



3

PATHS

Peripheral Vascular Disease Therapy

TO

Coronary Artery Disease Therapy

GROWTH

Cardiac Lead Removal System

Spectranetics[®]

we get your blood flowing[®]

Annual Report 2004

THE SPECTRANETICS CORPORATION

Spectranetics develops, manufactures and markets single-use medical devices used in minimally invasive surgical procedures within the cardiovascular system in conjunction with its proprietary CVX-300® excimer laser system.

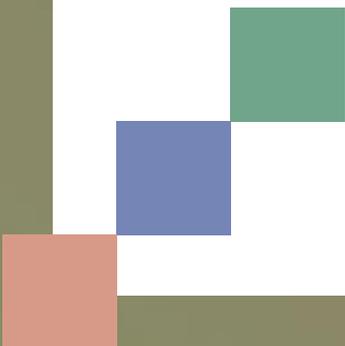
Our photo ablation technology treats complex cardiovascular disease by ablating plaque, thrombus and calcium into tiny particles that are easily absorbed into the blood stream. Our disposable catheters use high-energy “cool” ultraviolet light to safely remove arterial blockages and the scar tissue holding problematic cardiac leads in place, reducing complications and improving clinical outcomes.

2004 HIGHLIGHTS

- **FDA clearance received** in April to market CLiRpath® (Cool Laser Revascularization for peripheral artery therapy)
- **25% increase** in total revenue over 2003 = **\$34.7 million**
- **Net income of \$3.0 million** (includes income tax benefit of \$1.5 million)
- Cash, cash equivalents and current and long-term investment securities totaled **\$17.4 million** versus \$13.3 million in 2003

Forward-Looking Statements

This annual report contains forward-looking statements. For a list of the risks and uncertainties that could cause actual results to differ from anticipated results, please see the “Risk Factors” section of Management’s Discussion and Analysis.



TO OUR SHAREHOLDERS

I am pleased to report that 2004 was a very successful year for Spectranetics. We exceeded our financial targets for revenue, net income and cash flow. Equally important to our financial success, we made excellent progress in achieving our key strategic initiatives of expanding our indications to include peripheral arterial disease (PAD), building credibility for our technology through eight publications in peer reviewed medical journals, increasing disposable product revenues and growing our installed base of laser systems.

New Clinical Indication

Of particular significance for Spectranetics was the 510(k) clearance from the U.S. Food and Drug Administration (FDA) to expand the indications for our laser catheters to include the treatment of PAD, by treating total occlusions not crossable by a guidewire. We believe our technology is well suited to treat the most severe form of PAD known as critical limb ischemia (CLI). Over one million people in the United States suffer from CLI and this condition results in more than 100,000 amputations each year. Our technology provides a minimally invasive alternative to amputation by restoring straightline blood flow and, in clinical trials, demonstrated six month limb salvage rates greater than 90% in this severely debilitated and underserved patient population.

We exceeded our financial targets for revenue, net income and cash flow.

FDA 510(k) clearance received to market CLiRpath® catheters for the treatment of PAD.

We launched our CLiRpath catheters for this indication in May 2004 and customer acceptance has been very encouraging. This successful launch was highlighted with stories about the use of our CLiRpath technology in television news segments and print media serving major U.S. markets where physicians began performing procedures with outstanding results and very satisfied patients.

To support the launch, we expanded our field sales organization by seven people. We plan to hire an additional seven to ten sales professionals in 2005. Our sales force focused their initial efforts on 120 target accounts, which had a laser and an identified physician performing peripheral endovascular procedures. We exceeded our CLiRpath sales objectives as we received orders from 154 hospitals, representing nearly half of our U.S. installed base.

Growth in Disposable Products

In addition to expanding the application of our “cool” laser technology to a new market, PAD, we also were able to increase the penetration of our existing core business of coronary atherectomy and cardiac lead removal through the introduction of new products, increased presence at major cardiovascular meetings, development of compelling clinical data and scientific publications in peer reviewed journals.

The primary focus of our coronary atherectomy products is the treatment of chronic total occlusions (CTOs). With the recent introduction of drug eluting stents, cardiologists have a heightened interest in treating CTOs as a result of improved long-term outcomes. Our Point 9™ X80 catheter is gaining increased recognition as the best product for treating CTOs that cannot be crossed with a balloon. Our new Quick-Cross® Support² Catheters have the lowest tip profile and are the only support catheters with multiple distal radiopaque markers for improved assessment of lesion and vessel length that enable precise stent placement. Our Point 9 X80 catheter was featured in two live cases at the initial CTO Summit Meeting in New York, held in January 2004. A clinical study was also published in the February 2004 issue of *Catheterization and Cardiovascular Interventions*, demonstrating a 92% success rate in crossing CTOs that were balloon resistant or highly calcified.

Our CLeaRS™ lead removal system remains the standard of care for removing the scar tissue holding problematic pacemaker and defibrillator leads in place. With the improved reimbursement for bi-ventricular ICDs, an increasing number of patients with standard pacemakers are being upgraded to these new devices. Since these newer ICDs have three leads, more physicians are explanting the original pacemaker lead to make room for the new leads. We continue to educate physicians on the potential complications associated with “abandoned” leads and highlight the safety and effectiveness of our CLeaRS system as compared to traditional mechanical techniques for lead removal.

Growth in Installed Base of Lasers

Against a goal of 25 to 30 new laser customers for the year, we placed 34 lasers during 2004, including 23 during the second half of the year. Placement of new lasers reflects a new sales focus on high volume interventional hospitals. By year-end we had 417 laser systems installed worldwide with 311 in the U.S.

We believe this focus on laser placements at targeted hospitals will strengthen our higher margin disposable products business and will be a significant long-term growth driver. Our goal is to have each hospital performing multiple modalities, such as coronary and peripheral atherectomy, as well as cardiac lead removal. In 2005 our goal is to place at least 40 new lasers.

Against a goal of 25 to 30 new laser customers for the year, we placed 34 lasers during 2004, including 23 during the second half of the year.

Looking to 2005 and Beyond

As we continue executing the strategic plan we formulated in 2003, we have defined clear objectives for 2005 to enable Spectranetics to achieve its long-term goals.

Our top priority is to expand our CLiRpath capability and further penetrate the market for PAD in general and CLI in particular. We plan to improve existing products by adding features to shorten procedure time and broaden our product line by developing catheters that will create larger lumens to allow us to better treat the larger diameter superficial femoral artery. We expect to introduce at least one new larger lumen catheter in the second half of 2005.

Our second priority is focused on CTOs, which represent almost 15% of all coronary procedures. We are developing a new Prima laserwire to treat CTOs, which are not crossable by standard mechanical guidewires. This year, we also plan to introduce the smallest interventional catheter in the world, a Point 7 millimeter laser catheter that will also be targeted at crossing and treating CTOs.

Our final priority will focus on identifying the best opportunities for our technology in treating thrombus. Our laser catheters are particularly well suited to ablate thrombus with minimal distal embolization, and treating thrombus may be the perfect target for our catheters. We intend to develop a better understanding of the science behind "laser thrombectomy" and its potential synergy with thrombolytics. In 2005 we expect to complete a pilot trial for acute myocardial infarction, and initiate a pilot trial for treating acute limb ischemia.

2004 Financial Performance

Our 2004 financial results showed significant growth in all key indicators as compared with 2003. Total revenue increased 25 percent to \$34.7 million, driven by increases in all major product categories and services. Laser equipment and rental revenue increased 34 percent, disposable product revenue increased 21 percent, and service and other revenue increased 35 percent.

Reflecting our strategic commitment to place new lasers at hospitals with high interventional volume and focusing on sales of higher-margin disposable products versus capital equipment, gross margins improved to 75 percent in 2004, up from 72 percent in 2003. The significant growth in all of these areas led to an improvement in net income to \$3.0 million, which includes a \$1.5 million income tax benefit.

Our continued efforts to shift the revenue mix in favor of disposable products are designed to provide a more predictable revenue stream going forward as well as continue to contribute to improved gross margins. In 2005 we anticipate reinvesting most of the incremental gross profit into continued

Our top priority is to expand our CLiRpath capability and further penetrate the market for PAD in general and CLI in particular.

***In 2004 total revenue
increased 25 percent to
\$34.7 million.***

expansion of our field sales and clinical organizations, key product development and clinical study programs, and the staffing of two key executive positions.

At the close of 2004, our cash, cash equivalent and current and long-term investment securities stood at \$17.4 million, an increase of \$4.1 million from the prior year. We entered 2005 debt-free and with adequate cash reserves to move forward on all key development fronts.

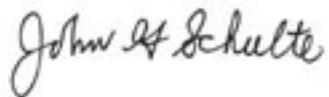
Summary

In summary, Spectranetics is well positioned for continued growth in the future. We plan to remain profitable and cash flow positive, while investing in our sales organization, research, development and clinical research to help us achieve long-term revenue growth.

We are poised to deliver breakthrough technologies and procedures to treat complex cardiovascular disease to save lives, and, in turn, create value for our shareholders.

In closing, I would like to thank the entire Spectranetics team for their dedication and exceptional accomplishments. Only through their efforts were we able to make this past year such a successful one for Spectranetics.

Sincerely,



John G. Schulte
President & Chief Executive Officer

April 2005

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, 2004

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
*(State or other jurisdiction of
incorporation or organization)*

84-0997049
*(I.R.S. Employer
Identification No.)*

96 Talamine Court
Colorado Springs, Colorado 80907
(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 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 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 an accelerated filer. Yes No

The aggregate market value of the voting stock of the Registrant, as of June 30, 2004 computed by reference to the closing sale price of the voting stock held by non-affiliates on such date, was \$137,054,697.

As of March 23, 2005, there were outstanding 25,146,665 shares of Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement for its 2005 Annual Meeting of Shareholders, to be filed with the Securities and Exchange Commission not later than April 30, 2005, are incorporated by reference into Part III as specified herein.

PART I

The information set forth in this annual report on Form 10-K includes “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, and is subject to the safe harbor created by that section. 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 below and include, but are not limited to, the following:

- Market acceptance of excimer laser atherectomy technology;
- Increased pressure on expense levels resulting from expanded marketing and clinical activities;
- Dependence on new product development and new applications for excimer laser technology;
- Uncertain success of the Company’s strategic direction;
- Technological changes resulting in product obsolescence;
- Intellectual property claims of third parties;
- Adverse state or federal legislation and regulation;
- Product defects;
- Availability of vendor-sourced component products at reasonable prices; and
- The risk factors listed from time to time in our filings with the Securities and Exchange Commission as well as those set forth in Item 7 — “Management’s Discussion and Analysis of Financial Condition and Results of Operations — 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.

ITEM 1. *Business*

General

We develop, manufacture, market and distribute single-use medical devices used in minimally invasive surgical procedures within the cardiovascular system in conjunction with our proprietary excimer laser system. Excimer laser technology delivers comparatively cool ultraviolet energy in short, controlled energy pulses to ablate or remove tissue. Our excimer laser system includes the CVX-300[®] laser unit and various fiber-optic delivery devices, including disposable catheters and sheaths. Our excimer laser system is the only excimer laser system approved in the United States and Europe for use in multiple, minimally invasive cardiovascular applications. Our excimer laser system is used in complex atherectomy procedures to open clogged or obstructed arteries in the coronary and peripheral vascular system. It is also used to remove lead wires from patients with implanted pacemakers or cardioverter defibrillators, which are electronic devices that regulate the heartbeat. On April 29, 2004, we obtained 510(k) marketing clearance from the Food and Drug Administration (FDA) for a laser-based treatment of total occlusions (blockages) in the legs not crossable with a guidewire. Some of the patients with total occlusions in the leg suffer from critical limb ischemia (CLI), a debilitating condition that begins with resting leg pain and often leads to tissue loss or amputation as a result of a lack of blood flow to the legs.

Although 89% of our revenue was derived in the United States for the year ended December 31, 2004, we also have regulatory approval to market our products in two key international markets. In Europe, we have the required approvals to market our products for the same indications that are approved in the United States. We have also received approval to market certain coronary atherectomy products in Japan, and are seeking additional approvals there for our newer coronary, peripheral and lead removal products. During 2003, we appointed a new distributor, DVx Japan, who is assisting us in pursuing reimbursement approval. We currently expect reimbursement approval in 2006, although there are no assurances that reimbursement approval will be

received then, if at all. We do not expect significant revenue increases in Japan until reimbursement approval is received.

Spectranetics is a Delaware corporation formed in 1984. Our principal executive offices are located at 96 Talamine Court, Colorado Springs, Colorado 80907. Our telephone number is (719) 633-8333.

Our corporate website is located at www.spectranetics.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.

Strategy

Our strategy includes the following key points:

- *Leverage technical expertise in generation and delivery of excimer energy.* We have designed our excimer laser platform to support multiple existing and potential therapeutic applications for the treatment of cardiovascular disease. We are exploring additional applications of our core excimer laser technology for novel treatments of coronary and other vascular conditions.

In April 2004, we received 510(k) marketing clearance from the FDA for the use of certain of our products to treat total occlusions in the legs that are not crossable with a guidewire. The treatment options for these patients were limited to bypass surgery or amputation. This approval represents the first minimally invasive treatment option for these patients. We are currently gathering clinical data for laser-based treatment of acute myocardial infarction (AMI, or heart attack) and saphenous vein grafts (heart bypass grafts that develop blockages). We expect to complete the clinical research in saphenous vein grafts during the first half of 2005. We are currently FDA-approved to treat saphenous vein grafts so the clinical data from this trial, if successful, will be used for marketing the clinical advantages of our technology. The clinical research associated with a laser-based treatment of AMI is in the feasibility stage and is also expected to be completed during the first half of 2005. After review of the clinical data obtained from the feasibility trial, we will decide whether to pursue a randomized pivotal trial, which may take two to three years to complete. We are also in the initial stages of scientific research exploring the use of our technology to treat blockages caused by the formation of thrombus (blood clots).

- *Gather and develop clinical data for publication in peer-reviewed journals.* Our physician customers adopt products and technologies primarily based on available clinical data. Historically, the clinical data for our technology, especially in coronary artery disease therapy, has been limited. However, during 2004, there were eight clinical publications highlighting the use of excimer laser technology for the treatment of peripheral vascular disease, chronic total occlusions and heart attacks.
- *Expand disposable device revenues from existing customer base.* By training additional cardiologists, surgeons and other specialists at existing customer hospitals and introducing physicians already familiar with our products to new products and applications, we intend to increase our revenue stream from sales of current and future disposable products to existing customers. Through our existing marketing and sales team, we are currently focused on the three markets we currently serve — coronary atherectomy, peripheral atherectomy and the removal of pacemaker or defibrillator leads.
- *Expand installed customer base.* We intend to expand our customer base by continuing to focus our sales efforts on cardiac centers that perform the majority of interventional procedures. For the years ended December 31, 2004 and 2003, respectively, we placed 34 and 23 laser systems in new accounts. At December 31, 2004, our total worldwide installed base was 417 laser systems (311 in the United States). In addition to an outright sale of our laser systems, we offer several alternatives to our customers for the acquisition of our excimer lasers, including evaluation and fee rental programs. During 2004, most of our new laser placements were evaluation programs and we expect that to continue into 2005.

Technology

Excimer laser ablation removes plaque, thrombotic materials, or tissue by delivering relatively cool excimer laser energy to a blockage or lesion. This laser beam breaks down the molecular bonds of plaque or tissue in a process known as photoablation, without significant thermal damage to surrounding tissue. The laser ablation of the material reduces the particles to about the size of a red blood cell, which is easily absorbed into the blood stream. This helps to avoid a potential complication known as distal embolization, which is caused by particles dislodged during an angioplasty or atherectomy procedure that create a blockage elsewhere in the vascular system.

Laser ablation involves the insertion of a laser catheter or sheath into an artery or vein through a small incision. It is used with conventional angioplasty tools, such as guidewires and sheaths. When the tip of the catheter or sheath has been placed at the site of the blockage or lesion, the physician activates the laser beam to ablate the plaque or tissue.

CVX-300® Excimer Technology

Our proprietary CVX-300 excimer laser unit is designed for use in a variety of cardiovascular applications. When coupled with our fiber-optic laser devices, the system generates and delivers 308 nanometer wavelength ultraviolet energy pulses to a lesion to remove plaque or tissue. The 308 nanometer wavelength is on the relatively “cool” end of the ultraviolet spectrum. The excimer laser is considered a contact laser, ablating material that is less than 50 microns from the tip of the laser catheter or sheath.

On February 19, 1993, the Food and Drug Administration (FDA) approved the Spectranetics CVX-300 excimer laser unit and 1.4 and 1.7 millimeter diameter fiber-optic catheters for the following six indications for use in the treatment of coronary artery disease:

- saphenous vein grafts;
- total occlusions crossable by a guidewire;
- ostial lesions (blockages at the beginning of arteries);
- lesions with moderate calcification;
- long lesions; and
- lesions where angioplasty balloon failures have occurred.

Additional catheter sizes and improved models to treat the six original indications have been approved by the FDA over the ensuing years. On October 15, 2001, we received FDA approval for the use of the Spectranetics excimer laser and related catheters for a seventh coronary indication — for use within restenosed stents prior to brachytherapy (radiation therapy). On April 29, 2004, we received 510(k) clearance to market certain of our products for the treatment of total blockages in the legs that are not crossable with a guidewire. In all of these complex atherectomy indications, we offer an adjunct to traditional balloon angioplasty, stents and atherectomy (rotational cutters and burrs) devices. We believe the use of the laser adjunctively with other traditional percutaneous treatments provides superior clinical outcomes in complex lesions that are not well-suited to stand-alone balloon angioplasty or stenting. Unlike conventional balloons that merely compress arterial plaque against the stent or vessel wall, laser atherectomy dissolves the blockage.

The CVX-300 excimer laser unit was initially approved for lead removal procedures on December 9, 1997, with several additional approvals following in later years as we expanded our lead removal product line.

In November 1994, we received ISO 9001 certification from the TÜV Product Service GmbH (TÜV) in Munich, Germany, which allows us to market our products in the European Community within compliance of the manufacturing quality regulations. We hold EC Cert G1990821401007, G7011221401012 and G7020221401013; QA Cert Q1Z020321401014 with EN 550 Supplement with inclusion of ISO 13485:1996. In addition, we received CMDCAS (Canadian) certification by TÜV during January 2002. We have received CE (Communaute Europeene) mark registration for 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.

On September 28, 2001, in conjunction with our Japanese distributor, we received regulatory approval from the Japanese Ministry of Health and Welfare (MHW) to market our laser and various sizes of our Extreme®, Vitesse® E and Vitesse® C coronary catheters in Japan. We have submitted our application for reimbursement approval for these products in Japan. We do not expect our sales in Japan to increase unless and until reimbursement approval is attained. We are working with our current distributor, DVx Japan, to secure reimbursement approval and, if successful, expect this to occur sometime in 2006. In addition, we are in various stages of the submission process to obtain regulatory approval in Japan for some of our newer products.

Initial FDA approval for use of the excimer laser for coronary applications was based on the results of the Percutaneous Excimer Laser Coronary Angioplasty Study, which evaluated a registry of laser usage in blocked coronary arteries in 2,432 patients with a mean age of 63 years. Clinical success (i.e., reduction in the size of the lesion to less than 50 percent of the diameter of the artery without heart attack, death, or the need for emergency bypass surgery during hospitalization) was achieved in 89% of these patients. Of note, there was no difference in success rate or complications for long lesions, total occlusions crossable with a guidewire, saphenous vein grafts and aorto-ostial lesions, suggesting that complex lesions could be safely and effectively treated with excimer laser coronary atherectomy.

We believe that the CVX-300 system provides the following benefits:

- *Dissolves underlying tissue.* The process of photoablation dissolves the tissue causing the blockage as opposed to merely compressing it against the arterial wall, as with balloon angioplasty. We believe that the process of photoablation helps to reduce the incidence of distal embolization, whereby particles are dislodged from the lesion being treated, causing a blockage elsewhere in the vascular system.
- *Reduced procedure time.* Patient outcome audits, which compare excimer laser procedures to rotational atherectomy, reveal the excimer laser method shortens procedure times and reduces radiation exposure to the patient from fluoroscopic imaging used during the procedure.
- *Ease of use.* During a laser procedure, it may be necessary to adjust laser energy output. The CVX-300 laser unit is computer-controlled, which allows the physician to change energy levels without interrupting the treatment to remove the catheter from the patient for recalibration. This feature also enables the physician to begin the procedure with the minimum level of energy that might be required and, if necessary, to easily adjust the energy level upward during the procedure.

Product Applications

Excimer Laser Atherectomy

Coronary Excimer Laser Atherectomy. Percutaneous coronary intervention, or PCI, is a minimally invasive medical procedure used to treat coronary artery disease, or atherosclerosis, and is performed by interventional cardiologists and radiologists. We estimate there are approximately 1,000,000 PCI procedures performed annually in the United States. We estimate that approximately 40 to 45 percent of these patients could benefit from the use of our products, particularly in complex lesions.* In these complex indications, we offer an adjunct to traditional balloon angioplasty and stenting or the need for coronary bypass surgery. Unlike conventional balloons that merely compress arterial plaque against the stent or vessel wall, laser atherectomy dissolves the material. We believe the use of laser technology makes the treatment of complex lesions much less complicated. We focus our marketing and sales efforts in the U.S. and Europe on saphenous vein grafts, total occlusions crossable by a guidewire and in-stent restenoses, but also are approved for use in four other indications:

- ostial lesions (blockages at the beginning of arteries);
- lesions with moderate calcification;

- long lesions; and
- lesions where angioplasty balloon failures have occurred.

Peripheral Laser Atherectomy. Approximately 8 — 10 million people in the United States suffer from peripheral vascular disease. For the approximately 5 million patients with peripheral vascular disease that are symptomatic, symptoms range from claudication, or pain while walking, to critical limb ischemia, or pain while resting that may lead to ulcerations of the lower extremities and can often result in amputation. We estimate that approximately 200,000 bypass surgeries and 100,000 amputations are performed annually in the United States as a result of peripheral vascular blockages.* In addition, we estimate that about 400,000 people in the United States are treated for leg pain through either balloon angioplasty, stent implantation, and drug therapy.* Laser therapy is being used as an alternative treatment to bypass surgery, amputation, percutaneous transluminal angioplasty, or mechanical atherectomy. Certain of our products are marketed in the U.S. and Europe for the treatment of total blockages in the legs that are not crossable with a guidewire.

Clinical Trials. On January 26, 2001, Spectranetics received FDA approval to begin Phase 2 of the LACI trial, which deals with multi-vessel peripheral vascular disease in patients presenting with critical limb ischemia (CLI). Patients with CLI have severe circulatory disease resulting in resting leg pain, non-healing ulcers of the foot or lower leg, or gangrenous areas that are likely candidates for amputation (Rutherford Categories 4, 5, and 6). Frequently, these patients also suffer from coronary artery disease, hypertension and diabetes. The Phase 2 trial enrolled 145 patients at 15 domestic and several European sites. The primary endpoint of Phase 2 was limb salvage (i.e., freedom from major amputation) for a 6-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, advisory panel 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, 2003, we submitted data on 47 patients that showed a 95% limb salvage rate (i.e., no major amputations) among surviving patients six months after the procedure. 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. We submitted this data in a 510(k) application to the FDA during January 2004. There was no difference in serious adverse events as compared with the entire set of patients treated in the LACI trial. 510(k) clearance was received from the FDA on April 29, 2004.

The PELA trial enrolled 250 patients in a randomized trial comparing excimer laser treatment followed with balloon angioplasty to balloon angioplasty alone. The trial was designed to test the safety and efficacy of treating total occlusions (blockages) of at least 10 centimeters in length within the superficial femoral artery (SFA). The trial was designed to show superiority of the laser group over the balloon only group. The clinical results showed equivalence in most study endpoints, including the primary endpoint, which was primary patency (the degree in which the artery is open) as measured by $\leq 50\%$ diameter stenosis (blockage) at one year by ultrasound with no reintervention. The largest catheters used in the trial were 2.5mm in diameter as compared to vessel sizes treated in excess of 6.0 mm in diameter. We believe that the low catheter diameter in relation to vessel diameter adversely affected results and we are now evaluating product development opportunities for larger catheter diameters.

Disposable Laser Catheters. We have developed a broad selection of proprietary laser devices designed to meet physician needs and multiple indications for use, including excimer laser coronary atherectomy and peripheral excimer laser atherectomy in the upper and lower leg. Early laser catheters contained only a few large optical fibers to transmit the laser energy. These early devices were stiff, had difficulty accessing arterial anatomy and suffered from poor ablation characteristics. Current innovative laser catheter designs contain

hundreds of very small diameter, flexible glass fibers that can access more difficult-to-reach coronary anatomy. The smaller fibers also produce better laser energy distribution at the tip of the catheter for more uniform ablation.

Laser catheters are designed to provide several advantages over other atherectomy devices. These catheters, which we produce in sizes ranging from 0.9 to 2.5 millimeters in diameter, consist of concentric or eccentric bundles of optical fibers mounted within a thin plastic tubing. Fibers are coupled to the laser using a patented intelligent connector, which requires no adjustments by the physician. This connector provides information about the device being used to the CVX-300 laser unit computer, which controls the calibration cycle and energy output. The catheter's combination of trackability, flexibility and ablation characteristics enables the physician to access difficult-to-treat lesions. Our line of disposable catheters includes the following:

- *Extreme® Laser Catheter.* In October 1993, the FDA approved the Extreme® laser concentric catheter, which was our first high-performance coronary laser catheter. It is an over-the-wire (OTW) catheter with good flexibility and an active ablation area covering a high percentage of the catheter tip. Other catheter features include the patented metal rim tip designed for visualization and alignment and a proprietary lubricious coating for easy access. The Extreme® laser catheter is available in 0.9, 1.4, 1.7, 2.0, 2.2 and 2.5 millimeter tip diameters. Spectranetics has received the CE Mark of approval for use of its Extreme atherectomy line of catheters in Europe, and has received approval from the MHW to market the 1.4, 1.7 and 2.0 millimeter size Extreme catheters in Japan (but has not yet received reimbursement approval in Japan). This product line is marketed under the CLiRpath® brand name and was approved for marketing within the peripheral vascular system as a result of our FDA 510(k) clearance obtained in April 2004.
- *Vitesse® E Laser Catheter.* The Vitesse® E eccentric rapid-exchange (Rx) laser catheter is our first directional coronary laser catheter. The 1.7 millimeter diameter catheter was approved by the FDA in July 1995, and the 2.0 millimeter catheter was approved by the FDA in September 1997. Spectranetics received the CE Mark of approval for use of these atherectomy catheters in Europe in March 1997 and MHW approval for use in Japan in September 2001, but we are still awaiting Japanese reimbursement approval. This catheter utilizes an eccentric (or one-sided) fiber array at the tip that can be rotated by the operator to create a larger channel through the blockage. This product line is labeled for use within the coronary vascular system.
- *Vitesse® Cos Catheter.* The Vitesse® Cos concentric laser catheter, which succeeded the Vitesse® C catheter, was approved by the FDA in January 2000. Like its predecessor (which received regulatory approval in the United States in October 1994 and in Japan in September 2001, with reimbursement approval in Japan still pending), this is a rapid-exchange (Rx) catheter, which incorporates a "monorail design" that can be threaded onto and exchanged over a guidewire more conveniently than over-the-wire models. It is also compatible with a wide range of guidewires. The fibers in the Vitesse® Cos are "optimally spaced" and laboratory tests have demonstrated that it produces greater debulking, or plaque removal, compared with its predecessor catheter. The Vitesse® Cos laser catheter is available in 1.4, 1.7 and 2.0 millimeter tip diameters. In Europe, we received the CE Mark of approval for this laser catheter in December 1998. This product line is labeled for use within the coronary vascular system.
- *POINT 9™ Millimeter Catheter.* The POINT 9™ concentric catheter comes in both the Extreme (OTW) and Vitesse (Rx) models. The Vitesse model received CE Mark and FDA approvals in July and August 2000, respectively. The Extreme model received CE Mark approval in Europe in August 1999 and FDA approval in the United States in July 2000. The POINT 9 millimeter catheters are our smallest diameter atherectomy catheters and are designed for use in vessels as small as 1.5 millimeters in diameter, as well as larger vessels with total occlusions passable by a guidewire or where angioplasty balloon failures have occurred. On June 13, 2001, Spectranetics received FDA approval to market the POINT 9 X-80 catheter, which has the ability to use higher laser parameters to penetrate lesions where balloon failures have occurred and other difficult-to-treat lesions crossable by a guidewire. The

Extreme version of this product line is labeled for use within the coronary and peripheral vascular system. The Vitesse version of this product line is used within the coronary vascular system.

- *Spectranetics Support Catheter*[™]. In November 1999, we received clearance from the FDA to market the Spectranetics Support Catheter in the .014 and .018 inch models. A larger .035 inch model was approved by the FDA in September 2002. This is a non-laser-based accessory product designed for use in the cardiovascular system to support and assist standard guidewires to facilitate initial crossing of the blockage. It also facilitates exchange of standard guidewires without losing access to the blockage. We also received the CE Mark of approval in March 1999 to market the .014 and .018 inch support catheter in Europe; and the .035 inch model received the CE Mark of approval in July 2002. In February 2004, we received clearance to market the Quick-Cross[™] support catheter, which is the second generation of the Spectranetics Support Catheter. These products are used in both the coronary and peripheral vascular system.

Total atherectomy revenue during the year ended December 31, 2004 was \$13,520,000, an increase of 33% from \$10,155,000 during the year ended December 31, 2003. The revenue growth was largely driven from the sales of CLiR*path* products that were the subject of the April 29, 2004 510(k) clearance for use within the peripheral vascular system.

Cardiac Lead Removal Systems

Background. Over 800,000 patients worldwide are implanted with pacemakers and implantable cardioverter defibrillators, or ICDs, annually.* Pacemakers and ICDs are electronic devices that regulate the heartbeat. We believe that approximately 3% of these patients will eventually require pacemaker or ICD lead replacement. The current standard of care is to simply cap the replaced lead and leave it in the body. Our goal is to change the standard of care through the education of physicians as to the complications and associated costs of leaving the replaced leads in the body.

Competitive methods available to remove implanted leads include open-chest surgery and transvenous removal with plastic sheaths, each of which has significant drawbacks. For example, open-chest surgery is costly and traumatic to the patient. The plastic sheath method sometimes results in damage to the cardiovascular system, thereby necessitating surgery, and may cause the lead to disassemble during the removal procedure.

For the year ended December 31, 2004, lead removal product revenue was \$12,137,000, an increase of 11% from \$10,972,000 during the year ended December 31, 2003. The key driver of this revenue growth is an expanding patient population eligible for implantable cardioverter defibrillators (ICD), based on recent clinical research conducted by the large pacing companies (Guidant, Medtronic, St. Jude). The clinical research has shown that 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 ICD. Since there are more leads attached to an ICD and since they are typically larger in diameter, there is often a space problem in the subclavian vein when ICD's are implanted in patients that already have a pacemaker. Additionally, the potential for electrical "crosstalk" between the new and old leads is enhanced in this situation. As a result, the old leads are more likely to be removed in these situations.

We have initiated research aimed at identifying the complication rates associated with leads that are simply capped and left behind in the body. The research is using a sample of the Medicare database and we expect to conclude this research and publish the results during 2005. The goal of this research is to demonstrate that complication rates associated with capped leads are not insignificant, which may modify the standard of care to increase the number of pacemaker and defibrillator leads removed each year.

Clinical Trials. The PLEXES clinical trial was completed in October 1996 and demonstrated the SLS increased the complete lead removal success rate to 94 percent from 65 percent with mechanical lead removal techniques. This was a randomized trial that enrolled more than 750 patients. A more recent study completed in 1999 and published in December 2000 reported that using both the SLS and LLD increased the success rate to 98 percent.

Spectranetics Laser Sheath (SLS™). We have designed a laser-assisted lead removal device, the Spectranetics Laser Sheath (SLS), to be used with our CVX-300 excimer laser unit to remove implanted leads with minimal force. The SLS uses excimer laser energy focused through the tip of the SLS to facilitate lead removal by removing scar tissue surrounding the lead. In addition to resulting in less trauma and a lower complication rate, procedure time is reduced significantly.

The SLS consists of optical fibers arranged in a circle between inner and outer polymer tubing. The inner opening of the device is designed to allow a lead wire to pass through it as the device slides over the lead wire and toward the tip in the heart. Following the removal of scar tissue with the SLS, the lead wire is removed from the heart with counter-traction. We have been marketing our 12 French (Fr) SLS since December 1997. In September 1998, we received FDA market approval for our 14 Fr and 16 Fr Spectranetics Laser Sheaths, which are designed to free larger diameter implanted pacemaker and ICD leads. In February 2002, we received FDA approval to market an improved model of 16 Fr Laser Sheath. In May 2002, we received FDA approval to market an improved model of the 12 Fr and 14 Fr laser sheath. Spectranetics received the CE Mark of approval for use of its first generation laser sheath devices in Europe in February and July 1997, and second generation devices received the CE mark October 2001 and October 2002.

Lead Locking Device (LLD™). In October 1999, we received clearance from the FDA to market the LLD under a 510(k) application. This product was the first Spectranetics' product to go through the 510(k) regulatory process, which typically takes less time than other regulatory approval processes, such as pre-market approval or a pre-market approval supplement. We also received the CE Mark of approval for this product in Europe in March 1999. The LLD product complements our current SLS product line and, since it is not laser-based, can also be used in connection with the mechanical removal of pacemaker or defibrillator leads. The LLD is a novel mechanical device that assists in the removal of faulty leads by providing traction to the leads, which are typically wire spirals. The LLD is inserted into the center opening (i.e., lumen) of the lead and then a braid surrounding the LLD expands to fill and grip the entire length of the lead's inner circumference, in effect converting a spiral into a solid "pipe," which can more easily be extracted. Other devices on the market, which merely grip the lead at the far end, provide less stability and frequently release their grip on the lead. In March 2005, we received 510(k) clearance from the FDA for the LLD E, a next generation device that facilitates easier deployment in cardiac leads placed within tortuous anatomy in the coronary vascular system. It is also more easily visualized under angiography, which is a benefit to the physicians using the device.

Restenosed Stents

Background. Stents are thin, steel, slotted tubes or coils that are implanted through a percutaneous procedure to support the walls of coronary arteries. We estimate that approximately 900,000 stents are implanted in United States annually. Twenty to 25 percent of stents may develop blockages due to restenosis, or tissue ingrowth, which can lead to partial or total occlusion of the arteries, and 15 percent of them may be candidates for brachytherapy (radiation therapy)*. Several clinical trials are underway and some have concluded evaluating the use of drug-eluting stents, the next generation of stent technology. These stents are coated with various types of drugs designed to inhibit restenosis. Clinical data from these trials demonstrate that restenosis rates are reduced to rates less than 10% for certain lesions. As a result, we expect the annual number of restenosed stent procedures to decline.

Clinical Trials. On October 10, 2001, we received approval from the FDA to market our coronary atherectomy products to pretreat in-stent restenosis prior to brachytherapy. As a result, we concluded enrollment in our Laser Angioplasty in Restenosed Stents (LARS) trial, which had been conducted to study the use of our laser catheters in debulking stents which have restenosed. We no longer intend to pursue the broader in-stent restenosis label (with or without brachytherapy) in the United States. Spectranetics has received CE Mark approval to allow us to market our excimer laser atherectomy catheters throughout Europe for the treatment of restenosed stainless steel coronary stents, with or without brachytherapy.

Current Clinical Trials

AMI, or heart attack. We are conducting a prospective registry at up to 20 sites in the U.S. and Europe that will enroll at least 80 patients. The Extended FAMILI trial is a feasibility trial that will benchmark quantitative endpoints common in other AMI trials, such as myocardial blush scores and the reduction in infarct size for a subset of patients. The trial includes 30-day and 6-month clinical follow-up. Enrollment in the trial is nearing completion and we expect to have the 30-day follow-up and analysis complete sometime during the first half of 2005. After completion of the data analysis, a decision will be made whether to pursue a pivotal, randomized trial that may take two to three years to complete.

Saphenous vein grafts. We are conducting a prospective, post-market registry in up to 150 patients and 20 sites in the U.S. studying the use of laser atherectomy to treat blockages within saphenous vein grafts, a particularly challenging procedure for interventional cardiologists due to the potential for complications associated with distal embolization. The primary endpoint for the CORAL trial is a measurement of the complication rates, known as major adverse cardiac events (MACE). The MACE rates from the CORAL trial will be compared to MACE rates associated with the SAFER trial, which measured MACE rates using distal protection devices. The goal of this trial is to demonstrate the safety and efficacy of the laser in relation to distal protection devices, which are widely used and were proven to reduce MACE rates in the SAFER clinical trial. Enrollment in this trial is completed and the data analysis is being completed. We expect to complete the analysis sometime during the first half of 2005.

We are also considering the initiation of clinical research during 2005 focused on the treatment of peripheral vascular disease and chronic total occlusions in the coronary vascular system.

Sales and Marketing

Our sales goals are to increase the use of laser catheters and other disposable devices and to increase the installed base of excimer laser systems. We plan to introduce new physicians and institutions to the efficacy, safety, ease of use and growing indications of excimer laser technology through published studies of clinical applications. By leveraging the success of existing product applications, we hope to promote the use of our technology in new applications.

Providing customers with answers about the cost of acquisition, use of the laser and reimbursement codes is critical to the education process. Through the following marketing and distribution strategy, both in the United States and internationally, we believe that we will be positioned to capitalize not only on the core competency of excimer laser technology in coronary atherectomy, but also in lead extraction and in other new areas of development for excimer laser technology in the cardiovascular system.

Domestic Operations

As of March 2005, there are about 1,200 interventional cardiac catheterization laboratories in hospitals in the United States. We believe that approximately half of these cardiac catheterization laboratories perform a sufficient volume and complexity of procedures that would justify their acquisition of our excimer laser technology. Our United States sales efforts focus on the major cardiac catheterization labs, including teaching institutions, which perform the majority of interventional procedures. Our United States sales and marketing team consists of marketing managers, district sales managers and clinical sales representatives.

We are focused on expanding our product line and developing an appropriate infrastructure to support sales growth, and have increased our sales and marketing capabilities over the last few years through the addition of personnel to our marketing and sales team. Since the use of excimer laser technology is highly specialized, we believe that our marketing managers and direct sales team must have extensive knowledge about the use of our products and the various physician groups we serve. Our marketing activities are designed to support our direct sales team and include advertising and product publicity in trade journals, newsletters, continuing education programs, and attendance at trade shows and professional association meetings. We currently have three marketing managers who are responsible for global marketing activities for a given

market segment, i.e., coronary artery disease therapy, cardiac lead removal systems and peripheral vascular disease therapy.

As of February 28, 2005, we have 41 field sales employees consisting of a director of sales, 7 district sales managers and 33 clinical sales representatives. The 41 current field sales employees compares with 33 as of February 28, 2004. The roles of each member of the sales team are outlined below:

District Sales Managers are responsible for the overall management of a district, including sales of lasers and disposable products. They are directly responsible for the performance of the clinical sales representatives in their district.

Clinical Sales Representatives, who have experience working in hospital catheter labs, support the district managers. Their primary function is to assist in training our customers by standing in on cases, assisting in catheter and laser parameter selection, and helping ensure proper protocol and technique is used by clinicians. There are varying levels within this job category, including clinical specialist, senior clinical specialist, senior clinical account manager and senior account sales manager. The varying levels reflect increased experience with the Company and sales performance within their assigned geographic territory.

Our field team also includes 11 service engineers who are responsible for 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.

International Operations

In Europe, there are approximately 500,000 balloon angioplasty procedures performed annually in approximately 450 interventional cardiac catheterization laboratories.* In 1993, we began marketing and selling our products in Europe and surrounding areas through Spectranetics International, B.V., a wholly owned subsidiary, as well as through distributors.

In the fourth quarter of 2000, we made the decision to restructure our European operations and utilize a distributor in Germany, our largest European market. We now utilize distributors throughout Europe and the Middle East with the exception of France, The Netherlands and Belgium, where we utilize a direct sales force. In 2004, Spectranetics International, B.V., revenues totaled \$3,288,000, or 9 percent of our revenue.

In addition to the operations of Spectranetics International, B.V., we conduct international business in Japan and other selected countries in the Pacific Rim through distributors. In 2004, revenues from these foreign operations totaled \$614,000, or 2 percent of our revenue.

Foreign sales may be subject to certain risks, including export/import licenses, tariffs, other trade regulations and foreign medical regulations. 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. For more information, see “Risk Factors — We are Exposed to Problems That Come From Having International Operations” set forth in Item 7 — “Management’s Discussion and Analysis of Financial Condition and Results of Operations” herein.

Government Regulation

In the United States, all medical devices are subject to FDA regulation under the Medical Device Amendments of the Federal Food, Drug and Cosmetics Act, or FFDCFA, and are classified into one of three categories: Class I, Class II, and Class III. Products in Class I are the least invasive and pose the least amount of risk, while products in Class II pose more potential risk to patients, and Class III products provide the most

* Amounts were estimated by Spectranetics based on extrapolation from available industry data. Patient population estimates are subject to inherent uncertainties. We are unable to determine with any degree of certainty the number of procedures for any indication or the number of patients who are suitable for treatment using these procedures.

potential risk. The FDA approval process becomes more rigorous for products classified as higher potential risk.

Section 510(k) Devices

Section 510(k) of the FFDCA is available in certain instances for Class I and Class II products. It requires that before introducing most Class II and some Class I devices into interstate commerce, the company introducing the product must first submit information to the FDA demonstrating that the device is substantially equivalent in terms of safety and effectiveness to a device legally marketed prior to March 1976. When the FDA determines that the device is substantially equivalent, the agency issues a “clearance” letter that authorizes marketing of the product. The Support Catheter and LLD have been cleared by the FDA under the “510(k)” process. We have also received 510(k) clearance for catheters to be used in the treatment of total occlusions in the legs.

Subsequent to its initial introduction, a manufacturer may make changes to its previously cleared products. Under certain circumstances, a new 510(k) is required when a manufacturer makes a change that could significantly affect the device’s safety or effectiveness or the manufacturer makes a major change to the device’s intended use. Before implementing the change, the manufacturer is responsible for evaluating each change to determine whether to file a new 510(k). There is a risk that the FDA will not agree with the manufacturer’s decision and will require the filing of a new 510(k).

PMA Devices

The CVX-300 laser unit and most of our catheters used in the coronary anatomy are designated as Class III devices, except for the Support Catheter and LLD, which are coronary devices that were cleared under Section 510(k) of the FFDCA. Class III devices are devices that are represented to be life-sustaining or life-supporting, or that present potential serious risk of illness or injury. Class III devices are subject to the most rigorous FDA approval process, the pre-market approval, or PMA, process.

Pre-market approval of a Class III device generally requires the completion of three major steps. The first step involves the granting of an investigational device exemption, or IDE, by the FDA, which permits the proposed product to be used in controlled human clinical trials. Upon completion of a sufficient number of clinical cases to determine the safety and effectiveness of the proposed product for specific indications, a pre-market approval application is then prepared and submitted to the FDA for review. The pre-market approval application must contain the results of the clinical trials, the results of all relevant bench tests, laboratory and animal studies, a complete description of the device and its components, and a detailed description of the methods, facilities, and controls used to manufacture the device. In addition, the submission must include the proposed labeling and promotional literature. If the FDA determines that the pre-market approval application is sufficiently complete to permit a substantive review, the FDA will accept the application for filing.

Once the submission is accepted for filing, the FDA begins an in-depth review of the pre-market approval application, which represents the second major step in pre-market approval of a Class III device. An FDA review of a pre-market approval application generally takes one to two years from the date the pre-market approval application is accepted for filing, but may take significantly longer. The review time is often significantly extended by the FDA asking for more information or clarification of information already provided in the submission. During the review period, an advisory committee, typically a panel of clinicians, will likely be convened to review and evaluate the application and provide recommendations to the FDA at a public panel meeting as to whether the device should be approved. Companies are typically requested to make a presentation at the public panel meeting. The FDA is not bound by the recommendations of the advisory panel.

Toward the end of the pre-market approval review process, the FDA will generally conduct an inspection of the manufacturer’s facilities to ensure that the facilities are in compliance with applicable Good Manufacturing Practice requirements, which are outlined under FDA’s Quality System Regulation. If the FDA’s evaluations of both the pre-market approval application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of

conditions that must be met in order to secure final approval of the pre-market approval application. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will complete the third major step by issuing a pre-market approval letter, authorizing commercial marketing of the device for certain indications. If the FDA's evaluations of the pre-market approval application or manufacturing facilities are not favorable, the FDA will deny approval of the pre-market approval application or issue a "not approvable" letter. The FDA may also determine that additional clinical trials are necessary, in which case pre-market approval may be delayed for several years while additional clinical trials are conducted and submitted in an amendment to the pre-market approval application. The pre-market approval process can be expensive, uncertain and lengthy and a number of devices for which FDA approval has been sought by other companies have never been approved for marketing.

Modifications to a device that is the subject of a pre-market approval, its labeling, or manufacturing process may require approval by the FDA of pre-market approval supplements or new pre-market approval applications. Supplements to a pre-market approval application often require the submission of the same type of information required for an initial pre-market approval application, except that the supplement is generally limited to that information needed to support the proposed change from the product covered in the original pre-market approval application.

The chart below summarizes the month and year we obtained approval from the United States and international regulatory approval status of each of our products and procedures for their particular indications. The CE Mark designates regulatory approval throughout Europe, and the Ministry of Health and Welfare (MHW) grants regulatory approval in Japan. We have yet to receive reimbursement approval in Japan.

<u>Product and Procedure</u>	<u>FDA</u>	<u>CE Mark</u>	<u>MHW</u>
CVX-300®	2/93	9/96	9/01
Coronary Atherectomy			
Extreme®			
Vitesse® C	10/93	12/96	9/01
Vitesse® E	10/94	12/96	9/01
Vitesse® COS.....	9/97	2/97	9/01
POINT 9™ Extreme	1/00	12/98	
POINT 9™ Vitesse	7/00	8/99	
POINT 9™ X-80.....	8/00	7/00	
Restenosed stents prior to brachytherapy	6/01	6/02	
Restenosed stents*.....	10/01	1/98	
Support Catheter (.014 and .018 inch)	11/99	3/99	
Support Catheter (.035 inch)	9/02	7/02	
Quick Cross™ Support Catheters	2/04	2/04	
Pacing Lead and ICD Lead Extraction			
SLS 12 Fr	12/97	2/97	
SLS 14 Fr	9/98	7/97	
SLS 16 Fr	9/98	7/97	
SLS 16 Fr, improved	2/02	10/01	
SLS 12/14 Fr, improved	5/02	10/02	
LLD	10/99	3/99	
LLD E	03/05	01/05	
Peripheral Atherectomy	04/04	11/96	

* Includes pretreatment prior to brachytherapy

We received our initial investigational device exemption to perform excimer laser percutaneous coronary atherectomy in May 1989. In February 1991, we submitted our pre-market approval application, which was accepted for filing by the FDA in June 1991. On November 26, 1991, our pre-market approval application was reviewed by a public advisory panel, and we received a recommendation for approval of the CVX-300 laser unit and two sizes of our soft-rim catheters. As part of the approval process, we were inspected in October 1991 by the FDA to verify our compliance with Good Manufacturing Practices requirements. The final step in the approval process, the issuance of a letter by the FDA approving the application, occurred on February 19, 1993. In September 1993, we received pre-market approval for the Gen4-CVX300 laser. In March and December 1999, we received pre-market approval of modifications to the operating software for the CVX-300.

We cannot assure that the FDA will approve our current or future pre-market approval applications or supplements on a timely basis or at all. The absence of such approvals could have a material adverse impact on our ability to generate future revenues. For more information, see “Risk Factors — Failures in Clinical Trials May Hurt Our Business” set forth in Item 7 — “Management’s Discussion and Analysis of Financial Condition and Results of Operations” filed herewith.

Any products we manufacture or distribute pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA. Device manufacturers are required to register their establishments and list their devices with the FDA, and are subject to periodic inspections by the FDA and certain state agencies. The FFDCA requires devices to be manufactured in accordance with Quality System Regulation requirements, which impose certain process, procedure and documentation requirements upon us with respect to product development, manufacturing and quality assurance activities. We have developed systems and controls that we believe will enable us to comply with Quality System Regulation requirements; however, we cannot assure that we will be able to maintain compliance with these requirements.

In addition, the Medical Device Reporting, or MDR, regulation obligates us to inform the FDA whenever there is reasonable evidence to suggest that one of our devices may have caused or contributed to death or serious injury, or when one of our devices malfunctions and, if the malfunction were to recur, the device would be likely to cause or contribute to death or serious injury. There can be no assurance that the FDA will agree with our determinations as to whether particular incidents meet the threshold for MDR reporting.

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

Noncompliance with requirements under the FFDCA or accompanying regulations can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant pre-market approval, withdrawal of marketing approvals, and criminal prosecution. The FDA also has authority to request repair, replacement or refund of the cost of any device manufactured or distributed by us.

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 a FDA Certificate to Foreign Government verifying that the product complies with FFDCA 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 FFDCA and all applicable or pertinent regulations. The FDA may refuse to issue a Certificate to Foreign Government if significant outstanding Quality System Regulation violations exist.

We are 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. See “Risk Factors — Regulatory

Compliance is Very Expensive and Can Often Be Denied or Significantly Delayed” set forth in Item 7 — “Management’s Discussion and Analysis of Financial Condition and Results of Operations” filed herewith.

Competition

Methods for the treatment of cardiovascular disease are numerous and we expect them to increase in number. Almost all of our competitors have substantially greater financial, manufacturing, marketing and technical resources than we do. Consequently, we expect intense competition to continue in the marketplace. Although our excimer laser technology competes against stents and balloon angioplasty catheters, direct competition comes from manufacturers of atherectomy and thrombectomy devices. In the lead removal market, we compete worldwide with lead removal devices manufactured by Cook Vascular Inc. and we compete in Europe with devices manufactured by VascoMed.

We estimate that approximately 85% of coronary interventions involve the placement of a stent. The leading stent providers in the United States are SCIMED Life Systems, Inc. (a subsidiary of Boston Scientific Corporation), Cordis Corporation (a subsidiary of Johnson & Johnson Interventional Systems), Guidant Corporation, Medtronic, Inc. and JOMED N.V. The leading balloon angioplasty manufacturers are SCIMED, Cordis, Guidant and Medtronic. Manufacturers of atherectomy or thrombectomy devices include SCIMED, Guidant, Possis Medical, Inc. and Fox Hollow Technologies, Inc.

We believe that the primary competitive factors in the interventional cardiovascular market are:

- the ability to treat a variety of lesions safely and effectively;
- the impact of managed care practices and procedure costs;
- ease of use;
- size and effectiveness of sales forces; and
- research and development capabilities.

For more information, see “Risk Factors — We May Be Unable To Compete Successfully In Our Highly Competitive Industry In Which Many Other Competitors are Bigger Companies” set forth in Item 7 — Management’s Discussion and Analysis of Financial Condition and Results of Operations” filed herewith.

Research and Development

From inception through 1988, our primary emphasis in research and development was on the CVX-300 laser unit. Since 1988, our research and development efforts have focused on refinement of the CVX-300 laser unit and laser device technology. We are also exploring additional applications for the CVX-300 laser unit and are developing advanced laser devices designed to facilitate greater use in existing applications.

Our team of research scientists, engineers and technicians performs substantially all of our research and development activities. Our research and development expense, which also includes clinical studies and regulatory costs, totaled \$3,798,000 in 2004, \$2,713,000 in 2003, and \$3,309,000 in 2002. We expect these costs to increase in 2005 as we advance clinical research focused on peripheral vascular disease and heart attack combined with increased product development activities.

Manufacturing

We assemble and test substantially all of our product line and have vertically integrated a number of processes in an effort to provide increased quality and reliability of the components used in the production process. Many of the processes are proprietary and were developed by us. We believe that our level of manufacturing integration allows us to control costs, quality and process advancements, to accelerate new product development cycle time and to provide greater design flexibility. Raw materials, components and subassemblies used in our products are purchased from outside suppliers and are generally readily available from multiple sources.

Our manufacturing facilities are subject to periodic inspections by regulatory authorities, including Quality System Regulations compliance inspections by the FDA and TÜV, which is the European governing body equivalent to the FDA. We have undergone nine inspections by the FDA for Quality System Regulations compliance since 1990, and the TÜV has conducted an inspection each year since 1993. Each inspection resulted in a limited number of noted observations, to which we believe we have provided adequate responses.

We purchase certain components of our CVX-300 laser unit 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 we could obtain replacement components from alternative suppliers, we may be unable to do so. In addition, we may encounter difficulties in scaling up production of laser units and disposable devices and hiring and training additional qualified manufacturing personnel. Any of these difficulties could lead to quarterly fluctuations in operating results and adversely affect us.

Third-Party Reimbursement

Our CVX-300 laser unit and related fiber-optic laser devices are generally purchased by hospitals, which then bill various third party payers for the health care services provided to their patients. These payers include Medicare, Medicaid and private insurance payers. Most public and private insurance payers base their payment systems upon the Medicare Program. The Medicare Program reimburses hospitals based on predetermined amounts per diagnosis code for inpatient hospital services (those lasting 24 hours or more) and predetermined amounts per procedure performed for outpatient hospital services (those lasting less than 24 hours), and it reimburses physicians based on a fee schedule per procedure performed.

At present, many of our customers using the CVX-300 for laser atherectomy are obtaining reimbursement for inpatient hospital services under an atherectomy code. Lead removal procedures using the SLS are reimbursed using the same inpatient hospital codes for non-laser lead removal or lead removal and replacement. Hospital outpatient codes and physician services codes differentiate atherectomy procedures from PCI procedures utilizing only balloons or only balloons and stents.

Reimbursement amounts are generally adequate to cover the cost of laser ablation procedures. Procedure costs and payment rates vary depending on the complexity of the procedure, various patient factors and geographical location.

While we believe that a laser atherectomy procedure offers a less costly alternative for the treatment of certain types of heart disease, we cannot assure that the procedure will be viewed as cost-effective under changing reimbursement guidelines or other health care payment systems. For more information, see “Risk Factors — Failure Of Third Parties To Reimburse Medical Providers For Our Products May Reduce Our Sales” set forth in Item 7 — “Management’s Discussion and Analysis of Financial Condition and Results of Operations” filed herewith.

Product Liability and Insurance

Our business entails the risk of product liability claims. We maintain product liability insurance in the amount of \$5,000,000 per occurrence with an annual aggregate maximum of \$5,000,000. We cannot assure, however, that product liability claims will not exceed such insurance coverage limits or that such insurance coverage limits will continue to be available on acceptable terms, or at all. See “Risk Factors — Potential Product Liability Claims and Insufficient Insurance Coverage May Hurt Our Business and Stock Price” set forth in Item 7 — “Management’s Discussion and Analysis of Financial Condition and Results of Operations” filed herewith.

Employees

As of February 28, 2005, we had 160 full time employees, including 18 in research and development and clinical affairs, 53 in manufacturing and quality assurance, 79 in marketing, sales, field service and administration in the United States and 10 in marketing, sales and administration in Europe. 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 2. *Properties*

Our domestic operations are located in three buildings in Colorado Springs, Colorado. These facilities contain approximately 35,000 square feet of manufacturing space and approximately 15,000 square feet devoted to marketing, research and administrative activities. Two of these facilities are leased and have lease expiration dates through December 31, 2005 and March 1, 2006, respectively. We purchased for cash consideration the third facility, which was previously under lease, on March 29, 2005 for \$1,350,000.

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, 2008.

We believe these facilities are adequate to meet our requirements for the foreseeable future.

ITEM 3. *Legal Proceedings*

In July, 2003, Spectranetics filed a complaint in the United States District Court for the District of Colorado against Dr. Peter Rentrop, which Spectranetics amended in September 2003, seeking declaratory relief that (1) Spectranetics' products do not infringe any claims of Dr. Rentrop's United States Patent No. 6,440,125 (the "'125 patent"); (2) the claims of the '125 patent are invalid and unenforceable; and (3) in the event that the Court finds that the claims of the patent to be valid and enforceable, that Spectranetics is, through its employees, a joint owner of any invention claimed in the '125 patent. Spectranetics also brought claims against Dr. Rentrop for damages based upon Dr. Rentrop's (1) misappropriation of Spectranetics' trade secrets; (2) breach of the parties' Confidentiality Agreement; and (3) wrongful taking of Spectranetics' confidential and proprietary information.

On January 6, 2004, the United States Patent and Trademark Office issued to Dr Rentrop a continuation patent to the '125 patent, United States Patent No. 6,673,064 (the "'064 patent"). On the same day, Dr. Rentrop filed in the United States District Court for the Southern District of New York, a complaint for patent infringement against Spectranetics, under the '064 patent (the "New York case").

On January 26, 2004, the Court in Colorado granted Dr. Rentrop's Motion to Dismiss the Amended Complaint on the basis that the Court lacked personal jurisdiction over Dr. Rentrop, a resident of New York. Spectranetics decided to forgo appealing that decision; thus, there no longer is any case pending in Colorado.

On March 9, 2004, Spectranetics filed its Answer, Affirmative Defenses and Counterclaims against Dr. Rentrop in the New York case. Spectranetics' claim is that, in connection with consultation services provided to Spectranetics by Dr. Rentrop, Spectranetics provided Dr. Rentrop with confidential and proprietary information concerning certain of Spectranetics' laser catheter technology. Spectranetics claims that rather than keeping such information confidential as required by agreement with Spectranetics, Dr. Rentrop used the information to file patent applications associated with the '125 and '064 patents, which incorporate and claim inventions to which Spectranetics' personnel contributed significantly and materially, if not exclusively, thus entitling Spectranetics' personnel to designation at least as co-inventors. Spectranetics also seeks declaratory judgments of non-infringement, invalidity and unenforceability of the patents-in-suit, and has alleged counterclaims against Dr. Rentrop for breach of confidentiality agreement, misappropriation of trade secrets, and conversion. The discovery phase of this case is nearly complete and a trial date has been set for September 2005.

On June 24, 2004, the Court of Appeal of Amsterdam rejected an appeal made by Spectranetics International, B.V. (Spectranetics BV), on a judgment awarded to Cardiomedica S.p.A. (Cardiomedica), an Italian company, by the District Court of Amsterdam. Cardiomedica originally filed the suit in July 1999, and the lower court's judgment was rendered on April 3, 2002. The Court of Appeal of Amsterdam affirmed the lower court's opinion that an exclusive distributor agreement for the Italian market was entered into between

the parties for the three-year period ending December 31, 2001, and that Cardiomedica may exercise its right to compensation from Spectranetics BV for its loss of profits during such three-year period. The appellate court awarded Cardiomedica the costs of the appeal, which approximated \$20,000, and has referred the case back to the lower court for determination of the loss of profits. Cardiomedica asserts lost profits of approximately \$1,500,000, which is based on their estimate of potential profits during the three-year period. Spectranetics BV estimates that the lost profits to Cardiomedica for the period, plus estimated interest and awarded court costs, totaled \$273,000 for the three-year period, and such amount is included in accrued liabilities at December 31, 2004. We intend to vigorously defend the calculation of lost profits.

During August 2004, one of our licensors initiated arbitration proceedings involving a disagreement over royalties paid to them since the inception of a license agreement in October 2000. The disagreement centers on the treatment of certain service-based revenue, including repair and maintenance, and physician and clinical training services. We believe these are beyond the scope of the license agreement. We have accrued costs of \$1,732,000 associated with the resolution of this matter, which represents our best estimate of costs to resolve the matter based on previous negotiations with the licensor before arbitration was commenced. The first hearing related to this proceeding is scheduled in June 2005. Management intends to vigorously defend its position during the arbitration proceedings.

On or about August 30, 2004, Surmodics filed a lawsuit against Spectranetics in the United States District Court for the District of Minnesota, alleging that Spectranetics underpaid royalties for the period since January 2001 under a license agreement with SurModics. SurModics claims that Spectranetics took improper deductions from royalty-bearing revenue, resulting in an alleged underpayment. In February 2005, the Company settled its dispute with Surmodics and executed an amendment to the license agreement that incorporated such settlement. Under the terms of the amendment, which has a non-cancelable term of four years, the Company agreed to pay the licensor \$275,000 in back royalties. Such amount was included in accrued liabilities at December 31, 2004. Additionally, the license was converted to non-exclusive and the royalty rate for products sold using the associated technology was reduced effective October 1, 2004. The company also agreed to increase its minimum quarterly royalty payment to \$50,000 from \$25,000 beginning July 1, 2005.

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 our business.

ITEM 4. *Submission of Matters to a Vote of Security Holders*

None.

PART II

ITEM 5. *Market for the Registrant's Common Stock and Related Shareholder Matters*

Our Common Stock is traded on the The Nasdaq National Market under the symbol "SPNC." The table below sets forth the high and low sales prices for the Company's Common Stock as reported on The Nasdaq National Market for each calendar quarter in 2004 and 2003. 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.

	<u>High</u>	<u>Low</u>
Year Ended December 31, 2004		
1st Quarter	\$5.75	4.19
2nd Quarter	6.00	4.90
3rd Quarter	7.18	4.92
4th Quarter	5.75	3.42
Year Ended December 31, 2003		
1st Quarter	\$3.95	2.50
2nd Quarter	3.51	2.55
3rd Quarter	6.94	2.71
4th Quarter	6.56	2.29

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.

The closing sales price of our Common Stock on March 30, 2005, was \$5.21. On March 23, 2005, we had 684 shareholders of record.

The following table provides information as of December 31, 2004 about equity awards under the Company's equity compensation plans:

<u>Plan Category</u>	<u>Number of Securities to Be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)</u>	<u>Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)</u>	<u>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a) (c)</u>
Equity compensation plans approved by security holders(1)	4,258,429(2)	\$3.26(2)	1,435,196(3)
Equity compensation plans not approved by security holders(4)	100,000	4.65	—
Total	4,358,429	\$2.94	1,435,196

- (1) These plans consist of: (1) The 1997 Equity Participation Plan of the Spectranetics Corporation, (the "1997 Plan"), (2) The 1991 Equity Participation Plan of the Spectranetics Corporation (the "1991 Plan"), (3) The 1995 Director Equity Participation Plan (the "1995 Director Plan"), (4) The Advanced Interventional Systems Equity Participation Plan (the "AIS Plan") and (5) The Employee Stock Purchase Plan (the "ESPP Plan").
- (2) The Company is unable to ascertain with specificity the number of securities to be issued upon exercise of outstanding rights under the ESPP Plan or the weighted average exercise price of outstanding rights under the ESPP Plan. Accordingly, the number of shares listed in column (a) and the weighted average exercise price listed in column (b) apply only to options outstanding under the 1997 Plan, the 1991 Plan,

the 1995 Director Plan and the AIS Plan. The ESPP Plan provides that shares of the Company's Common Stock may be purchased at a per share price equal to 85% of the fair market value of the Common Stock at the beginning or end of the six month offering period, whichever is lower.

- (3) Of these shares of Common Stock, 910,528 remain available for issuance under the 1997 plan, and 524,668 remain available for issuance under the ESPP Plan. No shares of Common Stock are available for future issuance under the 1991 Plan, the 1995 Director Plan, or the AIS Plan.
- (4) The plans consist of an option agreement between the Company and Emile Geisenheimer, dated April 17, 1996 (the "Geisenheimer Agreement"), pursuant to which an option to purchase 100,000 shares of Common Stock was granted in return for certain consulting services Mr. Geisenheimer rendered to the Company. The option granted to Mr. Geisenheimer had an exercise price of \$4.66 per share which was equal to the fair market value of the Company's Common Stock on the grant date. 50,000 shares vested on April 17, 1997 and 50,000 shares vested on April 17, 1998.

ITEM 6. *Selected Consolidated Financial Data*

The following selected consolidated financial data, as of and for each year in the five-year period ended December 31, 2004, are 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 elsewhere in this annual report. The selected balance sheet data as of December 31, 2004 and 2003, and statement of operations data for each year in the three-year period ended December 31, 2004, have been derived from our audited financial statements also included elsewhere herein. The selected historical balance sheet data as of December 31, 2002, 2001 and 2000, and statement of operations data for the years ended December 31, 2001 and 2000, are derived from, and are qualified by reference to, audited financial statements of the Company not included herein.

	Years Ended December 31,				
	2004	2003	2002	2001	2000
	(In thousands, except per share data)				
STATEMENT OF OPERATIONS DATA:					
Revenue	\$34,708	27,869	28,097	27,808	26,900
Cost of revenue	8,801	7,900	8,983	8,459	8,282
Selling, general and administrative	19,347	15,261	14,586	14,277	17,843
Research, development and other technology	5,355	3,812	4,510	4,915	5,287
Proxy contest and settlement obligations	—	—	1,837	—	—
Litigation settlement costs, net	—	—	—	—	3,654
Reorganization costs and litigation reserves	—	(32)	—	—	1,200
Operating income (loss)	1,205	928	(1,819)	157	(9,366)
Other income, net	229	106	323	433	838
Income (loss) before income taxes	1,434	1,034	(1,496)	590	(8,528)
Income tax benefit (expense)	1,518	(105)	(65)	—	(170)
Net income (loss)	<u>\$ 2,952</u>	<u>929</u>	<u>(1,561)</u>	<u>590</u>	<u>(8,698)</u>
Income (loss) from continuing operations per share:					
Basic	\$ 0.12	\$ 0.04	(0.07)	0.03	(0.36)
Diluted	\$ 0.11	\$ 0.04	(0.07)	0.02	(0.36)
Weighted average common shares outstanding:					
Basic	25,080	24,254	23,809	23,547	23,298
Diluted	27,060	25,443	23,809	24,161	23,298

	As of December 31,				
	2004	2003	2002	2001	2000
	(In thousands, except per share data)				
BALANCE SHEET DATA:					
Working capital	\$13,662	11,966	10,508	3,552	11,337
Cash, cash equivalents, and investment securities	17,410	13,281	11,430	12,884	11,921
Restricted cash	—	1,133	1,123	—	—
Property, plant, & equipment, net	4,362	3,633	3,478	4,119	4,760
Total assets	33,038	26,082	23,836	25,713	27,360
Long-term liabilities	83	173	—	57	1,649
Shareholders' equity	23,489	18,212	15,855	16,657	15,716

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

Forward-Looking Statements

The information set forth in this annual report on Form 10-K includes “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, and is subject to the safe harbor created by that section. 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 below and include, but are not limited to, the following:

- Market acceptance of excimer laser atherectomy technology;
- Increased pressure on expense levels resulting from expanded marketing and clinical activities;
- Dependence on new product development and new applications for excimer laser technology;
- Uncertain success of the Company's strategic direction;
- Technological changes resulting in product obsolescence;
- Intellectual property claims of third parties;
- Adverse state or federal legislation and regulation;
- Product defects;
- Availability of vendor-sourced component products at reasonable prices; and
- The risk factors listed from time to time in our filings with the Securities and Exchange Commission as well as those set forth in Item 7 — “Management's Discussion and Analysis of Financial Condition and Results of Operations — 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.

Corporate Overview

We develop, manufacture, market and distribute single-use medical devices used in minimally invasive surgical procedures within the cardiovascular system in conjunction with our proprietary excimer laser system. Excimer laser technology delivers comparatively cool ultraviolet light in short, controlled energy pulses to ablate or remove tissue. Our excimer laser system includes the CVX-300[®] laser unit and various fiber-optic delivery devices, including disposable catheters and sheaths. Our excimer laser system is the only excimer laser system approved in the United States and Europe for use in multiple, minimally invasive cardiovascular applications. Our excimer laser system is used in complex atherectomy procedures to open clogged or obstructed arteries in the coronary and peripheral vascular system. It is also used to remove lead wires from patients with implanted pacemakers or cardioverter defibrillators, which are electronic devices that regulate

the heartbeat. On April 29, 2004, we obtained 510(k) marketing clearance from the Food and Drug Administration (FDA) for a laser-based treatment of total occlusions (blockages) in the legs not crossable with a guidewire. Some of the patients with total occlusions in the leg suffer from critical limb ischemia (CLI), a debilitating condition that begins with resting leg pain and often leads to tissue loss or amputation as a result of a lack of blood flow to the legs. We believe the excimer laser is particularly well suited to treat thrombus-laden lesions. We are in the early stages of scientific research in this area and have initiated clinical research for a laser-based treatment of saphenous vein grafts and acute myocardial infarction, or heart attack. We are currently sponsoring ongoing clinical trials as described below:

AMI, or heart attack. We are conducting a prospective registry at up to 20 sites in the U.S. and Europe that will enroll at least 80 patients. The Extended FAMILI trial is a feasibility trial that will benchmark quantitative endpoints common in other AMI trials, such as myocardial blush scores and the reduction in infarct size for a subset of patients. The trial includes 30-day and 6-month clinical follow-up. Enrollment in the trial is nearing completion and we expect to have the 30-day follow-up and analysis complete sometime during the first half of 2005. After completion of the data analysis, a decision will be made to pursue a pivotal, randomized trial that may take two to three years to complete.

Saphenous vein grafts. We are conducting a prospective, post-market registry in up to 150 patients and 20 sites in the U.S. studying the use of laser atherectomy to treat blockages within saphenous vein grafts, a particularly challenging procedure for interventional cardiologists due to the potential for complications associated with distal embolization. The primary endpoint for the CORAL trial is a measurement of the complication rates, known as major adverse cardiac events (MACE). The MACE rates from the CORAL trial will be compared to MACE rates associated with the SAFER trial, which measured MACE rates using distal protection devices. The goal of this trial is to demonstrate the safety and efficacy of the laser in relation to distal protection devices, which are widely used and were proven to reduce MACE rates in the SAFER clinical trial. Enrollment in this trial is completed and the data analysis is being completed. We expect to complete the analysis sometime during the first half of 2005.

We are also considering the initiation of clinical research during 2005 focused on the treatment of peripheral vascular disease and chronic total occlusions in the coronary vascular system.

Our business strategy is to develop additional applications for our excimer laser, increase utilization of our FDA-approved products, and continue to expand our installed base of laser systems, which totals 417 as of December 31, 2004.

Net income was \$2,952,000 or \$0.11 per diluted share for the year ended December 31, 2004, compared with net income of \$929,000 or \$0.04 per diluted share for the year ended December 31, 2003. Net income for the year ended December 31, 2004 included a \$1,615,000 income tax benefit, which represents the release of a valuation allowance that is no longer required on specific deferred taxes. At December 31, 2004, we have recorded a net deferred tax asset of \$1,615,000 which represents our best estimate of the amount of our deferred tax assets that is more likely than not to be realized through the reduction of income taxes payable in future years.

Our financial guidance for 2005 is for revenue in the range of \$40 to \$43 million, driven primarily by the following key factors:

- Continued growth in our coronary and lead removal product lines;
- Growth in our existing peripheral product line, driven by the CLiR*path* products that received FDA clearance in April 2004; and
- Potential growth associated with new products in the peripheral atherectomy market that may be launched in late 2005, depending on the completion of product development cycles and regulatory clearance.

Net income is anticipated to be in the range of \$1.0 million to \$1.5 million and gross margin as a percentage of sales is expected to be in the mid-seventies. This guidance assumes reinvestment of most of the incremental gross margin into continued expansion of the field sales and clinical organizations, key product

development and clinical study programs, and the staffing of two key executive officer positions. This revenue guidance also assumes 40 to 50 new laser placements in 2005. We expect revenue and net income to strengthen throughout the year; however, 2005 first quarter revenue and net income is expected to be less than 2004 fourth quarter levels, which is consistent with historical seasonal patterns.

In assessing our 2005 financial guidance, we considered many factors and assumptions including, but not limited to, current and projected sales trend data; status, timing and progression of the Company's development projects; current and projected spending levels to support sales, marketing, development and administrative activities; and other risk factors discussed separately herein. The above guidance does not take into account the effect of expensing stock options, which will be required in financial statements beginning July 1, 2005.

Revenue by Product Line

	<u>2004</u>	<u>2003</u>	<u>2002</u>
	(In thousands)		
Laser equipment	\$ 3,772	2,824	5,082
Disposable Products	25,657	21,127	19,161
Service	5,187	3,973	3,813
Other, net of allowance for sales returns*	<u>92</u>	<u>(55)</u>	<u>41</u>
Total Revenue	<u>\$34,708</u>	<u>27,869</u>	<u>28,097</u>

* Other revenue consists of sales of custom products offset by a provision for sales returns.

Financial Results by Geographical Segment

	<u>2004</u>	<u>2003</u>	<u>2002</u>
	(In thousands)		
Revenue			
United States	\$31,420	25,023	25,480
Europe	<u>3,288</u>	<u>2,846</u>	<u>2,617</u>
Total Revenue	<u>\$34,708</u>	<u>27,869</u>	<u>28,097</u>
	<u>2004</u>	<u>2003</u>	<u>2002</u>
	(In thousands)		
Net income			
United States	\$ 2,990	807	(1,800)
Europe	<u>(38)</u>	<u>122</u>	<u>239</u>
Total Net Income	<u>\$2,952*</u>	<u>929</u>	<u>(1,561)</u>

* Includes an income tax benefit of \$1,518. At December 31, 2004, we have recorded a net deferred tax asset of \$1,615,000 which represents our best estimate of the amount of our deferred tax assets that is more likely than not to be realized through the reduction of income taxes payable in future years.

Year Ended December 31, 2004, Compared With Year Ended December 31, 2003

Revenue during the year ended December 31, 2004 was \$34,708,000, an increase of 25% compared with \$27,869,000 during the year ended December 31, 2003, as a result of increased revenue in all revenue categories, but driven primarily by growth in disposable products revenue.

Disposable products revenue was \$25,657,000 for the year ended December 31, 2004, which was 21% higher than disposable products revenue of \$21,127,000 during the same period in 2003. The revenue growth

was almost entirely due to unit volume increases; however, a small price increase initiated in April 2004 across virtually all of our disposable products contributed to approximately \$370,000, or 2%, of revenue growth in 2004 as compared with 2003.

We separate our disposable products revenue into two separate categories — atherectomy and lead removal. For the year ended December 31, 2004, our atherectomy revenue totaled \$13,520,000 (53% of disposable products revenue) and our lead removal revenue totaled \$12,137,000 (47% of our disposable products revenue). Atherectomy revenue grew 33% and was the main driver of disposable product revenue growth in 2004 compared with 2003. Atherectomy revenue includes products used in both the coronary and peripheral vascular system. Atherectomy revenue growth is primarily due to the launch of our *CLiRpath* product line in May 2004, following April 2004 FDA clearance to market these products to treat total occlusions in the legs that are not crossable with a guidewire. The FDA clearance covered catheter sizes ranges from .9 millimeters in diameter to 2.5 millimeters in diameter. Most of these catheters were marketed for coronary use prior to the FDA clearance; however, the catheters with a diameter from 2.0 millimeters to 2.5 millimeters were new products not previously marketed. These new catheters accounted for \$3,000,000 of revenue for the period between May 1, 2004 and December 31, 2004 and accounted for most of the revenue growth within the atherectomy product line.

Lead removal revenue grew 11% during 2004 compared with 2003. We continue to believe our lead removal revenue is increasing primarily as a result of the increase in use of implantable cardioverter defibrillators (ICD), devices that regulate heart rhythm. When an ICD is implanted, it often replaces a pacemaker. In these cases, the old pacemaker leads are likely to be removed to avoid potential electrical interference with the new ICD leads. Recent clinical studies (MADIT and ScD-Heft) have expanded the patient population that may benefit from defibrillator implants. The results of the MADIT clinical trial became available in 2003 and the SCD-Heft clinical trial results were made public in February 2004. Growth in the implantable defibrillator market may accelerate, depending on the establishment of referral patterns to electrophysiologists for this expanded patient pool and the additional reimbursement recently established for the hospitals and electrophysiologists who treat these patients. Generally, growth in the implantable defibrillator market contributes to growth in our lead removal business, since the leads attached to the implantable defibrillator are larger in diameter and there are more leads attached to the current generation of implantable defibrillators. For patients who already have a pacemaker or defibrillator with leads attached, this causes a space problem in the vein and enhances the potential for electrical cross-talk between the leads. Therefore, the “old” leads are more likely to be removed in this situation. Although we expect our lead removal business to continue to grow, there can be no assurances to that effect. The standard of care in this market is to cap leads and leave them behind rather than lead removal. We have initiated programs to examine the costs and frequency of complications associated with abandoned leads, but there are no assurances that these programs will be successful or will change the current standard of care.

We expect that these favorable market dynamics will contribute to lead removal revenue growth in 2005; however, there can be no assurances this will occur.

Laser equipment revenue in 2004 was \$3,772,000 compared with \$2,824,000 in 2003, which represents an increase of 34%. The increase is primarily due to higher average selling prices in 2004 (\$116,000 in 2004 versus \$85,000 in 2003) and a slight increase in unit volumes sold (21 in 2004 versus 19 in 2003). Average selling prices may vary significantly from year to year based on geographic mix and age of the laser systems. The age of the laser system sold relates to those customers who elected to purchase a laser system that had previously been used under an evaluation or rental program. We believe that laser system placements is a more relevant metric for measuring our progress within the equipment business, as it represents new customers that have elected to acquire a laser system, whether it be from an outright sale from inventory, or an evaluation or rental program. The laser system placement represents an opportunity to sell our high-margin disposable products. As of December 31, 2004 our worldwide installed base of laser systems was 417 (311 in the United States) compared with 383 (282 in the United States) as of December 31, 2003. This represents new laser placements in 2004 of 34 laser systems compared to 23 new laser systems placed during 2003. The increase in laser placements in 2004 is largely driven by customer interest in our *CLiRpath* product line used for the treatment of peripheral vascular disease.

Service revenue of \$5,187,000 during 2004 increased 31% from \$3,973,000 during 2003. Service revenue is generated through the repair and maintenance services offered to our customers and is associated exclusively with our laser systems. The growth in service revenue is a result of an increase in our installed base and a higher number of customers that have elected to purchase service contracts.

Gross margin increased to 75% as a percentage of revenue during the year ended December 31, 2004 as compared with 72% during the year ended December 31, 2003. The improved gross margin is primarily attributable to increased manufacturing efficiencies within laser system and catheter manufacturing as a result of increased unit volumes. Increased selling prices as discussed previously also contributed to the improved gross margin.

Selling, general and administrative expenses increased 27% to \$19,347,000 for the year ended December 31, 2004 as compared with \$15,261,000 in 2003, due to the following:

- Selling expenses increased \$2,300,000 as a result of:
 - Personnel-related costs of \$625,000 associated with the hiring of seven additional employees in 2004 within our clinical sales and training organization. These increased costs include salaries, recruiting and travel costs.
 - Commission costs of \$750,000 as a result of higher revenue and additional employees.
 - Costs of \$450,000 associated with the operations of Spectranetics International, B.V., our wholly-owned subsidiary in the Netherlands that serves the European market. Approximately \$200,000 of this increase is associated with the strengthening euro in relation to the U.S. dollar. The remainder is due to increased personnel-related costs.
 - Marketing costs of \$325,000 as a result of attendance at an increasing number of tradeshow and conventions combined with additional physician training costs incurred primarily in peer-to-peer clinical training sessions.
 - Depreciation costs of \$150,000 associated with a higher number of evaluation and rental systems in place at December 31, 2004 compared with 2003. Refer to the “Liquidity and Capital Resources” section of this report for a further discussion of these programs.
- General and administrative expenses increased \$1,700,000 as a result of:
 - Personnel-related costs of \$300,000 associated with increased staffing.
 - Company-wide incentive compensation of \$500,000 based primarily on financial performance in relation to previously established targets.
 - Sarbanes-Oxley compliance costs of \$500,000.
 - Legal fees of \$400,000. Legal matters are discussed further within the “Legal Proceedings” section of this report.

Research, development and other technology expenses include royalty expenses, research and development expenses, and clinical study expenses. For the year ended December 31, 2004, research, development and other technology expenses rose 40% to \$5,355,000 from \$3,812,000 during the year ended December 31, 2003. The reasons for the increases are shown below:

- Royalty expenses increased \$450,000 as a result of settlement costs of \$275,000 related to a dispute with one of our license holders (See the “Legal Proceedings” section of this document for a further discussion of this matter) combined with increased royalty costs as a result of higher revenues.
- Personnel-related costs of \$250,000 due to the hiring of additional engineering staff for the development of new catheter products for our technology.
- Product development costs of \$200,000.

- Clinical study costs of \$600,000 related to the advancement of clinical research focused on laser-based treatment of heart attacks, complications associated capped pacemaker or defibrillator leads, saphenous vein grafts and peripheral vascular disease.

Other income of \$229,000 for the year ended December 31, 2004 increased from other income during 2003 of \$106,000 due to the increased interest-earning investments and an increased interest rate yield consistent with overall changes in the interest rate environment during 2004. Our investment securities portfolio consists primarily of government or government agency securities with maturities less than two years.

Income tax benefit for the year ended December 31, 2004 totaled \$1,518,000 and includes the release of \$1,615,000 related to a valuation allowance that is no longer required on specific deferred tax assets. The amount represents the value of net operating losses and future temporary deductible differences between book and taxable income that are more likely than not going to be realized in the form of reduced taxable income in future years. Income tax expense recorded during the year ended December 31, 2003 represents alternative minimum taxes and state income taxes.

Net income for the year ended December 31, 2004 was \$2,952,000, or \$0.11 per diluted share, compared with \$929,000 or \$0.04 per diluted share during the year ended December 31, 2003. Net income increased in 2004 based on the reasons discussed herein.

Year Ended December 31, 2003, Compared With Year Ended December 31, 2002

Revenue in 2003 was \$27,869,000, down \$228,000, or one percent, compared with 2002. The decrease is due primarily to a decline in equipment revenue of \$2,258,000, or 44%, offset by increased disposable products revenue of \$1,966,000, or 10%.

Equipment revenue of \$2,824,000 declined 44% in 2003 compared with 2002 primarily as a result of a change in focus away from equipment sales and towards disposable product sales. Equipment revenue was affected by the July 2003 adoption of the provisions of Emerging Issues Task Force (EITF) No. 21 *Revenue Arrangements with Multiple Deliverables*, which modified our revenue recognition policy for the sale of laser equipment by requiring the retail value of service provided during the one-year warranty period to be treated as a separate unit of accounting. Accordingly, the retail value of service provided during the warranty period (\$27,000 annually) is deducted from the invoiced price of the laser system and recorded as deferred revenue which is recognized as revenue on a straight-line basis during the warranty period. As a result of the adoption of this provision, equipment revenue in 2003 was reduced by \$213,000. A discussion of EITF 00-21 is provided in the New Accounting Pronouncements section of this document. During the first quarter of 2003, we re-deployed three field sales employees dedicated to laser equipment sales as a result of the difficulties encountered in selling laser equipment. These field sales resources were re-deployed to focus on the sale of disposable products, which is a higher margin recurring revenue stream. For the year ended December 31, 2003, we placed (sold from inventory, rented or provided for evaluation) 23 excimer laser systems compared with 33 in 2002, bringing our total installed base of laser systems to 383 (282 in the United States). We sold (either an outright sale from inventory or a sale conversion from evaluation or rental programs) 18 laser systems during 2003 as compared with 42 laser systems sold in 2002. Laser units sold as a result of a sales conversion from an evaluation or rental program are not counted as a placement that increases the installed base since they were counted originally when the unit was placed as an evaluation or rental unit. The decreased laser equipment revenue reflects lower unit sales of laser systems as a result of eliminating our dedicated equipment sales staff early in 2003 combined with a special price promotion on laser systems sold through September 30, 2002, which contributed to increased unit volumes in 2002. We expect that a stabilized annual laser equipment revenue level is in the range of \$2,000,000 to \$3,000,000.

Disposable products revenue, which primarily consists of single-use catheter products, increased \$1,966,000, or 10%, compared with 2002. This was an important driver of our improved profitability since disposable product gross margins generally range from 75 — 80%. Disposable product sales consist of two main product lines — atherectomy and lead removal. Our atherectomy revenue was essentially flat compared with 2002 and totaled \$10,155,000 for the year ended December 31, 2003. This follows two consecutive years of declining revenue within this segment. We believe this business has stabilized as a result of our focused

sales efforts on treating saphenous vein grafts, total occlusions, and in-stent restenosis prior to brachytherapy (radiation) treatment. Furthermore, we believe the clinical research we've initiated in the area of saphenous vein grafts and acute myocardial infarction has elevated our profile among our physician customers which has led to new institutions willing to revisit their use of our excimer laser technology. Our lead removal revenue increased \$2,011,000 or 22%, to \$10,972,000 in 2003 compared with 2002. The launch of our second generation laser sheath in late 2002 contributed to this growth, which was driven by unit volume increases. Additionally, the market for implantable defibrillators has grown and is expected to grow in the future as a result of clinical research recently completed (Madiet and SCD-Heft clinical trials) that expand the patient pool eligible for implantable defibrillators.

Service revenue increased four percent in 2003, due to the larger installed base of the Company's excimer laser systems.

Fluctuation in euro currency rates during the year ended December 31, 2003, as compared with the year ended December 31, 2002, caused an increase in consolidated revenue of \$263,000, or approximately one percent.

The provision for sales returns, which is recorded as a reduction in revenue and relates to estimated product returns, for the years ended December 31, 2003 and 2002, was \$92,000 and \$301,000, respectively. As a result, revenue increased \$209,000. The provision for sales returns decline in 2003 compared with 2002 is due to a decreased rate of historical product returns.

Gross margin increased to 72 percent in 2003, from 68 percent in 2002. This increase was due to a shift in product mix to a higher proportion of disposable product revenue, which generate higher margins than laser equipment and service revenue.

Operating expenses were \$19,126,000 in 2003 compared with \$21,018,000 in 2002. Operating expenses in 2002 include proxy contest and settlement obligations of \$1,837,000.

Selling, general and administrative expenses increased 5 percent to \$15,261,000 in 2003 from \$14,586,000 in 2002, due to the following:

- Selling expenses increased approximately \$570,000 primarily as a result of the explanation below. We expect selling expenses to increase in 2004 since we have hired three additional clinical trainers.
- Two additional clinical training employees were hired in 2003 as compared with 2002, which resulted in increased costs of approximately \$200,000.
- Approximately \$260,000 of increased costs are associated with unfavorable exchange rate fluctuations of the U.S. dollar in relation to the euro, which is the functional currency of our wholly-owned subsidiary, Spectranetics International, B.V.
- General and administrative expenses increased approximately \$100,000 in 2003 as compared with last year as a result of increased incentive compensation to senior and mid-level management arising from the achievement of financial goals set at the beginning of 2003. We also expect general and administrative costs to increase in 2004 as a result of inflation and consulting costs associated with Sarbanes-Oxley compliance (estimated between \$150,000 and \$250,000). Incentive compensation may increase dependent on achievement of corporate financial objectives.

Research, development and other technology expense includes research and development, clinical studies, regulatory, and royalties expenses. This category of expenses declined \$698,000 or 15 percent, in 2003 to \$3,812,000. The overall decrease is primarily due to a \$600,000 decrease in clinical studies as a result of the completion of the PELA and LACI clinical studies in late 2002. Royalty expenses declined \$100,000 due to product mix changes (laser equipment revenue declined in 2003 and bears a higher royalty rate than disposable product revenue which increased in 2003).

Proxy contest charges and settlement obligations totaled \$1,837,000 during 2002. Further discussion of these costs is contained in the footnotes to our financial statements.

Other income of \$86,000 relates primarily to interest income and is down from \$343,000 in 2002. The decline is a result of declining interest yields on our interest-bearing investment securities, which consist of money market accounts, highly rated commercial paper and government-backed investment securities.

Net income was \$929,000 in 2003, or \$0.04 per diluted share, compared with a net loss of \$1,561,000, or \$0.07 per diluted share, in 2002. The net loss in 2002 includes proxy contest charges and settlement obligations of \$8,837,000.

Income Taxes

At December 31, 2004, we have net operating loss carryforwards for United States federal income tax purposes of approximately \$44 million. This amount does not include approximately \$23 million of net operating loss carryforwards which are limited under Section 382 of the Internal Revenue Code of 1986. No deferred tax asset has been provided for \$23 million of net operating losses as we have determined that we will not receive any future tax benefit from this \$23 million before their expiration.

We also have tax loss carryforwards in The Netherlands, which have no expiration date, of approximately \$30 million Euros (\$41 million U.S. dollars) available to offset future taxable income, if any. In 2004, The Netherlands tax authorities proposed that substantially all of the tax loss carryforwards be disallowed. We are actively defending these loss carryforwards. These foreign loss carryforwards have been fully reserved with a valuation allowance. If the tax loss carryforwards are ultimately disallowed, there will be no negative impact to the financial statements.

An alternative minimum tax credit carryforward of \$320,000 is available to offset future regular tax liabilities and has no expiration date. For alternative minimum tax purposes, we have unrestricted net operating loss carryforwards for United States federal income tax purposes of approximately \$43 million. This amount does not include approximately \$23 million of net operating loss carryforwards which are limited under Section 382 of the Internal Revenue Code of 1986. No deferred tax asset has been provided for \$23 million of net operating losses as we have determined that we will not receive any future tax benefit from this \$23 million before their expiration.

We also have research and experimentation tax credit carryforwards for federal income tax purposes at December 31, 2004 of approximately \$657,000, which are available to reduce future federal income taxes, if any, and expire at varying dates through 2024. This amount does not include approximately \$2 million of research and experimentation tax credit carryforwards which are limited under Section 382 of the Internal Revenue Code of 1986. No deferred tax asset has been provided for \$2 million of research and experimentation tax credits as we have determined that we will not receive any future tax benefit from this \$2 million before their expiration.

At December 31, 2004, based upon the level of historical income and projections for future income, we have recorded a net deferred tax asset of \$1,615,000, as we have determined it is more likely than not a portion of the deferred tax assets will be recoverable.

Liquidity and Capital Resources

As of December 31, 2004, we had cash, cash equivalents and current and long-term investment securities of \$17,410,000, an increase of \$4,129,000 from \$13,281,000 at December 31, 2003. We consider the total of cash, cash equivalents and investment securities to be available for operating activities since the cash equivalents and investment securities can be readily converted to cash.

Cash and cash equivalents were \$4,004,000 at December 31, 2004 compared with \$11,281,000 at December 31, 2003, a decrease of \$7,277,000. During 2004, we moved funds from cash and cash equivalents to current and long-term investment securities due to the increased interest rate yields we could earn on investment securities. All investment securities consist of government and government agency securities. Our current and long-term investment securities portfolio totaled \$13,406,000 at December 31, 2004 compared with \$2,000,000 at December 31, 2003. Long-term investment securities have a maturity of more than one year but no more than two years.

For the year ended December 31, 2004, cash provided by operating activities totaled \$1,176,000. These positive cash flows were driven primarily by net income offset by the non-cash benefit associated with the release of a portion of our valuation allowance associated with our deferred tax asset. We expect net income to be the primary driver of future cash flows provided by operating activities. Net income guidance for 2004 is a range between \$1,000,000 and \$1,500,000. Other potential uses of cash include growth in accounts receivable as a result of revenue growth and growth in the equipment held for rental or loan account as a result of expanding placement activity of our laser systems through evaluation or rental programs. We continue to stay focused on the management of accounts receivable as measured by days' sales outstanding and will continue this focus in 2004 with the goal of maintaining the current level of days' sales outstanding, although there can be no assurances this goal will be achieved. For the equipment held for rental or loan account, this account increases or decreases based on the level of evaluation or rental laser placements offset by sales of laser systems previously placed under evaluation or rental programs. We continue to expect the majority of our laser placement activity in 2005 to be in the form of evaluation or rental units. We estimate between 40 and 50 laser placements to occur during 2005.

For the year ended December 31, 2004, cash used by investing activities was \$10,801,000. The increased cash used by investing activities is primarily due to purchases of investment securities due to increasing interest rates in 2004 and the improved interest yields available on these securities compared with cash equivalents. This was partially offset by the the resolution of a legal dispute with one of our licensors that allowed us to reclassify \$1,133,000 from restricted cash to operating cash. Additionally, capital expenditures during 2004 totaled \$439,000. We are currently evaluating an upgrade to our company-wide business software platform and if we decide to implement this upgrade during 2005, capital expenditures would be at least \$1,000,000 during 2005. As of March 29, 2005, we also purchased a building that was under lease at December 31, 2004. The building is used primarily for catheter manufacturing and the purchase price was \$1,350,000.

Net cash provided by financing activities was \$2,243,000 during the year ended December 31, 2004. Financing activities consist of proceeds from sale of common stock to employees or former employees, primarily through the exercise of stock options but also as a result of stock purchases through the employee stock purchase plan.

At December 31, 2004 and 2003, we had placed a number of systems on rental or loan programs. A total of \$7,064,000 and \$5,843,000 was recorded as equipment held for rental or loan at December 31, 2004 and 2003, respectively, and is being depreciated over three to five years, depending on whether the laser system is new or remanufactured.

In 2004, we used two placement programs in addition to the sale of laser systems:

1. Evergreen rental program — This rental program was introduced in July 1999. Rental revenue under this program varies on a sliding scale depending on the customer's catheter purchases each month. Rental revenue is invoiced on a monthly basis and revenue is recognized upon invoicing. The laser unit is transferred to the equipment held for rental or loan account upon shipment, and depreciation expense is recorded within cost of sales based upon a three- to five-year expected life of the unit. As of December 31, 2004, 49 laser units were in place under the Evergreen program, all of which are in the United States.

2. Evaluation programs — We "loan" a laser system to an institution for use over a short period of time, usually three to six months. The loan of the equipment is to create awareness of our products and their capabilities, and 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 unit 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 a three- to five-year expected life of the unit. As of December 31, 2004, 72 laser units were in place under the evaluation program (40 in the United States, 32 outside the United States). These laser systems contribute to revenue immediately through the sales of disposable products to customers that have acquired a laser system under an evaluation program. During the years ended December 31, 2004 and 2003, 11 and 13 customers,

respectively, elected to purchase their evaluation laser systems, which accounted for a total of \$1,117,000 and \$1,107,000 of equipment revenue, respectively.

Contractual Obligations

The Company leases office space, furniture and equipment under noncancelable operating leases with initial terms that expire at various dates through 2008. Purchase obligations consist of purchase orders issued primarily for inventory. The future minimum payments under noncancelable operating leases and purchase obligations as of December 31, 2004 are as follows:

	<u>Total</u>	<u>Less Than 1 Year</u>	<u>1-3 Years</u>	<u>3-5 Years</u>	<u>More Than 5 Years</u>
Operating Leases	\$ 877	—	851	26	\$ —
Purchase Obligations	<u>1,045</u>	<u>993</u>	<u>52</u>	<u>—</u>	<u>—</u>
Total	<u>\$1,922</u>	<u>993</u>	<u>903</u>	<u>26</u>	<u>\$ —</u>

Conversion To The Euro

For the year ended December 31, 2004, Spectranetics International, B.V., used the euro as its functional currency. The euro was adopted as its functional currency on January 1, 2002. The conversion to the euro did not have a material effect on our consolidated results of operations.

Critical Accounting Policies

Our consolidated financial statements are affected by the accounting policies used and the estimates and assumptions made by management during their preparation.

Below is a discussion of our critical accounting policies and their impact on the preparation of our consolidated financial statements.

Use of Estimates. On an ongoing basis, management evaluates its estimates and judgments, including those relating to product returns, bad debts, inventories, income taxes, warranty obligations, royalty obligations, reorganization costs, contingencies, and 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. Carrying values of these assets and liabilities may differ under different assumptions or conditions.

Revenue Recognition. Revenue from the sale of our disposable products is recognized when products are shipped and title transfers to the customer. Revenue from the sale of excimer laser systems is recognized after completion of contractual obligations, which generally include delivery and installation of the system and, in some cases, completion of physician training. Our team of field service engineers are responsible for installation of each laser and, in some cases, participation in the training program at each site. 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. Revenue from service contracts is initially recorded as deferred revenue and recognized over the related service contract period, which is generally one year. Revenue from fee-for-service arrangements is recognized upon completion of the service.

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

Evergreen rental program — Rental revenue under this program varies on a sliding scale depending on the customer's catheter purchases each month. Rental revenue is invoiced on a monthly basis and revenue is recognized upon invoicing. The laser unit is transferred to the equipment held for rental or loan

account upon shipment, and depreciation expense is recorded within cost of sales based upon a three- to five-year expected life of the unit.

Evaluation programs — We “loan” a laser system to an institution for use over a short period of time, usually three to six months. The loan of the equipment is to create awareness of our products and their capabilities, and 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 unit 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 a three- to five-year expected life of the unit.

The Company adopted Emerging Issues Task Force Bulletin (EITF) 00-21, Revenue Arrangements with Multiple Deliverables, on July 1, 2003, which resulted in a modification of the Company’s revenue recognition policy on laser sales. The primary impact of the adoption of EITF 00-21 is to treat service provided during the one-year warranty period as a separate unit of accounting. As such, the fair value of this service is deferred and recognized as revenue on a straight-line basis over the related warranty period. Revenue allocated to the laser element is recognized upon completion of contractual obligations in the sales contract, which generally includes delivery and installation of the laser system and, in some cases, completion of physician training. Prior to July 1, 2003, revenue for the sale of laser equipment and the one-year warranty was recognized upon shipment of the laser. Deferred revenue associated with service to be performed during the warranty period totaled \$302,000 and \$213,000 as of December 31, 2004 and 2003, respectively. *Allowance for Sales Returns.* We estimate product sales returns based on historical experience. The provision 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. Although we believe our estimates are reasonable based on facts in existence at the time of estimation, these facts are subject to change.

Warranty liability. We generally provide a one-year warranty on the sale of our excimer laser. Through June 30, 2003, we recorded warranty expense for the one-year warranty period as cost of revenue at the time of sale. Warranty expense is an estimate based on historical experience related to warranty repairs. As warranty costs are incurred, they are charged against the warranty liability. As a result of EITF 00-21, which became effective July 1, 2003, warranty costs incurred for lasers sold after this date are recorded as expense in the period incurred.

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 financial statements. We have established liabilities for royalty payment obligations based on these calculations, which 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. We have recorded a loss contingency of approximately \$2.0 million related primarily to a disagreements with two of our existing licensors. We have accrued an estimated loss contingency based on the status of discussions with the license holders. There can be no assurances the loss contingency will be adequate. The disagreements center around the treatment of revenues attributed to training services we provide to our customers. We do not believe these revenues are within the scope of the license agreements and the licensors disagree. One of these disputes has been settled subsequent to December 31, 2004 and involved a payment of \$275,000 to settle the dispute over back royalties and other modifications to the license that impact future royalty obligations. See the “Commitments and Contingencies” footnote to our financial statements for a further discussion of these matters.

Stock-based compensation. We account for our stock-based compensation plans for employees in accordance with the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related interpretations. As such, compensation expense is recorded on the date of grant only if the current market price of the underlying stock exceeds the market price. No compensation cost has been recognized for original stock option grants to employees in the accompanying financial statements as all options granted had an exercise price equal to or above the market value of the underlying

common stock on the date of grant. Under Statement of Financial Accounting Standard No. 123, *Accounting for Stock-Based Compensation* (SFAS No. 123), entities are permitted to recognize as expense the fair value of all stock-based awards on the date of grant over the vesting period. Alternatively, SFAS No. 123 also allows entities to continue to apply the provisions of APB 25 and provide pro forma earnings (loss) and pro forma earnings (loss) per share disclosures for employee stock option grants as if the fair value based method defined in SFAS No. 123 had been applied. The Company has elected to continue to apply the provisions of APB 25 and provide the pro forma disclosures required by SFAS No. 123.

We account for nonemployee stock-based awards in accordance with SFAS No. 123 and related interpretations.

We calculate compensation expense for the disclosures required by SFAS No. 123 through the use of the Black-Scholes option pricing model, which incorporates assumptions as to volatility and expected option terms, among others. Should these underlying assumptions change, the calculated compensation expense could be materially different. Compensation expense as calculated under a fair value based model has historically been material to our financial statements. For the years ended December 31, 2004, 2003 and 2002, compensation expense, net of tax, related to stock option grants to employees totaled \$534,000, \$1,039,000 and \$1,760,000, respectively, which have been included in pro forma disclosures, but not included in determining net income (loss). As such, our statement of operations will be adversely affected when the new accounting pronouncement is adopted that requires the recording of compensation expense for stock options within our statement of operations. We currently expect to record compensation expense for stock options beginning on July 1, 2005, as required by the new accounting pronouncement.

Income Taxes. The Company accounts for income taxes pursuant to Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes*, which requires the use of 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. As of December 31, 2004, we have a net deferred tax asset of \$1,615,000.

New Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payments* ("Statement 123R"). Statement 123R, which is a revision of Statement 123 and supersedes APB Opinion No. 25, establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods or services, primarily focusing on transactions in which an entity obtains employee services. Statement 123R also requires companies to measure the cost of employee services received in exchange for an award of equity instruments (such as stock options and restricted stock) based on the grant-date fair value of the award, and to recognize that cost over the period during which the employee is required to provide service (usually the vesting period of the award). Statement 123R also requires companies to measure the cost of employee services received in exchange for an award of liability instruments (such as stock appreciation rights) based on the current fair value of the award, and to remeasure the fair value of the award at each reporting date.

Public companies are required to adopt Statement 123R as of the beginning of the first interim period that begins after June 15, 2005. The provisions of Statement 123R will affect the accounting for all awards granted, modified, repurchased or cancelled after July 1, 2005. The accounting for awards granted, but not vested, prior to July 1, 2005 will also be impacted. The provisions of Statement 123R allow companies to adopt the standard on a prospective basis or to restate all periods for which Statement 123 was effective. We expect to adopt Statement 123R on a prospective basis, and our financial statements for periods that begin

after June 15, 2005 will include pro forma information as though the standard had been adopted for all periods presented.

While we have not yet fully quantified the impact of adopting Statement 123R, we believe that such adoption could have a significant impact on our operating income and net earnings in the future. For the years ended December 31, 2004, 2003 and 2002, pro forma compensation expense, net of tax, related to equity instruments was \$534,000, \$1,039,000, and \$1,760,000. These amounts were disclosed, but not recorded, in the financial statements for the years ended December 31, 2004 and 2003.

In December 2002, the Emerging Issues Task Force (EITF) reached a consensus on EITF 00-21, *Revenue Arrangements with Multiple Deliverables*. The consensus defines the accounting for arrangements that include multiple deliverables and provides guidance on how the arrangement consideration should be measured, whether the arrangement should be divided into separate units of accounting and that the arrangement consideration should be allocated among the separate units of accounting based on their relative fair value, if applicable. Once the arrangement is separated into units of accounting, applicable revenue recognition should be applied to each separate unit of accounting.

The Company adopted Emerging Issues Task Force Bulletin (EITF) 00-21, *Revenue Arrangements with Multiple Deliverables*, on July 1, 2003, which resulted in a modification of the Company's revenue recognition policy on laser sales. The primary impact of the adoption of EITF 00-21 is to treat service provided during the one-year warranty period as a separate unit of accounting. As such, the fair value of this service is deferred and recognized as revenue on a straight-line basis over the related warranty period. Revenue allocated to the laser element is recognized upon completion of contractual obligations in the sales contract, which generally includes delivery and installation of the laser system and, in some cases, completion of physician training. Prior to July 1, 2003, revenue for the sale of laser equipment and the one-year warranty was recognized upon shipment of the laser. Deferred revenue associated with service to be performed during the warranty period totaled \$302,000 and \$213,000 as of December 31, 2004 and 2003, respectively.

Risk Factors

We Have a History of Losses and May Not Be Able to Maintain Profitability. We incurred losses from operations since our inception in June 1984 until the second quarter of 2001, and we incurred net losses in the first and second quarters of 2002. At December 31, 2004, we had accumulated \$73.4 million in net losses since inception. We expect that our research, development and clinical trial activities and regulatory approvals, together with future selling, general and administrative activities and the costs associated with launching our products for additional indications will result in significant expenses for the foreseeable future. Although we demonstrated profitability over the last three years and are focused on maintaining profitability, no assurance can be given that we will be able to maintain profitability in the future.

Increases in our Stock Price are Largely Dependent on our Ability to Grow Revenues. Revenue growth from current levels depends largely on our ability to successfully penetrate the peripheral atherectomy market with our recently introduced *CliRpath* product line targeted at total occlusions (blockages) in the legs. The success of this launch will require increased re-order rates from existing customers and adoption by new customers. Beyond the initial *CliRpath* product line launch, new products will need to be developed and FDA-approved to sustain revenue growth within the peripheral market. Additional clinical data and new products to treat coronary artery disease will likely be necessary to grow revenue within the coronary market.

Regulatory Compliance Is Expensive and Can Often Be Denied or Significantly Delayed. The industry in which we compete is subject to extensive regulation by the FDA and comparable state and foreign agencies. Complying with these regulations is costly and time consuming. International regulatory approval processes may take longer than the FDA approval process. If we fail to comply with applicable regulatory requirements, we 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, if existing regulations are changed or new regulations are adopted. For example, the FDA approval 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.

Failures in Clinical Trials May Hurt Our Business and Our Stock Price. All of Spectranetics' potential products are subject to extensive regulation and will require approval from the FDA and other regulatory agencies prior to commercial sale. The results from pre-clinical testing and early clinical trials may not be predictive of results obtained in large clinical trials. Companies in the medical device industry have suffered significant setbacks in various stages of clinical trials, even in advanced clinical trials, after apparently promising results had been obtained in earlier trials.

The development of safe and effective products is uncertain and subject to numerous risks. The product development process may take several years, depending on the type, complexity, novelty and intended use of the product. Larger competitors are able to offer larger financial incentives to their customers to support their clinical trials. Enrollment in our clinical trials may be adversely affected by clinical trials financed by our larger competitors. Product candidates that may appear to be promising in development may not reach the market for a number of reasons.

Product candidates may:

- be found ineffective;
- take longer to progress through clinical trials than had been anticipated; or
- require additional clinical data and testing.

Our Small Sales and Marketing Team May Be Unable To Compete With Our Larger Competitors or To Reach All Potential Customers. Many of our competitors have 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 team in making sales. Additionally, our field sales organization consists primarily of individuals with extensive clinical experience within hospital catheterization labs; however, their sales experience is limited. We are providing sales training and, as we add new field sales employees, will attempt to recruit candidates with more sales experience. However, there are no assurances that our sales training and recruiting will improve productivity within our field sales organization. Further, there may be more turnover within the field sales organization relative to past history as a result of our transition towards a higher level of sales skills.

Our Products May Not Achieve Market Acceptance. Excimer laser technology is generally used adjunctively with more established therapies for restoring circulation to clogged or obstructed arteries such as balloon angioplasty and stent implantation. Market acceptance of the excimer laser system depends on our ability to provide incremental clinical and economic data that shows the clinical efficacy and cost effectiveness of, and patient benefits from, excimer laser atherectomy used with balloon angioplasty and stent implantation.

We May Be Unable To Compete Successfully With Bigger Companies in Our Highly Competitive Industry. Our primary competitors are manufacturers of products used in competing therapies within the coronary and peripheral atherectomy markets, such as:

- bypass surgery (coronary and peripheral);
- atherectomy and thrombectomy, using mechanical methods to remove arterial blockages (coronary and peripheral);
- amputation (peripheral); and
- balloon angioplasty (peripheral).

We also compete with companies marketing lead extraction devices or removal methods, such as mechanical sheaths. In the lead removal market, we compete worldwide with lead removal devices manufactured by Cook Vascular Inc. and we compete in Europe with devices manufactured by VascoMed. We believe we are the lead removal market leader and are focusing our efforts on growing the market for the removal of pacemaker and defibrillator leads.

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

Almost all of our competitors have substantially greater financial, manufacturing, marketing and technical resources than we do. Larger competitors have a broader product line, which enables them to offer customers bundled purchase contracts and quantity discounts. We expect competition to intensify.

We believe that the primary competitive factors in the interventional cardiovascular market are:

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

Manufacturers of atherectomy or thrombectomy devices include Boston Scientific, Guidant, Possis Medical, Inc., Fox Hollow Technologies, Lumend, and Intraluminal Therapeutics.

Laser placement is a barrier to accessing patient cases for which our disposable products may be suited. Many competing products do not require an up-front investment in the form of a capital equipment purchase, lease, or rental.

Failure of Third Parties To Reimburse Medical Providers for Our Products May Reduce Our Sales. We sell our CVX-300 laser unit primarily to hospitals, which then bill third-party payers such as government programs and private insurance plans, for the services the hospitals provide using the CVX-300 laser unit. Unlike balloon angioplasty, laser atherectomy requires the purchase or lease of expensive capital equipment. In some circumstances, the amount reimbursed to a hospital for procedures involving our products may not be adequate to cover a hospital's costs. We do not believe that reimbursement has materially adversely affected our business to date, but continued cost containment measures by third-party payers could hurt our business in the future.

In addition, the FDA has required that the label for the CVX-300 laser unit state that adjunctive balloon angioplasty was performed together with laser atherectomy in most of the procedures we submitted to the FDA for pre-market approval. Adjunctive balloon angioplasty requires the purchase of a balloon catheter in addition to the laser catheter. While all approved procedures using the excimer laser system are reimbursable, some third-party payers attempt to deny reimbursement for procedures they believe are duplicative, such as adjunctive balloon angioplasty performed together with laser atherectomy. Third-party payers may also attempt to deny reimbursement 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 purchase our excimer laser systems.

Technological Change May Result in Our Products Becoming Obsolete. We derive substantially all of our revenue from the sale or lease of the CVX-300 laser unit, related disposable devices and service. Technological progress or new developments in our industry could adversely affect sales of our products. Many companies, some of which have substantially greater resources than we do, are engaged in research and development for the treatment and prevention of coronary artery disease and peripheral vascular disease. These include pharmaceutical approaches as well as development of new or improved angioplasty, atherectomy, thrombectomy or other devices. Our products could be rendered obsolete as a result of future innovations in the treatment of vascular disease.

Our European Operations May Not Be Successful or May Not Be Able To Achieve Revenue Growth. In January 2001, we established a distributor relationship in Germany, and now utilize distributors throughout

most of Europe. The sales and marketing efforts on our behalf by distributors in Europe could fail to attain long-term success.

We Are Exposed to the Problems That Come From Having International Operations. For the year ended December 31, 2004, our revenue from international operations represented 11 percent of consolidated revenue. Changes in overseas economic conditions, war, currency exchange rates, foreign tax laws or tariffs or other trade regulations could adversely affect our ability to market our products in these and other countries. The new product approval process in foreign countries is often complex and lengthy. For example, the reimbursement approval process in Japan has taken longer than anticipated due to the complexity of this process. As we expand our international operations, we expect our sales and expenses denominated in foreign currencies to expand.

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 unit from several sole source suppliers. We do not have guaranteed commitments from these suppliers and 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.

Potential Product Liability Claims and Insufficient Insurance Coverage May Hurt Our Business and Stock Price. We are subject to risk of product liability claims. We maintain product liability insurance with coverage and aggregate maximum amounts of \$5,000,000. The coverage limits of our insurance policies may be inadequate, and insurance coverage with acceptable terms could be unavailable in the future.

Our Patents and Proprietary Rights May Be Proved Invalid, Which Would Enable Competitors To Copy Our Products; We May Infringe Other Companies' Rights. We hold patents and licenses to use patented technology, and have patent applications pending. Any patents we have applied for may not be granted. In addition, our patents may not be sufficiently broad to protect our technology or to give us any competitive advantage. Our patents could be challenged as invalid 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 do not have patents in many foreign countries. We could be adversely affected if any of our licensors terminate our licenses to use patented technology.

There may be patents and patent applications owned by others relating to laser and fiber-optic technologies, which, if determined to be valid and enforceable, may be infringed by Spectranetics. 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. For example, we have been made aware of a patent issued to Dr. Peter Rentrop for a certain catheter with a diameter of less than 0.9 millimeters and are currently involved in litigation regarding this patent. See "Legal Proceedings" herein for further discussion of this litigation. We cannot guarantee a patent holder will not file a lawsuit against us and prevail. If we decide that we need to license technology, we may be unable to obtain these licenses on favorable terms or at all. We may not be able to develop or otherwise obtain alternative technology.

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.

Our Stock Price May Continue To Be Volatile. The market price of our common stock, similar to other small-cap medical device companies, has been, and is likely to continue to be, highly volatile. The following factors may significantly affect the market price of our common stock:

- fluctuations in operating results;
- announcements of technological innovations or new products by Spectranetics or our competitors;
- governmental regulation;
- developments with respect to patents or proprietary rights;
- public concern regarding the safety of products developed by Spectranetics or others;

- the initiation or cessation in coverage of our common stock, or changes in ratings of our common stock, by securities analysts;
- past or future management changes;
- litigation;
- general market conditions; and
- financing of future operations through additional issuances of equity securities, which may result in dilution to existing stockholders and falling stock prices.

Protections Against Unsolicited Takeovers in Our Rights Plan, Charter and Bylaws May Reduce or Eliminate Our Stockholders' Ability To Resell Their Shares at a Premium Over Market Price. We have a stockholders' rights plan that may prevent an unsolicited change of control of Spectranetics. The rights plan may adversely affect the market price of our common stock or the ability of stockholders to participate in a transaction in which they might otherwise receive a premium for their shares. Under the rights plan, rights to purchase preferred stock in certain circumstances have been issued to holders of outstanding shares of common stock, and rights will be issued in the future for any newly issued common stock. Holders of the preferred stock are entitled to certain dividend, voting and liquidation rights that could make it more difficult for a third party to acquire Spectranetics. No preferred stock has been issued under the stockholders' rights plan.

Our charter and bylaws contain provisions relating to issuance of preferred stock, special meetings of stockholders and amendments of the bylaws that could have the effect of delaying, deferring 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 delaying or deferring a change in control.

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

We are exposed to a variety of risks, including changes in interest rates affecting the return on our investments and foreign currency fluctuations. Our exposure to market rate risk for changes in interest rates relate primarily to our investment portfolio. We attempt to place our investments with high quality issuers and, by policy, limit the amount of credit exposure to any one issuer and do not use derivative financial instruments in our investment portfolio. We maintain an investment portfolio of various issuers, types and maturities, which consist of both fixed and variable rate financial instruments. Marketable securities are classified as available-for-sale, and consequently, are recorded on the balance sheet at fair value with unrealized gains or losses reported as a separate component in stockholders' equity, net of applicable taxes. At any time, sharp changes in interest rates can affect the value of our investment portfolio and its interest earnings. Currently, we do not hedge these interest rate exposures. Since our investment securities have maturities that are generally less than one year and never more than two years, we do not expect interest rate fluctuations to have a significant impact on the fair value of our investment securities. As of December 31, 2004, the unrealized loss on our investment securities was \$64,000.

As of December 31, 2004, we had cash and cash equivalents of \$4.0 million, and current and long-term investment securities of \$13.4 million. Overall average duration to maturity for all cash and marketable securities is less than one year with 80% of the portfolio under one year and the remaining 20% between one and two years. The weighted average interest rate earned on the portfolio is 2.4%. At December 31, 2004, the marketable securities consisted of government or government agency securities.

Our exposure to foreign currency fluctuations is primarily related to sales of our products in Europe, which are denominated 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, could incur unanticipated gains or losses. For the year ended December 31, 2004, approximately \$260,000 of increased revenue and \$194,000 of

increased operating expenses were the result of exchange rate fluctuations of the U.S. dollar in relation to the euro. Accordingly, the net impact of exchange rate fluctuations on consolidated net income for the year ended December 31, 2004 was an increase in net income of \$64,000.

ITEM 8. *Financial Statements and Supplementary Data*

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

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

None.

ITEM 9A. *Controls and Procedures*

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our 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 SEC 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 our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the quarter covered by this report. 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.

There has been no change in our internal controls over financial reporting during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

Management of the Company, including the Chief Executive Officer and the Chief Financial Officer, is responsible for establishing and maintaining adequate internal controls over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) of the Securities Exchange Act of 1934, as amended. The Company's internal controls were designed to provide reasonable assurance as to the reliability of its financial reporting and the preparation and presentation of the 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 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.

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 the Company's internal control over financial reporting. Management has concluded that the Company's internal control over financial reporting was effective as of December 31, 2004. KPMG LLP, an independent registered public accounting firm, has issued an attestation report on management's assessment of the Company's internal control over financial reporting.

/s/ John G. Shulte

JOHN G. SHULTE

President and Chief Executive Officer

/s/ Guy A. Childs

GUY A. CHILDS

Vice President, Chief Financial Officer

Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting

The Board of Directors and Shareholders

The Spectranetics Corporation:

We have audited management's assessment, included in the accompanying *Management's Annual Report on Internal Control over Financial Reporting*, that The Spectranetics Corporation and subsidiary (collectively, the Company) maintained effective internal control over financial reporting as of December 31, 2004, 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 maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, management's assessment that The Spectranetics Corporation and subsidiary maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Also, in our opinion, The Spectranetics Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of The Spectranetics Corporation and subsidiary as of December 31, 2004 and 2003, and the related consolidated statements of operations and other comprehensive income, shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2004, and our report dated March 30, 2005 expressed an unqualified opinion on those consolidated financial statements.

KPMG LLP

March 30, 2005
Denver, Colorado

PART III

ITEM 10. *Directors and Executive Officers of the Registrant*

The information required by Item 10 is incorporated by reference from the registrant's definitive Proxy Statement to be used in connection with its 2005 Annual Meeting of Shareholders.

Audit Committee Financial Expert. This information is incorporated by reference from the registrant's definitive Proxy Statement to be used in connection with its 2005 Annual Meeting of Shareholders.

Identification of the Audit Committee. This information is incorporated by reference from the registrant's definitive Proxy Statement to be used in connection with its 2005 Annual Meeting of Shareholders.

Section 16(a) Beneficial Ownership. This information is incorporated by reference from the registrant's definitive Proxy Statement to be used in connection with its 2005 Annual Meeting of Shareholders.

Code of Ethics. This information is incorporated by reference from the registrant's definitive Proxy Statement to be used in connection with its 2005 Annual Meeting of Shareholders.

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 2005 Annual Meeting of Shareholders.

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

The information required by Item 12 is incorporated by reference from the registrant's definitive Proxy Statement to be used in connection with its 2005 Annual Meeting of Shareholders.

ITEM 13. *Certain Relationships and Related Transactions*

The information required by Item 13 is incorporated by reference from the registrant's definitive Proxy Statement to be used in connection with its 2005 Annual Meeting of Shareholders.

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 2005 Annual Meeting of Shareholders.

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 at page F-1 of this Form 10-K.

(2) Financial Statement Schedule

Not applicable.

(3) Exhibits

See Exhibit Index on page 43.

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

Index to Consolidated Financial Statements

	<u>Page</u>
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets, December 31, 2004 and 2003	F-3
Consolidated Statements of Operations and Other Comprehensive Income (Loss), Years ended December 31, 2004, 2003, and 2002	F-4
Consolidated Statements of Shareholders' Equity, Years ended December 31, 2004, 2003, and 2002	F-5
Consolidated Statements of Cash Flows, Years ended December 31, 2004, 2003, and 2002	F-6
Notes to Consolidated Financial Statements	F-7

All other schedules are omitted because they are not applicable or because the required information is included in the consolidated financial statements or the notes thereto.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders
The Spectranetics Corporation:

We have audited the accompanying consolidated balance sheets of The Spectranetics Corporation and subsidiary (collectively, the Company) as of December 31, 2004 and 2003, and the related consolidated statements of operations and other comprehensive income (loss), shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2004. These consolidated financial statements are the responsibility of the Company's management. 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 financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of The Spectranetics Corporation and subsidiary as of December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 30, 2005, expressed an unqualified opinion on management's assessment of, and the effective operation of, internal control over financial reporting.

As discussed in note 1(k) to the consolidated financial statements, on July 1, 2003 the Company adopted Emerging Issues Task Force Abstract No. 00-21, *Revenue Arrangements with Multiple Deliverables*.

KPMG LLP

March 30, 2005
Denver, Colorado

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

**Consolidated Balance Sheets
December 31, 2004 and 2003**

	2004	2003
	(In thousands, except share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 4,004	11,281
Restricted cash	—	1,133
Investment securities available for sale	9,963	—
Trade accounts receivable, less allowance for doubtful accounts and sales returns of \$239 and \$460, respectively	6,456	4,729
Inventories, net	1,782	1,899
Deferred income taxes, net	88	—
Prepaid expenses and other current assets	835	621
Total current assets	23,128	19,663
Property and equipment, at cost:		
Manufacturing equipment and computers	6,283	6,498
Leasehold improvements	1,014	1,010
Equipment held for rental or loan	7,064	5,843
Furniture and fixtures	184	186
	14,545	13,537
Less accumulated depreciation and amortization	(10,183)	(9,904)
Net property and equipment	4,362	3,633
Goodwill, net	308	308
Other intangible assets, net	124	219
Long-term deferred income taxes, net	1,527	—
Other assets	146	259
Long-term investment securities available for sale	3,443	2,000
Total assets	\$ 33,038	26,082
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 871	1,129
Accrued liabilities	6,628	4,925
Deferred revenue	1,967	1,643
Total current liabilities	9,466	7,697
Accrued liabilities, net of current portion	27	75
Deferred revenue, net of current portion	56	98
Total liabilities	9,549	7,870
Commitments and contingencies		
Shareholders' 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 25,377,939 shares in 2004 and 24,452,491 shares in 2003	25	24
Additional paid-in capital	96,823	94,544
Accumulated other comprehensive income	50	5
Accumulated deficit	(73,409)	(76,361)
Total shareholders' equity	23,489	18,212
Total liabilities and shareholders' equity	\$ 33,038	26,082

See accompanying notes to consolidated financial statements.

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

**Consolidated Statements of Operations and Other Comprehensive Income (Loss)
Years ended December 31, 2004, 2003, and 2002**

	<u>2004</u>	<u>2003</u>	<u>2002</u>
	(In thousands, except share and per share amounts)		
Revenue	\$ 34,708	27,869	28,097
Cost of revenue	<u>8,801</u>	<u>7,900</u>	<u>8,983</u>
Gross profit	25,907	19,969	19,114
Operating expenses:			
Selling, general, and administrative	19,347	15,261	14,586
Research, development, and other technology	5,355	3,812	4,510
Proxy contest and settlement	—	—	1,837
Reorganization costs and litigation reserves reversal	<u>—</u>	<u>(32)</u>	<u>—</u>
Total operating expenses	<u>24,702</u>	<u>19,041</u>	<u>20,933</u>
Operating income (loss)	<u>1,205</u>	<u>928</u>	<u>(1,819)</u>
Other income (expense):			
Interest income	238	104	480
Interest expense	(17)	(17)	(157)
Other, net	<u>8</u>	<u>19</u>	<u>—</u>
	<u>229</u>	<u>106</u>	<u>323</u>
Income (loss) before income taxes	1,434	1,034	(1,496)
Income tax benefit (expense)	<u>1,518</u>	<u>(105)</u>	<u>(65)</u>
Net income (loss)	2,952	929	(1,561)
Other comprehensive income	<u>45</u>	<u>277</u>	<u>4</u>
Comprehensive income (loss)	<u>\$ 2,997</u>	<u>1,206</u>	<u>(1,557)</u>
Earnings (loss) per share:			
Net income (loss) per share, basic	<u>\$ 0.12</u>	<u>0.04</u>	<u>(0.07)</u>
Net income (loss) per share, diluted	<u>\$ 0.11</u>	<u>0.04</u>	<u>(0.07)</u>
Weighted average shares outstanding:			
Basic	25,080,097	24,254,449	23,809,159
Diluted	27,060,001	25,443,464	23,809,159

See accompanying notes to consolidated financial statements.

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

**Consolidated Statements of Shareholders' Equity
Years ended December 31, 2004, 2003, and 2002**

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
	(In thousands, except share amounts)					
Balances at January 1, 2002	23,599,500	\$24	92,638	(276)	(75,729)	16,657
Exercise of stock options	171,013	—	413	—	—	413
Shares purchased under employee stock purchase plan	107,231	—	201	—	—	201
Options granted for consulting services	—	—	36	—	—	36
Extended vesting period for terminated executives	—	—	88	—	—	88
Amortization of warrant expense	—	—	17	—	—	17
Unrealized loss on investment securities	—	—	—	(100)	—	(100)
Foreign currency translation adjustment	—	—	—	104	—	104
Net loss	—	—	—	—	(1,561)	(1,561)
Balances at December 31, 2002	<u>23,877,744</u>	<u>24</u>	<u>93,393</u>	<u>(272)</u>	<u>(77,290)</u>	<u>15,855</u>
Exercise of stock options	423,057	—	747	—	—	747
Shares purchased under employee stock purchase plan	151,690	—	295	—	—	295
Options granted for consulting services	—	—	109	—	—	109
Unrealized gain on investment securities	—	—	—	128	—	128
Foreign currency translation adjustment	—	—	—	149	—	149
Net income	—	—	—	—	929	929
Balances at December 31, 2003	<u>24,452,491</u>	<u>24</u>	<u>94,544</u>	<u>5</u>	<u>(76,361)</u>	<u>18,212</u>
Exercise of stock options	765,723	1	1,796	—	—	1,797
Shares purchased under employee stock purchase plan	159,725	—	446	—	—	446
Options granted for consulting services	—	—	37	—	—	37
Unrealized loss on investment securities	—	—	—	(64)	—	(64)
Foreign currency translation adjustment	—	—	—	109	—	109
Net income	—	—	—	—	2,952	2,952
Balances at December 31, 2004	<u><u>25,377,939</u></u>	<u><u>\$25</u></u>	<u><u>96,823</u></u>	<u><u>50</u></u>	<u><u>(73,409)</u></u>	<u><u>23,489</u></u>

See accompanying notes to consolidated financial statements.

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

**Consolidated Statements of Cash Flows
Years ended December 31, 2004, 2003, and 2002**

	<u>2004</u>	<u>2003</u>	<u>2002</u>
	(In thousands)		
Cash flows from operating activities:			
Net income (loss)	\$ 2,952	929	(1,561)
Adjustments to reconcile net income (loss) to net cash provided (used) by operating activities:			
Depreciation and amortization	1,534	1,556	1,693
Fair value of options granted for consulting services	37	109	36
Extended vesting of options for terminated executives	—	—	88
Deferred income taxes	(1,615)	—	—
Changes in operating assets and liabilities:			
Trade accounts receivable, net	(1,624)	(550)	687
Inventories	157	279	(270)
Equipment held for rental or loan, net	(1,646)	(1,019)	(415)
Prepaid expenses and other current assets	(227)	(20)	119
Other assets	128	26	130
Accounts payable and accrued liabilities	1,249	(885)	(1,337)
Deferred revenue	<u>231</u>	<u>547</u>	<u>208</u>
Net cash provided (used) by operating activities	<u>1,176</u>	<u>972</u>	<u>(622)</u>
Cash flows from investing activities:			
Sales of investment securities	19,624	11,985	2,049
Purchases of investment securities	(31,094)	(5,194)	(1,021)
Capital expenditures	(439)	(369)	(198)
Purchase of intangible assets	(25)	—	—
Net change in restricted cash	<u>1,133</u>	<u>(10)</u>	<u>(1,123)</u>
Net cash provided (used) by investing activities	<u>(10,801)</u>	<u>6,412</u>	<u>(293)</u>
Cash flows from financing activities:			
Proceeds from sale of common stock to employees	2,243	1,042	614
Principal payments on long-term debt and capital leases obligations	<u>—</u>	<u>(87)</u>	<u>(157)</u>
Net cash provided by financing activities	2,243	955	457
Effect of exchange rate changes on cash	<u>105</u>	<u>175</u>	<u>132</u>
Net increase (decrease) in cash and cash equivalents	(7,277)	8,514	(326)
Cash and cash equivalents at beginning of year	<u>11,281</u>	<u>2,767</u>	<u>3,093</u>
Cash and cash equivalents at end of year	<u>\$ 4,004</u>	<u>11,281</u>	<u>2,767</u>
Supplemental disclosures of cash flow information:			
Cash paid during the year for interest	\$ —	17	161
Cash paid during the year for income taxes	158	111	96

See accompanying notes to consolidated financial statements.

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

Notes to Consolidated Financial Statements
December 31, 2004 and 2003

(1) Summary of Significant Accounting Policies

(a) Organization, Nature of Business, and Basis of Presentation

The accompanying consolidated financial statements include the accounts of The Spectranetics Corporation, a Delaware corporation, and its wholly owned subsidiary, Spectranetics International, B.V. (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 surgical procedures within the vascular system in conjunction with its proprietary excimer laser system.

The preparation of the consolidated financial statements 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, intangibles, assets, valuation allowances for receivables, inventories and deferred income tax assets, and accrued warranty and royalty expenses. Actual results could differ from those estimates.

(b) 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 \$1,875,000 and \$8,522,000 at December 31, 2004 and 2003, respectively, consist primarily of money market accounts, commercial paper, and repurchase agreements stated at cost, which approximates fair value.

(c) 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. Past due balances over 30 days 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. The allowance for sales returns is the Company's best estimate of the amount of probable losses in the Company's existing accounts receivable due to future sales returns and price adjustments.

The allowance for sales returns is determined based upon an analysis of revenue transactions and historical experience of sales returns and price adjustments. Adjustments to customer account balances for returns and price adjustments are charged against the allowance for sales returns.

(d) Investment Securities

Investment securities at December 31, 2004 and 2003, are classified as available-for-sale for purposes of Financial Accounting Standards Board Statement No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and, accordingly are carried at fair value. The difference between cost and fair value is recorded as an unrealized gain or loss on investment securities and recorded within accumulated other comprehensive income (loss). At December 31, 2004 and 2003, the unrealized loss totaled \$65,000 and \$1,000, respectively. The Company's investment securities are comprised of U.S. Treasury and agency notes and have contractual maturities that range from six months to two years at December 31, 2004.

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

Notes to Consolidated Financial Statements — (Continued)

(e) Inventory

Inventory is stated at the lower of cost or market. Cost is determined using the first-in, first-out method.

(f) Property and Equipment

Property and equipment are recorded at cost. Repairs and maintenance costs are expensed as incurred. Equipment acquired under capital leases is recorded at the present value of minimum lease payments at the inception of the lease.

Depreciation is calculated using the straight-line method over the estimated useful lives of the assets of two to five years for manufacturing equipment, computers, and furniture and fixtures. Equipment held for rental or loan is depreciated using the straight-line method over three to five years. Equipment acquired under capital leases and leasehold improvements is amortized using the straight-line method over the shorter of the lease term or estimated useful life of the asset.

(g) Goodwill and Other Intangible Assets

Goodwill represents the excess of costs over fair value of assets of businesses acquired. The Company adopted the provisions of FASB Statement No. 142, *Goodwill and Other Intangible Assets*, as of January 1, 2002. Pursuant to Statement 142, goodwill and intangible assets acquired in a purchase business combination and determined to have indefinite useful lives are not amortized, but instead tested for impairment at least annually in accordance with the provisions of Statement 142. Statement 142 also requires that intangible assets with estimable useful lives be amortized over their respective estimated useful lives to their estimated residual values, and reviewed for impairment in accordance with FASB Statement No. 144, *Accounting for Impairment or Disposal of Long-Lived Assets*. Intangible assets, which consist primarily of patents, are amortized using the straight-line method over periods ranging from 5 to 13 years.

(h) Restricted Cash

Restricted cash at December 31, 2003 consisted of an escrow fund established pursuant to a dispute with a licensor of certain patents of the Company. The dispute was subsequently settled, and the funds were released to the Company during 2004.

(i) Long-Lived Assets

The Company accounts for long-lived assets in accordance with Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. Statement 144 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 anticipated 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. No impairments of long-lived assets have been recognized.

(j) Financial Instruments

At December 31, 2004 and 2003, the carrying value of financial instruments approximates 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.

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

Notes to Consolidated Financial Statements — (Continued)

(k) Revenue Recognition

Revenue from the sale of the Company's disposable products is recognized when products are shipped to the customer and title transfers. Revenue from the sale of excimer laser systems is recognized after completion of contractual obligations, which generally include delivery and installation of the systems and in some cases completion of physician training. The Company's field service engineers are responsible for installation of each laser and participation in the training program at each site. 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 service contracts is initially recorded as deferred revenue and recognized over the related service contract period, which is generally one year. Revenue from fee-for-service arrangements is recognized upon completion of the related service.

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

Evergreen rental program — Rental revenue under this program varies on a sliding scale depending on the customer's catheter purchases each month. Rental revenue is invoiced on a monthly basis and revenue is recognized upon invoicing. The laser unit is transferred to the equipment held for rental or loan account upon shipment, and depreciation expense is recorded within cost of sales based upon a three-to five-year expected life of the unit. As of December 31, 2004, 49 laser units were in place under the Evergreen program.

Evaluation programs — 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, and 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 unit 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 a three- to five-year expected life of the unit. As of December 31, 2004, 72 laser units were in place under the evaluation program.

The Company adopted Emerging Issues Task Force Bulletin (EITF) 00-21, *Revenue Arrangements with Multiple Deliverables*, on July 1, 2003, which resulted in a modification of the Company's revenue recognition policy for the sale of a laser. The primary impact of the adoption of EITF No. 00-21 is to treat service provided during the one-year warranty period as a separate unit of accounting. As such, the fair value of this service is deferred and recognized as revenue on a straight-line basis over the related warranty period and warranty 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 includes delivery and installation of the laser system and in some cases completion of physician training. Prior to July 1, 2003, revenue for the sale of laser equipment and the one-year warranty was recognized upon shipment of the laser. Deferred revenue associated with service to be performed during the warranty period totaled \$302,000 and \$213,000 as of December 31, 2004 and 2003, respectively.

(l) Warranties

The Company generally provides a one-year warranty on the sale of its excimer laser and the parts and labor during the warranty period are provided by the Company's field service engineers. Prior to July 1, 2003, the Company recorded estimated warranty expense as cost of revenue at the time of the sale based on historical experience. As warranty costs were incurred, they were charged against the warranty liability. As a

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

Notes to Consolidated Financial Statements — (Continued)

result of the adoption of EITF 00-21, service costs incurred for warranty periods beginning after July 1, 2003 are recorded as expense in the period incurred as noted above.

(m) 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 involve management estimates that require judgment.

(n) Stock-Based Compensation

The Company accounts for its stock-based compensation plans for employees in accordance with the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related interpretations. As such, compensation expense is recorded on the date of grant only if the current market price of the underlying stock exceeds the exercise price. No compensation cost has been recognized for stock option grants to employees in the accompanying financial statements as all options granted had an exercise price equal to or above the market value of the underlying common stock on the date of grant. Under FASB Statement No. 123, *Accounting for Stock-Based Compensation* (SFAS No. 123), and FASB Statement No. 148, *Accounting for Stock-Based Compensation — Transition and Disclosure, an amendment of SFAS No. 123* (SFAS No. 148), entities are permitted to recognize as expense the fair value of all stock-based awards on the date of grant over the vesting period. Alternatively, SFAS No. 123, as amended, also allows entities to continue to apply the provisions of APB 25 and provide pro forma earnings (loss) and pro forma earnings (loss) per share disclosures for employee stock option grants as if the fair-value-based method defined in SFAS No. 123, as amended, had been applied. The Company has elected to continue to apply the provisions of APB 25 and provide the pro forma disclosures required by SFAS No. 123, as amended.

The Company accounts for nonemployee stock-based awards in accordance with SFAS No. 123 and related interpretations.

The following table illustrates the effect on net income (loss) and earnings (loss) per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation.

	<u>Year Ended December 31</u>		
	<u>2004</u>	<u>2003</u>	<u>2002</u>
	(In thousands, except per share amounts)		
Net income (loss), as reported	\$2,952	929	(1,561)
Deduct total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	<u>(534)</u>	<u>(1,039)</u>	<u>(1,760)</u>
Pro forma net income (loss)	<u>\$2,418</u>	<u>(110)</u>	<u>(3,321)</u>
Earnings (loss) per share:			
Basic — as reported	\$ 0.12	0.04	(0.07)
Basic — pro forma	0.10	—	(0.14)
Diluted — as reported	0.11	0.04	(0.07)
Diluted — pro forma	0.09	—	(0.14)

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

Notes to Consolidated Financial Statements — (Continued)

(o) Research and Development

Research and development costs are expensed as incurred and totaled \$2,295,000, \$1,791,000, and \$1,795,000, for the years ended December 31, 2004, 2003, and 2002, respectively. The Company also sponsors clinical trials intended to obtain the necessary clinical data required to obtain approval from the Food and Drug Administration and other foreign governing bodies to market new applications for its technology. Costs associated with these clinical trials totaled \$1,503,000, \$922,000, and \$1,514,000, during the years ended December 31, 2004, 2003, and 2002, respectively.

(p) Foreign Currency Translation

The Company's functional currency is the U.S. dollar. Certain transactions of the Company and its subsidiary are denominated in currencies other than the U.S. dollar. Realized gains and losses from these transactions are included in the consolidated statements of operations as they occur.

Spectranetics International, B.V. used its local currency (Euro) as its functional currency for the years presented. 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 shareholders' equity as accumulated other comprehensive income (loss).

(q) Advertising Costs

The Company expenses advertising costs as incurred. Advertising costs of \$101,000, \$80,000, and \$118,000 were expensed in 2004, 2003, and 2002, respectively.

(r) Income Taxes

The Company accounts for income taxes pursuant to Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes*, which requires the use of 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.

(s) Reclassification

Certain amounts from the prior consolidated financial statements have been reclassified to conform with the 2004 presentation.

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

Notes to Consolidated Financial Statements — (Continued)

(2) Investment Securities

Investment securities consist of the following at December 31:

	<u>2004</u>	<u>2003</u>
	(In thousands)	
Short-term investments:		
U.S. Treasury and agency notes	\$9,963	—
Long-term investments:		
U.S. Treasury and agency notes with maturities > 1 year	\$3,443	2,000

The Company classifies investment securities with maturities of one year or less as short-term and maturities of greater than one year as long-term.

Unrealized loss at December 31, 2004 and 2003, respectively, was \$65,000 and \$1,000. For the years ended December 31, 2004 and 2002, the amount of unrealized loss included in other comprehensive income was \$64,000 and \$100,000, respectively. For the year ended December 31, 2003, an unrealized gain of \$128,000 was included in other comprehensive income. Realized gains and losses are determined using the specific identification method. There were no significant realized gains or losses during 2004, 2003, or 2002.

(3) Inventories

Inventories consist of the following as of December 31:

	<u>2004</u>	<u>2003</u>
	(In thousands)	
Raw materials	\$ 411	205
Work in process	351	603
Finished goods	1,049	1,121
Less reserve for obsolescence	(29)	(30)
	\$1,782	1,899

(4) Goodwill and Other Intangible Assets

Intangible Assets

Acquired intangible assets as of December 31 are as follows:

	<u>2004</u>	<u>2003</u>
	(In thousands)	
Patents and other assets	\$ 3,808	3,783
Less accumulated amortization	(3,684)	(3,564)
	\$ 124	219

Aggregate amortization expense for amortizing intangible assets was \$118,000 and \$244,000 for the years ended December 31, 2004 and 2003, respectively. Estimated amortization expense for the next five years is \$72,000 in 2005, \$29,000 in 2006, and \$1,000 in 2007, 2008, and 2009.

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

Notes to Consolidated Financial Statements — (Continued)

Goodwill

During 2001, the Company entered into a series of purchase and license agreements with Fogazzi, an Italian medical device manufacturer. The Company acquired certain assets from Fogazzi and has granted a license to Fogazzi for the manufacture of certain laser catheters used to treat blockages in the leg. Goodwill of \$340,000 was recorded, and \$32,000 of amortization expense was recognized during the year ended December 31, 2001. In accordance with the provisions of FASB Statement No. 142, *Goodwill and Other Intangible Assets*, which was adopted January 1, 2002, no amortization expense has been recorded for the years ended December 31, 2004 and 2003. At December 31, 2004 and 2003, the balance of goodwill was \$308,000.

The Company evaluates goodwill and other intangible assets for impairment in accordance with the provisions of Statement 142. The Company has not recognized an impairment loss as a result of such analyses.

(5) Accrued Liabilities

Accrued liabilities consist of the following as of December 31:

	2004	2003
	(In thousands)	
Accrued payroll and employee related expenses	\$2,480	1,803
Accrued royalty expense	2,210	1,460
Accrued clinical study expense	197	105
Employee stock purchase plan liability	158	193
Accrued legal expenses	102	51
Accrued warranty expense	54	206
Other accrued expenses	1,427	1,107
	\$6,628	4,925

(6) Stock-Based Compensation and Employee Benefit Plans

At December 31, 2004 and 2003, the Company had two stock-based compensation plans which are described below.

(a) Stock Option Plans

The Company maintains stock option plans which provide for the grant of incentive stock options, nonqualified stock options, and stock appreciation rights. The plans provide that incentive stock options be granted with exercise prices not less than the fair value at the date of grant. Options granted through December 31, 2004 generally vest over one to four years and expire ten years from the date of grant. Options granted to the board of directors generally vest over three years from date of grant and expire ten years from the date of grant. During 2003 certain option grants to key executives contain performance-based features based on market value triggers ranging from \$8 per share to \$10 per share. If these market value triggers are achieved during the four years subsequent to the grant date the options will vest over the standard four year period. Otherwise, the options will cliff vest nine years and six months following the option grant date. At December 31, 2004, there were 910,528 shares available for future issuance under these plans.

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

Notes to Consolidated Financial Statements — (Continued)

The following is a summary of option activity during the three-year period ended December 31, 2004:

	<u>Shares Under Option</u>	<u>Weighted Average Exercise Price</u>
Options outstanding at January 1, 2002	5,073,795	\$3.09
Granted	347,692	2.78
Exercised	(171,013)	2.41
Canceled	<u>(311,573)</u>	3.50
Options outstanding at December 31, 2002	4,938,901	3.06
Granted	1,270,000	2.83
Exercised	(423,057)	1.77
Canceled	<u>(1,004,970)</u>	3.78
Options outstanding at December 31, 2003	4,780,874	2.95
Granted	528,170	5.08
Exercised	(766,412)	2.35
Canceled	<u>(184,203)</u>	3.17
Options outstanding at December 31, 2004	<u>4,358,429</u>	3.30

At December 31, 2004, the weighted average remaining contractual life of outstanding options was 6.13 years, and 2,851,112 options were exercisable at a weighted average exercise price of \$3.16 per share.

The per-share weighted average fair value of stock options granted during 2004, 2003, and 2002, was \$4.23, \$2.39, and \$2.13 per share, respectively, on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Risk free interest rate	3.5%	3.0%	2.7%
Expected life	5.5	5.2	6.8
Expected volatility	116.4%	106.4%	91.0%
Expected dividend yield	—%	—%	—%

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

Notes to Consolidated Financial Statements — (Continued)

Outstanding and Exercisable by Price Range as of December 31, 2004					
Range of Exercise Prices	Number Outstanding as of December 31, 2004	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable as of December 31, 2004	Weighted Average Exercise Price
\$1.01 - \$1.62	300,008	6.21	\$1.57	270,008	1.57
1.63 - \$2.08	399,530	5.10	1.74	372,403	1.72
2.10 - \$2.63	426,532	6.16	2.48	401,342	2.49
2.63 - \$2.63	701,000	8.15	2.63	102,521	2.63
2.66 - \$3.05	735,371	5.56	2.97	561,526	2.94
3.06 - \$3.80	566,000	5.48	3.41	444,088	3.41
3.81 - \$4.88	514,062	5.27	4.50	374,998	4.52
4.94 - \$5.35	518,426	6.95	5.09	182,226	4.94
5.60 - \$6.38	195,500	7.30	6.21	140,000	6.38
7.38 - \$7.38	<u>2,000</u>	5.18	7.38	<u>2,000</u>	7.38
	<u>4,358,429</u>			<u>2,851,112</u>	

During 2004, the Company granted 4,470 fully vested options to certain nonemployees for past services. The fair value of the options approximated \$12,000, as determined using the Black-Scholes options pricing model assuming no dividends, 98% volatility, risk-free interest rate of 4.5%, and an expected life of four years. This expense was recognized in 2004 and is included in selling, general and administrative expenses in the accompanying consolidated statement of operations and other comprehensive income (loss).

During 2003 and 2002, the Company granted 25,000 options each year to nonemployees for consulting services. The total fair value of the options is being amortized to expense on a straight-line basis over the vesting period. The expense recognized was \$26,000, \$108,000, and \$38,000 during the years ended December 31, 2004, 2003, and 2002, respectively, and is included in selling, general and administrative expenses in the accompanying statements of operations and other comprehensive income (loss). There are 12,500 unvested options at December 31, 2004.

(b) Stock Purchase Plan

In September 1992, the Company adopted an employee stock purchase plan which provides for the sale of up to 850,000 shares of common stock. In June 2004, the plan was amended to increase the number of authorized shares by 500,000 to 1,350,000. The plan provides eligible employees the opportunity to acquire common stock in accordance with Section 423 of the Internal Revenue Code of 1986. Stock can be purchased each six-month period per year (twice per year). The purchase price is equal to 85% of the lower of the price at the beginning or the end of the respective six-month period. Shares issued under the plan totaled 159,725, 151,690, and 107,231 in 2004, 2003, and 2002, respectively.

The weighted average fair value of the employees' purchase rights granted in 2004, 2003, and 2002 that was included in the accompanying pro forma stock-based compensation disclosure was \$1.42, \$1.83, and

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

Notes to Consolidated Financial Statements — (Continued)

\$0.84, respectively, per right, which was estimated using the Black-Scholes model with the following assumptions:

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Risk free interest rate	1.6%	0.9%	1.2%
Expected life	6 months	6 months	6 months
Expected volatility	56.9%	166.9%	89.0%
Expected dividend yield	—%	—%	—%

(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 contributions of \$135,000, \$126,000, and \$108,000 to the plan in 2004, 2003, and 2002, respectively, based on a match of 25% of the first 4% of each employee's contribution and an additional Company discretionary match.

(7) Net Income (Loss) Per Share

The Company calculates net income (loss) per share under the provisions of Statement of Financial Accounting Standards No. 128, *Earnings Per Share* (SFAS 128). Under SFAS No. 128, basic earnings 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 earnings per share is computed in a manner consistent with that of basic earnings per share while giving effect to all potentially dilutive common shares that were outstanding during the period using the treasury stock method. Potentially dilutive common shares which have been excluded from the computation of diluted loss per share as of December 31, 2004, 2003, and 2002 were 688,180, 1,355,317, and 3,683,533 because their effect would have been antidilutive.

	<u>2004</u>	<u>2003</u>	<u>2002</u>
	(In thousands)		
Net income (loss)	\$ 2,952	929	(1,561)
Common shares outstanding:			
Historical common shares outstanding at beginning of year	24,452	23,878	23,599
Weighted average common shares issued	<u>628</u>	<u>376</u>	<u>210</u>
Weighted average common shares outstanding — basic	25,080	24,254	23,809
Effect of dilution from stock options	<u>1,980</u>	<u>1,189</u>	<u>—</u>
Weighted average common shares outstanding — diluted	<u>27,060</u>	<u>25,443</u>	<u>23,809</u>
	<u>2004</u>	<u>2003</u>	<u>2002</u>
Net income (loss) per share, basic	\$0.12	0.04	(0.07)
Net income (loss) per share, diluted	0.11	0.04	(0.07)

(8) Leases

The Company leases office space, furniture and equipment under noncancelable operating leases with initial terms that expire at various dates through 2008. All assets held under capital leases were fully depreciated at December 31, 2004 and 2003.

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

Notes to Consolidated Financial Statements — (Continued)

The future minimum payments under noncancelable operating leases as of December 31, 2004, are as follows:

	<u>Operating Leases</u> (In thousands)
Years ending December 31:	
2005	\$544
2006	214
2007	93
2008	<u>26</u>
Total minimum lease payments	<u>\$877</u>

Rent expense under operating leases totaled approximately \$591,000, \$538,000, and \$495,000 for the years ended December 31, 2004, 2003, and 2002, respectively.

(9) Income Taxes

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

	<u>2004</u>	<u>2003</u>	<u>2002</u>
United States	\$2,139	912	(1,735)
Foreign	<u>(705)</u>	<u>122</u>	<u>239</u>
Income (loss) before income taxes	<u>\$1,434</u>	<u>1,034</u>	<u>(1,496)</u>

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

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Current:			
Federal	\$ 45	20	—
State	52	85	65
Foreign	<u>—</u>	<u>—</u>	<u>—</u>
	97	105	65
Deferred:			
Federal	(1,430)	—	—
State	(185)	—	—
Foreign	<u>—</u>	<u>—</u>	<u>—</u>
	<u>(1,615)</u>	<u>—</u>	<u>—</u>
Income tax expense (benefit)	<u>\$ (1,518)</u>	<u>105</u>	<u>65</u>

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

Notes to Consolidated Financial Statements — (Continued)

Income tax expense (benefit) 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):

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Computed expected tax expense (benefit)	\$ 488	352	(509)
Increase (reduction) in income taxes resulting from:			
State and local income taxes, net of federal impact	94	52	(75)
Nondeductible expenses	121	(25)	141
Change in valuation allowance	(2,218)	3,893	309
Foreign operations	—	(4,218)	16
Change in the beginning of the year balance of the valuation allowance for deferred tax assets allocated to income tax expense	—	(114)	—
Other, net	(3)	165	183
	<u>\$ (1,518)</u>	<u>105</u>	<u>65</u>

During 2004, the valuation allowance decreased by \$7,824,000. Such amount is reconciled to the above change in the valuation allowance of \$2,218,000 due primarily to the expiration of U.S. net operating losses and the adjustment of the research and experimentation tax credit which is limited under Section 382 of the Internal Revenue Code of 1986.

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

	<u>2004</u>	<u>2003</u>
	(In thousands)	
Current:		
Royalty reserve, due to accrual for financial reporting purposes	\$ 849	569
Warranty reserve, due to accrual for financial reporting purposes	15	51
Accrued liabilities, not deducted until paid for tax purposes	255	341
Inventories, principally due to accrual for obsolescence for financial reporting purposes, net of additional costs inventoried for tax purposes	47	36
Deferred revenue, due to deferral for financial reporting purposes	669	664
	<u>1,835</u>	<u>1,661</u>
Less valuation allowance	(1,747)	(1,661)
	<u>88</u>	<u>—</u>
Noncurrent:		
Net operating loss carryforwards — U.S. and related states	16,871	20,508
Foreign net operating loss carryforwards	14,048	14,292
Research and experimentation tax credit	657	2,928
Equipment, primarily due to differences in cost basis and depreciation methods	24	277
Alternative minimum tax credit	320	298
Total net deferred tax assets	31,920	38,303
Less valuation allowance	(30,393)	(38,303)
	<u>1,527</u>	<u>—</u>
Net deferred tax assets	<u>\$ 1,615</u>	<u>—</u>

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

Notes to Consolidated Financial Statements — (Continued)

Approximately \$658,000 of subsequently recognized tax benefits relating to the valuation allowance for deferred tax assets as of December 31, 2004 will be allocated to additional paid-in capital.

At December 31, 2004, the Company has net operating loss carryforwards for United States federal income tax purposes of approximately \$44 million. This amount does not include approximately \$23 million of net operating loss carryforwards which are limited under Section 382 of the Internal Revenue Code of 1986. No deferred tax asset has been provided for \$23 million of net operating losses as the Company has determined that it will not receive any future tax benefit from this \$23 million before their expiration.

As of December 31, 2004, the Company has unrestricted federal net operating loss carryforwards of approximately \$44 million to reduce future taxable income which expire as follows (in thousands):

	Regular Tax Net Operating Losses
Expiration date:	
2005	\$ 7,033
2006	12,268
2007	8,894
2008	970
2009	8,930
2010 through 2024	<u>5,842</u>
Total	<u>\$43,937</u>

The Company also has tax loss carryforwards in The Netherlands, which have no expiration date, of approximately 30 million Euros (\$41 million) available to offset future taxable income, if any. In 2004, The Netherlands tax authorities contacted the Company and are proposing to disallow substantially all of the tax loss carryforwards. The Company is actively defending these loss carryforwards. In 2004 and 2003, the foreign loss carryforwards were fully reserved with a valuation allowance. If the tax loss carryforwards are ultimately disallowed, there will be no negative impact to the consolidated financial statements due to the valuation allowance.

An alternative minimum tax credit carryforward of \$320,000 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 \$43 million. This amount does not include approximately \$23 million of net operating loss carryforwards which are limited under Section 382 of the Internal Revenue Code of 1986. No deferred tax asset has been provided for \$23 million of net operating losses as the Company has determined that it will not receive any future tax benefit from this \$23 million before their expiration.

The Company also has research and experimentation tax credit carryforwards at December 31, 2004, for federal income tax purposes of approximately \$657,000, which are available to reduce future federal income taxes, if any, and expire at varying dates through 2024. This amount does not include approximately \$2 million of research and experimentation tax credit carryforwards which are limited under Section 382 of the Internal Revenue Code of 1986. No deferred tax asset has been provided for \$2 million of research and experimentation tax credits as the Company has determined that it will not receive any future tax benefit from this \$2 million before their expiration.

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

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

Notes to Consolidated Financial Statements — (Continued)

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. In 2004, based upon the level of historical income and projections for future income, management determined it is more likely than not a portion of the deferred tax assets will be recoverable. Accordingly, in 2004, a deferred tax benefit was recorded for the reduction in the valuation allowance.

(10) Concentrations of Credit Risk

Financial instruments which potentially expose the Company to concentrations of credit risk, as defined by the Financial Accounting Standards Board's Statement No. 105, *Disclosure of Information About Financial Instruments with Off-Balance-Sheet Risk and Financial Instruments with Concentration of Credit Risk*, consist primarily of cash, cash equivalents, investment securities, and accounts receivable.

The Company's cash, cash equivalents, and investment securities consist of financial instruments issued by various institutions and government entities that management believes are credit worthy. 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 and Asia. No single customer represented more than 10% of 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, 2004.

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

(11) Segment and Geographic Reporting

An operating segment is a component of an enterprise whose operating results are regularly reviewed by the enterprise's chief operating decision maker to make decisions about resources to be allocated to the segment and assess its performance. The primary performance measure used by management is net income or loss. The Company operates in one distinct line of business consisting of developing, manufacturing, marketing, and distributing of a proprietary excimer laser system for the treatment of certain coronary and vascular conditions. The Company has identified two reportable geographic segments within this line of business: (1) U.S. Medical and (2) Europe Medical. U.S. Medical and Europe Medical offer the same products and services but operate in different geographic regions and have different distribution networks. Additional information regarding each reportable segment is shown below.

(a) U.S. Medical

Products offered by this reportable segment include an excimer laser unit (equipment), fiber-optic delivery devices (disposables), and the service of the excimer laser unit (service). The Company is subject to product approvals from the Food and Drug Administration (FDA). At December 31, 2004, FDA-approved products were used in multiple vascular procedures, including coronary and peripheral atherectomy as well as the removal of nonfunctioning leads from pacemakers and cardiac defibrillators. On April 29, 2004, the Company received 510(K) clearance from the FDA to sell fiber-optic delivery devices for the treatment of patients suffering from total occlusions (blockages) not crossable with a guide wire in their leg arteries. This segment's customers are primarily located in the United States; however, the geographic areas served by this segment also include Canada, Mexico, South America, the Pacific Rim, and Australia.

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

Notes to Consolidated Financial Statements — (Continued)

U.S. Medical is also corporate headquarters for the Company. Accordingly, research and development as well as corporate administrative functions are performed within this reportable segment. As of December 31, 2004, 2003, and 2002, cost allocations of these functions to Europe Medical have not been performed.

Revenue associated with intersegment transfers to Europe Medical was \$1,681,000, \$1,439,000, and \$1,338,000 for the years ended December 31, 2004, 2003, and 2002, respectively. Revenue is based upon transfer prices, which provide for intersegment profit that is eliminated upon consolidation. For each of the years ended December 31, 2004, 2003, and 2002, intersegment revenue and intercompany profits are not included in the segment information in the table shown below.

(b) Europe Medical

The Europe Medical segment is a marketing and sales subsidiary located in the Netherlands that serves Europe as well as the Middle East. Products offered by this reportable segment are the same as those offered by U.S. Medical. The Company has received CE mark approval for products that relate to four applications of excimer laser technology — coronary atherectomy, in-stent restenosis, lead removal, and peripheral atherectomy to clear blockages in leg arteries.

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):

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Revenue:			
Equipment	\$ 3,210	2,508	4,744
Disposables	23,241	18,787	17,098
Service	4,877	3,783	3,597
Other, net of provision for sales returns	<u>92</u>	<u>(55)</u>	<u>41</u>
Subtotal — U.S. Medical	<u>31,420</u>	<u>25,023</u>	<u>25,480</u>
Equipment	562	316	338
Disposables	2,416	2,340	2,063
Service	<u>310</u>	<u>190</u>	<u>216</u>
Subtotal — Europe Medical	<u>3,288</u>	<u>2,846</u>	<u>2,617</u>
Total revenue	<u>\$34,708</u>	<u>27,869</u>	<u>28,097</u>

In 2004, 2003, and 2002, no individual customer represented 10% or more of consolidated revenue.

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Interest income:			
U.S. Medical	\$227	93	469
Europe Medical	<u>11</u>	<u>11</u>	<u>11</u>
Total interest income	<u>\$238</u>	<u>104</u>	<u>480</u>

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

Notes to Consolidated Financial Statements — (Continued)

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Interest expense:			
U.S. Medical	\$ —	—	129
Europe Medical	<u>17</u>	<u>17</u>	<u>28</u>
Total interest expense	<u>\$ 17</u>	<u>17</u>	<u>157</u>
	<u>2004</u>	<u>2003</u>	<u>2002</u>
Depreciation expense:			
U.S. Medical	\$1,195	1,168	1,302
Europe Medical	<u>172</u>	<u>83</u>	<u>104</u>
Total depreciation	<u>\$1,367</u>	<u>1,251</u>	<u>1,406</u>
	<u>2004</u>	<u>2003</u>	<u>2002</u>
Amortization expense:			
U.S. Medical	\$ 158	290	272
Europe Medical	<u>9</u>	<u>15</u>	<u>15</u>
Total amortization	<u>\$ 167</u>	<u>305</u>	<u>287</u>
	<u>2004</u>	<u>2003</u>	<u>2002</u>
Segment net income (loss):			
U.S. Medical	\$2,990	807	(1,800)
Europe Medical	<u>(38)</u>	<u>122</u>	<u>239</u>
Total net income (loss)	<u>\$2,952</u>	<u>929</u>	<u>(1,561)</u>
	<u>2004</u>	<u>2003</u>	<u>2002</u>
Capital expenditures:			
U.S. Medical	\$ 430	357	187
Europe Medical	<u>9</u>	<u>12</u>	<u>11</u>
Total capital expenditures	<u>\$ 439</u>	<u>369</u>	<u>198</u>
	<u>2004</u>	<u>2003</u>	
Segment assets:			
U.S. Medical	\$29,786	23,363	
Europe Medical	<u>3,252</u>	<u>2,719</u>	
Total assets	<u>\$33,038</u>	<u>26,082</u>	

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

Notes to Consolidated Financial Statements — (Continued)

The Company operates in several countries outside of the United States. Revenue from foreign operations by segment is summarized as follows:

	<u>2004</u>	<u>2003</u>	<u>2002</u>
U.S. Medical	\$ 614	140	267
Europe Medical	<u>3,288</u>	<u>2,846</u>	<u>2,617</u>
Total foreign revenue	<u>\$3,902</u>	<u>2,986</u>	<u>2,884</u>

There were no individual countries, other than the United States, that represented at least 10% of consolidated revenue in 2004, 2003, or 2002. Long-lived assets located in foreign countries are concentrated in Europe, and totaled \$861,000 and \$863,000 as of December 31, 2004 and 2003, respectively.

(12) Reorganization Costs

During the year ended December 31, 2000, reorganization costs of \$1,200,000 primarily associated with the elimination of the direct sales organization in Germany were incurred. A rollforward of the accrued reorganization liability is as follows (in thousands):

	<u>Accrued at Beginning of Year</u>	<u>Amounts Paid</u>	<u>Adjustments</u>	<u>Accrued Costs at End of Year</u>
Year ended December 31, 2002:				
Termination and severance costs	\$187	107	—	80
Cancellation of contracts and leases	<u>4</u>	<u>—</u>	<u>—</u>	<u>4</u>
Total	<u>\$191</u>	<u>107</u>	<u>—</u>	<u>84</u>
Year ended December 31, 2003:				
Termination and severance costs	\$ 80	52	28	—
Cancellation of contracts and leases	<u>4</u>	<u>—</u>	<u>4</u>	<u>—</u>
Total	<u>\$ 84</u>	<u>52</u>	<u>32</u>	<u>—</u>

The termination and severance costs relate primarily to eight employees within the sales organization in Germany. Effective January 1, 2001, a direct sales organization was no longer used in Germany; instead, a distributor has been contracted to continue selling the Company's products in Germany. At December 31, 2003, all reorganization costs had been paid and the remaining balance of \$32,000 was reversed.

(13) Proxy Contest and Settlement

In 2002, a stockholder of the Company filed a preliminary proxy statement with the SEC in which he nominated two directors for election to the Company's board. Subsequent to the filing of the preliminary proxy statement, all of the then-executive officers of the Company signed a letter to the stockholder agreeing to vote in favor of such nominees. The executives, together with the stockholder that filed the preliminary proxy statement and one other stockholder, then filed a Schedule 13D with the SEC indicating that they were acting as a group (the 13D Group) in connection with the proxy statement. Subsequent to the filing of the Schedule 13D, all executives officers of the Company, with the exception of the president and chief executive officer (CEO), the vice president, finance and chief financial officer (CFO), and the vice president investor relations, rescinded their involvement in the 13D Group and stated their neutrality with respect to any proposals submitted to the stockholders by the Company or the 13D Group. The Company subsequently filed

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

Notes to Consolidated Financial Statements — (Continued)

a suit against the remaining members of the 13D Group for violation of federal securities laws, which was settled in 2002.

As part of the settlement, the Company dismissed with prejudice the lawsuits filed against the remaining members of the 13D Group, including the president and CEO, the vice president, finance and CFO, and the vice president investor relations, each of whom separated from the Company in 2002.

Costs associated with the proxy contest and subsequent settlement totaling \$1,837,000 were incurred in 2002. Such costs included termination and severance costs paid to the former executives, legal fees, public and investor relations fees, and various other costs. All settlement costs were paid by December 31, 2003.

(14) Commitments and Contingencies

In August 2004, one of the Company's licensors filed a lawsuit against the Company alleging that the Company underpaid royalties since January 2001 under a license agreement with the licensor. The licensor claimed that the Company took improper deductions from royalty-bearing revenue, resulting in an underpayment of the license fee. In February 2005, the Company settled its dispute with the licensor and executed an amendment to the license agreement that incorporated such settlement. Under the terms of the amendment, which has a noncancelable term of four years, the Company agreed to pay the licensor \$275,000 in back royalties. Such amount was included in accrued liabilities at December 31, 2004. Additionally, the license was converted to nonexclusive and the royalty rate for products sold using the associated technology was reduced effective October 1, 2004. The Company also agreed to increase its minimum quarterly royalty payment to \$50,000 from \$25,000 beginning July 1, 2005.

The Company has received an inquiry from another licensor regarding the level of past royalty payments since inception of a license agreement that was executed in October 2000. The disagreement over past royalty payments centers on the treatment of certain service-based revenue, including repair and maintenance, and physician and clinical training services. Management believes that these are beyond the scope of the license agreement. In August 2004, the licensor commenced arbitration proceedings as provided for under the license agreement, and a resolution to the matter is anticipated in mid to late 2005. The Company has accrued costs of approximately \$1,732,000 associated with the resolution of this matter, which represents management's best estimate of costs to resolve the matter based on previous negotiations with the licensor before arbitration was commenced. Management intends to vigorously defend its position in such arbitration proceedings.

On June 24, 2004, the Court of Appeal of Amsterdam rejected an appeal made by the Company on a judgment awarded to an Italian distributor (the Distributor) by the District Court of Amsterdam. The Distributor originally filed suit in July 1999, and the lower court's judgment was rendered in April 2002. The Court of Appeal of Amsterdam affirmed the lower court's opinion that an exclusive distributor agreement for the Italian market was entered between the parties for the three-year period ending December 31, 2001, and that the Distributor may exercise its right to compensation from the Company for its loss of profits during such three-year period. The appellate court awarded the Distributor the costs of the appeal and has referred the case back to the lower court for determination of the loss of profits. The Distributor asserts lost profits of approximately \$1,500,000, which is based on their estimate of potential profits during the three-year period. The Company estimates that the lost profits to the Distributor for the period, plus estimated interest and awarded court costs, totaled approximately \$273,000. Such amount was included in accrued liabilities at December 31, 2004. The Company intends to vigorously defend the calculation of lost profits.

The Company is involved in various other claims and legal actions arising in the ordinary course of business. In the opinion of management, the ultimate disposition of these matters will not have a material adverse effect on the Company's consolidated financial position, results of operations, or liquidity.

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

Notes to Consolidated Financial Statements — (Continued)

(15) Subsequent Event

On March 29, 2005, the Company acquired the building and land which houses its manufacturing facilities for \$1,350,000. A deposit of \$20,000 was paid to the seller in 2004, which was subsequently applied to the purchase price. The Company did not incur any debt associated with the purchase. As a result of the purchase, the lease for such property was terminated effective March 29, 2005, resulting in a reduction of future minimum rental payments of \$101,000 and \$68,000 in 2005 and 2006, respectively.

(16) Valuation and Qualifying Accounts

<u>Description</u>	<u>Balance at Beginning of Year</u>	<u>Additions Charged to Expense</u>	<u>Deductions</u>	<u>Balance at End of Year</u>
		(In thousands)		
Year ended December 31, 2002:				
Accrued warranty liability	\$ 324	545	434	435
Accrued royalty liability	2,419	1,201	2,215	1,405
Allowance for doubtful accounts and sales returns	642	447	534	555
Accrued litigation and reorganization reserves	494	—	261	233
Accrued proxy contest and settlement costs	—	1,781	1,555	226
Accrued inventory obsolescence reserves	63	61	63	61
Year ended December 31, 2003:				
Accrued warranty liability	\$ 435	56	285	206
Accrued royalty liability	1,405	1,099	1,044	1,460
Allowance for doubtful accounts and sales returns	555	2	97	460
Accrued litigation and reorganization reserves	233	—	182	51
Accrued proxy contest and settlement costs	226	—	226	—
Accrued inventory obsolescence reserves	61	9	40	30
Year ended December 31, 2004:				
Accrued warranty liability	\$ 206	—	152	54
Accrued royalty and litigation liability	1,511	1,830	858	2,483
Allowance for doubtful accounts and sales returns	460	(139)	82	239
Accrued inventory obsolescence reserves	30	83	84	29

(17) Selected Quarterly Financial Data (Unaudited)

	<u>2004</u>				<u>2003</u>			
	<u>Q1</u>	<u>Q2</u>	<u>Q3</u>	<u>Q4</u>	<u>Q1</u>	<u>Q2</u>	<u>Q3</u>	<u>Q4</u>
	(In thousands, except per share amounts)							
Net sales	\$7,787	8,657	8,934	9,330	6,977	6,545	6,901	7,446
Gross profit	5,656	6,495	6,811	6,945	4,869	4,754	4,947	5,399
Net income	135	401	479	1,937*	141	53	357	378
Net income per share:								
Basic	\$ 0.01	0.02	0.02	0.08	0.01	0.00	0.01	0.02
Diluted	0.01	0.01	0.02	0.07	0.01	0.00	0.01	0.01

* Includes \$1,615 of income tax benefit related to realization of deferred tax assets.

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
2.1	Agreement and Plan of Reorganization between The Spectranetics Corporation and Advanced Interventional Systems, Inc., dated January 24, 1994.(1)
2.1(a)	Amendment to Agreement and Plan of Reorganization between The Spectranetics Corporation and Advanced Interventional Systems, Inc., dated May 17, 1994.(2)
2.2	Certificate of Ownership and Merger of Advanced Interventional Systems, Inc. Into The Spectranetics Corporation, dated December 27, 1995.(13)
2.3	Merger Agreement dated as of May 24, 1999 among the Company, Polymicro Technologies, Inc., PMT Holdings, LLC, and Polymicro Technologies, LLC.(20)
3.1	Restated Certificate of Incorporation.(1)
3.1(a)	Certificate of Amendment to Restated Certificate of Incorporation.(12)
3.1(b)	Certificate of Amendment to Restated Certificate of Incorporation.(18)
3.2	Bylaws of the Company.(3)
3.2(a)	First Amendment to Bylaws.(26)
3.2(b)	Second Amendment to Bylaws.(27)
4.1	Form of Common Stock Certificate of the Company.(4)
4.2	Rights Agreement, dated as of May 6, 1996, between the Company and Norwest Bank Minnesota, N.A.(14)
10.1	Lease covering a portion of the Company's facilities between the Company and Duane and Donna Basse dated November 10, 1994.(12)
10.1(a)	Lease covering a portion of the Company's facilities between the Company and Duane and Donna Basse dated September 1, 1997.(14)
10.1(b)	Lease covering a portion of the Company's facilities between the Company and Duane and Donna Basse dated June 1, 2001.(25)
10.2	Lease covering a portion of the Company's facilities between the Company and American Investment Management dated February 17, 1995.(12)
10.2(a)	Lease covering a portion of the Company's facilities between the Company and John or Sharon Sanders dated December 23, 1997.(19)
10.2(b)	Lease covering a portion of the Company's facilities between the Company and John or Sharon Sanders dated December 8, 2000.(24)
10.2(c)	Lease covering a portion of the Company's facilities between the Company and John or Sharon Sanders dated June 1, 2003.(31)
10.3	Lease covering a portion of the Company's facilities between the Company and Full Circle Partnership III dated September 11, 1985.(3)
10.3(a)	Amendment to lease covering a portion of the Company's facilities between the Company and Full Circle Partnership III July 24, 1997.(19)
10.3(b)	Amendment to lease covering a portion of the Company's facilities between the Company and Full Circle Partnership III dated June 3, 2002.(28)
10.3(c)	Amendment to lease covering a portion of the Company's facilities between the Company and Full Circle Partnership III dated June 2, 2003.(30)
10.4(a)	Amendment to lease covering a portion of the Company's facilities between the Company and Talamine Properties dated February 15, 1992.(7)
10.4(b)	Amendment to lease covering a portion of the Company's facilities between the Company and Talamine Properties dated February 16, 1993.(1)
10.4(c)	Amendment to lease covering a portion of the Company's facilities between the Company and Talamine Properties dated October 3, 1994.(12)
10.5	1991 Stock Option Plan, as amended.(11)

<u>Exhibit Number</u>	<u>Description</u>
10.5(a)	1991 Stock Option Plan, as amended.(17)
10.6	1990 Incentive Stock Option Plan.(6)
10.7	1989 Incentive Stock Option Plan and First Amendment thereto.(6)
10.8	Nonemployee Director Stock Option Plan.(8)
10.8(a)	Stock Option Plan for Outside Directors.(10)
10.9	Employee Stock Purchase Plan (as amended).(9)
10.10	The 1997 Equity Participation Plan of The Spectranetics Corporation.(21)
10.10(a)	NonQualified Stock Option Agreement dated as of April 17, 1996, between the Company and Emile J. Geisenheimer.(21)
10.10(b)	NonQualified Stock Option Agreement dated as of March 3, 1997, between the Company and Joseph A. Largey.(21)
10.10(c)	Form of NonQualified Stock Option Agreement for Officers.(21)
10.10(d)	Form of NonQualified Stock Option Agreement for Employees.(21)
10.10(e)	Form of NonQualified Stock Option Agreement for Independent Directors.(21)
10.10(f)	Form of Incentive Stock Option Agreement for Officers.(21)
10.10(g)	Form of Incentive Stock Option Agreement for Employees.(21)
10.11	License Agreement with Patlex Corporation, dated January 1, 1992 (confidential treatment has been granted for portions of this agreement).(7)
10.12	License Agreement with Pillco Limited Partnership, dated February 1, 1993 (confidential treatment has been granted for portions of this agreement).(7)
10.13	Vascular Laser Angioplasty Catheter License Agreement with Bio-Metric Systems, Inc., dated April 7, 1992 (confidential treatment has been granted for portions of this agreement).(6)
10.14	Exclusive License Agreement between the United States of America and James B. Laudenslager and Thomas J. Pacala dated March 25, 1985; and Exclusive License Agreement between the United States of America and LAIS dated April 29, 1990.(5)
10.15	License Agreement between Medtronic, Inc. and the Company, dated February 28, 1997 (confidential treatment has been granted for portions of this agreement).(15)
10.16	License Agreement between United States Surgical Corporation and the Company, dated September 25, 1997 (confidential treatment has been granted for portions of this agreement).(16)
10.17	Supply Agreement between United States Surgical Corporation and the Company, dated September 25, 1997 (confidential treatment has been granted for portions of this agreement).(16)
10.18	Loan and Security Agreement between Silicon Valley Bank and the Company, dated December 24, 1997.(19)
10.19	Exclusive Purchase and Distribution Agreement between The Spectranetics Corporation and Orbus Medical Technologies, Inc. dated March 12, 1998 (confidential treatment has been granted for portions of this agreement).(18)
10.20	Form of Stock Purchase Agreement, dated as of December 22, 1998 among the Company and the stockholders named in the Company's Registration Statement on Form S-3 (File No. 333-69829).(22)
10.21	Employment Agreement between the Company and Henk Kos dated January 1, 1997.(22)
10.22	First Amendment to the 1997 Equity Participation Plan.(24)
10.23	Second Amendment to the 1997 Equity Participation Plan.(23)
10.24	Compromise, Settlement and Release Agreement dated October 25, 2000 between the Company, Edwards Lifesciences LLC, Baxter Healthcare Corporation and LaserSight Patents, Inc. (confidential treatment has been granted for portions of this agreement) (24)
10.25	Third Amendment to the 1997 Equity Participation Plan.(25)

<u>Exhibit Number</u>	<u>Description</u>
10.26	Agreement of Settlement and Compromise dated June 6, 2002, (the “Settlement Agreement”) by and among the Company, on the one hand, and Steven Sweet, Joseph Largey, Paul Samek, Lawrence McKinley, acting solely in his individual capacity, and Sharon Sweet, on the other hand, including the exhibits thereto.(26)
10.27	Separation Agreement between the Company and Joseph Largey, dated as of June 6, 2002, filed as exhibit E to the Settlement Agreement referenced in Exhibit 10.26.
10.28	Separation Agreement between the Company and Paul Samek, dated as of June 6, 2002, filed as Exhibit I to the Settlement Agreement referenced in Exhibit 10.26.
10.29	Form of Indemnification Agreement entered into between the Company and each of its directors as of May 10, 2002.(27)
10.30	Fourth Amendment to the 1997 Equity Participation Plan.(27)
10.31	Fifth Amendment to the 1997 Equity Participation Plan.(27)
10.32	Letter agreement dated January 20, 2003 between the Company and John G. Schulte.(29)
10.33	Asset purchase agreement between the Company and LaTIS, Inc.(30)
10.34	Settlement Agreement between the Company and Interlase Limited Partnership dated November 19, 2003.(31)
10.35	Third Amendment to Employee Stock Purchase Plan.(32)
21.1	Subsidiary of the Company.(25)
23.1	Consent of Independent Registered Public Accounting Firm.
31.1	Rule 13(a) — 14(a)/15d — 14(a) Certifications.
32.1	Section 1350 Certifications.

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- (1) Incorporated by reference to the Company’s 1993 Annual Report on Form 10-K filed on March 31, 1994.
 - (2) Incorporated by reference to exhibits previously filed by the Company with its Registration Statement on Form S-4 filed May 18, 1994 (File No. 33-79106).
 - (3) Incorporated by reference to exhibits previously filed by the Company with its Registration Statement on Form S-1, filed December 5, 1991 (File No. 33-44367).
 - (4) 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).
 - (5) Incorporated by reference to exhibits previously filed by LAIS with its Registration Statement on Form S-1 filed August 30, 1991 (File No. 33-42457).
 - (6) Incorporated by reference to exhibits previously filed by the Company with its Amendment No. 1 to the Registration Statement on Form S-1, filed January 10, 1992 (File No. 33-44367).
 - (7) Incorporated by reference to exhibits previously filed by the Company with its Annual Report for 1992 on Form 10-K filed March 31, 1993.
 - (8) Incorporated by reference to exhibits previously filed by the Company with its Registration Statement on Form S-8 filed April 1, 1992 (File No. 33-46725).
 - (9) Incorporated by reference to exhibits previously filed by the Company with its Registration Statement on Form S-8 filed December 30, 1994 (File No. 33-88088).
 - (10) Incorporated by reference to exhibits previously filed by the Company with its Registration Statement on Form S-8 filed November 16, 1995 (File No. 33-99406).
 - (11) Incorporated by reference to exhibits previously filed by the Company with its Registration Statement on Form S-8 filed October 6, 1994 (File No. 33-85198).
 - (12) Incorporated by reference to exhibits previously filed by the Company with its 1994 Annual Report on Form 10-K filed on March 31, 1995.

- (13) Incorporated by reference to the Company's 1995 Annual Report on Form 10-K filed on April 29, 1996.
- (14) Incorporated by reference to exhibits previously filed by the Company with its Current Report on Form 8-K filed on May 6, 1996.
- (15) Incorporated by reference to exhibits previously filed by the Company with its Form 10-Q for the quarter ended on March 31, 1997.
- (16) Incorporated by reference to exhibits previously filed by the Company with its Form 10-Q for the quarter ended on September 30, 1997.
- (17) Incorporated by reference to exhibits previously filed by the Company with its Registration Statement on Form S-8 filed July 19, 1996.
- (18) Incorporated by reference to exhibits previously filed by the Company with its Form 10-Q for the quarter ended on June 30, 1998.
- (19) Incorporated by reference to exhibits previously filed by the Company with its 1997 Annual Report on Form 10-K filed on March 30, 1998.
- (20) Incorporated by reference to exhibits previously filed by the Company with its Current Report on Form 8-K filed on June 8, 1999.
- (21) 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).
- (22) Incorporated by reference to exhibits previously filed by the Company with its Form 10-Q for the quarter ended March 31, 1999.
- (23) Incorporated by reference to exhibit previously filed by the Company with its Registration Statement on Form S-8 filed on November 22, 2000.
- (24) Incorporated by reference to exhibit previously filed by the Company with its 2000 Annual Report on Form 10-K filed on March 30, 2001.
- (25) Incorporated by reference to exhibit previously filed by the Company with its 2001 Annual Report on Form 10-K filed on March 30, 2002.
- (26) Incorporated by reference to exhibits previously filed by the Company with its Current Report on Form 8-K filed on June 7, 2002.
- (27) 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.
- (28) Incorporated by reference to exhibit previously filed by the Company with its 2002 Annual Report on Form 10-K filed on March 30, 2003.
- (29) Incorporated by reference to exhibits previously filed by the Company with its Quarterly Report on Form 10-Q for the quarter ended March 31, 2003.
- (30) 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.
- (31) Incorporated by reference to exhibit previously filed by the Company with its 2003 Annual Report on Form 10-K filed on March 29, 2004.
- (32) Incorporated by reference to exhibit previously filed by the Company with its Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.

CORPORATE INFORMATION

Board of Directors

David G. Blackburn ^{2,3}
Principal
TRG Cardiovascular

Cornelius C. Bond, Jr. ¹
Independent Consultant

R. John Fletcher ^{1,2,3}
Chief Executive Officer
Fletcher Spaght, Inc.

Emile J. Geisenheimer, Chairman ⁴
President
Madison Investment Partners, Inc.

Martin T. Hart ^{2,3}
Self-employed, Investor

Joseph M. Ruggio, MD ^{1,4}
Practicing Interventional Cardiologist, and
President & Chief Executive Officer
Pacific Cardiovascular Associates Medical Group, Inc.

John G. Schulte ⁴
President & Chief Executive Officer
The Spectranetics Corporation

Craig M. Walker, MD ⁴
Practicing Interventional Cardiologist, and
Founder, President & Medical Director
Cardiovascular Institute of the South

¹ Compensation Committee

² Audit Committee

³ Nominating Committee

⁴ Technology Committee

Executive Officers

John G. Schulte
President & Chief Executive Officer

Guy A. Childs
Vice President, Chief Financial Officer

Adrian E. Elfe
Vice President, Quality Assurance and Regulatory Affairs

Lawrence E. Martel, Jr.
Vice President, Operations

Corporate Headquarters

The Spectranetics Corporation
96 Talamine Court
Colorado Springs, CO 80907-5186

Tel: 719-633-8333 or 800-633-0960
Fax: 719-633-2248
Web site: www.spectranetics.com

Product Information

Please contact Customer Service
Tel: 719-633-8333 or 800-231-0978
Fax: 719-633-8791
Web site: www.spectranetics.com

Stock Data

NASDAQ: SPNC

Most newspapers list the company under NASDAQ
National Market Issues as "Spectranet."

As of March 30, 2005, there were 684 record holders
of common stock. This figure does not reflect beneficial
ownership of shares held in nominee name.

The company has never paid a cash dividend on its
common stock and has no intentions of doing so in the
foreseeable future.

Investor Inquiries

Please direct all inquiries for financial information, press
releases and any information filed with the SEC to Guy
Childs, Vice President, Chief Financial Officer, at Corporate
Headquarters.

Transfer Agent and Registrar

Shareholders needing stock transfers, replacement
certificates or a change of address, please contact:

Wells Fargo Bank Minnesota, N.A.
Shareholder Services Department
161 North Concord Exchange
P.O. Box 64854
St. Paul, MN 55164
Tel: 800-468-9716

Annual Meeting

Date: Thursday, June 7, 2005
Time: 10:00am Mountain Daylight Time
Location: Antlers Hilton Hotel
Address: 4 South Cascade Avenue
City/State: Colorado Springs, CO 80903

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