

"Cool" Laser Technology
for Multiple Cardiovascular
Procedures

- 1993 Coronary Artery Disease Therapy
- 1997 Cardiac Lead Removal Systems
- 2003 Peripheral Vascular Disease Therapy (FDA Review Pending)
- 2003 Treating Acute Myocardial Infarction (Clinical Research)
- 2003 Treating Ischemic Stroke (Research and Development)

Spectranetics[®]

we get your blood flowing™

CORPORATE PROFILE

Spectranetics is a medical device company that develops, manufactures and markets single-use medical devices used in minimally invasive surgical procedures within the cardiovascular system in conjunction with its proprietary excimer laser system. Our CVX-300® ultraviolet laser operates on the relatively cool end of the spectrum and is the only laser system approved by the FDA for multiple cardiovascular procedures including coronary atherectomy, treatment of in-stent restenosis prior to radiation therapy, and removal of problematic pacemaker and defibrillator leads. The Company is currently conducting two investigational trials designed to obtain FDA approval to market products in the United States for additional applications. The LACI (Laser Angioplasty to treat Critical Limb Ischemia) trial tests laser atherectomy to improve circulation to the lower leg. The PELA (Peripheral Excimer Laser Angioplasty) trial deals with blockages in arteries in the upper leg. Nearly all of the Company's FDA-approved and investigational applications have received Communauté Européennes (CE) mark registration for marketing within Europe. Spectranetics received regulatory approval from the Ministry of Health and Welfare to market its laser and various sizes of its Extreme® and Vitesse® C coronary catheters in Japan in October of 2001, and we are currently pursuing reimbursement approval there.



The Spectranetics Management Team

Pictured, left to right: Christopher Reiser, Ph.D., Vice President, Technology and Clinical Research; Guy A. Childs, Vice President, Chief Financial Officer; John G. Schulte, President and Chief Executive Officer; Bruce E. Ross, Executive Vice President, Customer and Product Programs; Lawrence E. Martel, Jr., Vice President, Operations; Adrian E. Elfe, Vice President, Quality Assurance and Regulatory Affairs.

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 to you in this, my first annual report as chief executive officer of Spectranetics. While new to this position, my seven-year tenure as an active member of the Spectranetics' Board of Directors provides me with an understanding of the challenges and opportunities ahead as we implement our strategic plan.

This past year Spectranetics faced a number of challenges, not the least of which was a proxy contest that resulted in several management changes. In spite of this significant and costly distraction, the Company was able to complete key clinical trials, post strong financial results in the second half of the year, and emerge better equipped for success in 2003 and beyond.

From a financial perspective, we achieved profitability in 2002 based on our core coronary and lead removal businesses, excluding one-time proxy contest charges. Exclusive of these costs and settlement obligations, income for 2002 was \$276,000, or \$0.01 per share, and revenue increased modestly from the prior year, reaching \$28.1 million. Net loss, inclusive of proxy contest charges totaling \$1,837,000, was \$1,561,000, or \$0.07 per share during 2002. We ended the year with a strong balance sheet, including \$11.4 million of cash and investment securities, which we believe is adequate to fund our current business plan.

We cannot look back on 2002 without acknowledging the extraordinary efforts of fellow board member, Emile Geisenheimer, who served as interim chief executive officer for nine months prior to my appointment. Emile helped stabilize our Company during turbulent times and worked closely with our extraordinarily capable management team, which enabled us to continue moving forward at a critical time. We enter 2003 with a

highly experienced senior management team that is prepared to take this company to the next level.

In 2002, we also achieved our stated clinical milestones of completing patient enrollment and follow-up on two major clinical trials – LACI (Laser Angioplasty for Critical Limb Ischemia) and PELA (Peripheral Excimer Laser Angioplasty) – resulting in a timely Pre-Market Approval (PMA) Supplement submission to the U.S. Food and Drug Administration (FDA) for LACI in January 2003.

The process of analyzing data for PELA is underway and, subject to the favorable outcome of our data analysis, we expect to submit a PMA Supplement to the FDA later in 2003.

We anticipate approval of our laser catheters for the treatment of critical limb ischemia at the end of this year, and we are preparing to form a new core business focusing on peripheral vascular disease. The market for treating patients with critical limb ischemia is both large and underserved by current therapies. As a result of these current poor treatment options, there were more than 80,000 amputations below the knee last year in the United States alone. Since this represents a significant new opportunity for Spectranetics, we are actively preparing for an expected FDA approval late this year.

Importantly, in 2002, we refined our strategic plan and developed a focused approach for expanding the application of our laser in our core business of coronary and lead removal.

The Company was able to complete key clinical trials and post strong financial results in the second half of the year.

Our laser catheters have seven approved indications for treating coronary artery disease. To spur growth in our coronary business, we will be focusing on three coronary indications: treatment of saphenous vein grafts (SVG), in-stent restenosis prior to brachytherapy, and chronic total occlusions.

In addition, we are targeting new indications for treating acute myocardial infarction (AMI, or heart attack) and ischemic stroke, which are thrombus-laden lesions

We entered 2003 in a stronger position for growth, which is expected to accelerate in 2004 with our entry into the critical limb ischemia market.

where we believe our laser catheters can work extremely well. It is estimated that in the United States, there are more than 250,000 heart attacks treated by percutaneous medical devices annually, and as many as 600,000 episodes of ischemic stroke, or "brain attacks" each year.

We have initiated research to support the use of our laser technology to treat the primary cause of heart and brain attacks. For heart attacks, in addition to submitting to the FDA a retrospective registry, we have initiated a small prospective study with a world-renowned cardiologist, Dr. Antonio Colombo of Milan, Italy. We expect this small study will provide supporting data for a larger trial that ultimately could allow us to market the laser for the treatment of heart attacks. We are in the early stages of researching the use of our technology for ischemic stroke.

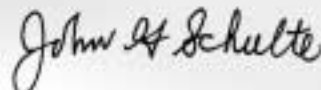
In our core business of pacemaker and defibrillator lead removal, Spectranetics sets the standard for hospitals with our CLearRS system. We have highly compelling clinical data showing that pacemaker and automatic implantable cardioverter defibrillator leads can be removed

with a dramatically higher success rate and with significantly fewer complications using our CLearRS system, when compared with traditional mechanical lead removal techniques. Furthermore, a recent published study demonstrated a 20 percent complication rate in abandoned, non-infected leads. Spectranetics will focus on educating and forming alliances with major implant companies to heighten awareness of the risk of capping leads and leaving them in place, versus removing them.

In summary, we entered 2003 in a stronger position for growth, which is expected to accelerate in 2004 with our entry into the critical limb ischemia market. We will build upon our proprietary platform technology and our growing installed base in our core business of coronary and lead removal. Beyond the near-term growth driver associated with the treatment of critical limb ischemia, we are building the pipeline of new applications, most importantly AMI and stroke.

In closing, I would like to recognize the extraordinary efforts of the Spectranetics management team this past year and thank all the employees of Spectranetics for their dedication and loyalty. We look forward to realizing the potential benefits our technology provides for patients, for physicians using our technology and ultimately for our shareholders.

Sincerely,



John G. Schulte

March 2003

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

For the fiscal year ended December 31, 2002

or

- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number 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 28, 2002 computed by reference to the closing sale price of the voting stock held by non-affiliates on such date, was \$47,298,979.

As of March 12, 2003, there were outstanding 24,014,416 shares of Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement for its 2003 Annual Meeting of Shareholders, to be filed with the Securities and Exchange Commission not later than April 30, 2003, 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;
- 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 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.

We also have regulatory approval to market our products in two key international markets. In conjunction with our distributor Heiwa Bussan Co., Ltd., we have received approval to market some of our coronary atherectomy products in Japan, and are seeking additional approvals there for our newer coronary products and our lead removal product line. In Europe, in addition to our coronary atherectomy and lead removal product lines, we also have approval to market our products to treat artery blockages in the upper and lower leg. We are currently sponsoring clinical trials in order to obtain regulatory approval in the United States to market our products domestically for use in the upper and lower leg.

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 hyperlink 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 vascular conditions. During 2002, we completed two major clinical trials — LACI (Laser Angioplasty to treat Critical Limb Ischemia) and PELA (Peripheral Excimer Laser Angioplasty).

We submitted a Pre-Market Approval Supplement (PMAS) to the Food and Drug Administration (FDA) in January 2003, which requests clearance to commercially market certain products for the treatment of critical limb ischemia. We anticipate FDA approval in late 2003 for this new application of our technology.

We are currently analyzing the data from the PELA trial and, if the clinical data warrants, a submission to the FDA is expected during 2003.

We are also exploring the use of our technology to treat blockages caused by the formation of thrombus (blood clots). We are currently gathering clinical data for laser-based treatment of acute myocardial infarction (AMI, or heart attack) and performing laboratory animal studies for laser treatment of ischemic stroke. Both heart attacks and ischemic stroke result from blockages largely as a result of thrombus formation.

- *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 devices to existing customers. In 2002, we trained 188 physicians in the general use of our equipment to address blockages in the coronary vasculature and 38 physicians for the removal of problematic pacemaker and defibrillator leads. There is no assurance that the physicians trained will become routine laser catheter users.
- *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, 2002 and December 31, 2001, respectively, we placed 33 and 15 laser systems in new accounts. At December 31, 2002 our total worldwide installed base was 360 laser systems (260 in the United States). In early 2002, we implemented a temporary price promotion of \$90,000 on our laser systems compared with our list price of \$249,000. The price promotion contributed to the increased number of laser systems placed in 2002 compared with 2001. The price promotion for laser systems officially ended on September 30, 2002; however, quotes that were outstanding and contained promotional pricing as of September 30, 2002 will be honored. In addition to an outright sale of our laser systems, we offer several alternatives to our customers to allow the acquisition of our excimer lasers in 2003, including evaluation, fee rental and leasing through a third-party leasing organization.

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. We believe that the 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. 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.

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 an additional coronary indication — for use within restenosed stents prior to brachytherapy (radiation therapy). In all of these coronary atherectomy indications, we offer an alternative or adjunct to traditional balloon angioplasty, stents and atherectomy (rotational cutters and burrs) devices. Unlike conventional balloons that merely compress arterial plaque against the stent or vessel wall, laser atherectomy dissolves the material, resulting in a larger diameter opening.

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 the CMDCAS (Canadian) certification was recommended by TÜV during our last audit in 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 distributor Heiwa Bussan Co., Ltd., 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, which may take up to two years to obtain. We do not expect our sales in Japan to increase unless and until reimbursement approval is attained. In addition, we are in various stages of the submission process to obtain regulatory approval in Japan for some of our newer products.

Since receiving FDA approval in 1993, more than 55,000 patients have been safely treated with excimer laser coronary atherectomy. Initial FDA approval for use of the excimer laser for coronary applications was based on the results of the Percutaneous Excimer Laser Coronary Angioplasty (PELCA) 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:

- *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.
- *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.

Product Applications

Excimer Laser Atherectomy

Background. 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 in the United States. We estimate that approximately 40 percent of these patients could benefit from the use of our products, particularly in complex lesions.* In these indications, we offer an alternative or adjunct to traditional balloon angioplasty or the need for coronary bypass surgery. Unlike conventional balloons that merely compress arterial plaque against the stent or vessel wall, laser atherectomy actually dissolves the material. We focus our marketing efforts on seven approved coronary indications:

- saphenous vein grafts;
- pretreatment of restenosed stents prior to brachytherapy.
- 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.

In Europe, we focus our marketing efforts on the approved coronary indications shown above as well as laser treatment of all in-stent restenoses and blockages in the arteries of the upper and lower legs.

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 in Europe. Early laser catheters contained

* 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.

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 and 2.0 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).
- *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.
- *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.
- *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.
- *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 assist in accessing and/or crossing lesions. The primary function is to support an angioplasty guidewire. 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.

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 5% of these patients will eventually require pacemaker or ICD lead removal. 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.

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. On February 1, 2002, Spectranetics received FDA approval to market an improved model of its 16 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 a randomized clinical trial completed in October 1996, the SLS increased the complete lead removal success rate to 94 percent from 65 percent with other techniques. 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.

* 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.

Peripheral Vascular Disease Therapy

Background. The prevalent treatment options for total blockages in the upper leg are medical management to minimize symptoms and bypass surgery. Amputation below the knee may be required for critical limb ischemia. We estimate that approximately 160,000 upper bypass surgeries and 80,000 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, or drug therapy.* Laser therapy is being evaluated as an alternative treatment to bypass surgery, amputation and conventional medical management. Our catheters for these applications are approved in Europe for use in treating peripheral vascular disease.

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 is limb salvage (i.e., freedom from major amputation) for a 6-month follow-up period. The last patient enrolled in the LACI trial in April 2002 and the six-month follow-up phase was completed in October 2002. The data from this trial was submitted in the form of a PMA Supplement to the FDA in January 2003 and we anticipate FDA approval in late 2003. Data from the trial indicated a 93% success rate as compared with 87% in the control group of 789 patients treated with a variety of standard therapies, including bypass surgery, in 1999. The incidence of serious adverse events was 33% in LACI compared with 60% in the control group.

On November 30, 2001, the last patient was enrolled in the PELA trial, a 250-patient randomized clinical trial, coordinated in the United States and Europe, to evaluate the use of laser technology in patients with total occlusions at least 10 centimeters in length in the upper leg. This trial is designed to treat intermittent claudication, or leg pain while walking, which generally occurs as a result of a blockage in the superficial femoral artery in the upper leg. The primary endpoint for the PELA trial is clinical patency, which is a measurement of the degree to which the artery is open, twelve months following the procedure. The one year follow-up phase of the PELA trial was completed in December 2002 and we are currently analyzing the data from the trial. If the clinical data warrants, a submission to the FDA requesting clearance to commercially market our products for the treatment of blockages in the upper leg, will be completed later this year. On December 21, 2001, Spectranetics received approval from the FDA to begin the PELA Phase 3 trial at 21 sites. PELA Phase 3 is a registry of up to 120 patients with total occlusions at least 10 centimeters in length in the upper leg.

We cannot assure that the clinical trials using excimer laser catheters to unblock peripheral arteries will demonstrate our technology is safe, will result in favorable success rates or, if the trials are successful, that we will receive FDA approval for these devices. We have received CE Mark of approval for our line of peripheral catheters in Europe.

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

* 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.

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.

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.

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

We estimate that there are about 1,500 interventional cardiac catheterization laboratories in hospitals in the United States.* 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 account managers.

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.

We currently have 29 field sales employees consisting of six district sales managers and 23 clinical account managers. 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 Account Managers in their district.

* 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.

Clinical Account Managers, 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.

Our field team also includes 10 service engineers who are responsible for installation of each laser and participate in the training program at each site. We provide a one-year warranty on laser sales, which includes parts, service 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 275,000 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 2002, Spectranetics International, B.V., revenues totaled \$2,617,000 or 9 percent of our revenue.

In addition to the operations of Spectranetics International, B.V., we conduct international business in the Pacific Rim, South America and Australia through distributors. In 2002, revenues from these foreign operations totaled \$267,000, or 1 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” filed herewith.

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 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 FFDCFA 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 the LLD have been precleared by the FDA under the “510(k)” process.

* 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.

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 related devices are designated as Class III devices. 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 major world market 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®	10/93	12/96	9/01
Vitesse® C	10/94	12/96	9/01
Vitesse® E	9/97	2/97	9/01
Vitesse® C _{OS}	1/00	12/98	9/01
POINT 9™ Extreme	7/00	8/99	
POINT 9™ Vitesse	8/00	7/00	
POINT 9™ X-80	6/01	6/02	
Restenosed stents prior to brachytherapy	10/01		
Restenosed stents*		1/98	
Support Catheter (.014 and .018 inch)	11/99	3/99	
Support Catheter (.035 inch)	9/02	7/02	
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	
Peripheral Atherectomy			
Upper leg (Trial completed. PMA Supplement submitted to FDA in 01/03.)	Pending	11/96	
Lower leg (Trial completed. Submission to FDA pending.)	Pending	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 FDCA 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 FDCA 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 FDCA requirements. To obtain a Certificate to Foreign Government, the device manufacturer must certify to the FDA that the product has been granted approval in the United States and that the manufacturer and the exported products are in substantial compliance with the FDCA and all applicable or pertinent regulations. The FDA may refuse to issue a Certificate to Foreign Government if significant outstanding Quality System 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 and Possis Medical, 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.

Patents and Proprietary Rights

We hold 36 issued United States patents, four issued patents in each of France, Germany, Italy and the Netherlands and one issued patent in Japan. Also, we have three United States patent applications pending and 10 foreign patent applications pending. Any patents for which we have applied may not be granted. Furthermore, our patents may not be sufficiently broad to protect our technology or to provide us with any competitive advantage. Our patents could be challenged as invalid or circumvented by competitors. In addition, the laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States. We could be adversely affected if any of our licensors terminates our licenses to use patented technology. We do not have patents in any foreign countries other than those listed above.

It is our policy to require our employees and consultants to execute confidentiality agreements upon the commencement of an employment or consulting relationship with us. Each agreement provides that all confidential information developed or made known to the individual during the course of the relationship will be kept confidential and not disclosed to third parties except in specified circumstances. In the case of employees, the agreements provide that all inventions developed by the individual shall be our exclusive property, other than inventions unrelated to our business and developed entirely on the employee’s own time. There can be no assurance that these agreements will provide meaningful protection for our trade secrets in the event of unauthorized use or disclosure of such information.

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

Litigation concerning patents and proprietary rights is time-consuming, expensive, unpredictable and could divert the efforts of our management. An adverse ruling could subject us to significant liability, require us to seek licenses and restrict our ability to manufacture and sell our products.

We hold several non-exclusive, royalty-bearing license agreements for patents covering basic areas of laser technology. In addition, we acquired an exclusive, royalty-bearing license for a proprietary catheter coating. Additional licenses held by us include an exclusive license to patents covering laser-assisted lead removal and an exclusive license relating to certain aspects of excimer laser technology in our products.

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 \$3,309,000 in 2002, \$3,496,000 in 2001, and \$3,911,000 in 2000.

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 eight 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 the same code as for balloon angioplasty, or for balloon angioplasty with stent. 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, 2003, we had 142 employees, including nine in research and development and clinical affairs, 58 in manufacturing and quality assurance, 67 in marketing, sales and administration in the United States and eight 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*

We lease a total of approximately 50,000 square feet 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. The leases for two of these facilities expire December 31, 2005 and June 30, 2004. The lease for the third facility expires December 31, 2003, but we have the option to renew it for an additional year.

Spectranetics International B.V. leases 4,394 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, 2003.

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

Item 3. *Legal Proceedings*

We are involved in a dispute over royalties payable to one of our licensors, Interlase LP, which has been in receivership since September 1998 under the supervision of a state court in Virginia. In addition, because the general partner of Interlase, Lucre Investments, Ltd., filed a voluntary chapter 7 petition on behalf of Interlase in 1999, there is also a pending bankruptcy proceeding in the United States Bankruptcy Court in the Eastern District of Virginia. In October 2002, the licensor completed an audit of our records relating to the license agreement and is claiming past royalties due of approximately \$1.1 million related to lead removal products as well as certain service revenue. They are also claiming forward royalties on these items for periods subsequent to October 2002. In connection with this dispute the licensor has threatened patent litigation, but no lawsuit has been filed to date. We disagree with the licensor’s assertion that additional royalties are due and have filed a complaint in the United States District Court in Denver, Colorado seeking a declaratory judgment that: (1) Spectranetics and the products at issue do not infringe patents that are subjects of the Agreement; and (2) Spectranetics does not owe any additional sums as contended by the licensor under the terms of the agreement and the licensor does not have the right to terminate the agreement as a result of its improper claims. No ruling has been made on the filed complaint.

In March 2003, Interlase filed a complaint in the United States District Court for the Eastern District of Virginia claiming Spectranetics is in breach of a patent license agreement entered into in 1993 and is infringing on the patents that are the subject of the license agreement. In the complaint, Interlase claims an amount in controversy in excess of \$1 million, exclusive of interest and costs, in addition to certain other forms of relief, such as treble damages, a declaratory judgment and injunctive relief, all relating to royalties allegedly owed to or due Interlase in the future associated with certain lead removal products and certain services the Company provides to its customers. We intend to vigorously defend our position on this matter.

The Company is involved in 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 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 2002 and 2001. 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, 2002		
1st Quarter	\$4.64	\$3.35
2nd Quarter	4.44	1.80
3rd Quarter	2.05	1.00
4th Quarter	3.05	1.45
Year Ended December 31, 2001		
1st Quarter	\$3.06	\$1.38
2nd Quarter	3.24	1.31
3rd Quarter	2.74	1.50
4th Quarter	4.25	1.70

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 12, 2003, was \$2.99. On March 12, 2003, we had 731 shareholders of record.

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, 2002, 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, 2002 and 2001, and statement of operations data for each year in the three-year period ended December 31, 2002, have been derived from our audited financial statements also included elsewhere herein. The selected historical balance sheet data as of December 31, 2000, 1999 and 1998, and statement of operations data for the years ended December 31, 1999 and 1998, are derived from, and are qualified by reference to, audited financial statements of the Company not included herein. The data for Polymicro Technologies, Inc., the Company's wholly-owned subsidiary that was sold in June 1999, is reflected as a discontinued operation and therefore excluded from net income (loss) from continuing operations.

	Years Ended December 31,				
	2002	2001	2000	1999	1998
	(In thousands, except per share data)				
STATEMENT OF OPERATIONS DATA:					
Revenue	\$28,097	\$27,808	\$26,900	\$22,305	\$18,565
Cost of revenue	8,983	8,459	8,282	7,397	7,347
Selling, general and administrative	14,671	14,277	17,843	13,902	12,288
Research, development and other technology	4,510	4,915	5,287	4,622	3,161
Proxy contest and settlement obligation	1,837	—	—	—	—
Litigation settlement costs, net	—	—	3,654	—	—
Reorganization costs and litigation reserves	—	—	1,200	1,358	—
Operating income (loss)	(1,904)	157	(9,366)	(4,974)	(4,231)
Other income, net	343	433	838	758	95
Net income (loss) from continuing operations	<u>(1,561)</u>	<u>590</u>	<u>(8,528)</u>	<u>(4,216)</u>	<u>(4,136)</u>
Net income (loss)	<u><u>\$(1,561)</u></u>	<u><u>\$ 590</u></u>	<u><u>\$(8,698)</u></u>	<u><u>\$ 5,169</u></u>	<u><u>\$(3,275)</u></u>
Income (loss) from continuing operations per share					
Basic	\$ (0.07)	\$.03	\$ (0.36)	\$ (0.19)	\$ (0.22)
Diluted	\$ (0.07)	\$.02	\$ (0.36)	\$ (0.19)	\$ (0.22)
Weighted average common shares outstanding:					
Basic	23,809	23,547	23,298	22,407	19,018
Diluted	23,809	24,161	23,298	22,407	19,018

	As of December 31,				
	2002	2001	2000	1999	1998
BALANCE SHEET DATA:					
Working capital	\$10,508	\$ 3,552	\$11,337	\$ 8,957	\$ 4,536
Cash, cash equivalents, and investments	11,430	12,884	11,921	20,125	4,158
Restricted Cash	1,123	—	—	—	—
Equipment, net	3,478	4,119	4,760	3,675	3,129
Total assets	23,836	25,713	27,360	34,038	21,385
Long-term debt including capital lease obligations, net of current portion	—	57	1,649	411	1,433
Shareholders' equity	15,855	16,657	15,716	23,386	11,268
Book value per common share outstanding	\$ 0.67	\$ 0.69	\$ 0.67	\$ 1.04	\$ 0.59

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;
- 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 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.

In addition to our core business described above, we also manufacture and distribute certain products as an original equipment manufacturer for other medical device companies. Revenue from this business represents less than 2% of consolidated revenue and gross margin and has historically been in the range of \$150,000 to \$250,000 per year. Revenue within this business is derived primarily from one customer and we have been notified by this customer that it is in the process of moving the business to another supplier. As a result, we do not expect revenue in future quarters from this customer.

Our business strategy is to increase utilization of our FDA-approved products, expand our installed base of laser systems, and develop additional applications for our excimer laser system. In 1993, the FDA approved for commercialization our CVX-300 laser system and the first generation of our fiber-optic coronary atherectomy catheters. Several improvements and additions to our coronary angioplasty product line have been made since 1993 and have been approved for commercialization by the FDA. In 1997, we secured FDA approval to use our excimer laser system for removal of pacemaker and defibrillator leads, and we secured FDA approval in 2001 to market our product for use in restenosed (clogged) stents (thin steel mesh tubes used to support the walls of coronary arteries) as a pretreatment prior to brachytherapy (radiation therapy). In 2002, we completed two clinical trials evaluating the use of our excimer laser system to treat blocked arteries in the upper (PELA) and lower leg (LACI). We submitted the clinical data from the LACI trial to the FDA in January 2003 and anticipate an FDA approval in late 2003, however, there are no assurances that an FDA approval will be received. We are currently evaluating the clinical data from the PELA trial and, if the clinical data warrants, anticipate submitting the clinical data to the FDA during 2003.

The year ended December 31, 2002, was the second full year of profitability, excluding the impact of the costs associated with the proxy contest and settlement obligations. Net loss was \$1,561,000, or \$0.07 per diluted share during the year ended December 31, 2002 compared with net income of \$590,000, or \$0.02 per diluted share in 2001. Excluding the impact of the proxy contest and settlement obligations, income was \$276,000 for the year ended December 31, 2002.

Our financial guidance for 2003 is for revenue growth in the range of two percent to five percent compared with 2002, which would yield net income in the range of \$500,000 to \$1,000,000. This financial guidance does not assume any revenue associated with a potential approval to market our products for the treatment of critical limb ischemia, since approval of this new indication is not expected until late 2003. However, this guidance does reflect key investments, such as costs to prepare for market launch of our products to treat critical limb ischemia.

Geographical Results of Operations (Overview)

Revenue

	<u>2002</u>	<u>2001</u>	<u>2000</u>
	(In thousands)		
United States	\$25,480	\$25,584	\$24,052
Europe	<u>2,617</u>	<u>2,224</u>	<u>2,848</u>
Total	<u>\$28,097</u>	<u>\$27,808</u>	<u>\$26,900</u>

Net income (loss) from continuing operations

	<u>2002</u>	<u>2001</u>	<u>2000</u>
	(In thousands)		
United States	\$(1,800)	\$445	\$(6,165)
Europe	<u>239</u>	<u>145</u>	<u>(2,363)</u>
Total	<u>\$(1,561)</u>	<u>\$590</u>	<u>\$(8,528)</u>

Year Ended December 31, 2002, Compared With Year Ended December 31, 2001

Revenue in 2002 was \$28,097,000, up \$289,000, or one percent, from 2001. The increase is due to a 12 percent increase in equipment revenue and a two percent increase in service revenue. Disposable catheter revenue in 2002 was consistent with 2001 levels.

Equipment revenue increased 12 percent primarily as a result of increased laser sales resulting from a \$90,000 special price promotion, which ended September 30, 2002. For the year ended December 31, 2002, we placed (sold from inventory, rented or provided for evaluation) 33 excimer laser systems compared with 15 in 2001, bringing our total installed base of laser systems to 360 (260 in the United States). We sold (either an outright sale from inventory or a sale conversion from evaluation or rental programs) 42 laser systems during 2002 as compared with 18 laser systems sold in 2001. Note that 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. Disposable products revenue, which primarily consists of single-use catheter products, was essentially unchanged from 2001. A three percent increase in revenue from lead removal devices was offset by a three percent decline in coronary atherectomy catheters. The decline in coronary atherectomy catheters reflects large orders during the first nine months of 2001 from several accounts. We have not observed decreased catheter utilization in these accounts and expect them to re-order as inventory levels are reduced.

Service revenue increased two percent in 2002, due to the larger installed base of the Company's excimer laser systems.

Gross margin decreased to 68 percent in 2002, from 70 percent in 2001. This decrease was due to a shift in product mix to a higher proportion of excimer laser systems, which generate lower margins than disposable products and service revenue, especially during the \$90,000 special price promotion.

Operating expenses, excluding proxy contest charges and settlement obligations of \$1,837,000, were \$19,181,000, compared with \$19,192,000 in 2001.

Selling, general and administrative expenses increased 3 percent to \$14,671,000 from \$14,277,000 in 2001, due to the following:

- Selling expenses increased approximately \$1,100,000, primarily as a result of the following:
 - Four additional field sales employees were hired in 2002 as compared with 2001, which resulted in increased costs of approximately \$700,000.
 - Approximately \$300,000 was spent in 2002 to prepare for the launch of our products to treat critical limb ischemia. These costs include the hiring of a dedicated product manager, consulting costs to explore Medicare/Medicaid reimbursement issues, and creative concepts related to the development of marketing materials. No costs of this nature were incurred in 2001.
 - Approximately \$100,000 of physician training costs due to a higher number of physicians trained compared with last year for use of our technology in coronary atherectomy and lead removal procedures.
- General and administrative expenses decreased approximately \$750,000 in 2002 as compared with last year as a result of the following:
 - Approximately \$550,000 related to reduced personnel costs associated with the termination of the Company's President and Chief Executive Officer, Chief Financial Officer, and Vice President, Corporate Relations during the second quarter of 2002.
 - Approximately \$200,000 associated with reduced legal expenses due to the settlement of litigation with Cook Vascular, Inc. in 2001. No litigation costs of this nature were incurred during 2002.

Research, development and other technology expense includes research and development, clinical studies, regulatory, and royalties expenses. This category of expenses declined \$405,000, or eight percent, in 2002 to \$4,510,000. The overall decrease is primarily due to a decrease in clinical studies as a result of reduced

costs associated with the LARS trial, which was substantially completed in the fourth quarter of 2001. These costs were partially offset by increased costs associated with the clinical trials to treat peripheral leg arteries which were both completed in late 2002.

Proxy contest charges and settlement obligations totaled \$1,837,000 during 2002. Further discussion of these costs is contained in footnote 15 to our financial statements.

Interest income decreased 19 percent to \$480,000, due primarily to lower yields on our investment securities, which consist primarily of U.S. government and agency obligations with original maturities of less than two years. Interest expense of \$157,000 compares with \$150,000 in 2001 and relates primarily to the discount calculated on the settlement obligation for patent infringement litigation concluded in 2000. The final payment on this settlement obligation was made in November 2002.

Net loss was \$1,561,000 in 2002, or \$0.07 per diluted share, compared with net income of \$590,000, or \$0.02 per diluted share, in 2001. Excluding proxy contest charges and settlement obligations, 2002 income would have been \$276,000, or \$0.01 per diluted share.

Year Ended December 31, 2001, Compared With Year Ended December 31, 2000

Revenue in 2001 was \$27,808,000, up \$908,000, or three percent, from 2000. The increase is due to an eight percent increase in equipment revenue, a two percent increase in disposable products revenue and a seven percent increase in service revenue.

Equipment revenue increased eight percent due to increased rental revenue under the Company's Evergreen rental program. Revenue from laser units sold in 2001 was approximately the same as 2000. For the year ended December 31, 2001, we placed (sold, rented or provided for evaluation) 15 excimer laser systems compared with 48 in 2000. The decrease in laser placements is primarily a result of fewer placements under our laser evaluation program, which does not generate up-front equipment revenue.

At December 31, 2001, the installed base included 327 excimer laser systems (230 in the United States), compared with 312 at December 31, 2000 (215 in the United States).

The increase in disposable products revenue, which primarily consists of single-use catheter products, is comprised of a three percent increase in lead removal devices and a significant increase in peripheral atherectomy catheters from a small base, partially offset by a two percent decline in coronary atherectomy catheters.

Service revenue increased seven percent in 2001, as the larger installed base of the Company's excimer laser systems in the United States offset the impact of utilizing distributors to perform service in Europe in 2001.

Gross margin increased to 70 percent in 2001, from 69 percent in 2000. This improvement was a combination of higher average selling prices on lasers and disposable products sales, combined with increased manufacturing efficiencies.

Operating expenses declined 31 percent in 2001 to \$19,192,000, compared with \$27,984,000 in 2000. In 2000, net litigation settlement costs of \$3,654,000 and reorganization costs of \$1,200,000 were recognized. Excluding those costs, operating expenses declined 17 percent in 2001 for the reasons discussed below.

For the year ended December 31, 2001, we consolidated several operating expense line items. "Selling, general and administrative" includes marketing and sales and general and administrative expenses. "Research, development and other technology" includes research and development, clinical studies, regulatory expenses and royalties. For the year ended December 31, 2000, we reclassified regulatory expenses as part of research and development costs; in prior years, regulatory expenses had been included in "General and administrative" expense. All prior years have been reclassified to conform to the current presentation.

Selling, general and administrative expenses of \$14,277,000 were down 20 percent from \$17,843,000 in 2000, due to a 25 percent decline in marketing and sales expense and a seven percent decline in general and administrative expense. The restructuring of our European operation, which eliminated our direct sales force

in Germany and switched to a distributor-based sales model, accounted for more than half of the decline in marketing and sales expense. The remainder was due to widespread expense reductions within the U.S. sales and marketing organization, including lower travel and entertainment expenses, and decreased expenditures for conventions and advertising. General and administrative expenses were down due to a variety of cost reductions, the most significant of which was reduced legal expenses.

Research, development and other technology expense includes research and development, clinical studies, regulatory, and royalties expenses. This category of expenses declined \$372,000, or seven percent, in 2001 to \$4,915,000. The overall decrease is primarily due to a 19 percent reduction in research and development expenses, primarily attributable to the cancellation of a research contract with an outside entity. Clinical studies and regulatory expenses were consistent with prior year levels. Royalties expense increased three percent from the prior year amount, primarily due to additional royalties related to the litigation settlement in October 2000.

Interest income decreased 36 percent to \$594,000, due primarily to lower yields on our investment securities, which consist primarily of U.S. government and agency obligations with original maturities of less than two years. Interest expense of \$150,000 increased 44 percent from the prior year due to the interest related to installments on past royalties in connection with the litigation settlement entered into during the year ended December 31, 2000.

Net income was \$590,000 in 2001, compared with a loss of \$8,698,000 in 2000. In 2000, the Company recognized a \$3,654,000 litigation settlement expense, \$1,200,000 of reorganization costs, and \$170,000 of tax expense related to the sale of a discontinued operation. Excluding these costs, our net loss was \$3,674,000 in 2000. The improvement in net income, excluding these costs, of \$4,264,000 was primarily due to \$3,938,000 of operating expense reductions combined with slightly higher revenue, which was primarily a result of increased selling prices for lasers and disposable products, and improved manufacturing efficiencies.

Income Taxes

At December 31, 2002, we had net operating loss carryforwards for U.S. federal income tax purposes of approximately \$54 million, which are available to offset future federal taxable income, if any, and expire at varying dates from 2003 through 2022. The annual use of the net operating loss carryforwards is limited under Section 382 of the Internal Revenue Code of 1986. An alternative minimum tax credit carryforward of \$253,000 is available to offset future tax liabilities and has no expiration date. The Company also has tax loss carryforwards in the Netherlands, which have no expiration date, of approximately \$29 million Euros (\$30 million U.S. dollars) available to offset future taxable income, if any.

We also had research and experimentation tax credit carryforwards for federal income tax purposes at December 31, 2002, of approximately \$3 million, which are available to reduce future federal income taxes, if any, and expire at varying dates through 2021. The annual use of portions of the research and experimentation credit carryforwards is also limited under Section 382 of the Internal Revenue Code of 1986.

Liquidity and Capital Resources

As of December 31, 2002, we had cash, cash equivalents and investment securities of \$11,430,000, down \$1,454,000 from \$12,884,000 at December 31, 2001.

For the year ended December 31, 2002, cash used by operating activities totaled \$622,000, which was primarily a result of a reduction in accounts payable and accrued liabilities of \$1,337,000, and a \$415,000 increase in equipment held for rental or loan. These uses of cash were partially offset by cash earnings (net income plus depreciation and amortization) of \$132,000, a \$687,000 reduction of accounts receivable resulting from focused working capital management and a \$208,000 increase in deferred revenue. The reduction in accounts payable and accrued liabilities related primarily to the final installment on past royalties agreed upon as part of the litigation settlement in 2000.

For the year ended December 31, 2002, cash provided by investing activities was \$830,000. The increased cash provided by investing activities is primarily due to fluctuations in our investment portfolio mix between

cash, cash equivalents and investment securities. This was partially offset by capital expenditures during the year ended December 31, 2002, of \$198,000, compared with \$290,000 during the same period last year. We do not expect our capital requirements to change significantly in 2003 compared with 2002 levels.

Net cash provided by financing activities was \$457,000 during the year ended December 31, 2002. Financing activities consist primarily of proceeds from sale of common stock to employees, either through the exercise of stock options or the employee stock purchase plan, partially offset by principal payments on long-term debt and capital lease obligations. At December 31, 2002, total debt, including capital lease obligations, was \$82,000.

In October 2002, we funded an escrow account in connection with a dispute from one of our licensors. The licensor claims that additional royalties totaling \$1.1 million are due relating to lead removal products and other service-based revenue. The licensor threatened to seek an injunction to prohibit us from selling lead removal devices. We believe all royalties due under the license agreement have been paid and, in response to the licensor's threats, we set aside in an escrow account the disputed amount of \$1.1 million, which has been reclassified to restricted cash until the dispute is resolved. We have filed a complaint in Colorado against the licensor. To date, no legal action has been taken by the licensor.

At December 31, 2002 and 2001, we had placed a number of systems on rental or loan programs. A total of \$5,031,000 and \$5,089,000 was recorded as equipment held for rental or loan at December 31, 2002 and 2001, respectively, and is being depreciated over three to five years.

In 2002, 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.

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, 2002, 28 laser units were in place under the evaluation program.

At the beginning of 2002, we ran a price promotion in which we offered lasers for sale at \$90,000, compared with a list price of \$249,000. The \$90,000 price promotion ended September 30, 2002; however, we will continue to honor special pricing for quotes that were outstanding as of September 30, 2002. As of December 31, 2002, 44 laser units were in place under the Evergreen program.

We believe our liquidity and capitalization as of December 31, 2002 are sufficient to meet our operating and capital requirements at least through December 31, 2003

Conversion To The Euro

For the year ended December 31, 2002 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 financial 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 products is recognized when products are shipped and title transfers to the customer. Revenue from product maintenance contracts is deferred and recognized ratably over the contract period.

Revenue from the rental of our excimer laser systems is recognized on a monthly basis based on a calculated rental fee. For Evergreen rental units, the calculated rental fee depends on the monthly catheter purchases of each customer.

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 today, these facts are subject to change.

Warranty liability. We generally provide a one-year warranty on the sale of our excimer laser. We record 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.

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 today, the estimates are subject to change based on changes in the underlying facts and assumptions used to develop these estimates.

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, 2002, 2001 and 2000, compensation expense related to stock option grants to employees totaled \$1,760,000, \$2,345,000 and \$2,214,000, respectively, which have been included in pro form disclosures, but not included in determining net income. As such, our statement of operations would be adversely affected should new accounting pronouncements be adopted that require the recording of compensation expense within our statement of operations.

Restricted Cash. During 2002, we established an escrow account in connection with a dispute over royalty obligations owed to one of our licensors. We believe we have paid all royalties due under the license agreement. The funds may be disbursed from the escrow account upon the earlier of the resolution of the dispute or two years. The funds in the escrow account totaling \$1,123,000 have been recorded as restricted cash on our balance sheet at December 31, 2002.

Income Taxes. We account 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.

A valuation allowance is required to the extent it is more likely than not that a deferred tax asset will not be realized. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. As of December 31, 2002, we have a net deferred tax asset of \$36,137,000. We have established a valuation allowance equal to the deferred tax asset due to the uncertainty of realization because of our history of operating losses. Should we demonstrate consistent and continued profitability, the valuation allowance will be evaluated and a deferred tax asset may be recorded within our financial statements.

New Accounting Pronouncements

In June 2002, the FASB issued SFAS No. 146, *Accounting for Exit or Disposal Activities*. SFAS No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies EITF Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)*. SFAS No. 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred instead of the date of an entity's commitment to an exit plan. This Statement also establishes that fair value is the objective for initial measurement of the liability. Severance pay under Statement No. 146, in many cases, would be recognized over time rather than upfront for employees who render future services beyond a minimum retention period. The minimum retention period would be based on the legal notification period, or if there is no such requirement, 60 days. The provisions of SFAS No. 146 are effective for the Company for disposal activities initiated after December 31, 2002. Management does not believe adoption of this statement will have a material impact on the Company's financial position, results of operations or cash flows.

In December 2002, the FASB issued SFAS no. 148, *Accounting for Stock-Based Compensation — Transition and Disclosure — an amendment of FASB Statement No. 123*. SFAS No. 148 amends FASB No. 123, *Accounting for Stock-Based Compensation* to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of Statement 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The provisions of SFAS No. 148 are effective for the Company in fiscal 2003 and in fiscal 2002 for certain disclosures. Management does not believe the adoption of this statement will have a material impact on the Company's financial position, results of operations or cash flows as the Company does not currently plan to change to the fair value based method of accounting for stock-based employee compensation.

Risk Factors

We Have a History of Losses and May Not Be Able to Maintain Profitability. We incurred net 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, 2002, we had accumulated \$77.3 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. No assurance can be given that we will be able to achieve and maintain profitability in the future.

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.

Our Products May Not Achieve Market Acceptance. Excimer laser technology competes 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 adequate clinical and economic data that shows the clinical efficacy and cost effectiveness of, and patient benefits from, excimer laser atherectomy and lead removal.

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, such as:

- balloon angioplasty, which uses a balloon to push obstructions out of the way;
- stent implantation;
- open chest bypass surgery; and
- atherectomy and thrombectomy, using mechanical methods to remove arterial blockages.

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.

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.

We estimate that approximately 80 percent 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 and Possis Medical, Inc.

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. 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.

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 upper and lower leg has taken 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.

We cannot guarantee that we will gain FDA approval to market the use of our excimer laser system to treat blocked arteries in the upper and lower leg. If we do not receive these FDA approvals, our business will suffer.

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, 2002, our revenue from international operations represented 10 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. 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 terminates our licenses to use patented technology. Although we have established reserves for royalty payment obligations based on a process of calculating royalty obligations associated with our licensed technology, the process involves management estimates that require judgement and there can be no assurance that these reserves will be adequate.

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 for a certain catheter with a diameter of less than .9 millimeters. We are in the process of reviewing the patent to determine its validity and enforceability. 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;
- past or future management changes;
- 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.

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*

Our primary market risks include changes in foreign currency exchange rates and interest rates. Market risk is the risk of potential loss arising from adverse changes in market rates and prices, such as foreign currency exchange and interest rates. We do not use financial instruments to any degree to manage these risks. The Company does not use financial instruments to manage changes in commodity prices and does not hold or issue financial instruments for trading or other speculative purposes. Our debt consists of obligations with fixed interest rates ranging from 5.75 percent to 8 percent. The Company does not consider the potential losses in future earnings, cash flows and fair values from reasonable near-term changes in exchange rates or interest rates to be material.

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.

PART III

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

The information appearing under the captions “Proposal 1 — Election of Directors”, “Executive Officers” and “Section 16 (a) Beneficial Ownership Reporting Compliance” of the registrant’s definitive Proxy Statement to be used in connection with its 2003 Annual Meeting of Shareholders is incorporated herein by reference.

Item 11. *Executive Compensation*

Information appearing under the captions “Executive Compensation”, “Grants of Stock Options”, “Stock Option Exercises and Fiscal Year-End Stock Option Value”, “Director Compensation” and “Compensation Committee Interlocks and Insider Participations” of the Company’s 2003 Proxy Statement is incorporated herein by reference.

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

Information appearing under the caption “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plans” of the Company’s 2003 Proxy Statement is incorporated herein by reference.

Item 13. *Certain Relationships and Related Transactions*

Not applicable.

PART IV

Item 14. *Controls and Procedures*

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the 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.

Within 90 days prior to the date of this report, we carried out an evaluation, under the supervision 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. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective.

We have evaluated our systems of internal controls and have not identified any significant deficiencies or material weaknesses. There have been no significant changes in our internal controls or in other factors that could significantly affect our internal controls subsequent to the date we completed our evaluation.

Item 15. Exhibits and Reports on Form 8-K

(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 35.

(b) *Reports on Form 8-K*

Not applicable.

CERTIFICATIONS

I, John G. Schulte, President and Chief Executive Officer of The Spectranetics Corporation, certify that:

1. I have reviewed this annual report on Form 10-K of The Spectranetics Corporation;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
 - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ JOHN G. SCHULTE

John G. Schulte
President and Chief Executive Officer

Date: March 28, 2003

I, Guy A. Childs, Vice President, Chief Financial Officer of The Spectranetics Corporation, certify that:

1. I have reviewed this annual report on Form 10-K of The Spectranetics Corporation;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
 - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ GUY A. CHILDS

Guy A. Childs
Vice President, Chief Financial Officer

Date: March 28, 2003

THE SPECTRANETICS CORPORATION
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	<u>Page</u>
Index to Financial Statements:	
Independent Auditors' Report	F-2
Consolidated Balance Sheets, December 31, 2002 and 2001	F-3
Consolidated Statements of Operations, Years Ended December 31, 2002, 2001, and 2000	F-4
Consolidated Statements of Shareholders' Equity, Years Ended December 31, 2002, 2001, and 2000	F-5
Consolidated Statements of Cash Flows, Years Ended December 31, 2002, 2001, and 2000	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.

Independent Auditors' Report

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, 2002 and 2001, 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, 2002. 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 auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits 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, 2002 and 2001, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2002, in conformity with accounting principles generally accepted in the United States of America.

Denver, Colorado
January 31, 2003 (Except as to Note 18
which is as of March 28, 2003)

THE SPECTRANETICS CORPORATION AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS
December 31, 2002 and 2001

	2002	2001
	(In thousands, except share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 2,767	\$ 3,093
Investment securities available for sale	8,663	2,046
Trade accounts receivable, less allowance for doubtful accounts and sales returns of \$555 and \$642, respectively	4,042	4,717
Inventories, net	2,125	1,795
Prepaid expenses and other current assets	676	900
Total current assets	18,273	12,551
Equipment and leasehold improvements, at cost:		
Manufacturing equipment and computers	6,408	6,253
Leasehold improvements	941	861
Equipment held for rental or loan	5,031	5,089
Furniture and fixtures	197	179
	12,577	12,382
Less accumulated depreciation and amortization	(9,099)	(8,263)
Net equipment and leasehold improvements	3,478	4,119
Intangible assets, net	771	1,015
Other assets	191	283
Restricted cash	1,123	—
Long-term investment securities available for sale	—	7,745
Total assets	\$23,836	\$ 25,713
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 695	\$ 273
Accrued liabilities	5,924	7,562
Deferred revenue	1,064	993
Current portion of long-term debt	79	153
Current portion of capital lease obligations	3	18
Total current liabilities	7,765	8,999
Accrued liabilities, net of current portion	104	—
Deferred revenue, net of current portion	112	—
Long-term debt, net of current portion	—	57
Total liabilities	7,981	9,056
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: 23,877,744 shares in 2002 and 23,599,500 shares in 2001	24	24
Additional paid-in capital	93,393	92,638
Accumulated other comprehensive loss	(272)	(276)
Accumulated deficit	(77,290)	(75,729)
Total shareholders' equity	15,855	16,657
Commitments and contingencies (notes 5, 6, 7, 8, 9, 11, 15, and 16)		
Total liabilities and shareholders' equity	\$23,836	\$ 25,713

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, 2002, 2001, and 2000

	<u>2002</u>	<u>2001</u>	<u>2000</u>
	(In thousands, except share and per share amounts)		
Revenue	\$ 28,097	\$ 27,808	\$ 26,900
Cost of revenue	<u>8,983</u>	<u>8,459</u>	<u>8,282</u>
Gross profit	19,114	19,349	18,618
Operating expenses:			
Selling, general, and administrative	14,671	14,277	17,843
Research, development, and other technology	4,510	4,915	5,287
Proxy contest and settlement	1,837	—	—
Litigation settlement costs, net	—	—	3,654
Reorganization costs and litigation reserves	<u>—</u>	<u>—</u>	<u>1,200</u>
Total operating expenses	<u>21,018</u>	<u>19,192</u>	<u>27,984</u>
Operating income (loss)	<u>(1,904)</u>	<u>157</u>	<u>(9,366)</u>
Other income (expense):			
Interest expense	(157)	(150)	(104)
Interest income	480	594	923
Other, net	<u>20</u>	<u>(11)</u>	<u>19</u>
	<u>343</u>	<u>433</u>	<u>838</u>
Net income (loss) from continuing operations	(1,561)	590	(8,528)
Discontinued operations:			
Income taxes of discontinued industrial subsidiary, Polymicro Technologies, Inc.	<u>—</u>	<u>—</u>	<u>(170)</u>
Gain/income (income taxes) from discontinued operations	<u>—</u>	<u>—</u>	<u>(170)</u>
Net income (loss)	(1,561)	590	(8,698)
Other comprehensive income (loss)	<u>4</u>	<u>(29)</u>	<u>(119)</u>
Comprehensive income (loss)	<u>\$ (1,557)</u>	<u>\$ 561</u>	<u>\$ (8,817)</u>
Earnings per common and common equivalent share:			
Net income (loss) from continuing operations	\$ (0.07)	\$ 0.03	\$ (0.36)
Income (loss) from discontinued operations	<u>—</u>	<u>—</u>	<u>(0.01)</u>
Net income (loss) per share	<u>\$ (0.07)</u>	<u>\$ 0.03</u>	<u>\$ (0.37)</u>
Earnings per share — assuming full dilution:			
Income (loss) from continuing operations	\$ (0.07)	\$ 0.02	\$ (0.36)
Income (loss) from discontinued operations	<u>—</u>	<u>—</u>	<u>(0.01)</u>
Net income (loss) per share	<u>\$ (0.07)</u>	<u>\$ 0.02</u>	<u>\$ (0.37)</u>
Weighted average shares outstanding:			
Basic	23,809,159	23,547,380	23,298,145
Diluted	23,809,159	24,161,269	23,298,145

See accompanying notes to consolidated financial statements.

**THE SPECTRANETICS CORPORATION
AND SUBSIDIARY**

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

Years ended December 31, 2002, 2001, and 2000

	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Other Comprehensive Income (Loss)</u>	<u>Accumulated Deficit</u>	<u>Total Shareholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>				
	(In thousands, except share amounts)							
Balances at December 31, 1999	—	\$—	23,037,188	\$23	\$91,112	\$(128)	\$(67,621)	\$23,386
Exercise of stock options	—	—	335,479	—	895	—	—	895
Shares purchased under employee stock purchase plan	—	—	53,213	—	142	—	—	142
Options granted for consulting services	—	—	—	—	8	—	—	8
Amortization of warrant expense	—	—	—	—	102	—	—	102
Unrealized gain on investments	—	—	—	—	—	(43)	—	(43)
Foreign currency translation adjustment	—	—	—	—	—	(76)	—	(76)
Net loss	—	—	—	—	—	—	(8,698)	(8,698)
Balances at December 31, 2000	—	—	23,425,880	23	92,259	(247)	(76,319)	15,716
Exercise of stock options	—	—	11,095	—	35	—	—	35
Shares purchased under employee stock purchase plan	—	—	162,525	1	203	—	—	204
Options granted for consulting services	—	—	—	—	40	—	—	40
Amortization of warrant expense	—	—	—	—	101	—	—	101
Unrealized gain on investments	—	—	—	—	—	14	—	14
Foreign currency translation adjustment	—	—	—	—	—	(43)	—	(43)
Net income	—	—	—	—	—	—	590	590
Balances at December 31, 2001	—	—	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	—	\$—	23,877,744	\$24	\$93,393	\$(272)	\$(77,290)	\$15,855

See accompanying notes to consolidated financial statements.

THE SPECTRANETICS CORPORATION AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years ended December 31, 2002, 2001, and 2000

	<u>2002</u>	<u>2001</u>	<u>2000</u>
	(In thousands)		
Cash flows from operating activities:			
Net income (loss)	\$(1,561)	\$ 590	\$(8,698)
Adjustments to reconcile net income (loss) to net cash provided (used) by operating activities:			
Income taxes (gain on sale) of Polymicro Technologies, Inc.	—	—	170
Depreciation and amortization	1,693	1,832	1,731
Options granted for consulting services	36	40	8
Extended vesting of options for terminated executives	88	—	—
Changes in operating assets and liabilities:			
Trade accounts receivable, net	687	1,359	(580)
Inventories	(270)	773	136
Equipment held for rental or loan, net	(415)	(529)	(1,876)
Prepaid expenses and other current assets	119	(271)	(110)
Other assets	130	(86)	(150)
Accounts payable and accrued liabilities	(1,337)	(2,305)	2,103
Deferred revenue and other liabilities	208	(214)	(338)
Net cash provided (used) by operating activities	<u>(622)</u>	<u>1,189</u>	<u>(7,604)</u>
Cash flows from investing activities:			
Capital expenditures	(198)	(290)	(579)
Sale (purchases) of investment securities, net	<u>1,028</u>	<u>(51)</u>	<u>5,455</u>
Net cash provided (used) by investing activities	<u>830</u>	<u>(341)</u>	<u>4,876</u>
Cash flows from financing activities:			
Proceeds from sale of common stock to employees	614	238	1,037
Principal payments on long-term debt and capital leases obligations	<u>(157)</u>	<u>(162)</u>	<u>(986)</u>
Net cash provided by financing activities	457	76	51
Effect of exchange rate changes on cash	132	(26)	(28)
Net change in restricted cash	<u>(1,123)</u>	<u>—</u>	<u>—</u>
Net increase (decrease) in cash and cash equivalents	(326)	898	(2,705)
Cash and cash equivalents at beginning of year	<u>3,093</u>	<u>2,195</u>	<u>4,900</u>
Cash and cash equivalents at end of year	<u>\$ 2,767</u>	<u>\$ 3,093</u>	<u>\$ 2,195</u>
Supplemental disclosures of cash flow information:			
Cash paid during the year for interest	\$ 161	\$ 157	\$ —

See accompanying notes to consolidated financial statements.

THE SPECTRANETICS CORPORATION AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2002 and 2001

(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 cardiovascular system in conjunction with its proprietary excimer laser system.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ significantly 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 \$1,819,000 and \$3,076,000 at December 31, 2002 and 2001, respectively, consist primarily of money market accounts, commercial paper and repurchase agreements stated at cost, which approximates fair value.

(c) Investment Securities

Investment securities at December 31, 2002 and 2001, 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 loss. At December 31, 2002 and 2001, the unrealized loss totaled \$129,000 and \$29,000, respectively.

(d) Inventory

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

(e) Equipment and Leasehold Improvements

Equipment and leasehold improvements 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 two 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.

THE SPECTRANETICS CORPORATION AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

(f) Intangible Assets

Intangible assets, which consist primarily of patents, are amortized using the straight-line method over periods ranging from 5 to 13 years.

(g) Restricted Cash

Restricted cash consists of an escrow fund established pursuant to a dispute with a licensor of certain patents of the Company. The funds may be disbursed from the escrow account upon the earlier of the resolution of the dispute or two years.

(h) 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*. This statement requires that long-lived assets and certain identifiable intangibles be reviewed for impairment 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 adjustments for this impairment of long-lived assets have been recognized.

(i) Financial Instruments

At December 31, 2002 and 2001, 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, accounts payable, long-term debt and settlement obligations.

(j) Revenue Recognition

Revenue from the sale of the Company's products is recognized when products are shipped to the customer and title transfers. Revenue from services are recognized when performed and revenue from prepaid product maintenance contracts and equipment rentals is deferred and recognized ratably over the contract period. The Company bills for product maintenance contracts in advance and records a liability for the deferred revenue.

Revenue from the rental of the Company's Eximer laser systems is recognized on a monthly basis based on a calculated rental fee. The calculated rental fee depends on the monthly catheter purchases of each customer.

(k) Warranties

The Company generally provides a one-year warranty on the sale of its excimer laser when products are shipped to the customer and bases its estimate on historical experience. The Company records warranty expense within cost of revenue at the time of the sale. As warranty costs are incurred, they are charged against the warranty liability.

THE SPECTRANETICS CORPORATION AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

(l) 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.

(m) 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 Statement of Financial Accounting Standards 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.

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>2002</u>	<u>2001</u>	<u>2000</u>
	(In thousands, except per share amounts)		
Net income (loss), as reported	\$(1,561)	\$ 590	\$ (8,698)
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	<u>(1,760)</u>	<u>(2,345)</u>	<u>(2,214)</u>
Pro forma net income	<u><u>\$(3,321)</u></u>	<u><u>\$(1,755)</u></u>	<u><u>\$(10,912)</u></u>
Earnings (loss) per share:			
Basic — as reported	(0.07)	0.03	(0.37)
Basic — pro forma	(0.14)	(0.07)	(0.47)
Diluted — as reported	(0.07)	0.02	(0.37)
Diluted — pro forma	(0.14)	(0.07)	(0.47)

(n) Research and Development

Research and development costs are expensed as incurred and totaled \$1,795,000, \$1,770,000, and \$2,185,000 for the years ended December 31, 2002, 2001, and 2000, 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

THE SPECTRANETICS CORPORATION AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

associated with these clinical trials totaled \$1,514,000, \$1,726,000 and \$1,726,000 during the years ended December 31, 2002, 2001, and 2000, respectively.

(o) Foreign Currency Translation

The Company's primary functional currency is the U.S. dollar. Certain transactions of the Company and its subsidiary are consummated 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 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 loss.

(p) Advertising Costs

The Company expenses advertising costs as incurred. Advertising costs of \$118,000, \$55,000, and \$69,000 were expensed in 2002, 2001, and 2000, respectively.

(q) 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.

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

(2) Investment Securities

Investment securities consist of the following at December 31:

<u>Short-term investments</u>	<u>2002</u>	<u>2001</u>
	(In thousands)	
U.S. Treasury and agency notes	\$4,542	\$1,035
Corporate notes	<u>4,121</u>	<u>1,011</u>
Total	<u>\$8,663</u>	<u>\$2,046</u>
<u>Long-term investments</u>		
U.S. Treasury and agency notes	\$—	\$4,592
Corporate notes	<u>—</u>	<u>3,153</u>
Total	<u>\$—</u>	<u>\$7,745</u>

Unrealized loss at December 31, 2002 and 2001, respectively, was \$129,000 and \$29,000, which has been included in other comprehensive loss. Realized gains and losses are determined using the specific identification

THE SPECTRANETICS CORPORATION AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

method. There were no significant realized gains or losses during 2002 or 2001. Contractual maturities of all investment securities at December 31, 2002 were less than one year.

(3) Inventories

Inventories consist of the following as of December 31:

	<u>2002</u>	<u>2001</u>
	(In thousands)	
Raw materials	\$ 275	\$ 259
Work in process	398	372
Finished goods	<u>1,452</u>	<u>1,164</u>
	<u>\$2,125</u>	<u>\$1,795</u>

(4) Intangible Assets

Intangible assets as of December 31 are as follows:

	<u>2002</u>	<u>2001</u>
	(In thousands)	
Acquired cost	\$4,123	\$ 4,123
Less accumulated amortization	<u>(3,352)</u>	<u>(3,108)</u>
	<u>\$ 771</u>	<u>\$ 1,015</u>

(5) Accrued Liabilities

Accrued liabilities consist of the following as of December 31:

	<u>2002</u>	<u>2001</u>
	(In thousands)	
Accrued payroll and employee related expenses	\$1,997	\$2,102
Accrued royalty expense	1,405	2,419
Accrued warranty expense	435	324
Accrued clinical study expense	260	537
Accrued legal and reorganization expenses	285	521
Accrued proxy contest and settlement	226	—
Other accrued expenses	<u>1,316</u>	<u>1,659</u>
	<u>\$5,924</u>	<u>\$7,562</u>

(6) Debt

During 1993, the Company issued a note payable in the amount of \$1,050,000 to obtain certain patent rights. The note was for a ten-year period with annual payments of \$105,000 due on May 1st. The note was non-interest bearing and was discounted to \$827,000, using a discount rate of 5.75%. At December 31, 2002, the note had been paid in full.

During 1998, the Company entered into a \$330,000 loan agreement collateralized by equipment held for rental or loan owned by Spectranetics International, B.V. The loan bears interest at 6.51% per annum and matures in December 2003. At December 31, 2002, the amount outstanding on this loan was \$79,000.

THE SPECTRANETICS CORPORATION AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

(7) Litigation Settlement

In October 2000, the Company entered into a settlement and release agreement with Baxter Healthcare Corporation (and its spin-off company, Edwards Life Sciences LLC) (collectively, Baxter) related to a patent infringement lawsuit filed by Baxter in August 1999. The agreement provided that the Company and Baxter each release all claims and counterclaims against each other, and Spectranetics enter into a license agreement for use of certain patents in the United States and abroad until the expiration of the last patent on November 15, 2005.

The Company is required to pay a royalty through the life of the patents. In addition, the Company recorded a net charge of \$3,654,000 during the year ended December 31, 2000, to reflect the cost of past royalties to the agreement date and legal fees related to this suit, offset by release of the Company's prior obligation to provide defined medical devices to United States Surgical Corporation, a division of Tyco International. United States Surgical Corporation transferred certain assets to Baxter in July 1999. In addition, Baxter returned to the Company 15 laser systems for resale. The payments for past royalties were made in three annual installments beginning in November 2000. As of December 31, 2002, all past royalties had been fully paid.

(8) Stock-based Compensation and Employee Benefit Plans

At December 31, 2002 and 2001, 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, non-qualified 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, 2002, 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. At December 31, 2002, there were 2,121,191 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, 2002:

	<u>Shares Under Option</u>	<u>Weighted- Average Exercise Price</u>
Options outstanding at December 31, 1999.....	3,880,196	\$3.21
Granted	1,152,737	3.61
Exercised	(335,479)	2.67
Canceled	<u>(282,214)</u>	3.50
Options outstanding at December 31, 2000.....	4,415,240	3.33
Granted	937,557	2.11
Exercised	(11,095)	3.00
Canceled	<u>(267,907)</u>	3.82
Options outstanding at December 31, 2001.....	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.....	<u>4,938,901</u>	\$3.06

At December 31, 2002, the weighted average remaining contractual life of outstanding options was 6.1 years, and 4,053,475 options were exercisable at a weighted average exercise price of \$3.05 per share.

The per-share weighted-average fair value of stock options granted during 2002, 2001, and 2000, was \$2.13, \$1.55 and \$2.73 per share, respectively, on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	<u>2002</u>	<u>2001</u>	<u>2000</u>
Risk free interest rate	2.7%	4.3%	5.0%
Expected life	6.75	6.20	6.06
Expected volatility.....	91.0%	91.0%	101.0%
Expected dividend yield	0.0%	0.0%	0.0%

THE SPECTRANETICS CORPORATION AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Outstanding and Exercisable by Price Range as of December 31, 2002					
Range of Exercise Prices	Number Outstanding as of December 31, 2002	Weighted-Average Remaining Contractual Life (Years)	Weighted-Average Exercise Price	Number Exercisable as of December 31, 2002	Weighted-Average Exercise Price
\$.84-1.12	104,917	4.11	\$0.84	104,917	\$0.84
1.31-1.56	489,255	7.78	1.55	398,678	1.55
1.60-1.63	517,431	8.48	1.62	434,672	1.63
1.72-2.39	418,818	6.09	1.97	300,563	1.92
2.39-2.66	512,888	7.34	2.57	281,702	2.61
2.69-3.03	637,766	5.63	3.00	608,903	3.00
3.06-3.13	205,000	5.25	3.11	202,187	3.11
3.19-3.31	585,000	4.35	3.31	583,125	3.31
3.31-3.95	543,161	6.70	3.56	391,205	3.48
3.99-8.25	<u>924,665</u>	5.65	5.26	<u>747,523</u>	5.21
	<u>4,938,901</u>	6.10	3.06	<u>4,053,475</u>	3.05

During the year ended December 31, 2002, the Company modified certain executive options to extend the vesting and exercisability as part of their severance packages. The modification was accounted for under APB 25 as the employees were no longer providing services and resulted in a charge of approximately \$88,000 which is included in selling, general, and administrative expenses in the accompanying consolidated statement of operations.

(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. 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 six-month period. Shares issued under the plan totaled 107,231, 162,525, and 53,213 in 2002, 2001, and 2000, respectively.

Under SFAS No. 123, compensation cost is recognized for the fair value of the employees' purchase rights. The weighted average fair value of purchase rights granted in 2002, 2001, and 2000 was \$0.84, \$1.43, and \$0.91, respectively, per right, which was estimated using the Black-Scholes model with the following assumptions:

	2002	2001	2000
Risk free interest rate	1.2%	1.70%	5.20%
Expected life	6 months	6 months	6 months
Expected volatility	89.0%	94.0%	109.0%
Expected dividend yield	0.0%	0.0%	0.0%

(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 has accrued contributions

THE SPECTRANETICS CORPORATION AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

of \$54,000 to the plan in 2002 based on a match of 25% of the first 4% of each employees contribution. The Company made no matching contributions to the Plan for the years ended December 31, 2001 and 2000.

(9) 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, 2002 and 2001 were 563,182 and 572,370 because their effect would have been antidilutive.

	<u>2002</u>	<u>2001</u>	<u>2000</u>
	(In thousands)		
Net income (loss):			
Income (loss) from continuing operations	\$(1,561)	590	(8,528)
Gain/income (income taxes) from discontinued operations	<u>—</u>	<u>—</u>	<u>(170)</u>
Net income (loss)	<u><u>\$ (1,561)</u></u>	<u><u>590</u></u>	<u><u>(8,698)</u></u>
Common shares outstanding:			
Historical common shares outstanding at beginning of year	23,599	23,426	23,037
Weighted average common shares issued	210	121	261
Weighted average common shares outstanding — basic	23,809	23,547	23,298
Effect of dilution stock options	<u>—</u>	<u>614</u>	<u>—</u>
Weighted average common shares outstanding — diluted	<u><u>23,809</u></u>	<u><u>24,161</u></u>	<u><u>23,298</u></u>
Earnings per common and common equivalent share:			
Income (loss) from continuing operations	\$ (0.07)	0.03	(0.36)
Income (loss) from discontinued operations	<u>—</u>	<u>—</u>	<u>(0.01)</u>
Net income (loss) per share	<u><u>\$ (0.07)</u></u>	<u><u>0.03</u></u>	<u><u>(0.37)</u></u>
Earnings per share, assuming full dilution:			
Income (loss) from continuing operations	\$ (0.07)	0.02	(0.36)
Income (loss) from discontinued operations	<u>—</u>	<u>—</u>	<u>(0.01)</u>
Net income (loss) per share	<u><u>\$ (0.07)</u></u>	<u><u>0.02</u></u>	<u><u>(0.37)</u></u>

(10) Leases

The Company leases certain equipment under capital leases, and office space, furniture and equipment under noncancelable operating leases with initial terms that expire at various dates through 2006.

All assets held under capital leases were fully depreciated at December 31, 2002 and 2001.

THE SPECTRANETICS CORPORATION AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The present value of future minimum capital lease payments and future minimum lease payments under noncancelable operating leases as of December 31, 2002, are as follows:

	<u>Capital Leases</u>	<u>Operating Leases</u>
	(In thousands)	
Years ending December 31:		
2003	\$3	\$ 479
2004	—	369
2005	—	253
2006	<u>—</u>	<u>5</u>
Total minimum lease payments	<u>3</u>	<u>\$1,106</u>
Less amounts representing interest	<u>—</u>	
Present value of net minimum lease payments	<u>\$3</u>	

Rent expense under operating leases totaled approximately \$495,000, \$525,000, and \$562,000 for the years ended December 31, 2002, 2001, and 2000, respectively.

(11) Income Taxes

At December 31, 2002, the Company has net operating loss carryforwards for United States federal income tax purposes of approximately \$54 million, which are available to offset future federal taxable income, if any, and expire at varying dates from 2003 through 2022. The annual use of the net operating loss carryforwards is limited under Section 382 of the Internal Revenue Code of 1986.

An alternative minimum tax credit carryforward of \$253,000 is available to offset future regular tax liabilities and has no expiration date. The Company also has research and experimentation tax credit carryforwards at December 31, 2002, for federal income tax purposes of approximately \$3 million, which are available to reduce future federal income taxes, if any, and expire at varying dates through 2022. The annual use of portions of the research and experimentation credit carryforwards is also limited under Section 382.

THE SPECTRANETICS CORPORATION AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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

	<u>2002</u>	<u>2001</u>
	(In thousands)	
Current:		
Royalty reserve, due to accrual for financial reporting purposes	\$ 548	\$ 967
Warranty reserve, due to accrual for financial reporting purposes	147	107
Accrued liabilities, not deducted until paid for tax purposes	510	749
Inventories, principally due to accrual for obsolescence for financial reporting purposes, net of additional costs inventoried for tax purposes	16	(21)
Deferred revenue, due to deferral for financial reporting purposes	414	377
Noncurrent:		
Net operating loss carryforwards — U.S. and related states	21,146	20,559
Foreign net operating loss carryforwards	10,074	10,022
Research and experimentation tax credit	2,947	2,889
Equipment, primarily due to differences in cost basis and depreciation methods	44	(71)
Alternative minimum tax credit	253	253
Other	<u>38</u>	<u>83</u>
Total net deferred tax assets	36,137	35,914
Less valuation allowance	<u>(36,137)</u>	<u>(35,914)</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

The Company has recorded a valuation allowance equal to the gross deferred tax asset at December 31, 2002 and 2001, due to the uncertainty of realization. The net change in the valuation allowance includes the effect of state income taxes, temporary differences for financial statement and tax purposes, and the utilization of the Company's net operating loss and other carryforwards.

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

	<u>2002</u>	<u>2001</u>	<u>2000</u>
Computed expected tax expense (benefit)	\$(531)	\$ 201	\$(2,900)
Increase (reduction) in income taxes resulting from:			
State and local income taxes, net of federal benefit	(32)	42	(338)
Permanent differences	141	144	144
Change in valuation allowance	223	(8,379)	2,932
Change in or utilization of net operating loss carryforward	—	8,100	—
Foreign operations	16	(108)	162
Other, net	<u>183</u>	<u>—</u>	<u>—</u>
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

THE SPECTRANETICS CORPORATION AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

(12) 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 and Europe. 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, 2002.

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

(13) 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, 2002, FDA-approved products were used in conjunction with coronary atherectomy as well as the removal of non-functioning leads from pacemakers and cardiac defibrillators. 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.

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, 2002, 2001, and 2000 cost allocations of these functions to Europe Medical have not been performed.

Revenue associated with intersegment transfers to Europe Medical was \$1,338,000, \$1,074,000, and \$1,626,000 for the years ended December 31, 2002, 2001, and 2000, 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, 2002, 2001, and 2000, intersegment revenue and intercompany profits are not included in the segment information in the table shown below.

THE SPECTRANETICS CORPORATION AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

(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 three applications of excimer laser technology — coronary atherectomy, lead removal and peripheral atherectomy to clear blockages in leg arteries.

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

	<u>2002</u>	<u>2001</u>	<u>2000</u>
Revenue:			
Equipment	\$ 4,744	\$ 4,429	\$ 3,603
Disposables	17,098	17,396	17,162
Service	3,597	3,440	2,936
Other	<u>41</u>	<u>319</u>	<u>351</u>
Subtotal — U.S. Medical	<u>25,480</u>	<u>25,584</u>	<u>24,052</u>
Equipment	338	113	588
Disposables	2,063	1,825	1,708
Service	<u>216</u>	<u>286</u>	<u>552</u>
Subtotal — Europe Medical	<u>2,617</u>	<u>2,224</u>	<u>2,848</u>
Total revenue	<u>\$28,097</u>	<u>\$27,808</u>	<u>\$26,900</u>

In 2002, 2001, and 2000, no individual customer represented 10% or more of consolidated revenue.

	<u>2002</u>	<u>2001</u>	<u>2000</u>
Interest income:			
U.S. Medical	\$ 469	\$ 574	\$ 910
Europe Medical	<u>11</u>	<u>20</u>	<u>13</u>
Total interest income	<u>\$ 480</u>	<u>\$ 594</u>	<u>\$ 923</u>
Interest expense:			
U.S. Medical	\$ 129	\$ 132	\$ 89
Europe Medical	<u>28</u>	<u>18</u>	<u>15</u>
Total interest expense	<u>\$ 157</u>	<u>\$ 150</u>	<u>\$ 104</u>
Depreciation expense:			
U.S. Medical	\$1,302	\$1,419	\$1,302
Europe Medical	<u>104</u>	<u>28</u>	<u>89</u>
Total depreciation	<u>\$1,406</u>	<u>\$1,447</u>	<u>\$1,391</u>

THE SPECTRANETICS CORPORATION AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	<u>2002</u>	<u>2001</u>	<u>2000</u>
Amortization expense:			
U.S. Medical	\$ 272	\$ 342	\$ 340
Europe Medical	<u>15</u>	<u>43</u>	<u>—</u>
Total amortization	<u>\$ 287</u>	<u>\$ 385</u>	<u>\$ 340</u>
Segment net income (loss):			
U.S. Medical	\$(1,800)	\$ 445	\$(6,165)
Europe Medical	<u>239</u>	<u>145</u>	<u>(2,363)</u>
Total net income (loss)	<u>\$(1,561)</u>	<u>\$ 590</u>	<u>\$(8,528)</u>
Capital expenditures:			
U.S. Medical	\$ 187	\$ 290	\$ 566
Europe Medical	<u>11</u>	<u>—</u>	<u>13</u>
Total capital expenditures	<u>\$ 198</u>	<u>\$ 290</u>	<u>\$ 579</u>
Segment assets:			
U.S. Medical	\$21,636	\$24,141	
Europe Medical	<u>2,200</u>	<u>1,572</u>	
Total assets	<u>\$23,836</u>	<u>\$25,713</u>	

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

	<u>2002</u>	<u>2001</u>	<u>2000</u>
U.S. Medical	\$ 267	\$ 746	\$ 306
Europe Medical	<u>2,617</u>	<u>2,224</u>	<u>2,848</u>
Total foreign revenue	<u>\$2,884</u>	<u>\$2,970</u>	<u>\$3,154</u>

There were no individual countries, other than the United States, that represented at least 10% of consolidated revenue in 2002, 2001, or 2000. Long-lived assets located in foreign countries are concentrated in Europe, and totaled \$658,000 and \$429,000 as of December 31, 2002 and 2001, respectively.

THE SPECTRANETICS CORPORATION AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

(14) Reorganization Costs

During the year ended December 31, 2000, reorganization costs primarily associated with the elimination of the direct sales organization in Germany totaled \$1,200,000 and are as follows (in thousands):

	<u>Accrued at Beginning of Year</u>	<u>Amounts Paid</u>	<u>Accrued Costs at End of Year</u>
Year ended December 31, 2001:			
Termination and severance costs	\$ 700	\$513	\$187
Legal fees	150	150	—
Cancellation of contracts and leases	172	168	4
Other	<u>38</u>	<u>38</u>	<u>—</u>
Total	<u>\$1,060</u>	<u>\$869</u>	<u>\$191</u>
Year ended December 31, 2002:			
Termination and severance costs	\$ 187	\$107	\$ 80
Legal fees	—	—	—
Cancellation of contracts and leases	4	—	4
Other	<u>—</u>	<u>—</u>	<u>—</u>
Total	<u>\$ 191</u>	<u>\$107</u>	<u>\$ 84</u>

Additional costs of \$140,000 relate primarily to a provision for bad debt expense associated with the restructuring as of December 31, 2000. At December 31, 2002, this provision had a balance of \$15,000.

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. The remaining reorganization costs accrued at December 31, 2002 are expected to be paid in 2003.

(15) Proxy Contest and Settlement

On April 26, 2002, a stockholder of the Company, Steven W. Sweet, filed a preliminary proxy statement with the SEC in which he nominated two directors for election at the Company's 2002 Annual Meeting, then scheduled to take place on June 4, 2002. On May 3, 2002, all of the executive officers of the Company signed a letter addressed to Mr. Sweet agreeing to vote in favor of Mr. Sweet's director nominees. On May 13, 2002, Mr. Sweet, together with Joseph A. Largey, the former President and Chief Executive Officer of the Company, Paul C. Samek, the former Vice President, Finance and Chief Financial Officer of the Company, Lawrence R. McKinley, Sharon L. Sweet, a sibling of Steven W. Sweet (collectively, the Sweet Group) and the other executive officers of the Company filed a Schedule 13D with the SEC indicating that they were acting as a group (the 13D Group) in connection with Mr. Sweet's proxy solicitation. On May 14, 2002, the executive officers of the Company, other than Messrs. Largey and Samek and Ms. Sweet, signed a letter addressed to Mr. Sweet withdrawing from the 13D Group and from Mr. Sweet's proxy solicitation group and stating their neutrality with respect to any proposals submitted to the stockholders by the Company or the Sweet Group. Subsequently, Mr. Sweet filed additional proxy materials adding four proposals for consideration at the June 4, 2002 Annual Meeting. On May 15, 2002, the Company announced that it had deferred its 2002 Annual Meeting in order to give the Company's stockholders more time to fully consider recent developments. On May 23, 2002, the Company filed an action in the United States District of Delaware against the members of the Sweet Group for violation of federal securities laws.

THE SPECTRANETICS CORPORATION AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

On June 6, 2002, the Company reached a definitive agreement that resolved disputes among the Company and the members of the Sweet Group. As part of the settlement, the parties agreed to the following:

- The withdrawal by the Sweet Group of its director nominees as well as the other matters it had proposed for the Annual Meeting and agreed to vote at the Annual Meeting for the election of Messrs. Geisenheimer and Schulte, who are current members of the board of directors, and the Company dismissed with prejudice the lawsuits filed against the Sweet Group.
- The appointment to the Board of two new directors who are unaffiliated with, and independent of, any of the Company's current directors and the Sweet Group and who are approved in good faith by the Board and Mr. Sweet, which approval shall not be unreasonably withheld. One of the new directors will fill a vacancy on the Board created by the resignation of Mr. Largey, which became effective on June 18, 2002, and the other new director will replace a current member of the Board, who will retire from the Board upon the appointment of a replacement director. Heidrick & Struggles, a nationally recognized executive recruiting firm, has been retained by the Company to assist in identifying the new directors. As of December 31, 2002, one of the two new directors has been appointed and the search is on-going for the open seat.
- The retention by the Company of a nationally recognized consultant to recommend a program for equity incentives, including stock options, for outside directors and to submit the program recommended by the independent consultant to a vote of the stockholders at the Annual Meeting. The recommendations of the consultant were submitted to a shareholder vote and approved at the Annual Shareholders' meeting held on August 5, 2002.

The resolution also settled all claims between the Company and Messrs. Largey and Samek and Ms. Sweet, each of whom has separated from the Company.

Costs associated with the proxy contest and settlement are shown below (in thousands):

	Costs Incurred During the Year Ended December 31, 2002	Amounts Paid During 2002	Accrued Costs as of December 31, 2002
Termination and severance costs	\$ 570	\$ (336)	\$ 234
Legal fees reimbursed to Mr. Sweet	100	(100)	—
Legal fees	756	(684)	72
Public and investor relations	135	(106)	29
Proxy solicitor	69	(49)	20
Other advisory fees	151	(147)	4
Other fees	—	(133)	(133)
Total	<u>\$1,781</u>	<u>\$(1,555)</u>	<u>\$ 226</u>

Additional costs of \$56,000 relate primarily to costs associated with extending the vesting period of stock options of terminated executives. The remaining settlement costs accrued at December 31, 2002 are expected to be paid in 2003.

(16) Commitments and Contingencies

The Company is obligated under various licensing and royalty agreements, which require the Company to pay royalties based on a percentage of net sales of certain products, subject to minimum and maximum

THE SPECTRANETICS CORPORATION AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

amounts for certain agreements. The agreements expire at various dates concurrent with the expiration dates of the respective patents.

(17) 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, 2000:				
Accrued warranty liability	\$ 410	\$ 280	\$ 395	\$ 295
Accrued royalty liability	279	6,666	3,367	3,578 (a)
Allowance for doubtful accounts and sales returns	120	371	93	398
Accrued litigation and reorganization reserves . . .	1,288	1,452	1,026	1,714
Year ended December 31, 2001:				
Accrued warranty liability	295	240	211	324
Accrued royalty liability	3,578	1,419	2,578	2,419 (b)
Allowance for doubtful accounts and sales returns	398	332	88	642
Accrued litigation and reorganization reserves . . .	1,714	—	1,220	494
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

(a) Total includes \$3,080,000 of litigation settlement obligations, consisting of \$1,665,000 in accrued liabilities and \$1,415,000 classified as long-term portion of settlement obligation.

(b) Total includes \$1,540,000 of litigation settlement obligations.

(18) Subsequent Event

The Company is involved in a dispute over royalties payable to one of its licensors, Interlase LP, which has been in receivership since September 1998 under the supervision of a state court in Virginia. In addition, because the general partner of Interlase, Lucre Investments, Ltd., filed a voluntary chapter 7 petition on behalf of Interlase in 1999, there is also a pending bankruptcy proceeding in the United States Bankruptcy Court in the Eastern District of Virginia. In October 2002, the licensor completed an audit of the Company's records relating to the license agreement and is claiming past royalties due of approximately \$1.1 million related to lead removal products as well as certain service revenue. They are also claiming forward royalties on these items for periods subsequent to October 2002. The Company disagrees with the licensor's assertion that additional royalties are due and has filed a complaint in the United States District Court in Denver, Colorado seeking a declaratory judgment that: (1) Spectranetics and the products at issue do not infringe patents that are subjects of the Agreement; and (2) Spectranetics does not owe any additional sums as contended by the licensor under the terms of the agreement and the licensor does not have the right to terminate the agreement as a result of its improper claims. No ruling has been made on the filed complaint.

In March 2003, Interlase filed a complaint in the United States District Court for the Eastern District of Virginia claiming Spectranetics is in breach of a patent license agreement entered into in 1993 and is

THE SPECTRANETICS CORPORATION AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

infringing the patents that are the subject of the license agreement. In the complaint, Interlase claims an amount in controversy in excess of \$1 million, exclusive of interest and costs, in addition to certain other forms of relief, such as treble damages, a declaratory judgment and injunctive relief. The claims for relief all relate to royalties allegedly owed to or due Interlase in the future associated with certain lead removal products and certain services the Company provides to its customers. The Company believes the claims are not justified and plans to vigorously defend its position.

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

(19) Selected Quarterly Financial Data (Unaudited)

	2002				2001			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
	(in thousands, except per share amounts)							
Net sales	\$7,059	\$ 6,463	\$7,157	\$7,418	\$6,027	\$7,403	\$7,214	\$7,164
Gross profit	4,791	4,434	4,794	5,095	4,217	5,016	5,055	5,061
Net income (loss)	\$ (17)	\$(2,259)	\$ 227	\$ 488	\$ (556)	\$ 182	\$ 522	\$ 442
Net income (loss) per share — basic and fully diluted	\$(0.00)	\$ (0.09)	\$ 0.01	\$ 0.02	\$(0.02)	\$ 0.01	\$ 0.02	\$ 0.02

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)
10.3	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.
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)
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)

<u>Exhibit Number</u>	<u>Description</u>
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)
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)

<u>Exhibit Number</u>	<u>Description</u>
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)
21.1	Subsidiary of the Company.(25)
23.1	Consent of Independent Auditors.

- (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.

CORPORATE INFORMATION

BOARD OF DIRECTORS

Cornelius C. Bond, Jr.^{1,2}
Independent Consultant

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

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

Martin T. Hart²
Self-employed, Investor

Joseph M. Ruggio, MD¹
*Practicing Interventional Cardiologist, and
President & Chief Executive Officer
Pacific Cardiovascular Associates Medical Group, Inc.*

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

¹ Compensation Committee

² Audit Committee

EXECUTIVE OFFICERS

John G. Schulte
President & Chief Executive Officer

Bruce E. Ross
*Executive Vice President, Customer and Product
Programs*

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

Christopher Reiser, Ph.D.
Vice President, Technology and Clinical Research

CORPORATE HEADQUARTERS

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

Tel: 719-633-8333 or 800-633-0960

Fax: 719-633-2248

Web: www.spectranetics.com

PRODUCT INFORMATION

Please contact Customer Service

Tel: 719-633-8333 or 800-231-0978

Fax: 719-633-8791

Web: www.spectranetics.com

STOCK DATA

Nasdaq: SPNC
Most newspapers list the company under Nasdaq
National Market Issues as "Spectranet."

As of March 13, 2003, there were 731 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.
Shareowner Services Department
161 North Concord Exchange
P. O. Box 64854
St. Paul, MN 55164
Tel: 800-468-9716
Email: www.wellsfargo.com/com/shareowner_services

ANNUAL MEETING

Date: June 26, 2003
Time: 10:00 a.m. Mountain Daylight Time
Location: Antlers Adam's Mark Hotel
Address: 4 S Cascade
Colorado Springs, Colorado 80903

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The Spectranetics Corporation

96 Talamine Court
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