses in our statement of comprehensive income (loss), further described below.

Selling, general and administrative. Selling, general and administrative (SG&A) expenses increased 17% compared with 2011. As a percentage of revenue, SG&A expenses increased to 59% of revenue in 2012 compared with 55% in 2011.

Within SG&A, marketing and selling expenses increased $8.1 million, or 15%, year-over-year, due primarily to the following:

- A $5.1 million increase in VI and LM marketing expense, primarily due to (1) the hiring of PAD awareness managers in selected VI sales territories, whose objective is to increase awareness of PAD in the communities they serve, (2) the expansion of our marketing capabilities to include strategy and product portfolio management and (3) costs associated with the launch of the GlideLight lead extraction laser sheath and increased marketing and physician training events.

- A $3.0 million increase in VI, LM and international field sales expense, primarily due to increased incentive compensation on higher revenue and additional field sales positions.

Also within SG&A, general and administrative expenses increased $3.6 million, or 24%, with increased personnel expenses primarily due to the hiring of our chief executive officer in August 2011 and other senior executives in 2011 and 2012, an increase in stock compensation expense, an increase in outside consulting costs associated with regulatory compliance and an increase in company-wide performance-based incentive compensation expense tied to achievement of goals established at the beginning of the year.

Research, development and other technology. Research, development and other technology expenses of $16.8 million in 2012 decreased $0.9 million, or 5%, from $17.7 million in 2011. As a percentage of revenue, research, development and other technology expenses decreased to 12% of revenue in 2012 from 14% of revenue in 2011. Costs included within research, development and other technology expenses are product development costs, clinical studies costs and royalty costs associated with various license agreements with third-party licensors. We expect these expenses to increase as a percentage of revenue in 2013 as we increase headcount and otherwise expand our overall product development activities. Fluctuations in these costs were as follows:

- Royalty expenses decreased by $1.4 million compared with 2011 due to the termination of a royalty agreement in the first quarter of 2012, slightly offset by increases in ongoing royalties paid based on increased sales of products incorporating licensed technology;

- Product development costs decreased by $0.8 million compared with 2011 due to a temporary decrease in project activity, as project teams transitioned from completed projects to new projects; and

- Clinical studies costs increased by approximately $1.3 million compared with 2011 primarily due to costs related to the EXCITE ISR trial.

Acquisition-related costs. In the fourth quarter of 2012, we incurred $0.3 million in legal and other costs related to our acquisition of products from Upstream Peripheral Technologies Ltd. on January 7, 2013. The base purchase price of the acquisition was $5.5 million with additional future milestone payments based on product and manufacturing transfer and one-third of revenues for 2014, 2015 and 2016. We expect the Upstream acquisition will be accounted for as a business combination and we will record the assets acquired and the estimated future contingent consideration at their respective fair values as of the acquisition date during the first quarter of 2013. In 2013 and beyond, we expect to incur additional intangible asset amortization and contingent consideration expense (accretion of the contingent consideration liability) related to the products acquired, which we estimate in the range of $1.6 million - $2.0 million in 2013. See Note 15, “Subsequent Event—Acquisition,” of the consolidated financial statements included in Part IV, Item 15 of this annual report for further discussion of this matter.

Federal investigation legal and accrued indemnification costs. In the fourth quarter of 2011, we recorded a $0.4 million reduction in our accrual for indemnification costs to reflect a change in our estimate of the range of our contingent liability for indemnification obligations we have to three former employees related to a federal investigation. See Note 14, “Commitments and Contingencies,” of the consolidated financial statements included in Part IV, Item 15 of this annual report for further discussion of this matter.

Settlement costs—license agreement dispute. In the fourth quarter of 2011, we recorded a $1.8 million charge related to the termination of a license agreement which was executed in January 2012. Royalty expenses paid or accrued under the license agreement for the year ended December 31, 2011 were approximately $1.5 million; royalty expenses were not incurred subsequent to the effective date of the termination agreement. See Note 13, “Settlement costs—license agreement dispute,” of the consolidated financial statements included in Part IV, Item 15 of this report for further discussion of this matter.

Litigation charge. We were engaged in a dispute since 1999 with Cardiomedica. In 2009, a Dutch court issued a ruling in favor of Cardiomedica, requiring us to pay $0.6 million, which ruling Cardiomedica appealed. In September 2011, the Dutch Court of Appeals issued a ruling in favor of Cardiomedica, requiring us to pay to Cardiomedica an additional $0.6 million in damages plus $0.2 million in interest. We paid and expensed this amount in September 2011.

Other income (expense). In 2011, other expense included litigation related interest expense of $0.2 million. As discussed above, in September 2011, the Dutch Court of Appeals issued a ruling in favor of Cardiomedica, requiring us to pay to Cardiomedica $0.6 million for lost profits plus $0.2 million in interest. We paid and expensed this amount in September 2011. Other items within other income (expense) include interest income and foreign currency transaction gains and losses. Realized gains and losses on foreign currency transactions are primarily due to the cash settlement in dollars of intercompany transactions with our Dutch subsidiary, whose functional currency is the euro.

Income before income taxes

Pre-tax income for the year ended December 31, 2012 was $3.0 million, compared with pre-tax income of $1.1 million for the year ended December 31, 2011. The current year results included $0.3 million of acquisition related costs, and the prior year results included $2.0 million of litigation and settlement costs, as described above.

Income tax expense

We recorded income tax expense of $0.7 million in 2012, which included approximately $0.3 million of currently payable income tax expense in foreign jurisdictions and $0.1 million of state income taxes currently payable for the year ended December 31, 2012. Additionally, we recorded deferred federal and state tax expense of $0.3 million representing a deferred tax liability related to the difference between book and tax accounting for our goodwill, which is amortized over 15 years for tax purposes but not amortized for book purposes. We continue to maintain a valuation allowance for substantially all of our deferred tax assets including our U.S. net operating losses, and therefore we did not incur current U.S. federal tax expense against our pretax income during the year ended December 31, 2012.

Our ability to realize the benefit of our deferred tax assets will depend on the generation of future taxable income through profitable operations. Due to our history of losses and the lack of sufficient certainty of generating future taxable income, we have recorded a full valuation allowance against our deferred tax assets, as we continue to believe there is sufficient uncertainty surrounding the realization of our U.S. deferred tax assets through future taxable income. We will continue to assess the need for a valuation allowance in future periods. In the event there is a change in circumstances in the future which would affect the utilization of our deferred tax assets, the tax provision in that period would be adjusted by the amount of the assets then deemed to be realizable. We do not expect to reduce the valuation allowance against our U.S. deferred tax assets to below 100% of its gross amount until we have a sufficient historical trend of taxable income and can predict future income with a higher degree of certainty. Because we continue to maintain a full valuation allowance against our deferred tax assets, our effective tax rate is currently lower than it would be if there were no valuation allowance.

See Note 10, “Income Taxes,” to our consolidated financial statements included in Part IV, Item 15 of this annual report for further discussion of our income tax provision.

Net income

We recorded net income for the year ended December 31, 2012 of $2.2 million, or $0.06 per fully diluted share, compared with net income of $0.9 million, or $0.03 per fully diluted share, for the year ended December 31, 2011.

Functional currency

The functional currency of Spectranetics International B.V., Spectranetics Deutschland GmbH and Spectranetics Austria GmbH is the euro. All revenue and expenses are translated to U.S. dollars in the consolidated statements of operations using weighted average exchange rates during the year. Fluctuations in currency rates during the year ended December 31, 2012 as compared with the year ended December 31, 2011 caused a decrease in consolidated revenue of approximately $1.2 million and a decrease in consolidated net income of approximately $0.5 million.

Year Ended December 31, 2011 Compared with Year Ended December 31, 2010

Selected Consolidated Statements of Comprehensive Income (Loss) Data

The following tables present Consolidated Statements of Comprehensive Income (Loss) data for the years ended December 31, 2011 and December 31, 2010 based on the percentage of revenue for each line item, as well as the dollar and percentage change of each of the items.

	For the year ended December 31,					
(in thousands, except for percentages)	2011	% of rev(1)	2010	% of rev(1)	$ change	% change
Revenue						
Disposable products revenue:						
Vascular intervention	$ 62,264	49 %	$ 60,224	51 %	$ 2,040	3 %
Lead management	46,480	37	41,162	35	5,318	13
Total disposable products revenue	108,744	85	101,386	86	7,358	7
Service and other revenue	10,122	8	9,380	8	742	8
Laser revenue:						
Equipment sales	3,269	3	1,937	2	1,332	69
Rental fees	5,152	4	5,214	4	(62)	(1)
Total laser revenue	8,421	7	7,151	6	1,270	18
Total revenue	**127,287**	100	**117,917**	100	**9,370**	8
Gross profit	91,564	72	83,886	71	7,678	9
Operating expenses						
Selling, general and administrative	70,502	55	66,665	57	3,837	6
Research, development and other technology	17,729	14	14,900	13	2,829	19
Federal investigation legal and accrued indemnification costs	(370)	—	6,798	6	(7,168)	(105)
Settlement costs—license agreement dispute	1,821	1	—	—	1,821	nm
Litigation charge	596	—	—	—	596	nm
Employee termination costs	—	—	1,630	1	(1,630)	nm
Asset impairment charge	—	—	939	1	(939)	nm
Total operating expenses	**90,278**	71	**90,932**	77	**(654)**	(1)
Operating income (loss)	**1,286**	1	**(7,046)**	(6)	**8,332**	nm
Other income (expense)	(161)	—	215	—	(376)	nm
Income (loss) before income taxes	**1,125**	1	**(6,831)**	(6)	**7,956**	nm
Income tax expense	231	—	6,232	5	(6,001)	nm
Net income (loss)	**$ 894**	1 %	**$ (13,063)**	(11)%	**$ 13,957**	nm

(1) Percentage amounts may not add due to rounding.
nm = not meaningful.

Revenue and gross margin

Revenue for the year ended December 31, 2011 was $127.3 million, an increase of 8% as compared with $117.9 million for the year ended December 31, 2010. Of the $9.4 million revenue increase, approximately 80% was in disposables product revenue and 20% was in laser and service revenue. This resulted in a slight change in our product mix year-over-year, with disposables products generating 85% of revenue in 2011 compared with 86% in 2010. Service and other revenue remained stable at 8% of total revenue in both years. Revenue from laser equipment sales and rentals increased to 7% of total revenue in 2011 compared with 6% in 2010.

VI revenue increased 3% in 2011 compared with 2010. VI sales include three product categories: peripheral atherectomy, which increased 4%; crossing solutions, which were flat year-over-year; and coronary atherectomy and thrombus management, which increased 9%, all compared with 2010. Increased peripheral atherectomy product sales were primarily related to higher sales to stand-alone physician clinics, which provide increased access for patients at a potentially lower cost to the healthcare system. Crossing solutions product sales were flat year-over-year, in spite of increased competition. The increase in coronary atherectomy and thrombus management revenue was primarily due to increased coronary atherectomy product sales, due primarily to increased use of our products within existing accounts, partially offset by a reduction in sales of the ThromCat ® XT catheter in Europe, due to a greater focus on products with higher sales volumes.

LM revenue grew 13% in 2011 as compared with 2010. We believe our LM revenue continues to increase primarily as a result of an expanding market for lead extractions due to increasing infection rates and increased indications for lead extraction set forth by the Heart Rhythm Society. We believe clinical data, including results from the four-year LExICon study published in February 2010, supports the safety and efficacy of removing pacemaker and defibrillator leads. In addition, we received reimbursement approval in Japan for the LLD ® lead locking device in April 2011, which allowed us to make available our complete lead management system in Japan. This resulted in a significant increase in LM revenue in Japan.

Service and other revenue increased 8%, to $10.1 million in 2011 from $9.4 million in 2010, due primarily to our increased installed base of laser systems.

Laser equipment revenue increased to $8.4 million in 2011 from $7.2 million in 2010. Equipment sales revenue, which is included in laser equipment revenue, increased 69% from 2010. We sold 29 laser systems in 2011 compared with 14 in 2010. Rental revenue decreased 1% in 2011 as compared with the prior year, with increased revenue from straight rentals offset by a decrease in Cap-Free (fee per procedure) revenue.

We placed 129 laser systems with new customers during 2011 compared with 78 during the prior year. Of those new laser placements, 60 laser systems were transfers from the existing installed base in 2011 compared with 38 transfers in 2010. In recent quarters, we have placed more focus on redeploying laser systems from hospitals with low laser-based catheter utilization to hospitals or offices where we believe utilization will be higher, in order to increase productivity per laser system. The new placements brought our worldwide installed base of laser systems to 1,011 (770 in the U.S.) at December 31, 2011, compared to 942 (726 in the U.S.) at December 31, 2010.

On a geographic basis, revenue in the United States was $105.9 million in 2011, an increase of 5% from the prior year. International revenue was $21.4 million, an increase of 26% from 2010. The increase in international revenue was due to increases in both VI and LM disposables and laser equipment revenue. We recorded nine international laser system sales in 2011 compared with six laser system sales in 2010. Fluctuations in foreign exchange rates also contributed $0.9 million to the 2011 revenue increase compared with 2010.

Gross margin in 2011 was 72% compared with 71% in 2010. The increase was due to a combination of changes in product mix and improved manufacturing efficiencies. Our revenue increase in 2011 included a higher percentage of laser disposables, which carry higher gross margins than non-laser catheters, as compared with the prior year. Margins can fluctuate based on a number of factors, including manufacturing efficiencies and product mix.

Operating expenses

Operating expenses were $90.3 million in 2011, a decrease of 1% from $90.9 million in 2010. Operating expenses represented 71% of total revenue in 2011 as compared with 77% of total revenue in 2010. Operating expenses in 2011 and 2010 included a number of items which are separately disclosed components within operating expenses in our statement of operations. In 2011, these items totaled $2.0 million, compared with $9.4 million in 2010, and they are further described below.

Selling, general and administrative. Selling, general and administrative (SG&A) expenses increased 6% in 2011 compared with 2010. As a percentage of revenue, SG&A expenses decreased to 55% of revenue in 2011 compared with 57% in 2010.

Within SG&A, marketing and selling expenses increased $3.3 million, or 6%, year-over-year, due primarily to the following:

- a $1.9 million increase in VI and LM marketing expense, due to new hires and increased marketing and training events,
- a $1.4 million increase in international sales expense due in part to new hires, increased performance-based incentive compensation and a $0.5 million impact of foreign currency fluctuations.

Also within SG&A, general and administrative expenses increased $0.5 million, or 4%, year-over-year, with increases in company-wide performance-based incentive compensation expense partially offset by a decrease in outside consulting costs associated with regulatory compliance.

Research, development and other technology. Research, development and other technology expenses were approximately $17.7 million in 2011, an increase of 19% from $14.9 million in 2010. As a percentage of revenue, research, development and other technology costs increased to 14% of revenue in 2011 from 13% of revenue in 2010, due to our investments primarily in new product development projects and the EXCITE ISR clinical trial. Costs included in research, development and other technology expenses are product development costs, clinical studies costs and royalty costs associated with various license agreements with third-party licensors. Fluctuations in these costs were as follows:

- Product development and related regulatory costs increased approximately $1.3 million compared with 2010 due to an increase in headcount and in materials expenses related to new product development projects;
- Clinical studies expense increased by approximately $1.1 million due primarily to costs associated with the EXCITE ISR clinical trial; and
- Royalty expenses increased by approximately $0.3 million due to higher sales of products incorporating technology that we license.

Federal investigation legal and accrued indemnification costs. In the third quarter of 2010, we recorded a $6.5 million charge to accrue the low end of our estimate of the range of our contingent liability for indemnification

obligations we had to three former employees who were indicted on charges related to a federal investigation. In addition, in 2010, we had $0.3 million of legal costs associated with the federal investigation. In the fourth quarter of 2011, we recorded a $0.4 million reduction in our accrual for indemnification costs to reflect a change in our estimate. We estimated that our total costs in these matters would total approximately $6.1 million as compared with the original $6.5 million estimate. The $0.4 million adjustment to our accrual reduced the remaining liability as of December 31, 2011 to approximately $2.9 million, which was paid during 2012. The actual expenses may be higher or lower than the estimate depending upon final resolution of the proceedings. Factors that may cause us to increase the accrual include but are not limited to the success or failure of an appeal, and in particular, a successful appeal that results in the order of a new trial. See Note 14, "Commitments and Contingencies," of the consolidated financial statements included in Part IV, Item 15 of this annual report for further discussion of this matter.

Settlement costs—license agreement dispute. In the fourth quarter of 2011, we recorded a $1.8 million charge related to the termination of a license agreement because the underlying cause of the dispute and likelihood of a settlement to resolve such dispute existed as of December 31, 2011. In January 2012, we terminated a license agreement, dated February 1997, with Medtronic, Inc. In 2011, the parties disputed whether royalties were owed under the license agreement. Under a termination agreement, we paid Medtronic $3.0 million in January 2012 in settlement of all obligations under the license agreement, and neither party has any further rights or obligations under the license agreement. We had accrued royalty expenses in the amount of $1.2 million prior to the termination settlement; therefore, we recorded the $1.8 million charge as settlement costs—license agreement dispute in our financial statements for the quarter ended December 31, 2011. See Note 13, "Settlement costs—license agreement dispute," of the consolidated financial statements included in Part IV, Item 15 of this report for further discussion of this matter.

Litigation charge. We were engaged in a dispute since 1999 with Cardiomedica. In 2009, a Dutch court issued a ruling in favor of Cardiomedica, requiring us to pay $0.6 million, which ruling Cardiomedica appealed. In September 2011, the Dutch Court of Appeals issued a ruling in favor of Cardiomedica, requiring us to pay to Cardiomedica an additional $0.6 million in damages plus $0.2 million in interest. We paid and expensed this amount in September 2011.

Employee termination costs. In the third quarter of 2010, we terminated 14 employees, primarily within the Vascular Intervention sales organization, as a result of a strategic re-alignment of certain sales territories designed to improve sales productivity. As a result, we recorded severance obligations totaling $0.7 million in the third quarter of 2010. Effective November 1, 2010, an executive retired from his positions as chairman, president, and chief executive officer. In connection with his retirement and release of claims, we paid the executive $0.5 million, equal to one-year's salary, which was the amount payable under his employment agreement in connection with termination of his employment. In addition, outstanding stock options held by the executive to purchase 140,279 shares of our common stock became fully vested in accordance with their terms, resulting in non-cash stock compensation expense of $0.4 million. These amounts, along with certain health insurance premiums, were recorded in the three months ended December 31, 2010.

Asset impairment charge. In the third quarter of 2010, we wrote off a capital project in process that was no longer expected to be completed and used, due to an EPA ruling that effectively limited the useful life of the asset.

Other income (expense). In 2011, other expense included litigation related interest expense of $0.2 million. As discussed above, in September 2011, the Dutch Court of Appeals issued a ruling in favor of Cardiomedica, requiring us to pay to Cardiomedica $0.6 million for lost profits plus $0.2 million in interest. We paid and expensed this amount in September 2011. Other items within other income (expense) include interest income and foreign currency transaction gains and losses. Realized gains and losses on foreign currency transactions are primarily due to the cash settlement in dollars of intercompany transactions with our Dutch subsidiary, whose functional currency is the euro.

Income (loss) before income taxes

Pre-tax income for the year ended December 31, 2011 was $1.1 million, compared with a pre-tax loss of $(6.8) million for the year ended December 31, 2010. The current year results included $2.0 million of litigation and settlement costs, and the prior year results included $9.4 million of litigation costs and impairment charges, as described above.

Income tax expense

We recorded income tax expense of $0.2 million in 2011. This was primarily the result of taxes currently payable in state and foreign jurisdictions as well as deferred tax expense arising from net deferred tax liabilities after consideration of the substantial valuation allowance against our deferred tax assets. Income tax expense in 2011 included approximately $0.4 million of income tax expense in foreign jurisdictions and $0.1 million of state income taxes currently payable for the year ended December 31, 2011. Additionally, we recorded deferred federal and state tax expense of $0.2 million representing a deferred tax liability related to the difference between book and tax accounting for our goodwill, which is amortized over 15 years for tax purposes but not amortized for book purposes.

The remainder of our tax NOLs in the Netherlands expired unutilized at the end of 2011. However, prior to expiration we entered into a strategic tax transaction with the approval of the Dutch tax authority which allowed Spectranetics International B.V. (BV) to sell its assets including goodwill to a newly created subsidiary of BV. The transaction allowed BV to offset the gain from the sale of the assets with a portion of its NOL prior to expiration. The new subsidiary will be allowed to amortize the tax-basis goodwill over ten years for tax purposes. We therefore recorded a $0.5 million tax benefit in the fourth quarter of 2011 representing our estimate of the actual utilization of the extended tax deduction in future years.

In 2010, we increased our valuation allowance against our U.S. deferred tax asset to 100%. The effect of the valuation allowance adjustment was to increase our provision for income taxes by $6.1 million for the year ended December 31, 2010. Events in 2010, primarily the third quarter 2010 indictment of former employees, the related $6.5 million accrual for indemnification costs for these employees, and the possibility that such costs could exceed the estimated accrual, caused us to conclude that we no longer met the accounting criteria for recognizing a portion of our deferred tax asset. Income tax expense also included approximately $142,000 comprised of state and foreign income taxes payable for the year ended December 31, 2010.

Net income (loss)

We recorded net income for the year ended December 31, 2011 of $0.9 million, or $0.03 per fully diluted share, compared with a net loss of $(13.1) million, or $(0.39) per share, for the year ended December 31, 2010.

Functional currency

The functional currency of Spectranetics International B.V., Spectranetics Deutschland GmbH and Spectranetics Austria GmbH is the euro. All revenue and expenses are translated to U.S. dollars in the consolidated statements of operations using weighted average exchange rates during the year. Fluctuations in currency rates during the year ended December 31, 2011 as compared with the year ended December 31, 2010 caused an increase in consolidated revenue of approximately $0.9 million and an increase in consolidated net income of approximately $0.4 million.

Liquidity and Capital Resources

As of December 31, 2012, we had cash and cash equivalents of $37.8 million, representing a decrease of $1.9 million from $39.6 million at December 31, 2011. During 2012, we had the following significant uses of cash: (i) $7.7 million of milestone payments to Kensey Nash Corporation (KNC) in connection with a 2008 acquisition, recorded as goodwill, (ii) a $3.0 million payment in settlement of all obligations under a terminated license agreement, which was accrued as of December 31, 2011, and (iii) approximately $3.2 million of payments of our accrued indemnification obligations to former employees. These items were non-recurring payments.

During the first quarter of 2013, we paid $6.5 million in the acquisition of certain products from Upstream Peripheral Technologies Ltd. We anticipate an additional milestone payment of $0.5 million in the third or fourth quarter of 2013. In addition, we are also required to pay Upstream one-third of revenues of the acquired products for 2014, 2015 and 2016. See further discussion of this matter in Note 15, "Subsequent event—acquisition," to our consolidated financial statements included in Part IV, Item 15 of this annual report.

We believe that our cash and cash equivalents, anticipated funds from operations and other sources of liquidity will be sufficient to meet our liquidity requirements for the foreseeable future based on our expected level of operations. However, we may need or seek additional funding earlier than anticipated. In the event that we require additional working capital to fund future operations and any future acquisitions, we may access available borrowings under our revolving line of credit with Wells Fargo Bank described below. We may also sell shares of our common stock or other equity securities, enter into credit and financing arrangements with one or more independent institutional lenders, or sell debt securities. A financing transaction may not be available on terms acceptable to us, or at all, and a financing transaction may be dilutive to our current stockholders.

Operating Activities. For the year ended December 31, 2012, cash provided by operating activities was $5.2 million, compared to $6.7 million for the year ended December 31, 2011. The primary sources and uses of cash were the following:

(1) Our net income of $2.2 million included approximately $13.5 million of non-cash expenses. Non-cash expenses included $9.9 million of depreciation and amortization, $3.1 million of stock-based compensation, $0.2 million of provision for excess and obsolete inventories, and a net change in deferred taxes of $0.4 million.

(2) Cash used as a result of a net increase in operating assets and liabilities of approximately $10.6 million was due primarily to the following:

- An increase in equipment held for rental or loan of $6.1 million as a result of continued placement of our laser systems through our rental and evaluation programs;
- The payment of $3.2 million of accrued indemnification costs;
- The payment of $3.0 million in settlement of all obligations under a terminated license agreement, which was accrued as of December 31, 2011;
- An increase in trade accounts receivable of approximately $1.8 million, due primarily to higher revenue in the latter half of the fourth quarter of 2012 as compared to the latter half of the fourth quarter of 2011; and
- An increase in inventory of $0.9 million, due primarily to increases in sales volumes.

These uses of cash were partially offset by an increase in accounts payable and accrued liabilities of $4.4 million, due primarily to an increase in accrued commissions and performance-based incentive compensation, an increase in other accrued operating expenses and the timing of vendor payments.

The table below presents the change in receivables and inventory in relative terms, through the presentation of financial ratios. Days sales outstanding are calculated by dividing the ending accounts receivable balance, net of allowances for sales returns and doubtful accounts, by the average daily sales for the quarter. Inventory turns are calculated by dividing annualized cost of sales for the quarter by ending inventory.

	December 31, 2012	December 31, 2011
Days Sales Outstanding	49	50
Inventory Turns	4.2	4.1

Investing Activities. For the year ended December 31, 2012, cash used in investing activities was $10.8 million, consisting of $7.7 million of payments to KNC recorded as additional goodwill and capital expenditures of $3.1 million, compared to $2.7 million for the year ended December 31, 2011. The capital expenditures included manufacturing equipment upgrades and replacements and additional capital items for research and development projects and additional computer equipment and software purchases.

Financing Activities. Cash provided by financing activities for the year ended December 31, 2012 was $3.8 million, comprised entirely of proceeds from the sale of common stock to employees, former employees and directors as a result of exercises of stock options and stock issuance under our employee stock purchase plan. This compares to cash provided by financing activities of $1.9 million for the year ended December 31, 2011.

At December 31, 2012 and 2011, we had no significant debt or capital lease obligations.

Line of Credit

In February 2011, we entered into a Credit and Security Agreement (Credit Agreement) with Wells Fargo Bank, National Association (Wells Fargo), acting through its Wells Fargo Business Credit operating division, for a three-year $15.0 million revolving line of credit. Pursuant to the terms of the Credit Agreement, we may borrow under the revolving line of credit subject to borrowing base limitations. These limitations allow us to borrow, subject to specified reserves, up to 85% of eligible domestic accounts receivable, defined as receivables aged less than 90 days from the invoice date along with specific exclusions for contra-accounts, concentrations, and other accounts otherwise deemed ineligible by Wells Fargo Business Credit. Borrowings under the revolving line bear interest at a variable rate equal to the lesser of the Wells Fargo prime rate plus 0.25% or the daily three month LIBOR plus 3.25%, or 3.5% at December 31, 2012. The margins on the base interest rates are subject to reduction if we achieve certain annual net income levels. Accrued interest on any outstanding balance under the revolving line is payable monthly in arrears. Our borrowing base, which represents the amount we can borrow under the revolving line of credit, was $10.8 million as of December 31, 2012.

The revolving line of credit is secured by a first priority security interest in substantially all of our assets. The Credit Agreement requires us to maintain a minimum of $10.0 million cash and investments at Wells Fargo and requires a lockbox arrangement. We are required to pay customary fees with respect to the facility, including a 0.25% fee on the average unused portion of the revolving line. If there are borrowings under the revolving line of credit, we will be subject to certain financial covenants including rolling 12-month adjusted EBITDA and minimum book net worth covenants.

The Credit 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 continuation of an event of default, amounts due under the Credit Agreement may be accelerated.

As of the date of this report, we had no borrowings under the revolving line of credit and there were no borrowings under the revolving line of credit during 2012.

Capital Resources

During the years ended December 31, 2012 and 2011, we purchased approximately $3.1 million and $2.7 million, respectively, of property and equipment for cash. During 2012 and 2011, we also invested approximately $6.1 million and $6.0 million, respectively, in laser equipment held for rental or loan under our rental and evaluation programs. These amounts are included in cash flows from operating activities. We expect to fund any capital expenditures in 2013 from cash and cash equivalents.

Contractual Obligations

We lease office space, furniture, vehicles and equipment under noncancelable operating leases with initial terms that expire at various dates through 2023. Purchase obligations consist of purchase orders issued primarily for inventory. Royalty obligations represent the minimum royalties due under license agreements. Clinical trial clinical research organization (CRO) obligations represent contractual monthly payments for services performed and milestone payments to our third-party CRO for the EXCITE ISR trial. The future minimum payments under noncancelable operating leases, purchase obligations, royalty obligations and clinical trial CRO obligations as of December 31, 2012 were as follows (in thousands):

	Total	One Year or Less	2-3 Years	4-5 Years	More Than 5 Years
Operating Leases	$ 16,453	$ 1,471	$ 3,311	$ 2,860	$ 8,811
Purchase Obligations	9,482	9,482	—	—	—
Royalty Obligations	6,220	740	1,480	1,480	2,520
Clinical trial CRO Obligations	2,099	1,035	1,064	—	—
Total	$ 34,254	$ 12,728	$ 5,855	$ 4,340	$ 11,331

We also have a contractual obligation to pay contingent consideration consisting of one-third of revenues for 2014, 2015 and 2016 of the products acquired from Upstream Peripheral Technologies, Ltd. in January 2013. See further discussion of this matter in Note 15, “Subsequent event—acquisition,” to our consolidated financial statements included in Part IV, Item 15 of this annual report.

Off-Balance Sheet Arrangements

We do not maintain any off-balance sheet arrangements in addition to operating leases that have, or that are reasonably likely to have, a material current or future effect on our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Healthcare Reform in the U.S.

The Patient Protection and Affordable Care Act includes a 2.3% excise tax on a majority of our U.S. sales, which took effect on January 1, 2013. The medical device excise tax will be included in operating expenses and will have a material effect on our financial position, results of operations and cash flows beginning in the first quarter of 2013. We estimate the impact of the medical device excise tax to be approximately $2.5 million in 2013.

Critical Accounting Policies and Estimates

We prepare our consolidated financial statements in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP). Our most significant accounting policies are described in Note 1 to our consolidated financial statements included in Part IV, Item 15 of this annual report. Below is a discussion of our critical accounting policies and their impact on the preparation of our consolidated financial statements.

Use of Estimates. We are required to make certain estimates, judgments and assumptions that we believe are reasonable based upon the information available. These estimates and assumptions affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the periods presented. On an ongoing basis, we evaluate our estimates and judgments, including those relating to the carrying amount of property and equipment, goodwill and intangible assets; allowances for receivables, inventories and deferred income tax assets; stock-based compensation expense; accrued indemnification costs; estimated clinical trial expenses; accrued estimates for incurred but not reported claims under partially self-insured employee health benefit programs; and loss contingencies, including those related to litigation. We base our estimates and judgments on historical experience and on various other factors we believe to be reasonable under the circumstances. These judgments and estimates form the basis for the carrying values of certain assets and liabilities that are not objectively available from other sources. Actual results could differ from those estimates, and the carrying values of these assets and liabilities may differ under different assumptions or conditions.

Revenue Recognition. 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. Revenue from the sale of our disposable products is recognized when products are shipped to the customer and title transfers. In general, customers do not have a right of return for credit or refund. However, we allow returns under certain circumstances and record an allowance for sales returns based on an analysis of revenue transactions and historical experience of sales returns and price adjustments. The allowance for sales returns is recorded as a reduction of revenue based on our estimates. Actual sales returns may vary depending on customer inventory levels, new product introductions and other factors. Revenue from the sale of excimer laser systems is recognized after completion of contractual obligations, which generally include delivery and installation of the systems. Our field service engineers are responsible for installation of each laser. We generally provide a one-year warranty on laser sales, which includes parts, labor and replacement gas. Upon expiration of the warranty period, we offer similar service to our customers under service contracts or on a fee-for-service basis. We recognize revenue from fee-for-service arrangements upon completion of the related service.

We account for service provided during the one-year warranty or service contract period as a separate unit of accounting in accordance with U.S. GAAP. As such, we defer the fair value of this service and recognize it as revenue on a straight-line basis over the related warranty or service contract period and warranty and service costs are expensed in the period they are incurred. Revenue allocated to the laser element is recognized upon completion of all contractual obligations in the sales contract, which generally include delivery and installation of the laser system.

In addition to the sale of laser systems, we also offer laser system placement programs, including flat-rate rentals and variable (depending on catheter purchases) rentals for which we invoice the customer and recognize revenue on a monthly basis. We also offer a “Cap-Free” program under which the customer does not pay a rental fee, but agrees to a catheter price list that includes a per-unit surcharge. We recognize the total surcharge as rental revenue upon shipment of the catheters, believing it to be the best measurement of revenue associated with the customers’ use of the laser system each month. Under the laser system placement programs, the laser system is transferred to the equipment held for rental or loan account upon shipment, and the depreciation expense related to the system is included in cost of revenue based upon a five year expected life of the laser system. Costs to maintain the equipment are expensed as incurred.

We sell to end-users in the United States and internationally as well as to certain international distributors. Sales to international distributors represented approximately 6% of our total revenue in 2012. Distributor agreements are in place with each distributor, which outline the significant terms of the transactions between the distributor and us. The terms and conditions of sales to our international distributors do not differ materially from the terms and conditions of sales to our domestic and international end-user customers. Sales to distributors are recognized either at shipment or a later date in accordance with the agreed upon contract terms with distributors, provided that we have received an order, the price is fixed or determinable, collectibility of the resulting receivable is reasonably assured, all contractual obligations have been met and we can reasonably estimate returns. We provide products to our distributors at agreed wholesale prices and do not typically provide any special right of return or exchange, discounts, significant sales incentives, price protection or stock rotation rights to any of our distributors.

Allowance for Doubtful Accounts. We use judgment in estimating the allowance for doubtful accounts based upon an aging of accounts receivable, historical experience and the overall quality of the receivables. We review individual accounts receivable balances for collectibility. Account balances are charged off against the allowance after all means of collection have been exhausted and the potential for recovery is remote. We believe our estimates regarding the collectibility of our accounts receivable are reasonable; however, if the financial condition of our customers were to deteriorate, significant additional allowances could be required.

Inventory Reserves. We calculate an inventory reserve for estimated obsolescence or excess inventory based on historical usage and sales, as well as assumptions about future demand for our products. We review and update our estimates for excess and obsolete inventory on a quarterly basis. The estimates we use for product demand are consistent with our sales forecasts and are also used for near-term production planning and inventory purchasing. Increases in the inventory reserves result in a corresponding expense which is generally recorded to cost of goods sold. We believe that our estimates for obsolete and excess inventory are reasonable based on facts in existence at the time of estimation. However, other factors, such as future product introductions, the introduction of competing technologies or changes in market demand, may require additional reserves, which could have a material effect on gross margins in any given period.

Royalty Liability. We license certain patents from various licensors pursuant to license agreements. Royalty expense is calculated pursuant to the terms of the license agreements and is included in research, development and other technology in the accompanying consolidated financial statements. We have established liabilities for royalty payment obligations based on these calculations, which may involve management estimates that require judgment. Although we believe the estimates to be reasonable based on facts in existence at the time of estimation, the estimates are subject to change based on changes in the underlying facts and assumptions used to develop these estimates.

Stock-based compensation. We measure all employee stock-based compensation awards using a fair value method and record such expense in our consolidated financial statements. We estimate the fair value of stock option awards on the date of grant using either the Black-Scholes options pricing model or a trinomial lattice model, both of which require management's estimates and assumptions regarding a number of complex and subjective variables including volatility, expected term of the options, and other inputs. In recognizing stock-based compensation expense, we also estimate future forfeitures based on historical forfeiture data. 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 and prior periods 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. Stock-based compensation expense recognized for the years ended December 31, 2012, 2011 and 2010 was $3.1 million, $2.5 million and $3.0 million, respectively.

Income Taxes. We account for income taxes using the asset and liability method of accounting for deferred income taxes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to

differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, operating losses and tax credit carryforwards. A valuation allowance is provided to the extent it is more likely than not that a deferred tax asset will not be realized. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. In 2012 and 2011, we maintained a valuation allowance for substantially all of our deferred tax assets including our U.S. net operating losses, due to the uncertainty about the realization of our U.S. deferred tax assets. See further discussion of our valuation allowance above under "Results of Operations."

Goodwill and Other Intangible Assets. Goodwill represents the excess of costs over the fair value of the identifiable net assets of businesses acquired. Goodwill and intangible assets acquired in a business combination and determined to have indefinite useful lives are not amortized, but instead tested for impairment at least annually and whenever events or circumstances indicate the carrying amount of the asset may not be recoverable. Management must use significant estimates and assumptions in evaluating whether or not impairment of goodwill and other intangible assets has occurred. Significant changes in these estimates and management's assumptions may reduce the carrying amount of these intangible assets.

Clinical Trial Costs. We sponsor clinical trials intended to obtain the necessary clinical data required to obtain approval from the FDA and other foreign regulatory agencies to market new applications for our technology. Costs associated with these clinical trials totaled $4.2 million, $3.0 million and $1.8 million during the years ended December 31, 2012, 2011, and 2010, respectively.

It is our policy to expense research and development costs as incurred. In certain cases, substantial portions of our clinical trials are performed by third-party CROs. These CROs generally bill monthly for services performed and additionally bill based upon milestone achievement. Milestone-based CRO fees are amortized to research and development expense over the period of time the contracted services required to earn milestone payments are performed, based upon the number of patients enrolled, "patient months" incurred and the duration of the study. We monitor patient enrollment, the progress of clinical studies and related activities through internal reviews of data reported to us by the CROs and correspondence with the CROs. Our estimates depend on the timeliness and accuracy of the data provided by the CROs regarding the status of the program and total program spending. We periodically evaluate our estimates to determine if adjustments are necessary or appropriate based on information we receive. If we have incomplete or inaccurate data, we may under- or over-estimate activity levels associated with clinical trials at a given point in time. In this event, we could record adjustments to research and development expenses in future periods when the actual activity level becomes known. Although we believe our estimates are reasonable based on facts in existence at the time of estimation, these facts are subject to change and our expenses in this area could fluctuate in future periods.

Medical Self-insurance Costs. Starting in October 2011, we are partially self-insured for certain claims relating to employee medical and dental benefit programs. The medical self-insurance program is administered by a third party and contains stop-loss provisions on both an individual claim basis and in the aggregate. We record claims incurred as an expense each period, including an estimate of claims incurred but not yet reported which is revised quarterly. We use claims data and historical experience, as applicable, to estimate liabilities for claims incurred but not yet reported. We believe that our self-insurance program accruals are adequate to cover future claims. Historical trends, however, may not be indicative of future claims, and revised estimates could significantly affect future expenses.

New Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2011-05 Comprehensive Income, which amended guidance for presenting comprehensive income. The

amendment requires us to present the components of net income and comprehensive income either as one continuous statement or as two consecutive statements. There is no longer the option to present items of other comprehensive income in the statement of stockholders' equity. The amended guidance was effective for us beginning January 1, 2012 on a retrospective basis, and we have elected to present the components of net income and comprehensive income as one continuous statement.

In July 2012, the FASB issued ASU 2012-02 Intangibles—Goodwill and Other, which updated guidance on the periodic testing of indefinite-lived intangible assets for impairment. This guidance will allow companies to assess qualitative factors to determine if it is more-likely-than-not that an indefinite-lived intangible asset might be impaired and whether it is necessary to perform the quantitative impairment test required under current accounting standards. This guidance will be effective for us for the year ending December 31, 2013, with early adoption permitted. The adoption of this guidance will not have an effect on our financial position, results of operations or cash flows.

In February 2013, the FASB issued ASU 2013-02, *Comprehensive Income: Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income*, which requires an entity to report the effect of significant reclassifications out of accumulated other comprehensive income either on the face of the statement where net income is presented, or as a separate disclosure in the notes to the financial statements. The new disclosure requirements are prospective and will be effective for our fiscal year ending December 31, 2013, with early adoption permitted. This update only requires additional disclosures, as such, the adoption of this standard will not have a material impact on our financial position, results of operations or cash flows, and the adoption of this guidance will not materially change the presentation of our consolidated financial statements.

We have considered all other recently issued accounting pronouncements and do not believe that such pronouncements are of significance, or potential significance, to us.

Non-GAAP Financial Measures

To supplement our consolidated financial statements prepared in accordance with U.S. GAAP, we use certain non-GAAP financial measures in this report. Reconciliations of these non-GAAP financial measures to the most directly comparable U.S. GAAP measures for the respective periods can be found in the tables below. An explanation of the manner in which our management uses these non-GAAP measures to conduct and evaluate our business and the reasons why management believes that these non-GAAP measures provide useful information to investors is provided following the reconciliation tables.

Reconciliation of revenue by geography to non-GAAP revenue by geography
on a constant currency basis
(000's, except percentages)
(unaudited)

	Year Ended					
	December 31, 2012			December 31, 2011	Change	
	Revenue, as reported	Foreign exchange impact as compared to prior period	Revenue on a constant currency basis	Revenue, as reported	As reported	Constant currency basis
United States	$ 117,436	$ —	$ 117,436	$ 105,933	11%	11%
International	22,849	1,227	24,076	21,354	7%	13%
Total revenue	$ 140,285	$ 1,227	$ 141,512	$ 127,287	10%	11%

Reconciliation of revenue by product line to non-GAAP revenue by product line
on a constant currency basis
(000's, except percentages)
(unaudited)

	Year Ended					
	December 31, 2012			December 31, 2011	Change	
	Revenue, as reported	Foreign exchange impact as compared to prior period	Revenue on a constant currency basis	Revenue, as reported	As reported	Constant currency basis
Vascular Intervention	$ 67,336	$ 533	$ 67,869	$ 62,264	8 %	9 %
Lead Management	55,186	588	55,774	46,480	19 %	20 %
Laser Equipment, Service & Other	17,763	106	17,869	18,543	(4)%	(4)%
Total revenue	$ 140,285	$ 1,227	$ 141,512	$ 127,287	10 %	11 %

The impact of foreign exchange rates is highly variable and difficult to predict. We use a constant currency basis to show the impact from foreign exchange rates on current period revenue compared to prior period revenue using the prior period's foreign exchange rates. In order to properly understand the underlying business trends and

performance of our ongoing operations, we believe that investors may find it useful to consider the impact of excluding changes in foreign exchange rates from our revenue.

We believe that presenting the non-GAAP financial measures used in this report provides investors greater transparency to the information used by our management for financial and operational decision-making and allows investors to see our results "through the eyes" of management. We also believe that providing this information better enables our investors to understand our operating performance and evaluate the methodology used by management to evaluate and measure such performance.

Non-GAAP financial measures have limitations as analytical tools and should not be considered in isolation or as a substitute for our financial results prepared in accordance with U.S. GAAP. For example, revenue growth rates stated on a constant currency basis, by their nature, exclude the impact of foreign exchange, which may have a material impact on U.S. GAAP revenue. Non-GAAP financial measures are not based on any comprehensive set of accounting rules or principles and therefore other companies may calculate similarly titled non-GAAP financial measures differently than we do, limiting the usefulness of those measures for comparative purposes.

ITEM 7A. *Quantitative and Qualitative Disclosure About Market Risk*

We are exposed to a variety of risks, primarily including foreign currency fluctuations. Our exposure to foreign currency fluctuations is primarily related to sales of our products in Europe, which are denominated primarily in the euro. Changes in the exchange rate between the euro and the U.S. dollar could adversely affect our revenue and net income. Exposure to foreign currency exchange rate risk may increase over time as our business evolves and our products continue to be introduced into international markets. Currently, we do not hedge against any foreign currencies and, as a result, we could incur gains or losses. Fluctuation in currency rates during the year ended December 31, 2012 as compared with the year ended December 31, 2011 caused a decrease in consolidated revenue of approximately $1.2 million and a decrease in consolidated net income of approximately $0.5 million.

Based on our overall foreign currency exchange rate exposure as of December 31, 2012, a 10% appreciation or depreciation of the U.S. dollar would have had a positive or negative impact on our consolidated revenue for the year ended December 31, 2012 of approximately $1.6 million.

The current macroeconomic environment is highly volatile, and continuing instability in global markets, including the ongoing turmoil in Europe related to sovereign debt issues and the stability of the euro, has contributed to a global economic downturn. During the year ended December 31, 2012, 13% of our revenue was generated in Europe. The ongoing financial crisis in the eurozone could impact our revenues and indirect credit exposure to certain of those governments through their public hospitals. We are actively monitoring the situations in these countries.

ITEM 8. *Financial Statements and Supplementary Data*

See the Index to Consolidated Financial Statements appearing in Part IV, Item 15 on page F-1 of this Annual Report.

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

None.

ITEM 9A. ***Controls and Procedures***

We maintain disclosure controls and procedures that are designed to ensure 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 such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Exchange Act Rule 13a-15(b), we carried out an evaluation, under the supervision of and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2012. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2012.

There has been no change in our internal control over financial reporting during the fiscal quarter ended December 31, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

Our management, including our Chief Executive Officer and Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our internal controls were designed to provide reasonable assurance as to the reliability of our financial reporting and the preparation and presentation of our consolidated financial statements for external purposes in accordance with accounting principles generally accepted in the United States and 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 our assets; (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 our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Management has used the framework set forth in the report entitled *Internal Control-Integrated Framework* published by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our internal control over financial reporting. Management has concluded that our internal control over financial reporting was effective as of December 31, 2012. KPMG LLP, an independent registered public accounting firm, has audited our accompanying consolidated financial statements and our internal control over financial reporting. The report of the independent registered public accounting firm is included in this Annual Report on Form 10-K.

ITEM 9B. ***Other Information***

None.

PART III

ITEM 10. ***Directors, Executive Officers and Corporate Governance***

The information required by Item 10 is incorporated by reference from the registrant's definitive Proxy Statement to be used in connection with its 2013 Annual Meeting of Stockholders, which will be filed within 120 days from December 31, 2012.

ITEM 11. ***Executive Compensation***

The information required by Item 11 is incorporated by reference from the registrant's definitive Proxy Statement to be used in connection with its 2013 Annual Meeting of Stockholders, which will be filed within 120 days from December 31, 2012.

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

The information required by Item 12 is incorporated by reference from the registrant's definitive Proxy Statement to be used in connection with its 2013 Annual Meeting of Stockholders, which will be filed within 120 days from December 31, 2012.

ITEM 13. ***Certain Relationships and Related Transactions, and Director Independence***

The information required by Item 13 is incorporated by reference from the registrant's definitive Proxy Statement to be used in connection with its 2013 Annual Meeting of Stockholders, which will be filed within 120 days from December 31, 2012.

ITEM 14. ***Principal Accountant Fees and Services***

The information required by Item 14 is incorporated by reference from the registrant's definitive Proxy Statement to be used in connection with its 2013 Annual Meeting of Stockholders, which will be filed within 120 days from December 31, 2012.

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Glossary of Terms

Ablation is the removal, break down or dissolution of tissue with an energy-based device, including a laser.

Angiography is a medical imaging technique in which an X-ray image is taken to visualize the inside or lumen of blood vessels and organs of the body.

Angioplasty is the repair or reconstruction of blood vessels damaged by disease or injury, often performed by inflating a balloon within the vessel lumen at the site of narrowing to reconstitute flow.

Atherectomy is a non-surgical procedure to open blocked coronary arteries or vein grafts by using a device on the end of a catheter to ablate, cut or shave away atherosclerotic plaque (a deposit of fat and other substances that accumulate in the lining of the artery wall).

Atherosclerosis is a disease of the arteries characterized by the deposition of plaques of fatty material on their inner walls.

Brachytherapy is a type of radiation treatment for cancer in which the source of the radiation is applied directly to the surface of the body.

A **catheter** is a tube-like instrument used to access a body cavity; in angioplasty, a catheter provides access to the artery for the delivery of a balloon or stent.

Claudication is cramping or pain in a leg caused by poor blood circulation.

A **coronary artery** is an artery of the heart that supplies oxygenated blood.

An **embolus** is a mass, such as an air bubble, a detached blood clot, or a foreign body, that travels through the bloodstream and lodges so as to obstruct or occlude a blood vessel.

Endovascular relates to a surgical procedure in which a catheter containing medications or miniature instruments is inserted into a blood vessel for the treatment of vascular disease.

The **superficial femoral artery (SFA)** is the chief artery of the thigh.

The **iliac** artery is situated near the **ilium**, the uppermost and widest of the three bones constituting either of the lateral halves of the pelvis.

An **implantable cardioverter defibrillator, or ICD**, is an electronic device to treat life-threatening heartbeat irregularities that is surgically implanted.

Infrainguinal means occurring below the groin. For example, **'infrainguinal arteries'** commonly means arteries in the legs.

The **infrapopliteal artery** is comprised of the **anterior tibial (AT), posterior tibial (PT)** and **peroneal,** which are the chief arteries below the knee.

Ischemia is an insufficient supply of blood to an organ, usually due to a blocked artery.

A **lead** is a wire or catheter that conducts energy between an implanted device and the body.

A **lesion** is a blockage in a blood vessel that is interrupting blood flow to the heart, often due to plaque; also called stenosis.

Lumen is the cavity or hollow space inside a blood vessel.

Myocardial infarction is the death of a portion of the heart muscle tissue due to a blockage or interruption in the supply of blood to the heart muscle.

Percutaneous means performed through the skin.

Peripheral arterial disease, or PAD, is characterized by clogged or obstructed arteries in the legs. The resulting lack of blood flow can cause leg pain and lead to tissue loss or amputation.

The **popliteal artery** is the chief artery of the knee.

Retrograde is insertion of the sheath toward the heart or head. In the groin or femoral artery, retrograde is the most common. In peripheral cases, this enables the physician to insert the sheath up toward the heart then over the iliac artery to treat the other leg.

Revascularization is a surgical procedure for the provision of a new, additional, or augmented blood supply to a body part or organ.

Occlusion is a blockage in a blood vessel.

Restenosis is the renarrowing of an artery in the same location of a previous treatment; clinical restenosis is the manifestation of an ischemic event, usually in the form of recurrent angina.

Stenosis is the narrowing of a blood vessel.

A **stent** is a tiny mesh cylinder that expands within a blood vessel and props open a previously clogged artery.

Thrombectomy is the removal of a thrombus from a blood vessel to restore circulation to the affected part.

Thrombosis is the formation of blood clots in arteries that can lead to myocardial infarction or death.

A **thrombus** is a stationary blood clot along the wall of a blood vessel, frequently causing vascular obstruction.

PART IV

ITEM 15. *Exhibits and Financial Statement Schedules*

(a) *Documents Filed as a Part of The Report*

(1) Consolidated Financial Statements

See Index to Consolidated Financial Statements on page F-1 of this Form 10-K.

(2) Financial Statement Schedules

Schedule II—Valuation and Qualifying Accounts is included within the Consolidated Financial Statements. All other schedules are omitted because the required information is inapplicable.

(3) Exhibits

See Exhibit Index immediately following the Consolidated Financial Statements.

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, in the City of Colorado Springs, State of Colorado, on this 13th day of March, 2013.

THE SPECTRANETICS CORPORATION

By: /s/ SCOTT DRAKE
Scott Drake
President and Chief Executive 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 in the capacities and on the date indicated.

Signature	Title	Date
/s/ SCOTT DRAKE Scott Drake	Director, President and Chief Executive Officer (Principal Executive Officer)	March 13, 2013
/s/ GUY A. CHILDS Guy A. Childs	Chief Financial Officer (Principal Financial and Accounting Officer)	March 13, 2013
/s/ ANNE MELISSA DOWLING Anne Melissa Dowling	Director	March 13, 2013
/s/ R. JOHN FLETCHER R. John Fletcher	Director and Chairman of the Board of Directors	March 13, 2013
/s/ WILLIAM C. JENNINGS William C. Jennings	Director	March 13, 2013
/s/ B. KRISTINE JOHNSON B. Kristine Johnson	Director	March 13, 2013
/s/ DANIEL A. PELAK Daniel A. Pelak	Director	March 13, 2013
/s/ JOSEPH M. RUGGIO, M.D. Joseph M. Ruggio, M.D.	Director	March 13, 2013
/s/ MARIA SAINZ Maria Sainz	Director	March 13, 2013
/s/ CRAIG M. WALKER, M.D. Craig M. Walker, M.D.	Director	March 13, 2013

THE SPECTRANETICS CORPORATION
AND SUBSIDIARIES

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

The Board of Directors
The Spectranetics Corporation:

We have audited the accompanying consolidated balance sheet of The Spectranetics Corporation and subsidiaries (the Company) as of December 31, 2012, and the related consolidated statements of comprehensive income (loss), stockholders' equity, and cash flows for the year ended December 31, 2012. In connection with our audit of the consolidated financial statements, we also have audited financial statement schedule II for the year ended December 31, 2012. We also have audited the Company's internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these consolidated financial statements and financial statement schedule, 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 Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule, and an opinion on the Company's internal control over financial reporting 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audit of the consolidated financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2012, and the results of its operations and its cash flows for the year ended December 31, 2012, 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 consolidated financial statements taken as a whole, present fairly, in all material respects, the information set forth therein for the year ended December 31, 2012. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control - Integrated Framework* issued by the COSO.

/s/ KPMG LLP

Denver, Colorado
March 13, 2013

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
The Spectranetics Corporation
Denver, Colorado

We have audited the accompanying consolidated balance sheet of The Spectranetics Corporation and Subsidiaries (the "Company") as of December 31, 2011, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2011. Our audits also included the financial statement schedule II for the years ended December 31, 2011 and 2010. The Company's management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements 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 consolidated financial statements are free of material misstatement. Our audits of the consolidated financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinions.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of The Spectranetics Corporation and Subsidiaries as of December 31, 2011, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2011, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the related consolidated financial statement schedule II for the years ended December 31, 2011 and 2010, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ EKSH LLLP

March 15, 2012
Denver, Colorado

THE SPECTRANETICS CORPORATION
AND SUBSIDIARIES

Consolidated Balance Sheets
December 31, 2012 and 2011

	2012	2011
	(In thousands, except share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 37,775	$ 39,638
Trade accounts receivable, less allowance for doubtful accounts and sales returns of $589 and $602, respectively	19,945	18,123
Inventories, net	9,288	8,542
Deferred income taxes, current portion, net	313	610
Prepaid expenses and other current assets	2,506	2,421
Total current assets	69,827	69,334
Property and equipment, net	27,006	27,249
Goodwill	13,296	11,569
Other intangible assets, net	20	111
Other assets	620	773
Total assets	$ 110,769	$ 109,036
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,996	$ 1,521
Accrued liabilities	16,001	24,256
Deferred revenue	2,196	2,183
Total current liabilities	20,193	27,960
Accrued liabilities, net of current portion	991	706
Deferred income taxes, noncurrent portion, net	888	860
Total liabilities	22,072	29,526
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Preferred stock, $0.001 par value. Authorized 5,000,000 shares; none issued	—	—
Common stock, $0.001 par value. Authorized 60,000,000 shares; issued and outstanding 34,887,763 and 33,957,408 shares, respectively	35	34
Additional paid-in capital	183,140	176,277
Accumulated other comprehensive loss	(618)	(715)
Accumulated deficit	(93,860)	(96,086)
Total stockholders' equity	88,697	79,510
Total liabilities and stockholders' equity	$ 110,769	$ 109,036

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

THE SPECTRANETICS CORPORATION
AND SUBSIDIARIES

Consolidated Statements of Comprehensive Income (Loss)
Years ended December 31, 2012, 2011 and 2010

	2012	2011	2010
	(in thousands, except share and per share amounts)		
Revenue	$ 140,285	$ 127,287	$ 117,917
Cost of products sold	37,927	35,723	34,031
Gross profit	102,358	91,564	83,886
Operating expenses:			
Selling, general and administrative	82,254	70,502	66,665
Research, development and other technology	16,846	17,729	14,900
Acquisition related costs	311	—	—
Settlement costs—license agreement dispute	—	1,821	—
Litigation charge	—	596	—
Federal investigation legal and accrued indemnification costs	—	(370)	6,798
Employee termination and lease abandonment costs	—	—	1,630
Asset impairment charge	—	—	939
Total operating expenses	99,411	90,278	90,932
Operating income (loss)	2,947	1,286	(7,046)
Other income (expense):			
Litigation-related interest expense	—	(230)	—
Interest income, net	8	81	223
Foreign currency transaction gain (loss)	(5)	(62)	4
Other, net	10	50	(12)
Total other income (expense)	13	(161)	215
Income (loss) before income taxes	2,960	1,125	(6,831)
Income tax expense	734	231	6,232
Net income (loss)	$ 2,226	$ 894	$ (13,063)
Income (loss) per share:			
Net income (loss) per share, basic	$ 0.06	$ 0.03	$ (0.39)
Net income (loss) per share, diluted	$ 0.06	$ 0.03	$ (0.39)
Other comprehensive income (loss), net of tax			
Foreign currency translation adjustments	97	(270)	(422)
Unrealized loss on short term investment securities	—	—	(43)
Comprehensive income (loss), net of tax	$ 2,323	$ 624	$ (13,528)
Weighted average common shares outstanding:			
Basic	34,376,847	33,458,287	33,091,262
Diluted	35,766,970	34,370,124	33,091,262

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

THE SPECTRANETICS CORPORATION
AND SUBSIDIARIES

Consolidated Statements of Stockholders' Equity
Years ended December 31, 2012, 2011 and 2010

(in thousands, except share amounts)	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balances at January 1, 2010	**33,064,217**	**$ 33**	**$ 168,792**	**$ (83,917)**	**$ 20**	**$ 84,928**
Comprehensive loss, net of tax	—	—	—	(13,063)	(465)	(13,528)
Exercise of stock options	72,515	—	130	—	—	130
Issuance of restricted stock	54,000	—	—	—	—	—
Paid in capital from stock-based compensation expense	—	—	2,968	—	—	2,968
Balances at December 31, 2010	**33,190,732**	**33**	**171,890**	**(96,980)**	**(445)**	**74,498**
Comprehensive income, net of tax	—	—	—	894	(270)	624
Exercise of stock options	539,059	1	1,267	—	—	1,268
Shares purchased under employee stock purchase plan	140,950	—	627	—	—	627
Issuance of restricted stock and vesting of restricted stock units	86,667	—	—	—	—	—
Paid in capital from stock-based compensation expense	—	—	2,493	—	—	2,493
Balances at December 31, 2011	**33,957,408**	**34**	**176,277**	**(96,086)**	**(715)**	**79,510**
Comprehensive income, net of tax	—	—	—	2,226	97	2,323
Exercise of stock options	693,707	1	2,922	—	—	2,923
Shares purchased under employee stock purchase plan	146,542	—	849	—	—	849
Issuance of restricted stock and vesting of restricted stock units	90,106	—	—	—	—	—
Paid in capital from stock-based compensation expense	—	—	3,092	—	—	3,092
Balances at December 31, 2012	**34,887,763**	**$ 35**	**$ 183,140**	**$ (93,860)**	**$ (618)**	**$ 88,697**

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

THE SPECTRANETICS CORPORATION
AND SUBSIDIARIES

Consolidated Statements of Cash Flows
Years ended December 31, 2012, 2011 and 2010

	2012	2011	2010
		(in thousands)	
Cash flows from operating activities:			
Net income (loss)	$ 2,226	$ 894	$ (13,063)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	9,883	9,962	9,963
Stock-based compensation expense	3,092	2,493	2,968
Provision for excess and obsolete inventories	156	534	238
Deferred income taxes	378	(83)	6,090
Indemnification costs (paid) accrued	(3,225)	(2,672)	6,012
License agreement settlement	(3,000)	—	—
Asset impairment charge	—	—	939
Changes in operating assets and liabilities:			
Trade accounts receivable, net	(1,791)	(2,552)	478
Inventories	(884)	(929)	229
Equipment held for rental or loan, net	(6,099)	(5,971)	(4,226)
Prepaid expenses and other current assets	(77)	(861)	607
Other assets	99	(276)	17
Accounts payable and accrued liabilities	4,399	6,305	(2,293)
Deferred revenue	4	(101)	(53)
Net cash provided by operating activities	5,161	6,743	7,906
Cash flows from investing activities:			
Proceeds from sale, redemption or maturity of investment securities	—	4,360	6,222
Purchases of investment securities	—	—	(760)
Capital expenditures	(3,079)	(2,661)	(3,877)
Additional consideration—acquisition milestone payments	(7,727)	—	—
Decrease in restricted cash	—	—	817
Net cash (used in) provided by investing activities	(10,806)	1,699	2,402
Cash flows from financing activities:			
Proceeds from the exercise of stock options and employee stock purchase plan	3,772	1,895	130
Net cash provided by financing activities	3,772	1,895	130
Effect of exchange rate changes on cash	10	(34)	(113)
Net (decrease) increase in cash and cash equivalents	(1,863)	10,303	10,325
Cash and cash equivalents at beginning of year	39,638	29,335	19,010
Cash and cash equivalents at end of year	$ 37,775	$ 39,638	$ 29,335
Supplemental disclosures of cash flow information:			
Cash paid during the year for interest	$ 46	$ 289	$ 12
Cash paid during the year for income taxes	$ 135	$ 142	$ 187

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

THE SPECTRANETICS CORPORATION
AND SUBSIDIARIES
Notes to Consolidated Financial Statements

NOTE 1 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization, Nature of Business, and Basis of Presentation

The accompanying consolidated financial statements include the accounts of The Spectranetics Corporation, a Delaware corporation, its wholly owned subsidiary, Spectranetics International, B.V., and its wholly owned subsidiaries, Spectranetics Deutschland GmbH and Spectranetics Austria GmbH (collectively, the Company). All intercompany balances and transactions have been eliminated in consolidation. The Company's primary business is the design, manufacture, and marketing of single use medical devices used in minimally invasive procedures within the cardiovascular system, many of which are used with the Company's proprietary excimer laser system, the CVX-300 ®. The Company has two operating segments that are identified on a geographic basis: (1) U.S. Medical and (2) International Medical. U.S. Medical and International Medical offer the same products and services but operate in different geographic regions, have different distribution networks and different regulatory environments.

Certain prior period amounts have been reclassified to conform to the current period presentation.

Use of Estimates

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States (U.S. GAAP) requires management of the Company to make a number of estimates and assumptions relating to the reported amount of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the period. Significant items subject to such estimates and assumptions include the carrying amount of property and equipment, goodwill and intangible assets; allowances for receivables, inventories and deferred income tax assets; stock-based compensation expense; accrued indemnification costs; estimated clinical trial expenses; accrued estimates for incurred but not reported claims under partially self-insured employee health benefit programs; and loss contingencies, including those related to litigation. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less to be cash equivalents. Cash equivalents of approximately $8.7 million and $23.1 million at December 31, 2012 and 2011, respectively, consisted primarily of money market accounts stated at cost. At times, the Company maintains deposits in financial institutions in excess of federally insured limits.

Financial Instruments

At December 31, 2012 and 2011, the carrying value of financial instruments approximated the fair value of the instruments based on terms and related interest rates. Financial instruments include cash and cash equivalents, investment securities, trade accounts receivable and accounts payable.

Trade Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses in the Company's existing accounts receivable. The Company determines the allowance for doubtful accounts based upon an aging of accounts

receivable, historical experience and management judgment. Accounts receivable balances are reviewed individually for collectibility. Account balances are charged off against the allowance after all means of collection have been exhausted and the potential for recovery is remote.

Inventory

Inventory is recorded at the lower of cost or market. Cost is determined using the first-in, first-out method. The Company calculates an inventory allowance for estimated obsolescence or excess inventory based on historical usage and sales, as well as assumptions about future demand for its products. These estimates for excess and obsolete inventory are reviewed and updated on a quarterly basis. Increases in the inventory allowance results in a corresponding expense, which is recorded to cost of goods sold.

Property and Equipment

Property and equipment are recorded at cost. Repairs and maintenance costs are expensed as incurred.

Depreciation is calculated using the straight-line method over the estimated useful lives of the assets of three to five years for manufacturing equipment, equipment held for rental or loan, computers, and furniture and fixtures. The building the Company owns, which had previously been a manufacturing facility and now houses certain general operations, is depreciated using the straight-line method over its estimated useful life of 20 years. Leasehold improvements are amortized using the straight-line method over the shorter of the lease term or estimated useful life of the asset.

Goodwill and Other Intangible Assets

Goodwill represents the excess of costs over the fair value of the identifiable net assets of businesses acquired. Goodwill and intangible assets acquired in a purchase business combination and determined to have indefinite useful lives are not amortized, but instead are tested for impairment at least annually and whenever events or circumstances indicate the carrying amount of the asset may not be recoverable. In its evaluation of goodwill and indefinite-lived intangible assets, the Company performs an assessment of qualitative factors to determine if it is more-likely-than-not that goodwill might be impaired and whether it is necessary to perform the two-step goodwill impairment test. The Company conducts its annual impairment test as of December 31 of each year. See further discussion of goodwill and other intangible assets in Note 4 below.

Long-Lived Assets

The Company accounts for long-lived assets in accordance with U.S. GAAP, which requires that long-lived assets and certain identifiable intangibles be reviewed for impairment at least annually and whenever events or circumstances indicate the carrying amount of an asset may not be recoverable. The carrying value of a long-lived asset is considered impaired when the expected undiscounted cash flows from such asset are separately identifiable and are less than the carrying value. Fair value is determined by reference to quoted market prices, if available, or the utilization of certain valuation techniques such as cash flows discounted at a rate commensurate with the risk involved. Assets to be disposed of are reported at the lower of the carrying amount or fair value, less cost to sell. In 2010, the Company wrote off a capital project in process that was no longer expected to be completed and used, due to an EPA ruling that effectively limited the useful life of the asset (see Note 3).

Intangible assets with finite lives are amortized over their respective estimated useful lives to their estimated residual values, and reviewed for impairment annually, or whenever events or circumstances indicate their

carrying amount may not be recoverable. Intangible assets, which consist primarily of patents, are amortized using the straight-line method over periods which currently range from four to six years.

Revenue Recognition

The Company recognizes 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. Revenue from the sale of the Company's disposable products is recognized when products are shipped to the customer and title transfers. In general, customers do not have a right of return for credit or refund. However, the Company allows returns under certain circumstances and records an allowance for sales returns based upon an analysis of revenue transactions and historical experience of sales returns and price adjustments. Write-offs to customer account balances for product returns and price adjustments are charged against the allowance for sales returns. Revenue from the sale of excimer laser systems is recognized after completion of contractual obligations, which generally include delivery and installation of the systems. The Company's field service engineers are responsible for installation of each laser. The Company generally provides a one-year warranty on laser sales, which includes parts, labor and replacement gas. Upon expiration of the warranty period, the Company offers similar service to its customers under service contracts or on a fee-for-service basis. Revenue from fee-for-service arrangements is recognized upon completion of the related service.

The Company accounts for service provided during the one-year warranty or service contract period as a separate unit of accounting in accordance with ASC 605-25, *Revenue Recognition—Multiple Element Arrangements* . As such, the fair value of this service is deferred and recognized as revenue on a straight-line basis over the related warranty or service contract period, and warranty and service costs are expensed in the period they are incurred. Revenue allocated to the laser element is recognized upon completion of all contractual obligations in the sales contract, which generally include delivery and installation of the laser system. Revenue recognized associated with service performed during the warranty period totaled $0.4 million, $0.5 million and $0.2 million for the years ended December 31, 2012, 2011 and 2010, respectively.

The Company offers four laser system placement programs, which are described below, in addition to the sale of laser systems:

Straight rental program. The Company offers a straight monthly rental program for laser systems, and customers pay rent of $2,500 to $3,500 per month under this program. Rental revenue is invoiced and recognized on a monthly basis. The laser system is transferred to the equipment held for rental or loan account upon shipment, and depreciation expense is included in cost of revenue based upon the five year expected life of the laser system. Costs to maintain the equipment are expensed as incurred. As of December 31, 2012, 168 laser systems were in place under the straight rental program as compared to 155 at December 31, 2011.

Volume based rental programs. Rental revenue under these programs varies on a sliding scale depending on the customer's catheter purchases (either unit or dollar volume) each month. Rental revenue is invoiced and recognized on a monthly basis. The laser system is transferred to the equipment held for rental or loan account upon shipment, and depreciation expense is included in cost of revenue based upon the five year expected life of the laser system. Costs to maintain the equipment are expensed as incurred. As of December 31, 2012, 202 laser systems were in place under the volume based programs as compared to 157 at December 31, 2011.

Cap-Free rental program. Under this program, the customer agrees to a catheter price list that includes a per-unit surcharge. Customers are expected but not required to make minimum purchases of catheters at regular intervals, and the Company reserves the right to have the laser system returned if the minimum purchases are not

made. The Company recognizes the total surcharge as rental revenue upon shipment of the catheters, believing it to be the best measurement of revenue associated with the customer's use of the laser system for the month. The laser system is transferred to the equipment held for rental or loan account upon shipment, and depreciation expense is included in cost of revenue based upon the five year expected life of the laser system. Costs to maintain the equipment are expensed as incurred. The Company no longer places new lasers under the Cap-Free program. As of December 31, 2012, 157 laser systems were in place under the Cap-Free program as compared to 180 at December 31, 2011.

Evaluation program. The Company "loans" laser systems to institutions for use over a short period of time, usually three to six months. The loan of the equipment is to create awareness of the Company's products and their capabilities. No revenue is earned or recognized in connection with the placement of a loaned laser, although sales of disposable products result from the laser placement. The laser system is transferred to the equipment held for rental or loan account upon shipment and depreciation expense is recorded within selling, general and administrative expense based upon the five year expected life of the laser system. Costs to maintain the equipment are expensed as incurred. As of December 31, 2012, 113 laser systems were in place under the evaluation program as compared to 103 at December 31, 2011.

The Company sells to end-users in the United States and internationally as well as to certain international distributors. Sales to international distributors represented approximately 6% of the Company's total revenue in 2012. Distributor agreements are in place with each distributor, which outline the significant terms of the transactions between the distributor and the Company. The terms and conditions of sales to the Company's international distributors do not differ materially from the terms and conditions of sales to its domestic and international end-user customers. Sales to distributors are recognized either at shipment or a later date in accordance with the agreed upon contract terms with distributors, provided that the Company has received an order, the price is fixed or determinable, collectibility of the resulting receivable is reasonably assured, all contractual obligations have been met and the Company can reasonably estimate returns. The Company provides products to its distributors at agreed wholesale prices and typically does not provide any special right of return or exchange, discounts, significant sales incentives, price protection or stock rotation rights to any of its distributors.

Deferred Revenue

Deferred revenue was $2.2 million and $2.2 million at December 31, 2012 and 2011, respectively. These amounts primarily relate to payments in advance for various product maintenance contracts in which revenue is initially deferred and recognized over the life of the contract, which is generally one year, and to deferred revenue associated with service provided to customers during the warranty period after the sale of equipment.

Royalty Liability

The Company licenses certain patents from various licensors pursuant to license agreements. Royalty expense is calculated pursuant to the terms of the license agreements. The Company has established reserves for royalty payment obligations based on these calculations, which may involve management estimates that require judgment.

Stock-Based Compensation

The Company measures all employee stock-based compensation awards using a fair value method and records such expense in its consolidated financial statements in accordance with ASC 718, *Stock Compensation*. The Company generally estimates the fair value of stock option awards on the date of grant using the Black-Scholes

options pricing model. For certain options, which contained vesting provisions that included a share price trigger, the Company estimated the fair value of the options using a trinomial lattice model. The estimated value of the portion of the award that is ultimately expected to vest, taking into consideration estimated forfeitures based on the Company's historical forfeiture rate, is recognized as expense over the requisite service periods in the Company's consolidated statement of operations. See further discussion and disclosures in Note 6.

Research, Development and Other Technology

Research and development costs are expensed as incurred and totaled $10.9 million, $11.6 million and $10.2 million for the years ended December 31, 2012, 2011 and 2010, respectively. Research, development and other technology costs also include royalty expenses that the Company pays to license certain intellectual property incorporated in the Company's products. Royalty expenses totaled $1.8 million, $3.2 million and $2.8 million for the years ended December 31, 2012, 2011 and 2010, respectively.

Clinical trial costs. The Company also sponsors clinical trials intended to obtain the necessary clinical data required to obtain approval from the U.S. Food and Drug Administration (FDA) and foreign regulatory agencies to market new applications for its technology. Costs associated with these clinical trials totaled $4.2 million, $3.0 million and $1.8 million for the years ended December 31, 2012, 2011 and 2010, respectively.

In certain cases, substantial portions of the Company's clinical trials are performed by third-party clinical research organizations (CROs). These CROs generally bill monthly for services performed and also bill based upon milestone achievement. For example, the Company has contracted with a CRO to provide clinical trial services for the EXCITE ISR study. If the Company prepays CRO fees, the Company records the prepayment as a prepaid asset and amortizes the asset into research, development and other technology expense over the period of time the contracted services are performed, based upon the number of patients enrolled, "patient months" incurred and the duration of the study. The Company also accrues for services as provided, when services are performed before the milestone payments are made. The Company monitors patient enrollment, the progress of clinical studies and related activities through internal reviews of data reported to the Company by the CROs and correspondence with the CROs. The Company periodically evaluates its estimates to determine if adjustments are necessary or appropriate based on information it receives.

Foreign Currency Translation

The Company's reporting currency is the U.S. dollar. Certain transactions of the Company and its subsidiaries are denominated in currencies other than the U.S. dollar. Spectranetics International, B.V., Spectranetics Deutschland GmbH and Spectranetics Austria GmbH use their local currency (euro) as their functional currency. Accordingly, net assets are translated to U.S. dollars at year-end exchange rates while income and expense accounts are translated at average exchange rates during the year. Adjustments resulting from these translations are reflected in stockholders' equity as accumulated other comprehensive income (loss). The cash flows from operations in foreign countries are translated at the average rate in the statements of cash flows. Changes in exchange rates with respect to amounts recorded in the balance sheet result in transaction gains and losses that are reflected in the statement of comprehensive income as unrealized or realized upon settlement of the transactions.

Advertising Costs

The Company expenses advertising costs as incurred. Advertising costs of approximately $1.0 million, $0.5 million and $0.3 million were expensed for the years ended December 31, 2012, 2011 and 2010, respectively.

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Medical Self-insurance Costs

Starting in October 2011, the Company is partially self-insured for certain claims relating to employee medical and dental benefit programs. The medical self-insurance program is administered by a third party and contains stop-loss provisions on both an individual claim basis and in the aggregate. The Company records claims incurred as an expense each period, including an estimate of claims incurred but not yet reported which is revised quarterly. The Company uses claims data and historical experience, as applicable, to estimate liabilities.

Income Taxes

The Company accounts for income taxes pursuant to ASC 740, *Income Taxes*. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, operating losses and research and development and alternative minimum tax credit carryforwards.

A valuation allowance is required to the extent it is more-likely-than-not that a deferred tax asset will not be realized. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date.

The Company recognizes the financial statement effects of a tax position when it is more-likely-than-not, based on technical merits, that the position will be sustained upon examination. The Company classifies penalty and interest expense related to income tax liabilities as an income tax expense. There are no significant interest and penalties recognized in the statement of operations or accrued on the balance sheet. See further discussion and disclosures in Note 10.

Recent Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2011-05 *Comprehensive Income*, which amended guidance for presenting comprehensive income. The amendment requires the Company to present the components of net income and comprehensive income either as one continuous statement or as two consecutive statements. There is no longer the option to present items of other comprehensive income in the statement of stockholders' equity. The amended guidance was effective for the Company beginning January 1, 2012 on a retrospective basis, and the Company has elected to present the components of net income and comprehensive income as one continuous statement.

In July 2012, the FASB issued ASU 2012-02 *Intangibles—Goodwill and Other*, which updated guidance on the periodic testing of indefinite-lived intangible assets for impairment. This guidance will allow companies to assess qualitative factors to determine if it is more-likely-than-not that an indefinite-lived intangible asset might be impaired and whether it is necessary to perform the quantitative impairment test requi red under current accounting standards. This guidance will be effective for the Company's fiscal year ending December 31, 2013, with early adoption permitted. The adoption of this guidance will not have an effect on the Company's financial position, results of operations or cash flows.

In February 2013, the FASB issued ASU 2013-02, *Comprehensive Income: Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income*, which requires an entity to report the effect of significant reclassifications out of accumulated other comprehensive income either on the face of the statement

where net income is presented, or as a separate disclosure in the notes to the financial statements. The new disclosure requirements are prospective and will be effective for the Company's fiscal year ending December 31, 2013, with early adoption permitted. This update only requires additional disclosures. As such, the adoption of this standard will not have a material impact on the Company's financial position, results of operations or cash flows. The Company does not anticipate that the adoption of this guidance will materially change the presentation of its consolidated financial statements.

The Company has considered all other recently issued accounting pronouncements and does not believe they are significant to the Company.

NOTE 2 — INVENTORIES

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

	December 31,	
	2012	2011
Raw materials	$ 2,573	$ 1,947
Work in process	1,887	1,830
Finished goods	4,828	4,765
Total inventories, net	$ 9,288	$ 8,542

NOTE 3 — PROPERTY AND EQUIPMENT

Property and equipment, net, consisted of the following (in thousands):

	December 31,	
	2012	2011
Equipment held for rental or loan	$ 40,180	$ 37,373
Manufacturing equipment and computers	22,888	21,368
Leasehold improvements	5,024	4,621
Furniture and fixtures	2,102	1,863
Building and improvements	1,276	1,245
Land	270	270
Less: accumulated depreciation and amortization	(44,734)	(39,491)
Total property and equipment, net	$ 27,006	$ 27,249

Depreciation expense for the years ended December 31, 2012, 2011 and 2010 was $8.9 million, $9.1 million and $9.1 million, respectively. In addition, software amortization expense for the years ended December 31, 2012, 2011 and 2010 was $0.9 million, $0.6 million and $0.6 million, respectively.

In September 2010, the Company wrote off a sterilizer system that was not yet placed in service. The total amount of the write-off was $0.9 million and was recorded as an "Asset impairment charge" in the consolidated statement of comprehensive income (loss) for the year ended December 31, 2010. During the assembly and

construction of the sterilizer asset, the EPA issued a ruling that phases out one of the gases used to operate the sterilizer, which effectively limited the cost-effectiveness and useful life of the asset.

NOTE 4 — GOODWILL AND OTHER INTANGIBLE ASSETS

Goodwill. The Company's goodwill relates primarily to the acquisition of the endovascular product lines of Kensey Nash Corporation (KNC) in 2008 for approximately $10.7 million plus milestone payments. The aggregate purchase price was allocated to the tangible and intangible assets acquired, in-process research and development and goodwill. At the acquisition date, $2.9 million was allocated to goodwill, and between 2008 and 2011, the Company made milestone payments in the amount of $2.5 million, which were recorded as additional goodwill.

In February 2012, the Company paid to KNC a sales milestone payment of $6 million. This amount was accrued and recorded as additional goodwill in the fourth quarter of 2011, when cumulative sales of the acquired products reached $20 million.

In March 2012, the Company recorded an additional $1.7 million of goodwill based on a final milestone payment to KNC under a Termination, Settlement Agreement and Mutual Release (the Termination Agreement) with KNC. Under the Termination Agreement, the Company paid the final milestone payment in connection with product development milestones associated with a smaller version of the ThromCat ® XT product, and the parties agreed that no further milestone or other payments would be due. The Termination Agreement also terminated the principal responsibilities of each party under the various agreements entered into between the Company and KNC in May 2008. The additional $1.7 million of goodwill was allocated to the U.S. Medical and International Medical reporting units (see Note 12) based on a percentage of revenue of the acquired products.

The change in the carrying amount of goodwill by reporting unit for the year ended December 31, 2012 was as follows (in thousands):

	U.S. Medical	International Medical	Total
Balance as of December 31, 2011	$ 6,165	$ 5,404	$ 11,569
Goodwill acquired during the year	760	967	1,727
Balance as of December 31, 2012	$ 6,925	$ 6,371	$ 13,296

Intangible Assets. Acquired intangible assets as of December 31, 2012 and 2011 consisted of the following (in thousands):

		December 31, 2012			December 31, 2011		
	Weighted average useful life (in years)	Gross carrying amount	Accumulated amortization	Net	Gross carrying amount	Accumulated amortization	Net
Patents	5	$ 4,273	$ (4,253)	$ 20	4,273	$ (4,162)	$ 111
Customer Relationships	3	500	(500)	—	500	(500)	—
Intangible assets, net		$ 4,773	$ (4,753)	$ 20	4,773	$ (4,662)	$ 111

Aggregate amortization expense for amortizing intangible assets was $0.1 million, $0.2 million and $0.3 million for the years ended December 31, 2012, 2011 and 2010, respectively. As of December 31, 2012, estimated amortization expense for intangible assets subject to amortization for 2013 is $20,000. Beginning in 2013, the Company will also record amortization expense related to intangible assets acquired from Upstream Peripheral Technologies Ltd. in January 2013 (see Note 15, "Subsequent Event—Acquisition").

As of December 31, 2012, the Company performed an assessment of qualitative factors to determine if it was more-likely-than-not that goodwill might be impaired and whether it was necessary to perform the two-step goodwill impairment test. The qualitative factors assessed included the market capitalization of the Company, economic and market considerations, overall financial performance and other events affecting the reporting units. Based on these qualitative factors, the Company determined that it was not necessary to perform the two-step goodwill impairment test as it was not more-likely-than-not that goodwill might be impaired. The Company also evaluated its long-lived intangible assets for impairment and concluded that no impairment had occurred as of December 31, 2012 or 2011.

NOTE 5 — ACCRUED LIABILITIES

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2012	2011
Accrued payroll and employee related expenses	$ 9,951	$ 8,064
Accrued taxes	1,003	516
Deferred rent	800	683
Accrued clinical study expense	671	353
Employee stock purchase plan liability	602	412
Accrued royalty expense and license agreement termination (see Note 13)	528	3,533
Accrued legal costs	479	496
Accrued indemnification costs (see Note 14)	10	2,900
Accrued acquisition milestone payment (see Note 4)	—	6,000
Other accrued expenses	2,948	2,005
Total accrued liabilities	16,992	24,962
Less: long-term portion	(991)	(706)
Accrued liabilities: current portion	$ 16,001	$ 24,256

NOTE 6 — STOCK-BASED COMPENSATION AND EMPLOYEE BENEFIT PLANS

At December 31, 2012 and 2011, the Company had two stock-based compensation plans and a 401(k) plan. These plans are described below.

(a) Stock Option Plan

The Company maintains stock option plans that provide for the grant of incentive stock options, nonqualified stock options, restricted stock awards, restricted stock units and stock appreciation rights. The plans provide that incentive stock options may be granted with exercise prices not less than the fair market value at the date of grant. Options granted through December 31, 2012 generally vest over four years and expire ten years from the date of grant. Restricted stock awards granted to non-employee members of the Board of Directors vest over one year. Restricted stock units granted to certain officers of the Company vest over four years. On May 31, 2012, at the Company's 2012 annual meeting of stockholders, stockholders approved an increase of 1.7 million shares in the maximum number of shares available under The Spectranetics Corporation 2006 Incentive Award Plan. At December 31, 2012, there were 1.9 million shares available for future issuance under these plans.

In December 2008, the Company issued options to purchase shares of common stock to certain of the Company's officers and employees subject to a market condition performance target, which would be achieved if and when the average of the closing market prices of the Company's common stock equaled or exceeded $9.00 per share for a period of ten consecutive trading days. In August 2011, the Company issued options to purchase 400,000 shares of common stock to the Company's chief executive officer, subject to a market condition performance target, which would be achieved if and when the average of the closing market prices of the Company's common stock equaled or exceeded $10.00 per share for a period of ten consecutive trading days. The $9.00 and $10.00 performance targets were achieved in March 2012 and, in each case, as of the day the target was achieved, a pro-rata number of options became immediately vested based on a four-year vesting period from the original grant date. The remaining unvested options will continue to vest over the remainder of the four-year period. The achievement of the performance target resulted in the acceleration of expense related to the options granted in 2008, which caused additional stock-based compensation expense of approximately $154,000 for the year ended December 31, 2012.

Valuation and Expense Information

The Company recognized stock-based compensation expense of $3.1 million, $2.5 million and $3.0 million for the years ended December 31, 2012, 2011 and 2010, respectively, which consisted of compensation expense related to (1) employee stock options based on the value of share-based payment awards that is ultimately expected to vest during the period, (2) restricted stock awards issued to certain of the Company's directors, (3) restricted stock units issued to certain of the Company's officers, and (4) the fair value of shares issued under the Company's employee stock purchase plan. In 2010, stock-based compensation expense also included $0.4 million related to the accelerated vesting of certain options of the Company's former chairman and chief executive officer in accordance with his employment agreement. Stock-based compensation expense is recognized based on awards ultimately expected to vest and is reduced for estimated forfeitures. The Company recognizes compensation expense for these awards on a straight-line basis over the service period. An income tax benefit of $0.7 million, $0.5 million and $0.8 million related to the exercise of stock options during the years ended December 31, 2012, 2011 and 2010, respectively, will be added to other paid-in capital if, and when, the tax benefit is realized.

For all options which are not subject to a market condition, the fair value of each share option award is estimated on the date of grant using the Black-Scholes pricing model based on assumptions noted in the following table. The Company's employee stock options have various restrictions including vesting provisions and restrictions

on transfers and hedging, among others, and are often exercised prior to their contractual expiration. Expected volatilities used in the fair value estimate are based on the historical volatility of the Company's common stock. The Company uses historical data to estimate share option exercises, expected term and employee departure behavior used in the Black-Scholes pricing model. The risk-free rate for periods within the contractual term of the share option is based on the U.S. Treasury yield in effect at the time of grant.

The following is a summary of the assumptions used for the stock options granted during the years ended December 31, 2012, 2011 and 2010 using the Black-Scholes pricing model:

	Year Ended December 31,		
	2012	2011	2010
Expected life (years)	5.9	5.9	6.0
Risk-free interest rate	0.75%	1.33%	1.79%
Expected volatility	66.35%	66.10%	66.20%
Expected dividend yield	—	—	—

The weighted average grant date fair value of options granted during the years ended December 31, 2012, 2011 and 2010 was $6.17, $2.39 and $3.46, respectively.

The following table summarizes stock option activity during the year ended December 31, 2012:

	Shares	Weighted Average Exercise Price	Weighted Avg. Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Options outstanding at January 1, 2012	3,491,561	$ 5.75		
Granted	776,575	10.48		
Exercised	(714,777)	4.59		
Canceled	(289,529)	6.94		
Options outstanding at December 31, 2012	3,263,830	$ 7.02	6.98	$ 25,287,567
Options exercisable at December 31, 2012	1,806,787	$ 6.19	5.52	$ 15,504,683

The aggregate intrinsic value in the preceding table represents the total pre-tax intrinsic value, based on the Company's closing stock price of $14.77 on December 31, 2012, which would have been received by the option holders had all option holders exercised their options as of that date. The total number of shares underlying in-the-money options exercisable as of December 31, 2012 was approximately 1.8 million. The total intrinsic value of options exercised during the years ended December 31, 2012, 2011 and 2010 was $5.1 million, $2.3 million and $0.3 million, respectively.

The following table summarizes restricted stock award activity during the year ended December 31, 2012:

	Shares	Weighted Average Grant-Date Fair Value
Restricted stock awards outstanding at January 1, 2012	$ 74,030	$ 5.84
Awarded	48,632	9.87
Vested	(74,030)	5.84
Awards outstanding at December 31, 2012	$ 48,632	$ 9.87

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The following table summarizes restricted stock unit activity during the year ended December 31, 2012:

	Shares	Weighted Average Purchase Price	Weighted Avg. Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Restricted stock units outstanding at January 1, 2012	206,800	$ —		
Awarded	—	—		
Vested/Released	(54,200)	—		
Forfeited	(26,250)	—		
Restricted stock units outstanding at December 31, 2012	126,350	$ —	1.3	$ 1,866,190

As of December 31, 2012, there was $5.1 million of total unrecognized compensation expense related to non-vested share-based compensation arrangements granted under the Company's stock option plans. This expense is based on an assumed future forfeiture rate of approximately 13.4% per year for Company employees and is expected to be recognized over a weighted-average period of approximately 2.7 years.

(b) Stock Purchase Plan

In June 2010, the Company's stockholders approved The Spectranetics Corporation 2010 Employee Stock Purchase Plan (ESPP). On May 31, 2012, at the Company's 2012 annual meeting of stockholders, stockholders approved an increase from 300,000 shares to 700,000 shares in the maximum number of shares available under the ESPP. As a result, the ESPP provides for the sale of up to 700,000 shares of common stock to eligible employees, limited to the lesser of 2,500 shares per employee per six-month period or a fair market value of $25,000 per employee per calendar year. Stock purchased under the ESPP is restricted from sale for one year following the date of purchase. Stock can be purchased from amounts accumulated through payroll deductions during each six-month period. The purchase price is equal to 85% of the lower of the fair market value of the Company's common stock at the beginning or end of the respective six-month 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.

The fair value of the shares offered for the six-month periods beginning January and July 2012 under the ESPP was determined on the date of grant using the Black-Scholes option-pricing model. The expected term of six months was based upon the offering period of the ESPP. Expected volatility was determined based on the historical volatility from daily share price observations for the Company's stock covering a period commensurate with the expected term of the ESPP. The risk-free interest rate is based on the six-month U.S. Treasury daily yield rate. The expected dividend yield is based on the Company's historical practice of electing not to pay dividends to its stockholders. For the years ended December 31, 2012, 2011 and 2010, the Company recognized $0.3 million, $0.2 million and $0.1 million of compensation expense, respectively, related to its ESPP.

(c) 401(k) Plan

The Company maintains a salary reduction savings plan under Section 401(k) of the Internal Revenue Code, which the Company administers for participating employees' contributions. All full-time employees are covered under the plan after meeting minimum service requirements. The Company accrued and paid contributions

of $0.8 million, $0.7 million and $0.7 million to the plan for the years ended December 31, 2012, 2011 and 2010, respectively. For all periods presented, Company contributions were based on a match of 50% of each employee's contribution, with the match-eligible contribution being limited to 6% of the employee's eligible compensation.

NOTE 7 — DEBT — LINE OF CREDIT

On February 25, 2011, the Company entered into a Credit and Security Agreement (Credit Agreement) with Wells Fargo Bank, National Association (Wells Fargo), acting through its Wells Fargo Business Credit operating division, for a three-year $15.0 million revolving line of credit. Pursuant to the terms of the Credit Agreement, the Company may borrow under the revolving line of credit subject to borrowing base limitations. These limitations allow the Company to borrow, subject to specified reserves, up to 85% of eligible domestic accounts receivable, defined as receivables aged less than 90 days from the invoice date along with specific exclusions for contra-accounts, concentrations, and other accounts otherwise deemed ineligible by Wells Fargo Business Credit. Borrowings under the revolving line bear interest at a variable rate equal to the lesser of the Wells Fargo prime rate plus 0.25% or the daily three month LIBOR plus 3.25%, or 3.5% at December 31, 2012. The margins on the base interest rates are subject to reduction if the Company achieves certain annual net income levels. Accrued interest on any outstanding balance under the revolving line is payable monthly in arrears. The Company's borrowing base, which represents the amount the Company can borrow under the revolving line of credit, was $10.8 million as of December 31, 2012.

The revolving line of credit is secured by a first priority security interest in substantially all of the Company's assets. The Credit Agreement requires the Company to maintain a minimum of $10.0 million cash and investments at Wells Fargo and requires a lockbox arrangement. The Company is required to pay customary fees with respect to the facility, including a 0.25% fee on the average unused portion of the revolving line. If there are borrowings under the revolving line of credit, the Company will be subject to certain financial covenants including rolling 12-month adjusted EBITDA and minimum book net worth covenants.

The Credit 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 continuation of an event of default, amounts due under the Credit Agreement may be accelerated.

As of the date of this filing, the Company had no events of default and no borrowings under the revolving line of credit, and there were no borrowings under the revolving line of credit during the year ended December 31, 2012.

NOTE 8 — NET INCOME (LOSS) PER SHARE

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding. Shares issued during the period and shares reacquired during the period are weighted for the portion of the period that they were outstanding. Diluted net income (loss) per share is computed in a manner consistent with that of basic net income (loss) per share while giving effect to all potentially dilutive common shares outstanding during the period, which include the assumed exercise of stock options and the assumed vesting of restricted stock using the treasury stock method.

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For the years ended December 31, 2012 and 2011, a weighted average of 0.6 million and 2.1 million stock options, respectively, were excluded from the computation of diluted earnings per share because their inclusion would have been anti-dilutive.

Diluted net loss per share was the same as basic net loss per share for the year ended December 31, 2010 as shares issuable upon the exercise of stock options and the vesting of restricted stock awards and units were anti-dilutive as a result of the net loss incurred for that period. As a result, all of the stock options, restricted stock awards and units outstanding to purchase 4.0 million weighted average shares at December 31, 2010 were excluded from the diluted net loss per share calculation because their inclusion would have been anti-dilutive.

A summary of the net income (loss) per share calculation is shown below (in thousands, except share and per share amounts):

	2012	2011	2010
Net income (loss)	$ 2,226	$ 894	$ (13,063)
Common shares outstanding:			
Historical common shares outstanding at beginning of year	33,883,378	33,136,732	33,064,217
Weighted average common shares issued	493,469	321,555	27,045
Weighted average common shares outstanding-basic	34,376,847	33,458,287	33,091,262
Effect of dilution from stock options	1,390,123	911,837	—
Weighted average common shares outstanding-diluted	35,766,970	34,370,124	33,091,262
Net income (loss) per share, basic	$ 0.06	$ 0.03	$ (0.39)
Net income (loss) per share, diluted	0.06	0.03	(0.39)

NOTE 9 — LEASES

The Company leases office space, furniture, vehicles and equipment under noncancelable operating leases with initial terms that expire at various dates through 2023.

The future minimum payments under noncancelable operating leases as of December 31, 2012, are as follows (in thousands):

	Operating Leases
Years ending December 31:	
2013	$ 1,471
2014	1,730
2015	1,581
2016	1,406
2017	1,453
Thereafter	8,812
Total minimum lease payments	$ 16,453

Rent expense under operating leases totaled approximately $1.9 million for each of the years ended December 31, 2012, 2011, and 2010, respectively.

In October 2012, the Company amended its existing lease at its headquarters in Colorado Springs, Colorado and simultaneously entered into a new building lease for 20,000 square feet adjacent to the Company's current headquarters in order to expand its facilities. The Company anticipates occupying the new facility in the third quarter of 2013. Both leases run concurrently through September 2023. The annual base rent of the combined facilities is approximately $1.1 million per year, subject to annual increases of 3 - 4% each year. The Company has the right to make tenant improvements in its current facility, which would result in an increase in the rentable square feet, causing a proportional increase in the base rent.

NOTE 10 — INCOME TAXES

The sources of income (loss) before income taxes are as follows (in thousands):

	2012	2011	2010
United States	$ 1,413	$ (292)	$ (7,850)
Foreign	1,547	1,417	1,019
Income (loss) before income taxes	$ 2,960	$ 1,125	$ (6,831)

Income tax expense attributable to loss before income taxes consists of the following (in thousands):

	2012	2011	2010
Current:			
Federal	$ —	$ —	$ —
State	84	107	105
Foreign	272	207	37
	356	314	142
Deferred:			
Federal	295	187	4,445
State	33	63	505
Foreign	50	(333)	1,140
	378	(83)	6,090
Income tax expense	$ 734	$ 231	$ 6,232

The Company continues to maintain a valuation allowance for substantially its entire gross deferred tax asset including its U.S. net operating losses. For the year ended December 31, 2012, the Company recorded deferred federal and state tax expense of $0.3 million, representing a deferred tax liability related to the difference between tax and book accounting for its goodwill, which is amortized over 15 years for tax purposes but not amortized for book purposes.

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Income tax expense attributable to income (loss) before income taxes differed from the amounts computed by applying the U.S. federal income tax rate of 34% to income (loss) before income taxes as a result of the following (in thousands):

	2012	2011	2010
Computed expected tax expense (benefit)	$ 1,006	$ 383	$ (2,323)
Increase (reduction) in income taxes resulting from:			
State and local income taxes, net of federal impact	94	50	(301)
Nondeductible stock compensation expense related to incentive stock options	112	1,316	449
Nondeductible expenses and municipal interest	138	262	186
Change in valuation allowance	(1,241)	(1,973)	8,571
Change in deferred rate	165	—	—
Foreign operations	(44)	621	(94)
Research and development credit	504	(428)	(256)
Income tax expense	$ 734	$ 231	$ 6,232

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The tax effects of temporary differences that give rise to significant portions of the deferred tax assets (liabilities) at December 31 are as follows (in thousands):

	2012	2011
Deferred tax assets:		
Current:		
License agreement dispute settlement, due to accrual for financial reporting purposes	$ —	$ 1,152
Accrued liabilities, not deducted until paid for tax purposes	906	1,961
Deferred revenue, due to deferral for financial reporting purposes	662	868
Inventories, principally due to accrual for obsolescence for financial reporting purposes, net of additional costs inventoried for tax purposes	562	576
	2,130	4,557
Less valuation allowance	(1,817)	(3,947)
Total deferred tax assets, current portion, net	313	610
Noncurrent:		
Net operating loss carryforwards-U.S. and related states	6,493	5,031
Charitable contribution carryover	31	—
Capital loss carryover	409	415
Amortization of intangibles	1,135	1,262
Stock compensation expense related to nonqualified stock options	2,034	2,064
Research and experimentation tax credit	1,873	2,302
Alternative minimum tax credit	298	298
Accrued liabilities, not deducted until paid for tax purposes	344	262
	12,617	11,634
Less valuation allowance	(10,964)	(10,075)
Deferred tax assets, noncurrent portion, net	1,653	1,559
Deferred tax liabilities:		
Noncurrent		
Equipment, primarily due to differences in cost basis and depreciation methods	(1,667)	(1,869)
Long-lived intangible assets	(874)	(550)
Total deferred tax liabilities, noncurrent portion, net	$ (888)	$ (860)

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An income tax benefit of $0.7 million, $0.5 million and $0.8 million related to the exercise of stock options for the years ended December 31, 2012, 2011 and 2010, respectively, will be added to other paid-in capital if, and when, the tax benefit is realized.

As of December 31, 2012, the Company has unrestricted United States federal net operating loss carryforwards of approximately $25.8 million to reduce future taxable income, which expire primarily from 2018 through 2032. The Company also has capital loss carryforwards of $1.1 million that expire in 2015 and 2016.

An alternative minimum tax credit carryforward of approximately $0.3 million is available to offset future regular tax liabilities and has no expiration date. For alternative minimum tax purposes, the Company has unrestricted net operating loss carryforwards for United States federal income tax purposes of approximately $25.8 million.

The Company also has research and experimentation tax credit carryforwards for federal income tax purposes at December 31, 2012 of approximately $2.1 million, which are available to reduce future federal income taxes, if any, and expire at varying dates through 2030.

The Company intends to indefinitely reinvest earnings from subsidiaries treated as foreign corporations for U.S. tax purposes.

In assessing the realizability of deferred tax assets, management considers whether it is more-likely-than-not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the projected future taxable income and tax planning strategies in making this assessment. Due to the Company's history of losses and the lack of sufficient certainty of generating future taxable income, the Company has recorded a full valuation allowance against substantially all of its gross deferred tax assets including its U.S. net operating losses. The Company will continue to assess the need for a valuation allowance in future periods and does not expect to reduce the valuation allowance against its deferred tax assets to below 100% of its gross amount until it has a sufficient historical trend of taxable income and can predict future income with a higher degree of certainty. In the event there is a change in circumstances in the future which would affect the utilization of the Company's deferred tax assets, the tax provision in that period would be adjusted by the amount of the assets then deemed to be realizable.

ASC 740, *Income Taxes*, requires reporting of taxes based on tax positions which meet a more-likely-than-not standard and which are measured at the amount that is more-likely-than-not to be realized. Differences between financial and tax reporting which do not meet this threshold are required to be recorded as unrecognized tax benefits.

As of January 1, 2012, the Company classified approximately $0.5 million of its credit carryforwards as uncertain and this amount is reported as a reduction of the Company's deferred tax asset. In 2012, this amount was adjusted by approximately $0.1 million due to expiring credits that are no longer subject to the uncertain tax position. In the fourth quarter of 2011, the Company evaluated its foreign operations and recorded an uncertain tax liability for foreign jurisdictions for which the Company was evaluating its liability, and in 2012 the Company determined that these amounts were currently payable and no longer uncertain.

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A reconciliation of the beginning and ending amounts of unrecognized tax liability is as follows (in thousands):

	Unrecognized Tax Liability
Balance at January 1, 2012	$ 465
Additions based on tax positions related to current year	—
Additions for tax positions of prior years	—
Reductions for tax positions of prior years	(175)
Settlements	—
Balance at December 31, 2012	$ 290

The Company classifies interest and penalties expense related to income tax liabilities as an income tax expense. There are no significant interest and penalties recognized in the statement of operations or accrued on the balance sheet.

The Company files tax returns in the U.S., the Netherlands, Germany and Austria. The tax years 2009 through 2012 remain open to examination by the major taxing jurisdictions to which the Company is subject. The IRS completed a corporate income tax audit during 2012 for the Company's 2009 and 2010 tax years. No adjustments were made as a result of the audit.

NOTE 11 — CONCENTRATIONS OF CREDIT RISK

The Company's investment policy is designed to limit the Company's exposure to concentrations of credit risk.

The Company's accounts receivable are due from a variety of health care organizations and distributors throughout the United States, Europe, the Middle East, Latin America and Asia. No single customer represented more than 10% of revenue or accounts receivable for any period. The Company provides for uncollectible amounts upon recognition of revenue and when specific credit problems arise. Management's estimates for uncollectible amounts have been adequate during historical periods, and management believes that all significant credit risks have been identified at December 31, 2012.

The Company has not entered into any hedging transactions nor any transactions involving financial derivatives.

NOTE 12 — SEGMENT AND GEOGRAPHIC REPORTING

The Company operates in one distinct line of business consisting of developing, manufacturing, marketing and distributing a proprietary excimer laser system and disposable products for the treatment of certain coronary and vascular conditions.

Within this line of business, the Company has identified two operating segments, which were identified on a geographic basis: (1) U.S. Medical and (2) International Medical. U.S. Medical and International Medical offer the same products and services but operate in different geographic regions, have different distribution networks and

different regulatory environments. Within U.S. Medical, the Company aggregates its two product lines, Vascular Intervention and Lead Management, based on their similar economic, operational and regulatory characteristics, consistent with the authoritative guidance on segment reporting.

Additional information regarding each operating segment is discussed below.

(a) U.S. Medical

Products offered by this segment include single-use medical devices used in minimally invasive procedures within the cardiovascular system, including fiber-optic devices and non-fiber-optic products (disposables), an excimer laser system (equipment), and the service of the excimer laser system (service). The Company is subject to product approvals from the FDA. At December 31, 2012, FDA-approved products were used in multiple vascular procedures, including coronary and peripheral atherectomy, aspiration and thrombectomy and the removal of cardiac lead wires from patients with pacemakers and cardiac defibrillators. This segment's customers are primarily located in the United States and Canada.

U.S. Medical is also corporate headquarters for the Company. All manufacturing, research and development as well as corporate administrative functions are performed within this reportable segment. As of December 31, 2012, 2011 and 2010, a portion of research, development and other technology expenses and general and administrative expenses incurred in the U.S. has been allocated to International Medical based on a percentage of revenue because these expenses support the Company's ability to generate revenue within the International Medical segment.

Manufacturing activities are performed entirely within the U.S. Medical segment. Revenue associated with intersegment product transfers to International Medical was $7.5 million, $6.5 million and $4.2 million for the years ended December 31, 2012, 2011 and 2010, respectively. Revenue is based upon transfer prices, which provide for intersegment profit that is eliminated upon consolidation.

(b) International Medical

The International Medical segment headquarters is located in the Netherlands, and serves Europe as well as the Middle East, Latin America (including Puerto Rico), Japan and the Pacific Rim. Products offered by this segment are substantially the same as those offered by U.S. Medical. The International Medical segment is engaged primarily in distribution activities, with no manufacturing or product development functions. Certain U.S. incurred research, development and other technology expenses and general and administrative expenses have been allocated to International Medical based on a percentage of revenue because these expenses support the Company's ability to generate revenue within the International Medical segment.

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Summary financial information relating to reportable segment operations is shown below. Intersegment transfers as well as intercompany assets and liabilities are excluded from the information provided (in thousands):

	2012	2011	2010
Revenue:			
U.S. Medical:			
Disposable products	$ 103,218	$ 90,849	$ 87,070
Service and other, net of allowance for sales returns	9,081	8,719	8,215
Equipment	5,137	6,365	5,723
Subtotal	117,436	105,933	101,008
International Medical:			
Disposable products	19,304	17,895	14,316
Service and other, net of allowance for sales returns	1,358	1,403	1,165
Equipment	2,187	2,056	1,428
Subtotal	22,849	21,354	16,909
Total revenue	**$ 140,285**	**$ 127,287**	**$ 117,917**

	U.S. Medical	International Medical	Total
2012			
Interest income	$ 70	$ 1	$ 71
Interest expense	63	—	63
Depreciation and amortization expense	8,705	1,178	9,883
Income tax expense	414	320	734
Segment operating income	1,037	1,910	2,947
Segment net income	656	1,570	2,226
Capital expenditures	3,063	16	3,079
Segment assets	$ 95,181	$ 15,588	$ 110,769

	U.S. Medical	International Medical	Total
2011			
Interest income	$ 139	$ 2	$ 141
Interest expense	59	231	290
Depreciation and amortization expense	8,801	1,161	9,962
Income tax expense (benefit)	431	(200)	231
Segment operating income	647	639	1,286
Segment net income	347	547	894
Capital expenditures	2,480	181	2,661
Segment assets	$ 92,446	$ 16,590	$ 109,036

	U.S. Medical	International Medical	Total
2010			
Interest income	$ 232	$ 3	$ 235
Interest expense	12	—	12
Depreciation and amortization expense	9,009	954	9,963
Income tax expense	5,055	1,177	6,232
Segment operating loss	(7,006)	(40)	(7,046)
Segment net loss	(11,853)	(1,210)	(13,063)
Capital expenditures	3,664	213	3,877
Segment assets	$ 83,262	$ 10,433	$ 93,695

In 2012, 2011 and 2010, no individual customer represented 10% or more of consolidated revenue. There were no individual countries, other than the United States, that represented at least 10% of consolidated revenue in 2012, 2011 or 2010. Long-lived assets, other than financial instruments and deferred tax assets, located in foreign countries are concentrated in Europe, and totaled $10.6 million and $8.4 million as of December 31, 2012 and 2011, respectively.

Revenue by Product Line

	For the years ended December 31,		
(in thousands)	**2012**	**2011**	**2010**
Revenue			
Disposable products revenue:			
Vascular intervention	$ 67,336	$ 62,264	$ 60,224
Lead management	55,186	46,480	41,162
Total disposable products revenue	122,522	108,744	101,386
Service and other, net of allowance for sales returns	10,439	10,122	9,380
Equipment	7,324	8,421	7,151
Total revenue	**140,285**	**127,287**	**117,917**

NOTE 13 — SETTLEMENT COSTS—LICENSE AGREEMENT DISPUTE

In January 2012, the Company entered into a Termination and Mutual Release with Medtronic, Inc. (Medtronic). The Termination Agreement terminates a License Agreement between the Company and Medtronic dated February 28, 1997 (the License Agreement). In 2011, the parties disputed whether royalties were owed under the License Agreement. Under the Termination Agreement, the Company paid to Medtronic $3.0 million in January 2012 in settlement of all obligations under the License Agreement, and neither party has any further rights or obligations under the License Agreement, including certain Medtronic rights that if exercised would have been unfavorable to the Company. The Termination Agreement also includes a mutual release under which each of the Company and Medtronic releases the other from all claims, whether known or unknown, arising under the License Agreement. The Company had accrued royalty expenses in the amount of $1.2 million related to the License

Agreement prior to the settlement; therefore, the Company recorded $1.8 million as settlement costs—license agreement dispute in the Company's financial statements for the quarter ended December 31, 2011, because the underlying cause of the dispute and likelihood of a settlement to resolve such dispute existed as of December 31, 2011.

The patents underlying the License Agreement were scheduled to expire in October 2013 and October 2014 in the U.S. and select foreign jurisdictions, respectively. Royalty expenses paid or accrued pursuant to the License Agreement for the year ended December 31, 2011 were approximately $1.5 million. Royalty expenses are not being incurred subsequent to the effective date of the Termination Agreement.

NOTE 14 — COMMITMENTS AND CONTINGENCIES

Indemnification of former officers and employees

The Company has indemnification obligations with three former employees who were charged in connection with a previous federal investigation of the Company. In February 2012, a trial was held for two of the defendants, which resulted in the acquittal of one defendant on all charges and acquittal of the other defendant on all charges except for one count of making false statements to federal investigators. The sentencing hearing for this defendant occurred in May 2012, and in June 2012, this defendant filed a notice of appeal. On March 12, 2012, the U.S. District Court of Colorado dismissed the charges against the third defendant who had previously been granted a separate trial. The Company was not a party to these trials.

In February 2012, the Company entered into agreements with two of the former employees under which it agreed to reimburse the two former employees an amount not to exceed $1.9 million and $0.5 million, respectively, for legal fees and expenses incurred by them on or after January 1, 2012, including the trial and any appeal that was not successful. In consideration of the former employees' agreement to this cap on legal fees and expenses, the Company released them from its rights to "clawback" legal fees and expenses advanced by the Company. In addition to the foregoing, each party generally released the other from all claims prior to the date of the agreements. The cap on legal fees and expenses, as well as the release and waiver of clawback rights and the general release of claims, are subject to certain exceptions in the case of a mistrial or successful appeal that results in an order for a new trial.

During the year ended December 31, 2012, the Company paid $3.2 million of indemnification costs. As of December 31, 2012, the Company had a remaining accrual for future indemnification costs of approximately $10,000. Additional expenses may be incurred in future periods depending upon the success or failure of an appeal, and in particular, a successful appeal that results in the order of a new trial.

Litigation

The Company is from time to time subject to, and is presently involved in, various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of its business. Such matters are subject to many uncertainties and to outcomes and the financial impacts of which are not predictable with assurance and that may not be known for extended periods of time. The Company records a liability in its consolidated financial statements for costs related to claims, settlements and judgments, where management has assessed that a loss is probable and an amount can be reasonably estimated. The Company's significant legal proceedings are discussed below. The costs associated with such proceedings or other legal proceedings that may be commenced

could have a material adverse effect on the Company's future consolidated results of operations, financial position or cash flows.

Fox/Sopkin

The Company and Spectranetics B.V., the Company's Dutch subsidiary, are defendants in a lawsuit brought in the District Court of Utrecht, the Netherlands (the Dutch District Court) by Kenneth Fox in 2004. Mr. Fox is an inventor named on patents licensed to the Company under a license agreement assigned to Interlase LP. Mr. Fox claims an interest in royalties payable under the license and seeks alleged back royalties of approximately $2.2 million. In June 2010, the Dutch District Court issued a ruling, followed by a decision that dismissed Mr. Fox's claims in their entirety against both the Company and its Dutch subsidiary. The court also awarded the Company a nominal amount as attorney's fees. In September 2010, Mr. Fox filed and served a notice of appeal to the Dutch Court of Appeals. Under Dutch law, the appeal entitles Mr. Fox to a new trial on the merits, though still taking into evidence the record that is already in the Dutch court system. A hearing on the merits occurred in November 2012. The Company intends to continue to vigorously defend against Mr. Fox's claims in this appeal.

In May 2011, the Company was served with a lawsuit that names the Company and the Company's Dutch subsidiary as defendants. The lawsuit was brought in the Dutch District Court by Barbara Joy Sopkin. Ms. Sopkin claims royalties on a license agreement, certain rights to which were allegedly transferred to her, which claims are similar in nature to the claims of Mr. Fox in his litigation. Ms. Sopkin claims damages of approximately $2 million and also claims interest on that amount from January 1, 2011. The proceedings formally commenced in July 2011, and a hearing on the claims was held in September 2012. In October 2012, the Dutch District Court rejected Ms. Sopkin's claims for damages in their entirety and awarded the Company a nominal amount as attorney's fees. In January 2013, Ms. Sopkin served the Company with a notice of her intent to appeal to the Dutch Court of Appeals. The Company intends to vigorously defend against Ms. Sopkin's claims in this matter.

The Company has no amounts accrued for the Fox or Sopkin litigation.

Cardiomedica

The Company was engaged in a dispute since 1999 with Cardiomedica S.p.A. (Cardiomedica), an Italian company, over the existence of a distribution agreement between Cardiomedica and the Company. In 2009, a Dutch District Court issued a ruling in favor of Cardiomedica, requiring the Company to pay $0.6 million, which ruling Cardiomedica appealed. In September 2011, the Dutch Court of Appeals issued a ruling in favor of Cardiomedica, requiring the Company to pay to Cardiomedica an additional $0.6 million in damages plus $0.2 million in interest. The Company paid and expensed this amount in September 2011.

Other

The Company is involved in other legal proceedings in the normal course of business and does not expect them to have a material adverse effect on its business.

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NOTE 15 — SUBSEQUENT EVENT — ACQUISITION

On January 7, 2013, the Company entered into an Asset Purchase Agreement (the Purchase Agreement) with Upstream Peripheral Technologies Ltd. (Upstream), and ARAN Research Development & Prototypes Ltd. (ARAN). Under the Purchase Agreement, the Company purchased certain product lines from Upstream: the Upstream Needle Holder (marketed by the Company under the name Quick-Access™ Needle Holder), the Upstream Support Catheter, and the Upstream GR Guiding Balloon Catheter (marketed by the Company under the name Quick-Cross Capture™ Guidewire Retriever).

The base purchase price under the Purchase Agreement was $5.5 million in cash, of which $1.5 million was deposited in an escrow account under standard terms and conditions. The Purchase Agreement provides for additional contingent payments by the Company of (a) $1.0 million based on successful transfer of product, manufacturing and regulatory related documentation (which payment was made in February 2013); (b) $500,000 upon first sales of products manufactured at a Company facility; (c) up to $1 million related to certain specified intellectual property milestones; and (d) one-third of revenues from the product lines purchased from Upstream in 2014, 2015 and 2016, subject to an overall cap as set forth in the Purchase Agreement. The Purchase Agreement also includes set-off rights and additional future escrow deposits as specified therein.

In connection with the transactions contemplated by the Purchase Agreement, the Company, Upstream, and ARAN entered into a Manufacturing, Supply and Regulatory Transition Services Agreement under which Upstream and ARAN will manufacture the products for the Company until regulatory approvals and manufacturing have transferred to the Company. In addition, Upstream, ARAN and two principals of Upstream have entered into non-competition agreements. Prior to the acquisition, the Company had no material relationships with Upstream or ARAN.

The Company expects the Upstream acquisition will be accounted for as a business combination and the Company will record the assets acquired and the estimated future consideration obligations at their respective fair values as of the acquisition date during the first quarter of 2013.

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NOTE 16 — SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

	2012				2011			
	Q1	Q2	Q3	Q4(1)	Q1	Q2	Q3(2)	Q4(3)
	(In thousands, except per share amounts)							
Net sales	$ 33,269	$ 35,035	$ 35,230	$ 36,751	$ 30,422	$ 32,214	$ 32,127	$ 32,524
Gross profit	24,301	25,515	25,606	26,936	21,495	22,901	23,444	23,724
Net income (loss)	12	636	905	673	(154)	584	109	355
Net income (loss) per share (4):								
Basic	$ 0.00	$ 0.02	$ 0.03	$ 0.02	$ (0.00)	$ 0.02	$ 0.00	$ 0.01
Diluted	0.00	0.02	0.03	0.02	(0.00)	0.02	0.00	0.01

(1) During the fourth quarter of 2012, the Company incurred $0.3 million in legal and other costs related the to acquisition of certain products from Upstream (for additional discussion, see Note 15).

(2) During the third quarter of 2011, the Company recorded a $0.8 million charge, which amount included $0.2 million of interest through September 2011, related to a September 2011 ruling by the Dutch Court of Appeals in favor of Cardiomedica (for additional discussion, see Note 14).

(3) During the fourth quarter of 2011, the Company recorded the following special charges or credits not related to the Company's regular, ongoing business: (i) a license agreement termination charge of $1.8 million (see Note 13) and (ii) a credit of $0.4 million representing a reduction in the Company's estimated liability related to indemnification agreements with three former employees.

(4) The sum of the quarterly net income per share amounts may not total to each full year amount because these computations are made independently for each quarter and for the full year, and take into account the weighted average number of common stock equivalent shares outstanding for each period.

THE SPECTRANETICS CORPORATION
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SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS

Description	Balance at Beginning of Year	Additions Charged (Credited) to Revenue, Costs or Expenses	Deductions(1)	Balance at End of Year
		(In thousands)		
Year ended December 31, 2012:				
Allowance for doubtful accounts and sales returns	$ 602	$ 959	$ 972	$ 589
Inventory reserves	925	156	167	914
Valuation allowance for deferred tax assets	14,022	(1,241)	—	12,781
Year ended December 31, 2011:				
Allowance for doubtful accounts and sales returns	790	765	953	602
Inventory reserves	779	534	388	925
Valuation allowance for deferred tax assets	18,412	(1,973)	2,417	14,022
Year ended December 31, 2010:				
Allowance for doubtful accounts and sales returns	$ 948	$ 921	$ 1,079	$ 790
Inventory reserves	380	418	19	779
Valuation allowance for deferred tax assets	12,735	8,571	2,894	18,412

(1) Deductions represent receivables written-off and credits granted for customer returns, inventory write-offs, and reductions in the valuation allowance for deferred tax assets due primarily to the use or expiration of net operating losses.

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EXHIBIT INDEX

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation. Incorporated by reference to exhibits previously filed by the Company with its Current Report on Form 8-K filed on June 16, 2009.
3.2	Amended and Restated Bylaws of The Spectranetics Corporation. Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on April 4, 2011.
4.1	Form of Common Stock Certificate of the Company. Incorporated by reference to exhibits previously filed by the Company with its Amendment No. 2 to the Registration Statement, filed January 24, 1992 (File No. 33-44367).
10.1	The 1997 Equity Participation Plan of The Spectranetics Corporation. Incorporated by reference to exhibits previously filed by the Company with its Registration Statement on Form S-8 filed June 17, 1998 (File No. 333-57015).
10.2	Form of NonQualified Stock Option Agreement for Officers. Incorporated by reference to exhibits previously filed by the Company with its Registration Statement on Form S-8 filed June 17, 1998 (File No. 333-57015).
10.3	Form of NonQualified Stock Option Agreement for Employees. Incorporated by reference to exhibits previously filed by the Company with its Registration Statement on Form S-8 filed June 17, 1998 (File No. 333-57015).
10.4	Form of NonQualified Stock Option Agreement for Independent Directors. Incorporated by reference to exhibits previously filed by the Company with its Registration Statement on Form S-8 filed June 17, 1998 (File No. 333-57015).
10.5	Form of Incentive Stock Option Agreement for Officers. Incorporated by reference to exhibits previously filed by the Company with its Registration Statement on Form S-8 filed June 17, 1998 (File No. 333-57015).
10.6	Form of Incentive Stock Option Agreement for Employees. Incorporated by reference to exhibits previously filed by the Company with its Registration Statement on Form S-8 filed June 17, 1998 (File No. 333-57015).
10.7	License Agreement between Medtronic, Inc. and the Company, dated February 28, 1997 (confidential treatment has been granted for portions of this agreement). Incorporated by reference to exhibits previously filed by the Company with its Form 10-Q for the quarter ended on March 31, 1997.
10.8	License Agreement between United States Surgical Corporation and the Company, dated September 25, 1997 (confidential treatment has been granted for portions of this agreement). Incorporated by reference to exhibits previously filed by the Company with its Form 10-Q for the quarter ended on September 30, 1997.
10.9	First Amendment to the 1997 Equity Participation Plan. Incorporated by reference to exhibit previously filed by the Company with its 2000 Annual Report on Form 10-K filed on March 30, 2001.
10.10	Second Amendment to the 1997 Equity Participation Plan. Incorporated by reference to exhibit previously filed by the Company with its Registration Statement on Form S-8 filed on November 22, 2000.
10.11	Third Amendment to the 1997 Equity Participation Plan. Incorporated by reference to exhibit previously filed by the Company with its 2001 Annual Report on Form 10-K filed on March 30, 2002.
10.12	Form of Indemnification Agreement entered into between the Company and each of its directors as of May 10, 2002. Incorporated by reference to exhibits previously filed by the Company with its Current Report on Form 8-K filed on June 7, 2002.

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Exhibit Number	Description
10.13	Fourth Amendment to the 1997 Equity Participation Plan. Incorporated by reference to exhibits previously filed by the Company with its Quarterly Report on Form 10-Q for the quarter ended June 30, 2002.
10.14	Fifth Amendment to the 1997 Equity Participation Plan. Incorporated by reference to exhibits previously filed by the Company with its Quarterly Report on Form 10-Q for the quarter ended June 30, 2002.
10.15	Asset purchase agreement between the Company and LaTIS, Inc. Incorporated by reference to exhibits previously filed by the Company with its Quarterly Report on Form 10-Q for the quarter ended June 30, 2003.
10.16	Settlement and Amendment to License Agreement executed in February 2005 and effective October 1, 2004 between the Company and Surmodics, Inc. (confidential treatment has been granted for portions of this agreement). Incorporated by reference to exhibit previously filed by the Company with its Quarterly Report on Form 10-Q for the quarter ended March 31, 2005.
10.17	Agreement of Lease by and between 9965 Federal Drive, LLC and The Spectranetics Corporation dated December 29, 2006. Incorporated by reference to exhibit previously filed by the Company with its 2006 Annual Report on Form 10-K filed on March 29, 2007.
10.18	Patent Purchase Agreement dated February 20, 2007 between The Spectranetics Corporation and Joseph M. Ruggio. Incorporated by reference to exhibit previously filed by the Company with its 2006 Annual Report on Form 10-K filed on March 29, 2007.
10.19	The Spectranetics Corporation 2006 Incentive Award Plan. Incorporated by reference to exhibit previously filed by the Company with its Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.
10.20	Second Amendment to The Spectranetics Corporation 2006 Incentive Award Plan, dated June 19, 2007. Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on June 22, 2007.
10.21	Third Amendment to The Spectranetics Corporation 2006 Incentive Award Plan, dated August 13, 2007. Incorporated by reference to exhibits previously filed by the Company with its Registration Statement on Form S-8 filed on August 14, 2007.
10.22	Form of Stock Option Grant Notice and Stock Option Agreement. Incorporated by reference to exhibits previously filed by the Company with its Registration Statement on Form S-8 filed on August 14, 2007.
10.23	Fourth Amendment to The Spectranetics Corporation 2006 Incentive Award Plan dated April 15, 2008. Incorporated by reference to exhibit previously filed by the Company with its Quarterly Report on Form 10-Q for the quarter ended March 31, 2008 filed on May 12, 2008.
10.24	Asset Purchase Agreement dated as of May 12, 2008 by and among Kensey Nash Corporation, ILT Acquisition Sub, Inc., Kensey Nash Holding Corporation and The Spectranetics Corporation. Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on May 13, 2008.
10.25	Manufacturing and Licensing Agreement dated as of May 30, 2008 between Kensey Nash Corporation and The Spectranetics Corporation (confidential treatment has been requested for portions of this exhibit). Incorporated by reference to exhibits previously filed by the Company with its Current Report on Form 8-K filed on June 5, 2008.
10.26	Development and Regulatory Services Agreement dated as of May 30, 2008 between Kensey Nash Corporation and The Spectranetics Corporation (confidential treatment has been requested for portions of this exhibit). Incorporated by reference to exhibits previously filed by the Company with its Current Report on Form 8-K filed on June 5, 2008.
10.27	Fifth Amendment to The Spectranetics Corporation 2006 Incentive Award Plan, dated June 18, 2008. Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on June 23, 2008.

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Exhibit Number	Description
10.28	Employment Agreement between Emile Geisenheimer and The Spectranetics Corporation, dated November 21, 2008 and effective as of October 21, 2008. Incorporated by reference to exhibits previously filed by the Company with its Current Report on Form 8-K/A filed on November 28, 2008.
10.29	Form of Time Vesting Stock Option Agreement, Form of Conditional Time Vesting Stock Option Agreement, and Form of Conditional Performance Vesting Stock Option Agreement. Incorporated by reference to exhibits previously filed by the Company with its Current Report on Form 8-K/A filed on November 28, 2008.
10.30	Form of Performance Vesting Stock Option Agreement for Employees. Incorporated by reference to exhibit previously filed by the Company with its Annual Report on Form 10-K for the year ended December 31, 2008 filed on March 16, 2009.
10.31	Form of Conditional Performance Vesting Stock Option Agreement for Employees. Incorporated by reference to exhibit previously filed by the Company with its Annual Report on Form 10-K for the year ended December 31, 2008 filed on March 16, 2009.
10.32	Form of Restricted Stock Award Agreement for Non-Employee Directors. Incorporated by reference to exhibit previously filed by the Company with its Quarterly Report on Form 10-Q for the quarter ended March 31, 2009 filed on May 11, 2009.
10.33	Sixth Amendment to The Spectranetics Corporation 2006 Incentive Award Plan. Incorporated by reference to exhibits previously filed by the Company with its Current Report on Form 8-K filed on June 16, 2009.
10.34	Development and Regulatory Services Agreement Amendment dated as of June 22, 2009, between Kensey Nash Corporation and The Spectranetics Corporation (confidential treatment has been requested for portions of this exhibit). Incorporated by reference to exhibits previously filed by the Company with Quarterly Report on Form 10-Q for the quarter ended June 30, 2009 filed on August 10, 2009.
10.35	Non-Prosecution Agreement dated December 28, 2009 by and among The Spectranetics Corporation and the United States Attorney's Office for the District of Colorado and the United States Department of Justice's Office of Consumer Litigation. Incorporated by reference to exhibits previously filed by the Company with its Current Report on Form 8-K filed on December 29, 2009.
10.36	Settlement Agreement dated December 22, 2009 by and among The Spectranetics Corporation and the United States of America, acting through the United States Department of Justice and the United States Attorney's Office for the District of Colorado, on behalf of the Office of Inspector General of the Department of Health and Human Services. Incorporated by reference to exhibits previously filed by the Company with its Current Report on Form 8-K filed on December 29, 2009.
10.37	Corporate Integrity Agreement dated December 22, 2009 between the Office of Inspector General of the Department of Health and Human Services and The Spectranetics Corporation. Incorporated by reference to exhibits previously filed by the Company with its Current Report on Form 8-K filed on December 29, 2009.
10.38	License Agreement dated December 30, 2009 between The Spectranetics Corporation and Peter Rentrop, M.D. Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on December 31, 2009.
10.39	Consulting Agreement between The Spectranetics Corporation and Craig M. Walker, MD, dated April 8, 2010. Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on April 12, 2010.
10.40	Letter Agreement between Shahriar Matin and The Spectranetics Corporation, dated April 12, 2010. Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on April 14, 2010.

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Exhibit Number	Description
10.41	The Spectranetics Corporation 2010 Employee Stock Purchase Plan. Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on June 29, 2010.
10.42	Seventh Amendment to The Spectranetics Corporation 2006 Incentive Award Plan. Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on June 29, 2010.
10.43	Form of Restricted Stock Unit Agreement. Incorporated by reference to exhibits previously filed by the Company with Quarterly Report on Form 10-Q for the quarter ended June 30, 2010 filed on August 6, 2010.
10.44	Stipulation of Settlement (In re Spectranetics Corporation Securities Litigation, Case No. 08-cv-2048-REB-KLM). Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on September 13, 2010.
10.45	Stipulation of Settlement (Kopp v. Geisenheimer, Case No. 08-cv-2102-REB-MJW). Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on September 21, 2010.
10.46	General Release between The Spectranetics Corporation and Emile Geisenheimer, effective as of November 25, 2010. Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on December 1, 2010.
10.47	Notice of Pendency and Settlement of Derivative Actions dated December 15, 2010. Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on December 17, 2010.
10.48	Independent Contractor Services Agreement dated as of January 31, 2011, between Emile J. Geisenheimer and The Spectranetics Corporation. Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on February 4, 2011.
10.49	Credit and Security Agreement between The Spectranetics Corporation and Wells Fargo Bank, National Association dated February 25, 2011, together with the Revolving Note and exhibits. Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on March 3, 2011.
10.50	Severance Agreement between The Spectranetics Corporation and Guy A. Childs dated March 1, 2011. Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on March 3, 2011.
10.51	Severance Agreement between The Spectranetics Corporation and Jason Hein dated March 1, 2011. Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on March 3, 2011.
10.52	Severance Agreement between The Spectranetics Corporation and Shahriar Matin dated March 1, 2011. Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on March 3, 2011.
10.53	First Amendment to The Spectranetics Corporation 2010 Employee Stock Purchase Plan. Incorporated by reference to exhibit previously filed by the Company with its Annual Report on Form 10-K filed on March 14, 2011.
10.54	Consulting Agreement between The Spectranetics Corporation and Craig M. Walker, MD, effective March 31, 2011. Incorporated by reference to exhibit previously filed by the Company with its Annual Report on Form 10-K filed on March 14, 2011.
10.55	Eighth Amendment to The Spectranetics Corporation 2006 Incentive Award Plan. Incorporated by reference to exhibit previously filed by the Company with its Annual Report on Form 10-K filed on March 14, 2011.
10.56	Form of Severance Agreement dated March 1, 2010 entered into between The Spectranetics Corporation and each of Roger Wertheimer and Francisco Rivas, executive officers of the Company. Incorporated by reference to exhibit previously filed by the Company with its Annual Report on Form 10-K filed on March 14, 2011.

Exhibit Number	Description
10.57	Employment Agreement between Scott Drake and The Spectranetics Corporation dated July 8, 2011 and effective as of August 10, 2011, which includes Exhibit A—Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement and Exhibit B—Stock Option Grant Notice and Stock Option Agreement. Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on July 12, 2011.
10.58	Form of Restricted Stock Unit Agreement. Incorporated by reference to exhibit previously filed by the Company with its Quarterly Report on Form 10-Q filed on August 5, 2011.
10.59	Form of Restricted Stock Award Agreement - Initial Grant. Incorporated by reference to exhibit previously filed by the Company with its Quarterly Report on Form 10-Q filed on August 5, 2011.
10.60	Form of Restricted Stock Award Agreement - Annual Grant. Incorporated by reference to exhibit previously filed by the Company with its Quarterly Report on Form 10-Q filed on August 5, 2011.
10.61	Amendment No. 1 to Patent Purchase Agreement dated June 27, 2011 between The Spectranetics Corporation and Joseph M. Ruggio, M.D. Incorporated by reference to exhibit previously filed by the Company with its Quarterly Report on Form 10-Q filed on August 5, 2011.
10.62	Termination and Mutual Release between The Spectranetics Corporation and Medtronic, Inc. effective January 19, 2012. Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on January 25, 2012.
10.63	Agreement Relating to Indemnification and Clawback Rights, and Release dated February 6, 2012, between The Spectranetics Corporation and John G. Schulte. Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on February 9, 2012.
10.64	Agreement Relating to Indemnification and Clawback Rights, and Release dated February 6, 2012, between The Spectranetics Corporation and Trung Pham. Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on February 9, 2012.
10.65	Indemnification Agreement dated March 13, 2012 between The Spectranetics Corporation and the Directors and certain officers of the Company. Incorporated by reference to exhibit previously filed by the Company with its Annual Report on Form 10-K filed on March 15, 2012.
10.66	Termination, Settlement Agreement and Mutual Release dated March 14, 2012 between The Spectranetics Corporation and Kensey Nash Corporation. Incorporated by reference to exhibit previously filed by the Company with its Annual Report on Form 10-K filed on March 15, 2012.
10.67	The Spectranetics Corporation 2006 Incentive Award Plan, as amended. Incorporated by reference to Appendix B previously filed by the Company with its Definitive Proxy Statement filed on April 17, 2012.
10.68	First Amendment to The Spectranetics Corporation 2010 Employee Stock Purchase Plan. Incorporated by reference to Appendix C previously filed by the Company with its Definitive Proxy Statement filed on April 17, 2012.
10.69	Agreement of Lease by and between COPT Interquest Hybrid I, LLC and The Spectranetics Corporation, executed October 2, 2012. Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on October 5, 2012.
10.70	Second Amendment to Agreement of Lease by and between 9965 Federal Drive, LLC and The Spectranetics Corporation, executed October 2, 2012. Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on October 5, 2012.
10.71	Asset Purchase Agreement, dated January 7, 2012, among the Company, Upstream Peripheral Technologies Ltd., and ARAN Research Development & Prototypes Ltd. Incorporated by reference to exhibit previously filed by the Company with its Current Report on Form 8-K filed on January 7, 2013.

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Exhibit Number	Description
21.1	Subsidiaries of the Company.
23.1	Consent of Independent Registered Public Accounting Firm (KPMG, LLP).
23.2	Consent of Independent Registered Public Accounting Firm (EKS&H LLLP).
31.1	Rule 13(a)-14(a)/15d-14(a) Certification of Chief Executive Officer.
31.2	Rule 13(a)-14(a)/15d-14(a) Certification of Chief Financial Officer.
32.1	Section 1350 Certification of Chief Executive Officer.
32.2	Section 1350 Certification of Chief Financial Officer.
101.INS	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema Document*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document*

* Users of this data are advised that, in accordance with Rule 406 of Regulation S-T promulgated by the SEC, this Interactive Data File is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

EXHIBIT 21.1

SUBSIDIARIES OF THE REGISTRANT

THE SPECTRANETICS CORPORATION
SUBSIDIARIES

SPECTRANETICS INTERNATIONAL B.V.
Established January 1993, Incorporated June 1993
Jurisdiction: The Netherlands

SPECTRANETICS II B.V.
Incorporated December 2011
Jurisdiction: The Netherlands
Subsidiary of Spectranetics International B.V.

SPECTRANETICS DEUTSCHLAND GMBH
Acquired May 2008
Jurisdiction: Germany
Subsidiary of Spectranetics International B.V.

SPECTRANETICS AUSTRIA GMBH
Incorporated December 2011
Jurisdiction: Austria
Subsidiary of Spectranetics International B.V.

SPECTRANETICS UK
Registered January 2012
Jurisdiction: United Kingdom
Subsidiary of Spectranetics International B.V.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
The Spectranetics Corporation:

We consent to the incorporation by reference in the registration statements (Nos. 333-184113, 333-184112, 333-169456, 333-169455, 333-155282, 333-163507, 333-08489, 333-50464, 333-57015, 333-117074, 333-140022, and 333-145435) on Form S-8 of The Spectranetics Corporation and subsidiaries of our report dated March 13, 2013, with respect to the consolidated balance sheet of The Spectranetics Corporation and subsidiaries as of December 31, 2012, and the related consolidated statements of comprehensive income (loss), stockholders' equity, and cash flows for the year ended December 31, 2012, and the related financial statement schedule II, and the effectiveness of internal control over financial reporting as of December 31, 2012, which report appears in the December 31, 2012 annual report on Form 10-K of The Spectranetics Corporation and subsidiaries.

/s/ KPMG LLP

Denver, Colorado
March 13, 2013

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Forms S-8 (Nos. 333-184113, 333-184112, 333-169456, 333-169455, 333-155282, 333-163507, 333-08489, 333-50464, 333-57015, 333-117074, 333-140022, 333-145435, and 333-163507) of The Spectranetics Corporation and subsidiaries of our report dated March 15, 2012, with respect to the consolidated financial statements for the years ended December 31, 2011 and 2010, which appears in this Form 10-K.

/s/ EKS&H LLLP

March 13, 2013
Denver, Colorado

Exhibit 31.1

Certification of Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Scott Drake, certify that:

1. I have reviewed this annual report on Form 10-K of The Spectranetics Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 13, 2013

/s/ Scott Drake

Scott Drake
Chief Executive Officer

Exhibit 31.2

Certification of Chief Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Guy A. Childs, certify that:

1. I have reviewed this annual report on Form 10-K of The Spectranetics Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 13, 2013

/s/ Guy A. Childs

Guy A. Childs
Chief Financial Officer

Exhibit 32.1

Certification of Chief Executive Officer

Pursuant to 18 U.S.C. §1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of The Spectranetics Corporation (the "Company") hereby certifies, to such officer's knowledge, that:

(i) the Annual Report on Form 10-K of the Company for the year ended December 31, 2012 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

March 13, 2013

/s/ Scott Drake

Scott Drake
Chief Executive Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 32.2

Certification of Chief Financial Officer

Pursuant to 18 U.S.C. §1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of The Spectranetics Corporation (the "Company") hereby certifies, to such officer's knowledge, that:

(i) the Annual Report on Form 10-K of the Company for the year ended December 31, 2012 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

March 13, 2013

/s/ Guy A. Childs

Guy A. Childs
Chief Financial Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.