Spectranetics®

we get your blood flowing®

"Cool" Laser Technology Positioned for the Future

Coronary Artery Disease Therapy

Cardiac Lead Removal System

Peripheral Vascular Disease Therapy

Annual Report 2003

Corporate Profile

The Spectranetics Management Team

Front row, left to right: Bruce E. Ross, Executive Vice President, Customer and Product Programs; John G. Schulte, President and Chief Executive Officer; Guy A. Childs, Vice President, Chief Financial Officer.

Back row, left to right: Adrian E. Elfe, Vice President, Quality Assurance and Regulatory Affairs; Lawrence E. Martel, Jr., Vice President, Operations; Sandra Guenette, Director, Human Resources; Christopher Reiser, Ph.D., Vice President, Technology and Clinical Research.

Spectranetics develops, manufactures and markets single-use medical devices used in minimally invasive surgical procedures within the cardiovascular system in conjunction with its proprietary "cool" ultraviolet excimer laser system. Our CVX-300® excimer laser is the only system approved by the FDA for multiple cardiovascular procedures, including coronary atherectomy and ablating the scar tissue holding problematic pacemaker and defibrillator cardiac leads in place. Within the coronary atherectomy market, we are focusing on two key FDA-approved indications: treating saphenous vein grafts and chronic total occlusions. We have initiated clinical research for a laser-based treatment of heart attacks and, if our feasibility trial is successful, plan to sponsor a pivotal randomized trial to begin in 2005. Nearly all of our FDA-approved and investigational applications have received Communautes Europeennes (CE) mark registration for marketing within Europe. We also received regulatory approval from the Ministry of Health and Welfare to market our laser and various sizes of our Extreme® and Vitesse® coronary catheters in Japan, and we are currently pursuing reimbursement approval there.

On January 14, 2004, we filed a 510(k) submission with the FDA seeking clearance to treat patients suffering from total occlusions (blockages) in their leg arteries with proprietary Spectranetics excimer laser catheters. The submission contains supporting clinical data obtained from a subset of the LACI (Laser Angioplasty for Critical limb Ischemia) trial, and was supplemented by data obtained from other clinical studies in the United States and Europe. CLI (Critical Limb Ischemia) is associated with multi-level arterial disease from the superficial femoral artery all the way down to the arteries below the knee and is dominated by total blockages rather than partial blockages. This is a debilitating condition resulting from a lack of blood flow to the lower extremities that can often lead to amputation.

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

2003 was a pivotal year for The Spectranetics Corporation. Financially, we were profitable for each quarter of the year, continuing a trend started in the second half of 2002. At year-end, Spectranetics had 383 laser systems installed worldwide and the strength of our disposable products business was very encouraging. We also made tangible progress towards expanding our indications, developing new products and beginning new clinical studies.

The continued growth in sales of our disposable products is a key component of our long-term strategy, and this past year we focused on growing our lead removal and coronary atherectomy catheter sales. In lead removal, the CLeaRS™ (Cardiac Lead Removal System) product sales hit record levels, up more than 22 percent over the prior year. Importantly, sales of ELCA® (Excimer Laser Coronary Atherectomy) catheters, following two consecutive years of decline, stabilized in 2003 as compared with 2002, which we believe bodes well for future growth in this product sector.

With a strengthened financial foundation and a revenue model shifted almost entirely to disposable products, we are now positioned to accelerate top line growth.

Financial Performance

Spectranetics posted net income for 2003 of $929,000, or $0.04 per diluted share, which compares favorably with a net loss during 2002 of $1,561,000, or $0.07 per diluted share. Excluding the proxy contest charges and settlement obligations, income for 2002 was $276,000. Our cash, cash equivalents and long-term investment securities position increased $1.9 million to a total of $13.3 million as of December 31, 2003.

The revenue mix in 2003 continued a promising trend with 95 percent of product sales coming from the disposable products category, which increased 10 percent compared with 2002. Total revenue for 2003 was essentially flat at $27.9 million, compared with $28.1 million for 2002, reflecting an important shift toward higher margin disposable products revenue and away from sales of capital equipment, which declined 44 percent in 2003. Most of the 23 new laser systems placed in 2003 were done so under the evaluation or rental program. Service revenue rose 4 percent to $4 million.

Growth Strategy

With a strengthened financial foundation and a revenue model shifted almost entirely to disposable products, we are now positioned to accelerate top line growth. Our growth strategy has two main drivers:

- ✓ Expand the application of our "cool" laser technology to a new market – peripheral vascular disease.
- ✓ Increase penetration of our existing core businesses of coronary atherectomy and lead removal through expanded indications, development of compelling clinical data and new products.

By executing these strategies, we should grow our installed base of laser systems in leading interventional hospitals and increase the utilization of laser catheters.

Last year we made considerable progress in areas we believe hold the greatest potential for advancing our technology into new markets and expanded clinical applications. This pursuit is the result of a strategy focused in areas where we believe our "cool" laser has a sustainable competitive advantage, namely thrombus-laden lesions and total occlusions.

New Markets – Peripheral Vascular Disease

One of the most exciting opportunities ever undertaken by Spectranetics is in the area of peripheral vascular disease. We believe we made a major breakthrough in applying our laser technology to the treatment of critical limb ischemia (CLI). CLI occurs when plaque or thrombus builds up in an artery and blocks blood flow to the lower leg. Following discussions with the FDA in January 2004, just three months after a U.S. Food and Drug Administration (FDA) Advisory Panel recommended non-approval of our pre-market approval (PMA) supplement for LACI (Laser Angioplasty for Critical limb Ischemia), we filed a 510(k) application to expand our laser technology to the endovascular treatment of total occlusions in the leg not crossable with standard guidewires. We are expecting the FDA's decision on our 510(k) application in the second quarter of 2004.

We are expecting the FDA's decision on our 510(k) application to treat total occlusions in the leg not crossable with standard guide-wires in the second quarter of 2004.

Over one million patients in the United States suffer from CLI, the most advanced form of peripheral vascular disease, which results in nearly 100,000 amputations every year. Without prompt revascularization to restore blood flow to the affected limb, the prognosis for limb salvage is poor; even with the most meticulous wound care program. Assuming we successfully obtain FDA approval, our next steps will include implementing the launch plan for this market opportunity approaching $200 million.

Increased Penetration – Core Business

Coronary Atherectomy

Approved Indications

In 2003 we completed the CORAL LAKE (COronary grafts Results following Atherectomy with Laser at Lakeland Regional Medical Center, Florida) registry, a single-center, retrospective registry of 119 patients that studied the use of the excimer laser for the treatment of degenerated saphenous vein grafts (SVGs). The registry data was presented at the Transcatheter Cardiovascular Therapeutics (TCT) conference in September 2003 and yielded an acute procedural success rate of 98 percent and an acute major adverse cardiac event (MACE) rate of only five percent.

In 2003 we began to focus our coronary atherectomy business on three key areas: treating chronic total occlusions (CTOs), saphenous vein grafts (SVGs) and acute myocardial infarction (AMI).

We also began the CORAL registry, a prospective multi-center registry to quantify acute and 30-day MACE rates in degenerative SVGs. We believe that using our laser technology prior to stenting will produce a better outcome. As of this writing, we have enrolled nearly 60 of the 150 patients who will be included in the study.

Lastly, we are focused on treating chronic total occlusions (CTOs) which are difficult to cross and treat. Today, with the advent of drug-eluting stents, cardiologists are more aggressively treating these lesions, creating an opportunity for us to show the value of the laser for this indication, which is the creation of a pilot channel through the blockage without significant complications.

CTOs represent the most frequent reason patients are referred for bypass surgery. Our Point 9™ X-80 laser catheter has been developed to treat CTOs and to address the challenge of crossing a space that often is so narrow that a balloon cannot be inserted. The 0.9 mm catheter is the smallest on the market today, and emits high energy that opens a channel to facilitate safely placing the balloon and stent. A study completed last year at the Montreal Heart Institute showed a lesion crossing success rate over 90% in CTOs and we expect this study to be published this year.

We also recently received 510(k) approval from the FDA to market our second-generation support catheters – Quick-Cross™ Support^2 Catheters. They are the only support catheters available with three distal radiopaque markers that are specifically spaced for improved assessment of lesion length and geometry. They also have a low crossing profile for crossing small vessels and CTOs. Quick-Cross Support^2 Catheters will be launched in the second quarter of 2004.

New Opportunities

Another element of our strategy to extend the application of the laser to the treatment of thrombus, or blood clots, is the laser's use in treating acute myocardial infarction (AMI), or heart attacks. Treating AMI is a potential $200 million market opportunity in the United States alone. This past year our multi-center, 151-patient retrospective registry, called CARMEL (Cohort of Acute Revascularization in Myocardial infarction with Excimer Laser), successfully supported our request to the FDA for a labeling change to our catheters that allows for individualization of use to treat patients with acute myocardial infarction, acute thrombosis and having an ejection fraction less than 30 percent. The CARMEL study was published in the *American Journal of Cardiology* in March 2004. We plan to follow up on this success with a prospective study on the use of the excimer laser for treating AMI patients, which may lead to a pivotal, randomized trial.

We are the market leader in removing damaged or infected pacemaker and defibrillator leads with our CLeaRS technology.

Cardiac Lead Removal

We are the market leader in removing damaged or infected pacemaker and defibrillator leads with our CLeaRS technology in this small, but growing segment. We will continue to focus on developing information, which will heighten awareness of safely removing leads with our laser technology versus capping leads and leaving them in place.

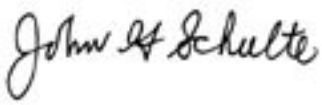
Summary

Our "cool" laser technology is well positioned for the future. With over 40 patents covering the use of our excimer laser and catheters, an increasingly successful strategy of placing laser systems at high-volume hospitals, the addition of prestigious new accounts around the world and a potential near-term new market opportunity to treat total occlusions in legs, we are poised to deliver breakthrough therapies for critical medical conditions and, in turn, create value for our shareholders.

Our "cool" laser technology is well positioned for the future and we are poised to deliver breakthrough therapies for critical medical conditions.

As always, I would like to recognize the exceptional efforts of the entire Spectranetics team and thank them for helping to make this past year a successful one for our company.

Sincerely,



John G. Schulte
President & CEO

March 2004

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

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

For the year ended December 31, 2003

or

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

For the transition period from to

Commission file number 0-19711

The Spectranetics Corporation

(Exact name of Registrant as specified in its charter)

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

96 Talamine Court
Colorado Springs, Colorado 80907
(Address of principal executive offices and zip code)

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

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

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

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

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

Indicate by check mark whether the Registrant is an accelerated filer. Yes ☐ No ☑

The aggregate market value of the voting stock of the Registrant, as of June 30, 2003 computed by reference to the closing sale price of the voting stock held by non-affiliates on such date, was $72,480,868.

As of March 12, 2004, there were outstanding 24,705,450 shares of Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement for its 2004 Annual Meeting of Shareholders, to be filed with the Securities and Exchange Commission not later than April 30, 2004, are incorporated by reference into Part III as specified herein.

PART I

The information set forth in this annual report on Form 10-K includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, and is subject to the safe harbor created by that section. You are cautioned not to place undue reliance on these forward-looking statements and to note that they speak only as of the date hereof. Factors that could cause actual results to differ materially from those set forth in the forward-looking statements are set forth below and include, but are not limited to, the following:

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

We disclaim any intention or obligation to update or revise any financial projections or forward-looking statements due to new information or other events.

Item 1. *Business*

General

We develop, manufacture, market and distribute single-use medical devices used in minimally invasive surgical procedures within the cardiovascular system in conjunction with our proprietary excimer laser system. Excimer laser technology delivers comparatively cool ultraviolet energy in short, controlled energy pulses to ablate or remove tissue. Our excimer laser system includes the CVX-300® laser unit and various fiber-optic delivery devices, including disposable catheters and sheaths. Our excimer laser system is the only excimer laser system approved in the United States and Europe for use in multiple, minimally invasive cardiovascular applications. Our excimer laser system is used in complex atherectomy procedures to open clogged or obstructed arteries in the coronary 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 are currently pursuing 510(k) marketing clearance from the Food and Drug Administration (FDA) for a laser-based treatment of total occlusions (blockages) in the legs not crossable with a guidewire. Some of the patients with total occlusions in the leg suffer from critical limb ischemia (CLI), which is a debilitating condition that begins with resting leg pain and often leads to tissue loss or amputation as a result of a lack of blood flow to the legs. A 510(k) application for treating patients with total occlusions not crossable with a guidewire was submitted to the FDA in January 2004 and we expect a response from the FDA, which may consist of additional questions, in April 2004.

We also have regulatory approval to market our products in two key international markets. 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. During 2003, we appointed a new distributor, DVx Japan, who will assist us in pursuing reimbursement approval. We currently expect reimbursement approval in 2006, although there are no assurances that reimbursement will be received then, if

at all. We do not expect revenue increases in Japan until reimbursement approval is received. In Europe, in addition to our coronary atherectomy and lead removal product lines, we have approval to market our products to treat artery blockages in the 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 link to a third-party website is provided at our corporate website to access our SEC filings free of charge promptly after such material is electronically filed with, or furnished to, the SEC. We do not intend for information found on our website to be part of this document.

Strategy

Our strategy includes the following key points:

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

  We submitted a Pre-Market Approval Supplement (PMAS) to the Food and Drug Administration (FDA) in January 2003, which requested approval to commercially market certain products for the treatment of critical limb ischemia. Even though the clinical trial endpoints were met, an advisory panel recommended non-approval of our application at a meeting held in October 2003, citing concerns about the clinical trial design (for example, comparisons to a historical control group as opposed to a randomized trial) and the specific benefit of the laser treatment since it was delivered adjunctively along with balloons and stents. The FDA followed the advice of the panel and notified us of the non-approval of our PMAS. Based on input from the advisory panel and the FDA, we compiled data for the laser-based treatment of patients with total occlusions not crossable with a guidewire. Most of the data was obtained from patients enrolled in the LACI trial and the data from these patients was supplemented by data from two other sites that did not participate in the LACI trial but followed the LACI clinical trial protocol. Based on FDA input, the application was submitted as a 510(k) application as compared with a pre-market approval (PMA) supplement submitted with the original LACI application. The 510(k) application is a less rigorous review cycle and has a 90 day response time compared with 180 days for a PMA supplement. We submitted our 510(k) application to the FDA in January 2004 and we expect a response from the FDA, which may consist of additional questions, in April 2004. The data showed that the limb salvage rate (no major amputations) among the 47 patients treated was 95% for those patients surviving six months following the procedure. There was no difference in serious adverse events as compared with the entire set of patients treated in the LACI trial. Although we believe the clinical data supports clearance to market our products for treatment of these patients, there can be no assurances that marketing clearance will be received from the FDA.

  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 saphenous vein grafts (heart bypass grafts that develop blockages). We expect to complete the clinical research in saphenous vein grafts in late 2004 or early 2005. We are currently FDA-approved to treat saphenous vein grafts so the clinical data from this trial, if successful, will be used for marketing the clinical advantages of our technology. The clinical research associated with a laser-based treatment of AMI is in the feasibility stage and is expected to be completed in late 2004 or early 2005. Assuming positive clinical data from the feasibility trial (Extended FAMILI), we expect to initiate a randomized pivotal trial, which will take at least two years to complete.

- *Gather and develop clinical data for publication in peer-reviewed medical journals.* Our physician customers adopt products and technologies primarily based on available clinical data. Historically, the clinical data for our technology, especially in coronary artery disease therapy, has been limited. During 2004, we expect the publication of clinical data in peer-reviewed medical journals, which will discuss the use of our laser technology to treat AMI (heart attack), saphenous vein grafts, chronic total occlusions and peripheral artery disease.
- *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. Through our existing marketing and sales team, we are currently focused on two FDA-approved indications in the coronaries — saphenous vein grafts and total occlusions — as well as the removal of pacemaker and defibrillator leads that require removal as a result of infection or fracture.
- *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, 2003 and December 31, 2002, respectively, we placed 23 and 33 laser systems in new accounts. At December 31, 2003 our total worldwide installed base was 383 laser systems (282 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 2003. 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 were honored. In addition to an outright sale of our laser systems, we offer several alternatives to our customers for the acquisition of our excimer lasers, including evaluation, 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. The laser ablation of the material reduces the particles to about the size of a red blood cell, which is easily absorbed into the blood stream. This helps to avoid a potential complication known as distal embolization, which is caused by particles dislodged during an angioplasty or atherectomy procedure that create a blockage elsewhere in the vascular system.

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

CVX-300® Excimer Technology

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

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

- saphenous vein grafts;
- total occlusions crossable by a guidewire;

- ostial lesions (blockages at the beginning of arteries);
- lesions with moderate calcification;
- long lesions; and
- lesions where angioplasty balloon failures have occurred.

Additional catheter sizes and improved models to treat the six original indications have been approved by the FDA over the ensuing years. On October 15, 2001, we received FDA approval for the use of the Spectranetics excimer laser and related catheters for a seventh coronary indication — for use within restenosed stents prior to brachytherapy (radiation therapy). In all of these complex coronary atherectomy indications, we offer an adjunct to traditional balloon angioplasty, stents and atherectomy (rotational cutters and burrs) devices. We believe the use of the laser makes the treatment of complex lesions simple. 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, we received CMDCAS (Canadian) certification by TÜV during January 2002. We have received CE (Communaute Europeene) mark registration for all of our current products. The CE mark indicates that a product is certified for sale throughout the European Union and that the manufacturer of the product complies with applicable safety and quality standards.

On September 28, 2001, in conjunction with our Japanese distributor, we received regulatory approval from the Japanese Ministry of Health and Welfare (MHW) to market our laser and various sizes of our Extreme®, Vitesse® E and Vitesse® C coronary catheters in Japan. We have submitted our application for reimbursement approval for these products in Japan, 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. We are working with our current distributor, DVx Japan, to secure reimbursement approval and, if successful, expect this to occur sometime in 2006. In addition, we are in various stages of the submission process to obtain regulatory approval in Japan for some of our newer products.

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

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

- *Dissolves underlying tissue.* The process of photoablation dissolves the tissue causing the blockage as opposed to merely compressing it against the arterial wall, as with balloon angioplasty. We believe that the process of photoablation helps to reduce the incidence of distal embolization, whereby particles are dislodged from the lesion being treated, causing a blockage elsewhere in the vascular system.
- *Reduced procedure time.* Patient outcome audits, which compare excimer laser procedures to rotational atherectomy, reveal the excimer laser method shortens procedure times and reduces radiation exposure to the patient from fluoroscopic imaging used during the procedure.

- *Ease of use.* During a laser procedure, it may be necessary to adjust laser energy output. The CVX-300 laser unit is computer-controlled, which allows the physician to change energy levels without interrupting the treatment to remove the catheter from the patient for recalibration. This feature also enables the physician to begin the procedure with the minimum level of energy that might be required and, if necessary, to easily adjust the energy level upward during the procedure.

Product Applications

Coronary 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 annually in the United States. We estimate that approximately 30 to 35 percent of these patients could benefit from the use of our products, particularly in complex lesions.* In these complex indications, we offer an adjunct to traditional balloon angioplasty and stenting or the need for coronary bypass surgery. Unlike conventional balloons that merely compress arterial plaque against the stent or vessel wall, laser atherectomy actually dissolves the material. We believe the use of laser technology makes the treatment of complex lesions simple. We focus our marketing and sales efforts on saphenous vein grafts, total occlusions crossable by a guidewire, and pre-treatment of restenosed stents prior to brachytherapy, but also are approved for use in four other indications:

- ostial lesions (blockages at the beginning of arteries);
- lesions with moderate calcification;
- long lesions; and
- lesions where angioplasty balloon failures have occurred.

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.

Total revenues associated with coronary excimer laser atherectomy were $10,155,000 for the year ended December 31, 2003, compared with $10,200,000 for the year ended December 31, 2002. We believe revenue has been declining for the last two years primarily as a result of a lack of recent, compelling clinical data supporting the use of the laser in the coronary vascular system combined with new atherectomy products introduced to the market during this period (for example, the cutting balloon). We have initiated clinical research in the area of saphenous vein grafts (CORAL and CORAL REEF) and acute myocardial infarction (Extended FAMILI). The completion and publication of this clinical data are key drivers to growth in coronary atherectomy revenues.

In 2003, clinical results from the CARMEL (Cohort of Acute Revascularization in Myocardial infarction with Excimer Laser) study successfully supported our request to the FDA for a labeling change to our catheters that allows for individualization of use treatment for patients with AMI, acute thrombosis or ejection fraction less than 30 percent. Under the new labeling, patients with these clinical conditions can be treated with the laser after individual consideration by their doctor. Additionally, we completed the CORAL LAKE (COronary grafts Results following Atherectomy with Laser at Lakeland Regional Medical Center, Florida) registry, that studied the use of the excimer laser for the treatment of degenerated saphenous vein grafts. We believe both studies included clinical data that supports the use of our technology in AMI and saphenous vein grafts, respectively.

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 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 support and assist standard guidewires to facilitate initial crossing of the blockage. It also facilitates exchange of standard guidewires without losing access to the blockage. We

also received the CE Mark of approval in March 1999 to market the .014 and .018 inch support catheter in Europe; and the .035 inch model received the CE Mark of approval in July 2002. In February 2004, we received clearance to market the Quick-Cross™ support catheter, which is the second generation of the Spectranetics Support Catheter.

Cardiac Lead Removal Systems

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

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

For the year ended December 31, 2003, lead removal product revenue was $10,972,000, an increase of 22% from $8,961,000 during the year ended December 31, 2002. The key driver of this revenue growth is an expanding patient population eligible for implantable cardioverter defibrillators (ICD), based on recent clinical research conducted by the large pacing companies (Guidant, Medtronic, St. Jude). The clinical research has shown that patients suffering from congestive heart failure as well as patients who have had prior heart attacks may have reduced mortality risk as a result of the implant of an ICD. Since there are more leads attached to an ICD and they are typically larger in diameter, there is often a space problem in the subclavian vein when ICD's are implanted in patients that already have a pacemaker. Additionally, the potential for electrical "crosstalk" between the new and old leads is enhanced in this situation. As a result, the old leads are more likely to be removed in these situations.

We plan to implement programs that will expand the lead removal market and will focus on programs that study the cost of complications associated with abandoned leads that have been capped and left in the body.

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

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

Lead Locking Device (LLD™). In October 1999, we received clearance from the FDA to market the LLD under a 510(k) application. This product was the first Spectranetics' product to go through the 510(k) regulatory process, which typically takes less time than other regulatory approval processes, such as pre-market approval or a pre-market approval supplement. We also received the CE Mark of approval for this

product in Europe in March 1999. The LLD product complements our current SLS product line and, since it is not laser-based, can also be used in connection with the mechanical removal of pacemaker or defibrillator leads. The LLD is a novel mechanical device that assists in the removal of faulty leads by providing traction to the leads, which are typically wire spirals. The LLD is inserted into the center opening (i.e., lumen) of the lead and then a braid surrounding the LLD expands to fill and grip the entire length of the lead's inner circumference, in effect converting a spiral into a solid "pipe," which can more easily be extracted. Other devices on the market, which merely grip the lead at the far end, provide less stability and frequently release their grip on the lead.

In 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.

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 200,000 upper bypass surgeries and 100,000 amputations are performed annually in the United States as a result of peripheral vascular blockages.* In addition, we estimate that about 400,000 people in the United States are treated for leg pain through either balloon angioplasty, stent implantation, and drug therapy.* Laser therapy is being evaluated as an alternative treatment to bypass surgery, amputation and conventional percutaneous transluminal angioplasty. 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. Data from the trial indicated a 93% success rate as compared with 87% in the historical control group of 789 patients treated with a variety of standard therapies, including bypass surgery. There were no statistical differences in serious adverse events between the LACI group and the historical control group. We submitted the clinical data from the LACI trial to the FDA in January 2003 and an advisory panel to the FDA reviewed our submission at a panel meeting on October 2, 2003. Although the clinical trial endpoints were achieved, the panel recommended non-approval, citing concerns over the non-randomized nature of the trial, use of a historical control group, and the inability to distinguish the specific benefit of laser treatment, since it was used adjunctively with balloons and stents. The FDA, which generally follows the advisory panel's recommendation, issued a non-approval letter following the panel meeting. Based on input at the advisory panel meeting and subsequent discussions with the FDA, we are pursuing 510(k) clearance to market our products to patients who have total occlusions that are not crossable with a guidewire, which is a subset of the LACI data. On January 14, 2004, we submitted data on 47 patients that showed a 95% limb salvage rate (i.e., no major amputations) among surviving patients six months after the procedure. The data consisted of 28 patients from the LACI trial supplemented with an additional 19 patients treated at two other sites that were not part of the original LACI trial but followed the LACI trial protocol. Based on FDA input, the application was submitted as a 510(k) application as compared to a pre-market approval (PMA) supplement submitted along with the original LACI application. The 510(k) application is a less rigorous review cycle and has a 90 day response time compared with 180 days for a PMA supplement. The response could be additional questions from the FDA or a definitive answer. If the response consists of additional questions, the 90-day review cycle may begin again with our response to the questions. We submitted this data in a 510(k) application to the FDA during January 2004 and it showed that the limb salvage rate among the 47 patients

treated was 95% for those patients surviving six months following the procedure. There was no difference in serious adverse events as compared with the entire set of patients treated in the LACI trial. Although we believe the data we have submitted supports FDA clearance, there are no assurances that FDA clearance will be received.

The PELA trial enrolled 250 patients in a randomized trial comparing excimer laser treatment followed with balloon angioplasty to balloon angioplasty alone. The trial was designed to test the safety and efficacy of treating total occlusions (blockages) of at least 10 centimeters in length within the superficial femoral artery (SFA). The trial was designed to show superiority of the laser group over the balloon only group. The clinical results showed equivalence in most study endpoints, including the primary endpoint, which was primary patency (the degree in which the artery is open) as measured by $\leq$ 50% diameter stenosis (blockage) at one year by ultrasound with no reintervention. The largest catheters used in the trial were 2.5mm in diameter as compared to vessel sizes treated in excess of 6.0 mm in diameter. We believe that the low catheter diameter in relation to vessel diameter adversely affected results and we are now evaluating product development opportunities for larger catheter diameters. We are currently evaluating our regulatory strategy as to the PELA data. We may or may not submit the data to the FDA requesting approval.

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 candidates for brachytherapy (radiation therapy)*. Several clinical trials are underway and some have concluded evaluating the use of drug-eluting stents, the next generation of stent technology. These stents are coated with various types of drugs designed to inhibit restenosis. Clinical data from these trials demonstrate that restenosis rates are reduced to rates less than 10% for certain lesions. As a result, we expect the annual number of restenosed stent procedures to decline.

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

Sales and Marketing

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

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

Domestic Operations

As of March 2004, there are about 1,200 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.

As of March 2004, we have 33 field sales employees consisting of a national sales manager, six district sales managers and 26 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.

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 participation 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 500,000 balloon angioplasty procedures performed.* 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 2003, Spectranetics International, B.V., revenues totaled $2,846,000 or 10 percent of our revenue.

In addition to the operations of Spectranetics International, B.V., we conduct international business in the Japan and other selected countries in the Pacific Rim through distributors. In 2003, revenues from these foreign operations totaled $140,000, or .5 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

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* 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.

policies, exchange rate fluctuations and international monetary conditions have not significantly affected our business to date. For more information, see "Risk Factors — We are Exposed to Problems That Come From Having International Operations" set forth in Item 7 — "Management's Discussion and Analysis of Financial Condition and Results of Operations" herein.

Government Regulation

In the United States, all medical devices are subject to FDA regulation under the Medical Device Amendments of the Federal Food, Drug and Cosmetics Act, or FFDCA, 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 FFDCA is available in certain instances for Class I and Class II products. It requires that before introducing most Class II and some Class I devices into interstate commerce, the company introducing the product must first submit information to the FDA demonstrating that the device is substantially equivalent in terms of safety and effectiveness to a device legally marketed prior to March 1976. When the FDA determines that the device is substantially equivalent, the agency issues a "clearance" letter that authorizes marketing of the product. The Support Catheter and LLD have been precleared by the FDA under the "510(k)" process. We are pursuing 510(k) clearance for catheters to be used in the treatment of total occlusions in the legs.

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

PMA Devices

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

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

Once the submission is accepted for filing, the FDA begins an in-depth review of the pre-market approval application, which represents the second major step in pre-market approval of a Class III device. An FDA review of a pre-market approval application generally takes one to two years from the date the pre-market approval application is accepted for filing, but may take significantly longer. The review time is often significantly extended by the FDA asking for more information or clarification of information already provided

in the submission. During the review period, an advisory committee, typically a panel of clinicians, will likely be convened to review and evaluate the application and provide recommendations to the FDA at a public panel meeting as to whether the device should be approved. Companies are typically requested to make a presentation at the public panel meeting. The FDA is not bound by the recommendations of the advisory panel.

Toward the end of the pre-market approval review process, the FDA will generally conduct an inspection of the manufacturer's facilities to ensure that the facilities are in compliance with applicable Good Manufacturing Practice requirements, which are outlined under FDA's Quality System Regulation. If the FDA's evaluations of both the pre-market approval application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure final approval of the pre-market approval application. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will complete the third major step by issuing a pre-market approval letter, authorizing commercial marketing of the device for certain indications. If the FDA's evaluations of the pre-market approval application or manufacturing facilities are not favorable, the FDA will deny approval of the pre-market approval application or issue a "not approvable" letter. The FDA may also determine that additional clinical trials are necessary, in which case pre-market approval may be delayed for several years while additional clinical trials are conducted and submitted in an amendment to the pre-market approval application. The pre-market approval process can be expensive, uncertain and lengthy and a number of devices for which FDA approval has been sought by other companies have never been approved for marketing.

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

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

Product and Procedure	FDA	CE Mark	MHW
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	
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	
Quick Cross™ Support Catheters	2/04	2/04	
Pacing Lead and ICD Lead Extraction			
SLS 12 Fr	12/97	2/97	
SLS 14 Fr	9/98	7/97	
SLS 16 Fr	9/98	7/97	
SLS 16 Fr, improved	2/02	10/01	
SLS 12/14 Fr, improved	5/02	10/02	
LLD	10/99	3/99	
Peripheral Atherectomy	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 and Our Stock Price" set forth in Item 7 — "Management's Discussion and Analysis of Financial Condition and Results of Operations" filed herewith.

Any products we manufacture or distribute pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA. Device manufacturers are required to register their establishments and list their devices with the FDA, and are subject to periodic inspections by the FDA and certain state agencies. The FFDCA requires devices to be manufactured in accordance with Quality System Regulation requirements,

which impose certain process, procedure and documentation requirements upon us with respect to product development, manufacturing and quality assurance activities. We have developed systems and controls that we believe will enable us to comply with Quality System Regulation requirements; however, we cannot assure that we will be able to maintain compliance with these requirements.

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

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

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

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

We are subject to certain federal, state and local regulations regarding environmental protection and hazardous substance controls, among others. To date, compliance with such environmental regulations has not had a material effect on our capital expenditures or competitive position. See "Risk Factors — Regulatory Compliance is 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 does not compete directly with 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 With Bigger Companies In Our Highly Competitive Industry" 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 39 issued United States patents, four issued patents in each of France, Germany, Italy and the Netherlands and two issued patents in Japan. Also, we have four United States patent applications pending and 12 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. See further discussion in Part I, Item 3. "Legal Proceedings."

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, an exclusive license relating to certain aspects of excimer laser technology in our products, and licenses to various patents on fluid-core catheters.

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 $2,713,000 in 2003, $3,309,000 in 2002, and $3,496,000 in 2001. We expect these costs to increase in 2004 as we advance clinical research focused on saphenous vein grafts and heart attack combined with increased product development activities. The decreased costs in 2003 are a result of the substantial completion in 2002 of clinical trial enrollment and follow-up in the LACI and PELA clinical trials. In 2003, we developed clinical trial protocols and initiated feasibility studies in the area of heart attacks and began enrollment in the saphenous vein graft trial (CORAL) during the second half of 2003. As a result, clinical studies costs decreased in 2003 compared with 2002. Regulatory and research and development expenses in 2003 were consistent with amounts spent in 2002.

Manufacturing

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

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

We purchase certain components of our CVX-300 laser unit from several sole source suppliers. We do not have guaranteed commitments from these suppliers, as we order products through purchase orders placed with these suppliers from time to time. While we believe we could obtain replacement components from alternative suppliers, we may be unable to do so. In addition, we may encounter difficulties in scaling up production of laser units and disposable devices and hiring and training additional qualified manufacturing personnel. Any of these difficulties could lead to quarterly fluctuations in operating results and adversely affect us.

Third-Party Reimbursement

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

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

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

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

Product Liability and Insurance

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

Employees

As of February 29, 2004, we had 144 full time employees, including 11 in research and development and clinical affairs, 55 in manufacturing and quality assurance, 67 in marketing, sales and administration in the United States and 11 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 1, 2004. We have exercised our option to extend the second lease for one year starting June 1, 2004 and ending on May 31, 2005. The lease for the third facility expires March 1, 2006, and we have the option to renew it for an additional year.

Spectranetics International B.V. leases 3,337 square feet in Leusden, The Netherlands. The facility houses our operations for the marketing and distribution of products in Europe, and the lease expires June 30, 2008.

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

Item 3. ***Legal Proceedings***

In December 2003, we settled 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 March 2003, Interlase filed a complaint in the United States District Court for the Eastern District of Virginia claiming Spectranetics breached a patent license agreement entered into in 1993 and infringed the patents that are the subject of the license agreement. In the complaint, Interlase claimed an amount in controversy in excess of $1 million, exclusive of interest and costs, in addition to certain other forms of relief. The claims for relief all related to royalties allegedly owed to or due Interlase in the future associated with lead removal products and certain service revenue.

On May 23, 2003, the United States District Court for Eastern District of Virginia granted Spectranetics' Motion and entered an order transferring the case titled *Interlase Limited Partnership v. The Spectranetics Corporation*, Civil No. 3:03CV265, to the United States District Court for the District of Colorado for all proceedings.

As a result of the settlement agreement executed in December 2003, all litigation relating to the Interlase matter has been dismissed in exchange for a one-time payment from Spectranetics to Interlase of $200,000. No past or future royalties are due on lead removal products. No future royalties are due on service revenue provided they do not exceed a certain percentage of total royalty-bearing revenue. The original license agreement entered into in 1993 was unchanged as a result of the settlement agreement.

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

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

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

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

The New York case is still in a very preliminary stage. While Spectranetics intends to vigorously litigate these claims, it is not adverse to a process whereby those claims may be favorably terminated at an early stage.

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 2003 and 2002. These quotations reflect inter-dealer prices,

without retail mark-up, mark-down or commissions, and may not necessarily represent the sales prices in actual transactions.

	High	Low
Year Ended December 31, 2003		
1st Quarter	$3.95	2.50
2nd Quarter	3.51	2.55
3rd Quarter	6.94	2.71
4th Quarter	6.56	2.29
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

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, 2004, was $5.22. On March 12, 2004, we had 728 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, 2003, 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, 2003 and 2002, and statement of operations data for each year in the three-year period ended December 31, 2003, have been derived from our audited financial statements also included elsewhere herein. The selected historical balance sheet data as of December 31, 2001, 2000 and 1999, and statement of operations data for the years ended December 31, 2000 and 1999, 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,				
	2003	2002	2001	2000	1999
	(In thousands, except per share data)				
STATEMENT OF OPERATIONS DATA:					
Revenue	$ 27,869	$ 28,097	$27,808	$26,900	$22,305
Cost of revenue	7,900	8,983	8,459	8,282	7,397
Selling, general and administrative	15,346	14,671	14,277	17,843	13,902
Research, development and other technology	3,812	4,510	4,915	5,287	4,622
Proxy contest and settlement obligations	—	1,837	—	—	—
Litigation settlement costs, net	—	—	—	3,654	—
Reorganization costs and litigation reserves	(32)	—	—	1,200	1,358
Operating income (loss)	843	(1,904)	157	(9,366)	(4,974)
Other income, net	86	343	433	838	758
Net income (loss) from continuing operations	929	(1,561)	590	(8,528)	(4,216)
Net income (loss)	$ 929	(1,561)	590	(8,698)	5,169
Income (loss) from continuing operations per share:					
Basic	$ 0.04	$ (0.07)	$ 0.03	$ (0.36)	$ (0.19)
Diluted	$ 0.04	$ (0.07)	$ 0.02	$ (0.36)	$ (0.19)
Weighted average common shares outstanding:					
Basic	24,254	23,809	23,547	23,298	22,407
Diluted	25,443	23,809	24,161	23,298	22,407

	As of December 31,				
	2003	2002	2001	2000	1999
	(In thousands, except per share data)				
BALANCE SHEET DATA:					
Working capital	$11,966	$10,508	$ 3,552	$11,337	$ 8,957
Cash, cash equivalents, and investment securities	13,281	11,430	12,884	11,921	20,125
Restricted cash	1,133	1,123	—	—	—
Property, plant, & equipment, net	3,633	3,478	4,119	4,760	3,675
Total assets	26,082	23,836	25,713	27,360	34,038
Long-term debt including capital lease obligations, net of current portion	—	—	57	1,649	411
Shareholders' equity	18,212	15,855	16,657	15,716	23,386
Book value per common share outstanding	$ 0.75	$ 0.67	$ 0.69	$ 0.67	$ 1.04

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. We believe the excimer laser is particularly well suited to treat thrombus-laden lesions and have initiated clinical research for a laser-based treatment of saphenous vein grafts and acute myocardial infarction, or heart attack.

Our business strategy is to develop additional applications for our excimer laser, gather and develop clinical data for publication in peer-reviewed medical journals, increase utilization of our FDA-approved products, and continue to expand our installed base of laser systems, which totals 383 as of December 31, 2003. 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 leg.

The PELA trial enrolled 250 patients in a randomized trial comparing excimer laser treatment followed with balloon angioplasty to balloon angioplasty alone. The trial was designed to test the safety and efficacy of treating total occlusions (blockages) of at least 10 centimeters in length within the superficial femoral artery (SFA). The trial was designed to show superiority of the laser group over the balloon only group. The clinical results showed equivalence in most study endpoints, including the primary endpoint, which was primary patency (the degree in which the artery is open) as measured by $\leq$ 50% diameter stenosis (blockage) at one year by ultrasound with no reintervention. The largest catheters used in the trial were 2.5mm in diameter as compared to vessel sizes treated in excess of 6.0 mm in diameter. We believe that the low catheter diameter in relation to vessel diameter adversely affected results and we are now evaluating product development opportunities for larger catheter diameters. We are currently evaluating our regulatory strategy as to the PELA data. We may or may not submit the data to the FDA requesting approval.

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. Data from the trial indicated a 93% success rate as compared with 87% in the historical control group of 789 patients treated with a variety of standard therapies, including bypass surgery. There were no statistical differences in serious adverse events between the LACI group and the historical control group. We submitted the clinical data from the LACI trial to the FDA in January 2003 and an advisory panel to the FDA reviewed our submission at a panel meeting on October 2, 2003. Although the clinical trial endpoints were achieved, the panel recommended non-approval, citing concerns over the non-randomized nature of the trial, use of a historical control group, and the inability to distinguish the specific benefit of laser treatment, since it was used adjunctively with balloons and stents. The FDA, which generally follows the advisory panel's recommendation, issued a non-approval letter following the panel meeting. Based on input at the advisory panel meeting and subsequent discussions with the FDA, we are pursuing clearance to market our products to patients who have total occlusions that are not crossable with a guidewire, which is a subset of the LACI data. On January 14, 2003, we submitted data on 47 patients that showed a 95% limb salvage rate (i.e., no major amputations) among surviving patients six months after the procedure. The data consisted of 28 patients from the LACI trial supplemented with an additional 19 patients treated at two other sites that were not part of the original LACI trial but followed the LACI trial protocol. Based on FDA input, the application was submitted as a 510(k)

application as compared to a pre-market approval (PMA) supplement submitted along with the original LACI application. The 510(k) application is a less rigorous review cycle and has a 90 day response time compared with 180 days for a PMA supplement. The response could be additional questions from the FDA or a definitive answer. If the response consists of additional questions, the 90-day review cycle begins again with our response to the questions. We submitted this data to the FDA in January 2004 and it showed that the limb salvage rate among the 47 patients treated was 95% for those patients surviving six months following the procedure. There was no difference in serious adverse events as compared with the entire set of patients treated in the LACI trial. Although we believe the data we have submitted supports FDA clearance, there are no assurances that FDA clearance will be received.

Net income was $929,000 or $.04 per diluted share for the year ended December 31, 2003, compared with a net loss of $1,561,000 or $.07 per diluted share for the year ended December 31, 2002. Excluding 2002 costs of $1,837,000 associated with the proxy contest and settlement obligations, income was $276,000 for the year ended December 31, 2002.

Our financial guidance for 2004 is for revenue growth in the range of five percent to seven percent compared with 2003, driven primarily by increased disposable product sales and reflecting 25 to 30 new laser placements. Net income is projected to be in the range of $500,000 to $1,000,000. However, there are no assurances that these results will be achieved. Our financial guidance assumes no revenue contribution from the treatment of total occlusions in patients with critical limb ischemia. However, it does reflect costs associated with the hiring of at least three new clinical account managers and the advancement of clinical research focused on a laser-based treatment of heart attacks.

Product Line Revenue (Overview)

	2003	2002	2001
		(In thousands)	
Laser equipment	$ 2,824	$ 5,082	$ 4,429
Disposables	21,127	19,161	19,221
Repair and maintenance	3,973	3,813	3,726
Other, net of provision for sales returns*	(55)	41	319
Total	$27,869	$28,097	$27,808

* Other revenue consists of sales of custom products offset by a provision for sales returns. Custom products sales in 2002 and 2001 consisted primarily of coated wire used by a single customer as a component of a medical device it sells to its customers. The customer moved this business to another supplier in 2003 which resulted in the declining revenue in 2003 noted in the above table.

Geographical Results of Operations (Overview)

Revenue	2003	2002	2001
		(In thousands)	
United States	$25,023	$25,480	$25,584
Europe	2,846	2,617	2,224
Total	$27,869	$28,097	$27,808

Net income (loss)	2003	2002	2001
		(In thousands)	
United States	$ 807	$(1,800)**	$ 445
Europe	122	239	145
Total	$ 929	$(1,561)	$ 590

** Includes $1,837 of costs associated with proxy contest and settlement obligations.

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

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

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

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

(radiation) treatment. Furthermore, we believe the clinical research we have initiated in the area of saphenous vein grafts and acute myocardial infarction has elevated our profile among our physician customers which has led to new institutions willing to revisit their use of our excimer laser technology. Our lead removal revenue increased $2,011,000 or 22%, to $10,972,000 in 2003 compared with 2002. The launch of our second generation laser sheath in late 2002 contributed to this growth, which was driven by unit volume increases. Additionally, the market for implantable defibrillators has grown and is expected to grow in the future as a result of clinical research recently completed (Madit and SCD-Heft clinical trials) that expand the patient pool eligible for implantable defibrillators. The results of the Madit clinical trial became available in 2003 and the SCD-Heft clinical trial results were made public in February 2004. Growth in the implantable defibrillator market may accelerate, depending on the establishment of referral patterns to electrophysiologists for this expanded patient pool and whether or not reimbursement will be established for the hospitals and electrophysiologists who treat these patients. Generally, growth in the implantable defibrillator market contributes to growth in our lead removal business, since the leads attached to the implantable defibrillator are larger in diameter and there are more leads attached to the current generation of implantable defibrillators. For patients who already have a pacemaker or defibrillator with leads attached, this causes a space problem in the vein and enhances the potential for electrical cross-talk between the leads. Therefore, the "old" leads are more likely to be removed in this situation. Although we expect our lead removal business to continue to grow, there can be no assurances to that effect. The standard of care in this market is to cap leads and leave them behind rather than lead removal. We have initiated programs to examine the costs and frequency of complications associated with abandoned leads, but there are no assurances that these programs will be successful or will change the current standard of care.

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

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

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

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

Operating expenses were $19,126,000 in 2003 compared with $21,018,000 in 2002. 2002 operating expenses, excluding proxy contest and settlement obligations of $1,837,000, were $19,181,000.

Selling, general and administrative expenses increased 5 percent to $15,346,000 in 2003 from $14,671,000 in 2002, due to the following:

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

Sarbanes-Oxley compliance (estimated between $150,000 and $250,000). Incentive compensation may increase dependent on achievement of corporate financial objectives.

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

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

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

Net income was $929,000 in 2003, or $0.04 per diluted share, compared with a net loss of $1,561,000, or $0.07 per diluted share, in 2002. Excluding proxy contest charges and settlement obligations incurred in 2002, 2002 income would have been $276,000.

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 14 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.

Income Taxes

At December 31, 2003, we had net operating loss carryforwards for U.S. federal income tax purposes of approximately $53 million, which are available to offset future federal taxable income, if any, and expire at varying dates from 2004 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 $298,000 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 ($36.7 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, 2003, of approximately $3 million, which are available to reduce future federal income taxes, if any, and expire at varying dates through 2023. 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.

We have generated significant operating losses from inception to date, the income tax impact of which has not been reflected in our financial statements. Deferred tax assets are recognized when it is more likely than not that the asset will be realized. We will need to generate taxable income to recognize available not operating losses in the future.

The Company has provided a valuation allowance offsetting its deferred tax assets as management believes, based on current information, that realizability is not more likely than not.

Liquidity and Capital Resources

As of December 31, 2003, we had cash, cash equivalents and investment securities of $13,281,000, an increase of $1,851,000 from $11,430,000 at December 31, 2002. In addition, we had classified $1,133,000 and $1,123,000 as restricted cash at December 31, 2003 and 2002, respectively since it was in an escrow account pending resolution of our dispute with Interlase (see Part I.,Item 3 "Legal Proceedings" for further discussion). Since the dispute has been resolved, the amounts from the escrow account have been disbursed to us during the quarter ending on March 31, 2004.

Cash and cash equivalents were $11,281,000 at December 31, 2003 compared with $2,767,000 at December 31, 2002, an increase of $8,514,000.

For the year ended December 31, 2003, cash provided by operating activities totaled $972,000. These positive cash flows were driven primarily by net income and we expect net income to be the primary driver of future cash flows provided by operating activities. Net income guidance for 2004 is a range between $500,000 and $1,000,000. Other potential uses of cash include growth in accounts receivable as a result of revenue growth and growth in the equipment held for rental or loan account as a result of expanding placement activity of our laser systems through evaluation or rental programs. We continue to stay focused on the management of accounts receivable as measured by days' sales outstanding and will continue this focus in 2004 with the goal of maintaining the current level of days' sales outstanding, although there can be no assurances this goal will be achieved. For the equipment held for rental or loan account, this account increases or decreases based on the level of evaluation or rental laser placements offset by sales of laser systems previously placed under evaluation or rental programs. We continue to expect the majority of our laser placement activity in 2004 to be in the form of evaluation or rental units.

For the year ended December 31, 2003, cash provided by investing activities was $6,412,000. The increased cash provided by investing activities is primarily due to proceeds from the maturity of investment securities that were reinvested in cash equivalents. This was partially offset by capital expenditures during the year ended December 31, 2003, of $369,000. Capital expenditures for the year ended December 31, 2002 were $198,000. We expect an increase of at least $100,000 in 2004 capital expenditures compared with 2003.

Net cash provided by financing activities was $955,000 during the year ended December 31, 2003. Financing activities consist primarily of proceeds from sale of common stock to employees or former employees, primarily through the exercise of stock options but also as a result of stock purchases through the employee stock purchase plan, partially offset by principal payments on long-term debt and capital lease obligations. At December 31, 2003, there was no debt or capital lease obligations.

In October 2002, we funded an escrow account in connection with a dispute with one of our licensors. The licensor claimed that additional royalties totaling $1.1 million were 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. The dispute was resolved in December 2003 through the one-time payment to the licensor, Interlase, of $200,000. No changes were made to the original license agreement entered into in 1993 as a result of the settlement. The settlement was finalized on December 31, 2003. Funds from the escrow account were released to Spectranetics in March 2004.

At December 31, 2003 and 2002, we had placed a number of systems on rental or loan programs. A total of $5,843,000 and $5,031,000 was recorded as equipment held for rental or loan at December 31, 2003 and 2002, respectively, and is being depreciated over three to five years, depending on whether the laser system is new or remanufactured.

In 2003, we used two placement programs in addition to the sale of laser systems:

1. Evergreen rental program — This rental program was introduced in July 1999. Rental revenue under this program varies on a sliding scale depending on the customer's catheter purchases each month.

Rental revenue is invoiced on a monthly basis and revenue is recognized upon invoicing. The laser unit is transferred to the equipment held for rental or loan account upon shipment, and depreciation expense is recorded within cost of sales based upon a three- to five-year expected life of the unit. As of December 31, 2003, 48 laser units were in place under the Evergreen program.

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, 2003, 29 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 continued to honor special pricing for quotes that were outstanding as of September 30, 2002. We believe our liquidity and capitalization as of December 31, 2003 are sufficient to meet our operating and capital requirements at least through December 31, 2004.

Contractual Obligations

The Company leases office space, furniture and equipment under noncancelable operating leases with initial terms that expire at various dates through 2008. Purchase obligations consist of purchase orders issued primarily for inventory. The future minimum payments under noncancelable operating leases and purchase obligations as of December 31, 2003 are as follows:

	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating Leases	$1,024	$ 495	$459	$70	$—
Purchase Obligations	815	784	31	—	—
Total	$1,839	$1,279	$490	$70	$—

Conversion to the Euro

For the year ended December 31, 2003, Spectranetics International, B.V., used the euro as its functional currency. The euro was adopted as its functional currency on January 1, 2002. The conversion to the euro did not have a material effect on our consolidated results of operations.

Critical Accounting Policies

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

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

Use of Estimates. On an ongoing basis, management evaluates its estimates and judgments, including those relating to product returns, bad debts, inventories, income taxes, warranty obligations, royalty obligations, reorganization costs, contingencies, and litigation. We base our estimates and judgments on historical experience and on various other factors we believe to be reasonable under the circumstances. These judgments and estimates form the basis for the carrying values of certain assets and liabilities that are not objectively available from other sources. Carrying values of these assets and liabilities may differ under different assumptions or conditions.

Revenue Recognition. Revenue from the sale of our disposable products is recognized when products are shipped and title transfers to the customer. Revenue from 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.

In July 2003, we adopted the provisions of Emerging Issues Task Force (EITF) No. 21 *Revenue Arrangements with Multiple Deliverables,* which modified our revenue recognition policy for the sale of laser equipment. The primary impact of the new pronouncement is to treat service provided during the one-year warranty period as a separate unit of accounting. As such, the retail value of this service is deferred and recognized as revenue on a straight-line basis over the warranty period. Revenue is recognized upon completion of all contractual obligations in the sales contract, which includes installation of the laser system and physician training. Prior to July 1, 2003, revenue for the sale of laser equipment was recognized upon shipment.

Allowance for Sales Returns. We estimate product sales returns based on historical experience. The provision for sales returns is recorded as a reduction of revenue based on our estimates. Actual sales returns may vary depending on customer inventory levels, new product introductions and other factors. Although we believe our estimates are reasonable based on facts in existence at the time of estimation, these facts are subject to change.

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

Royalty liability. We license certain patents from various licensors pursuant to license agreements. Royalty expense is calculated pursuant to the terms of the license agreements and is included in research, development and other technology in the accompanying financial statements. We have established liabilities for royalty payment obligations based on these calculations, which involve management estimates that require judgment. Although we believe the estimates to be reasonable based on facts in existence at the time of estimation, the estimates are subject to change based on changes in the underlying facts and assumptions used to develop these estimates. We have recorded a loss contingency of approximately $1.3 million related primarily to a disagreement with one of our existing licensors, Edwards Life Sciences (Edwards). We have accrued an estimated loss contingency based on the status of negotiations with Edwards. There can be no assurances the loss contingency will be adequate. The disagreement centers around the treatment of revenues attributed to training services we provide to our customers. We do not believe these revenues are within the scope of the license agreement and Edwards disagrees. In the event the disagreement is not resolved through our ongoing negotiations, our license agreement with Edwards contains an arbitration provision to settle the disagreement.

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, 2003, 2002 and 2001, compensation expense related to stock option grants to employees totaled $1,039,000, $1,760,000 and $345,000, respectively, which have been included in pro forma disclosures, but not included in determining net income (loss). 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.

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, 2003, we have a net deferred tax asset of $39,964,000. 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 and lack of significant profits generated in 2003. 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 December 2002, the Emerging Issues Task Force (EITF) reached a consensus on EITF 00-21, *Revenue Arrangements with Multiple Deliverables*. The consensus defines the accounting for arrangements that include multiple deliverables and provides guidance on how the arrangement consideration should be measured, whether the arrangement should be divided into separate units of accounting and that the arrangement consideration should be allocated among the separate units of accounting based on their relative fair value, if applicable. Once the arrangement is separated into units of accounting, applicable revenue recognition should be applied to each separate unit of accounting.

The pronouncement was effective July 1, 2003 and is applied prospectively by the Company. The primary impact of the new pronouncement is to treat service provided during the one-year warranty period as a separate unit of accounting. As such, the retail value of this service is deferred and recognized as revenue on a straight-line basis over the warranty period. Additionally, the Company's revenue recognition policy as it relates to laser equipment sales was modified so that revenue is recognized upon completion of all contractual obligations in the sales contract, which includes installation of the laser system and physician training. Prior to July 1, 2003, revenue for the sale of laser equipment was recognized upon shipment.

Risk Factors

We Have a History of Losses and May Not Be Able to Maintain Profitability. We incurred losses from operations since our inception in June 1984 until the second quarter of 2001, and we incurred net losses in the first and second quarters of 2002. At December 31, 2003, we had accumulated $76.4 million in net losses since inception. We expect that our research, development and clinical trial activities and regulatory approvals, together with future selling, general and administrative activities and the costs associated with launching our products for additional indications will result in significant expenses for the foreseeable future. Although we

have been profitable for six consecutive quarters, no assurance can be given that we will be able to maintain profitability in the future.

Regulatory Compliance Is Expensive and Can Often Be Denied or Significantly Delayed. The industry in which we compete is subject to extensive regulation by the FDA and comparable state and foreign agencies. Complying with these regulations is costly and time consuming. International regulatory approval processes may take longer than the FDA approval process. If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspensions or revocations of approvals, seizures or recalls of products, operating restrictions, criminal prosecutions and other penalties. We may be unable to obtain future regulatory approval in a timely manner, or at all, if existing regulations are changed or new regulations are adopted. For example, the FDA approval process for the use of excimer laser technology in clearing blocked arteries in the leg 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 leg. If we do not receive these FDA approvals, our business will suffer.

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 85 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.

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, 2003, 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. The new product approval process in foreign countries is often complex and lengthy. For example, the reimbursement approval process in Japan has taken longer than anticipated due to the complexity of this process. As we expand our international operations, we expect our sales and expenses denominated in foreign currencies to expand.

We Have Important Sole Source Suppliers and May Be Unable To Replace Them if They Stop Supplying Us. We purchase certain components of our CVX-300 laser unit from several sole source suppliers. We do not have guaranteed commitments from these suppliers and order products through purchase orders placed with these suppliers from time to time. While we believe that we could obtain replacement components from alternative suppliers, we may be unable to do so.

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

Our Patents and Proprietary Rights May Be Proved Invalid, Which Would Enable Competitors To Copy Our Products; We May Infringe Other Companies' Rights. We hold patents and licenses to use patented technology, and have patent applications pending. Any patents we have applied for may not be granted. In addition, our patents may not be sufficiently broad to protect our technology or to give us any competitive advantage. Our patents could be challenged as invalid or circumvented by competitors. In addition, the laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States. We do not have patents in many foreign countries. We could be adversely affected if any of our licensors terminates our licenses to use patented technology. We have received inquiries from two of our licensors regarding the level of past royalty payments. We have settled one dispute and have recently engaged in discussions with the other regarding their inquiries. The disagreement over past royalty payments centers on the treatment of certain service-based revenue, including repair and maintenance, and physician and clinical training services. We believe these services are beyond the scope of the license agreement. If our discussions do not resolve the dispute, our license agreement with the licensor provides for arbitration proceedings to settle this matter. We have accrued costs of $1.3 million associated with the resolution of this matter, which represents our best estimate of costs to resolve the matter based on the status of ongoing discussions. If the matter is referred to arbitration proceedings, we will vigorously defend our position that royalties are not owed on the service-based revenues in dispute.

There may be patents and patent applications owned by others relating to laser and fiber-optic technologies, which, if determined to be valid and enforceable, may be infringed by Spectranetics. Holders of certain patents, including holders of patents involving the use of lasers in the body, may contact us and request that we enter into license agreements for the underlying technology. For example, we have been made aware of a patent issued to Dr. Peter Rentrop for a certain catheter with a diameter of less than 0.9 millimeters and are currently involved in litigation regarding this patent. See "Item 3. — Legal Proceedings" for further discussion of this litigation. 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***

We are exposed to a variety of risks, including changes in interest rates affecting the return on our investments and foreign currency fluctuations. Our exposure to market rate risk for changes in interest rates relate primarily to our investment portfolio. We attempt to place our investments with high quality issuers and, by policy, limit the amount of credit exposure to any one issuer and do not use derivative financial instruments in our investment portfolio. We maintain an investment portfolio of various issuers, types and maturities, which consist of both fixed and variable rate financial instruments. Marketable securities are classified as available-for-sale, and consequently, are recorded on the balance sheet at fair value with unrealized gains or losses reported as a separate component in stockholders' equity, net of applicable taxes. At any time, sharp changes in interest rates can affect the value of our investment portfolio and its interest earnings. Currently, we do not hedge these interest rate exposures. Since our investment securities have maturities that are generally less than one year and never more than two years, we do not expect interest rate fluctuations to have a significant impact on the fair value of our investment securities. As of December 31, 2003, the unrealized loss on our investment securities was $1,000.

As of December 31, 2003, we had cash and cash equivalents of $11.3 million, marketable securities of $2.0 million and restricted marketable securities of $1.1 million. Overall average duration to maturity for all

cash and marketable securities is 0.3 years with 81 percent of the portfolio under one year and the remaining 19 percent between one and five years. The average interest rate earned on the portfolio was 1.4%. At December 31, 2003, the marketable securities consisted of government securities.

Our exposure to foreign currency fluctuations is primarily related to sales of our products in Europe, which are denominated in the euro. Changes in the exchange rate between the euro and the U.S. dollar could adversely affect our revenue and net income. Exposure to foreign currency exchange rate risk may increase over time as our business evolves and our products continue to be introduced into international markets. Currently, we do not hedge against any foreign currencies and, as a result, could incur unanticipated gains or losses. For the year ended December 31, 2003, approximately $263,000 of increased revenue and $260,000 of increased operating expenses were the result of exchange rate fluctuations of the U.S. dollar in relation to the euro. Accordingly, the net impact of exchange rate fluctuations on consolidated net income (loss) for the year ended December 31, 2003 was an increase of $3,000.

Item 8. ***Financial Statements and Supplementary Data***

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

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

None.

Item 9A. ***Controls and Procedures***

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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

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

PART III

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

The information required by Item 10 is incorporated by reference from the registrant's definitive Proxy Statement to be used in connection with its 2004 Annual Meeting of Shareholders.

Audit Committee Financial Expert. This information is incorporated by reference from the registrant's definitive Proxy Statement to be used in connection with its 2004 Annual Meeting of Shareholders.

Identification of the Audit Committee. This information is incorporated by reference from the registrant's definitive Proxy Statement to be used in connection with its 2004 Annual Meeting of Shareholders.

Section 16(a) Beneficial Ownership. This information is incorporated by reference from the registrant's definitive Proxy Statement to be used in connection with its 2004 Annual Meeting of Shareholders.

Code of Ethics. This information is incorporated by reference from the registrant's definitive Proxy Statement to be used in connection with its 2004 Annual Meeting of Shareholders.

Item 11. ***Executive Compensation***

The information required by Item 11 is incorporated by reference from the registrant's definitive Proxy Statement to be used in connection with its 2004 Annual Meeting of Shareholders.

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

The information required by Item 12 is incorporated by reference from the registrant's definitive Proxy Statement to be used in connection with its 2004 Annual Meeting of Shareholders.

Item 13. ***Certain Relationships and Related Transactions***

The information required by Item 13 is incorporated by reference from the registrant's definitive Proxy Statement to be used in connection with its 2004 Annual Meeting of Shareholders.

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

The information required by Item 14 is incorporated by reference from the registrant's definitive Proxy Statement to be used in connection with its 2004 Annual Meeting of Shareholders.

PART IV

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 39.

(b) *Reports on Form 8-K*

On October 16, 2003, the Company filed a current report on Form 8-K under Item 7. Financial Statements, Pro Forma Financial Information and Exhibits and Item 9. Regulation FD Disclosure (information provided under Item 12. Results of Operation and Financial Condition).

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Colorado Springs, State of Colorado, on this 29th day of March, 2004.

THE SPECTRANETICS CORPORATION

By: /s/ JOHN G. SCHULTE
John G. Schulte
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant in the capacities and on the date indicated.

Signature	Title	Date
/s/ JOHN G. SCHULTE John G. Schulte	President and Chief Executive Officer, Director (Principal Executive Officer)	March 29, 2004
/s/ GUY A. CHILDS Guy A. Childs	Vice President, Chief Financial Officer (Principal Financial and Accounting Officer)	March 29, 2004
/s/ DAVID G. BLACKBURN David G. Blackburn	Director	March 29, 2004
/s/ EMILE J. GEISENHEIMER Emile J. Geisenheimer	Director and Chairman of the Board of Directors	March 29, 2004
/s/ CORNELIUS C. BOND, JR. Cornelius C. Bond, Jr.	Director	March 29, 2004
/s/ R. JOHN FLETCHER R. John Fletcher	Director	March 29, 2004
/s/ JOSEPH M. RUGGIO, MD Joseph M. Ruggio, MD	Director	March 29, 2004
/s/ MARTIN T. HART Martin T. Hart	Director	March 29, 2004

THE SPECTRANETICS CORPORATION
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2003 and 2002, 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, 2003. 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of The Spectranetics Corporation and subsidiary as of December 31, 2003 and 2002, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States of America.

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

/s/ KPMG LLP

Denver, Colorado
January 30, 2004

THE SPECTRANETICS CORPORATION AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS
December 31, 2003 and 2002

	2003	2002
	(In thousands, except share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,281	$ 2,767
Restricted cash	1,133	—
Investment securities available for sale	—	8,663
Trade accounts receivable, less allowance for doubtful accounts and sales returns of $460 and $555, respectively	4,729	4,042
Inventories, net	1,899	2,125
Prepaid expenses and other current assets	621	676
Total current assets	19,663	18,273
Property and equipment, at cost:		
Manufacturing equipment and computers	6,498	6,408
Leasehold improvements	1,010	941
Equipment held for rental or loan	5,843	5,031
Furniture and fixtures	186	197
	13,537	12,577
Less accumulated depreciation and amortization	(9,904)	(9,099)
Net property and equipment	3,633	3,478
Goodwill, net	308	308
Other intangible assets, net	219	463
Other assets	259	191
Restricted cash	—	1,123
Long-term investment securities available for sale	2,000	—
Total assets	$ 26,082	$ 23,836
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,129	$ 695
Accrued liabilities	4,925	5,924
Deferred revenue	1,643	1,064
Current portion of long-term debt	—	79
Current portion of capital lease obligations	—	3
Total current liabilities	7,697	7,765
Accrued liabilities, net of current portion	75	104
Deferred revenue, net of current portion	98	112
Total liabilities	7,870	7,981
Commitments and contingencies		
Shareholders' equity:		
Preferred stock, $0.001 par value. Authorized 5,000,000 shares; none issued	—	—
Common stock, $0.001 par value. Authorized 60,000,000 shares; issued and outstanding 24,452,491 shares in 2003 and 23,877,744 shares in 2002	24	24
Additional paid-in capital	94,544	93,393
Accumulated other comprehensive income (loss)	5	(272)
Accumulated deficit	(76,361)	(77,290)
Total shareholders' equity	18,212	15,855
Total liabilities and shareholders' equity	$ 26,082	$ 23,836

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, 2003, 2002, and 2001

	2003	2002	2001
	(In thousands, except share amounts)		
Revenue	$ 27,869	$ 28,097	$ 27,808
Cost of revenue	7,900	8,983	8,459
Gross profit	19,969	19,114	19,349
Operating expenses:			
Selling, general, and administrative	15,346	14,671	14,277
Research, development, and other technology	3,812	4,510	4,915
Proxy contest and settlement	—	1,837	—
Reorganization costs and litigation reserves reversal	(32)	—	—
Total operating expenses	19,126	21,018	19,192
Operating income (loss)	843	(1,904)	157
Other income (expense):			
Interest expense	(17)	(157)	(150)
Interest income	104	480	594
Other, net	(1)	20	(11)
	86	343	433
Net income (loss)	929	(1,561)	590
Other comprehensive income (loss)	277	4	(29)
Comprehensive income (loss)	$ 1,206	$ (1,557)	$ 561
Earnings per common and common equivalent share:			
Net income (loss) per share, basic	$ 0.04	$ (0.07)	$ 0.03
Net income (loss) per share, fully diluted	$ 0.04	$ (0.07)	$ 0.02
Weighted average shares outstanding:			
Basic	24,254,449	23,809,159	23,547,380
Diluted	25,443,464	23,809,159	24,161,269

See accompanying notes to consolidated financial statements.

THE SPECTRANETICS CORPORATION AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
Years Ended December 31, 2003, 2002, and 2001

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
	(In thousands, except share amounts)					
Balances at 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
Exercise of stock options	423,057	—	747	—	—	747
Shares purchased under employee stock purchase plan	151,690	—	295	—	—	295
Options granted for consulting services	—	—	109	—	—	109
Unrealized gain on investment securities	—	—	—	128	—	128
Foreign currency translation adjustment	—	—	—	149	—	149
Net income	—	—	—	—	929	929
Balances at December 31, 2003	24,452,491	$24	$94,544	$ 5	$(76,361)	$18,212

See accompanying notes to consolidated financial statements.

THE SPECTRANETICS CORPORATION AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS
Years ended December 31, 2003, 2002, and 2001

	2003	2002	2001
		(In thousands)	
Cash flows from operating activities:			
Net income (loss)	$ 929	$(1,561)	$ 590
Adjustments to reconcile net income (loss) to net cash provided (used) by operating activities:			
Depreciation and amortization	1,556	1,693	1,832
Options granted for consulting services	109	36	40
Extended vesting of options for terminated executives	—	88	—
Changes in operating assets and liabilities:			
Trade accounts receivable, net	(550)	687	1,359
Inventories	279	(270)	773
Equipment held for rental or loan, net	(1,019)	(415)	(529)
Prepaid expenses and other current assets	(20)	119	(271)
Other assets	26	130	(86)
Accounts payable and accrued liabilities	(885)	(1,337)	(2,305)
Deferred revenue and other liabilities	547	208	(214)
Net cash provided (used) by operating activities	972	(622)	1,189
Cash flows from investing activities:			
Capital expenditures	(369)	(198)	(290)
Net change in restricted cash	(10)	(1,123)	—
Sale (purchases) of investment securities, net	6,791	1,028	(51)
Net cash provided (used) by investing activities	6,412	(293)	(341)
Cash flows from financing activities:			
Proceeds from sale of common stock to employees	1,042	614	238
Principal payments on long-term debt and capital leases obligations	(87)	(157)	(162)
Net cash provided by financing activities	955	457	76
Effect of exchange rate changes on cash	175	132	(26)
Net increase (decrease) in cash and cash equivalents	8,514	(326)	898
Cash and cash equivalents at beginning of year	2,767	3,093	2,195
Cash and cash equivalents at end of year	$11,281	$ 2,767	$ 3,093
Supplemental disclosures of cash flow information:			
Cash paid during the year for interest	$ 17	$ 161	$ 157
Cash paid during the year for income taxes	$ —	$ —	$ —

See accompanying notes to consolidated financial statements.

(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 the consolidated financial statements requires management of the Company to make a number of estimates and assumptions relating to the reported amount of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the period. Significant items subject to such estimates and assumptions include the carrying amount of property and equipment, intangible assets, valuation allowances for receivables, inventories and deferred income tax assets; and accrued warranty and royalty expenses. Actual results could differ from those estimates.

(b) Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less to be cash equivalents. Cash equivalents of approximately $8,522,000 and $1,819,000 at December 31, 2003 and 2002, respectively, consist primarily of money market accounts, commercial paper, and repurchase agreements stated at cost, which approximates fair value.

(c) Trade Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses in the Company's existing accounts receivable. The Company determines the allowance for doubtful accounts based upon an aging of accounts receivable and historical write-off experience. Past due balances over 30 days are reviewed individually for collectibility. Account balances are charged off against the allowance after all means of collection have been exhausted and the potential for recovery is remote. The allowance for sales returns is the Company's best estimate of the amount of probable losses in the Company's existing accounts receivable due to future sales returns and price adjustments.

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

(d) Investment Securities

Investment securities at December 31, 2003 and 2002, are classified as available-for-sale for purposes of Financial Accounting Standards Board Statement No. 115, *Accounting for Certain Investments in Debt and Equity Securities,* and, accordingly are carried at fair value. The difference between cost and fair value is recorded as an unrealized gain or loss on investment securities and recorded within accumulated other comprehensive income (loss). At December 31, 2003 and 2002, the unrealized loss totaled $1,000 and $129,000, respectively.

(e) Inventory

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

(f) Property and Equipment

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

Depreciation is calculated using the straight-line method over the estimated useful lives of the assets of two to five years for manufacturing equipment, computers, and furniture and fixtures. Equipment held for rental or loan is depreciated using the straight-line method over 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.

(g) Goodwill and Other Intangible Assets

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

(h) Restricted Cash

Restricted cash consists of an escrow fund established pursuant to a dispute with a licensor of certain patents of the Company. The dispute has been settled, and the funds are expected to be released to the Company during the quarter ending March 31, 2004.

(i) Long-Lived Assets

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

(j) Financial Instruments

At December 31, 2003 and 2002, 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.

(k) Revenue Recognition

Revenue from the sale of the Company's disposable products is recognized when products are shipped to the customer and title transfers. Revenue from services is recognized when performed and revenue from prepaid product maintenance contracts and equipment rentals is initially recorded as deferred revenue and recognized over the contract period on a straight-line basis.

Revenue from the rental of the Company's excimer 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. None of the revenue from the catheter purchases has been allocated to laser revenues. As a result of adopting Emerging Issues Task Force (EITF 00-21), which became effective on July 1, 2003, the revenue recognition policy for the sale of a laser was modified. The primary impact of the new pronouncement is to treat service provided during the one-year warranty period as a separate unit of accounting. As such, the retail value of this service is deferred and recognized as revenue on a straight-line basis over the warranty period. Revenue is recognized upon completion of all contractual obligations in the sales contract, which includes installation of the laser system and physician training. Prior to July 1, 2003, revenue for the sale of laser equipment was recognized upon shipment. During the year ended December 31, 2003, $243,000 of revenue associated with service to be performed during the warranty period was deferred and $30,000 of this amount was recognized.

(l) Warranties

The Company generally provides a one-year warranty on the sale of its excimer laser. Prior to July 1, 2003 the Company recorded warranty expense within cost of revenue at the time of the sale based on historical past experience. As warranty costs are incurred, they are charged against the warranty liability. As a result of EITF 00-21, warranty costs incurred for lasers sold after this date are recorded as expense in the period incurred to coincide with the recognition of deferred revenue.

(m) Royalty Liability

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

(n) Stock-Based Compensation

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

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

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

	Years Ended December 31		
	2003	2002	2001
	(In thousands, except per share amounts)		
Net income (loss), as reported	$ 929	$(1,561)	$ 590
Deduct total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(1,039)	(1,760)	(2,345)
Pro forma net loss	$ (110)	$(3,321)	$(1,755)
Earnings (loss) per share:			
Basic — as reported	0.04	(0.07)	0.03
Basic — pro forma	(0.00)	(0.14)	(0.07)
Diluted — as reported	0.04	(0.07)	0.02
Diluted — pro forma	(0.00)	(0.14)	(0.07)

(o) Research and Development

Research and development costs are expensed as incurred and totaled $1,791,000, $1,795,000, and $1,770,000 for the years ended December 31, 2003, 2002, and 2001, respectively. The Company also sponsors clinical trials intended to obtain the necessary clinical data required to obtain approval from the Food and Drug Administration and other foreign governing bodies to market new applications for its technology. Costs associated with these clinical trials totaled $922,000, $1,514,000, and $1,726,000 during the years ended December 31, 2003, 2002, and 2001, respectively.

(p) 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 income (loss).

(q) Advertising Costs

The Company expenses advertising costs as incurred. Advertising costs of $80,000, $118,000, and $55,000 were expensed in 2003, 2002, and 2001, respectively.

(r) Income Taxes

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

for deferred income taxes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases.

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.

(s) Reclassification

Certain 2002 amounts have been reclassed to conform with the 2003 presentation.

(2) Investment Securities

Investment securities consist of the following at December 31:

	2003	2002
	(In thousands)	
Short-term investments		
U.S. Treasury and agency notes	$ —	$4,542
Corporate notes	—	4,121
Total	$ —	$8,663
Long-term investments		
U.S. Treasury and agency notes	$2,000	—
Total	$2,000	$ —

Unrealized loss at December 31, 2003 and 2002, respectively, was $1,000 and $129,000, which has been included in other comprehensive income (loss). Realized gains and losses are determined using the specific identification method. There were no significant realized gains or losses during 2003 or 2002.

(3) Inventories

Inventories consist of the following as of December 31:

	2003	2002
	(In thousands)	
Raw materials	$ 201	$ 275
Work in process	589	398
Finished goods	1,109	1,452
	$1,899	$2,125

(4) Goodwill and Other Intangible Assets

Intangible Assets

Acquired intangible assets as of December 31 are as follows:

	2003	2002
	(In thousands)	
Patents and other assets	$ 3,783	$ 3,783
Less accumulated amortization	(3,564)	(3,320)
	$ 219	$ 463

Aggregate amortization expense for amortizing intangible assets was $244,000 for the years ended December 31, 2003 and 2002. Estimated amortization expense for the next five years is $117,000 in 2004, $72,000 in 2005, $27,000 in 2006, $0 in 2007 and 2008.

Goodwill

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

Upon adoption of Statement 142, the Company was required to evaluate its existing intangible assets and goodwill that were acquired in purchase business combinations, and to make any necessary reclassifications in order to conform to the new classification criteria in Statement 141 for recognition separate from goodwill. The Company also was required to reassess the useful lives and residual values of all intangible assets acquired, and make any necessary amortization period adjustments by the end of the first interim period after adoption. The Company was required to test goodwill for impairment as of January 1, 2002 and annually thereafter, in accordance with the provisions of Statement 142. The results of this analysis did not require the Company to recognize an impairment loss.

(5) Accrued Liabilities

Accrued liabilities consist of the following as of December 31:

	2003	2002
	(In thousands)	
Accrued payroll and employee related expenses	$1,996	$1,997
Accrued royalty expense	1,460	1,405
Accrued warranty expense	206	435
Accrued clinical study expense	105	260
Accrued legal and reorganization expenses	51	233
Accrued proxy contest and settlement	—	226
Other accrued expenses	1,107	1,368
	$4,925	$5,924

(6) Debt

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 matured in December 2003. At December 31, 2003 and 2002 the amount outstanding was $0 and $79,000, respectively.

(7) Stock-Based Compensation and Employee Benefit Plans

At December 31, 2003 and 2002, the Company had two stock-based compensation plans which are described below.

(a) Stock Option Plans

The Company maintains stock option plans which provide for the grant of incentive stock options, nonqualified stock options, and stock appreciation rights. The plans provide that incentive stock options be granted with exercise prices not less than the fair value at the date of grant. Options granted through December 31, 2003, generally vest over one to four years and expire ten years from the date of grant. Options granted to the board of directors generally vest over three years from date of grant and expire ten years from the date of grant. During 2003 certain option grants to key executives contain performance based features based on market value triggers ranging from $8 per share to $10 per share. If these market value triggers are achieved during the four years subsequent to the grant date the options will vest over the standard four year period. Otherwise, the options will cliff vest nine years and six months following the option grant date. At December 31, 2003, there were 1,258,123 shares available for future issuance under these plans.

The following is a summary of option activity during the three-year period ended December 31, 2003:

	Shares Under Option	Weighted Average Exercise Price
Options outstanding at December 31, 2000	4,415,240	$3.33
Granted	937,557	2.11
Exercised	(11,095)	3.00
Canceled	(267,907)	3.82
Options outstanding at December 31, 2001	5,073,795	3.09
Granted	347,692	2.78
Exercised	(171,013)	2.41
Canceled	(311,573)	3.50
Options outstanding at December 31, 2002	4,938,901	3.06
Granted	1,270,000	2.83
Exercised	(423,057)	1.77
Canceled	(1,004,970)	3.78
Options outstanding at December 31, 2003	4,780,874	$2.95

At December 31, 2003, the weighted average remaining contractual life of outstanding options was 6.08 years, and 3,168,823 options were exercisable at a weighted average exercise price of $3.03 per share.

The per-share weighted average fair value of stock options granted during 2003, 2002, and 2001, was $2.39, $2.13, and $1.55 per share, respectively, on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	2003	2002	2001
Risk free interest rate	3.0%	2.7%	4.3%
Expected life	5.2	6.8	6.2
Expected volatility	106.4%	91.0%	91.0%
Expected dividend yield	0.0%	0.0%	0.0%

Outstanding and Exercisable by Price Range as of December 31, 2003

Range of Exercise Prices	Number Outstanding as of December 31, 2003	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Weighted Average Exercise Value	Number Exercisable as of December 31, 2003	Weighted Average Exercise Price
$0.84 - 1.56	417,024	5.35	$1.39	429,533	374,777	$1.37
1.60 - 1.75	503,777	6.08	1.66	748,583	448,152	1.66
1.81 - 2.47	428,440	6.36	2.31	770,046	305,716	2.32
2.55 - 2.63	295,818	7.20	2.60	761,028	242,173	2.61
2.63 - 2.63	826,000	9.15	2.63	2,172,380	—	—
2.66 - 3.03	595,744	3.89	2.91	1,735,209	577,493	2.91
3.03 - 3.38	775,102	6.73	3.15	2,398,041	445,602	3.21
3.40 - 4.75	504,436	6.11	4.30	2,070,636	350,962	4.50
4.88 - 5.63	264,533	3.01	4.94	1,306,069	263,283	4.94
6.38 - 6.38	170,000	5.11	6.38	1,083,750	160,665	6.38
	4,780,874			13,475,275	3,168,823	

During 2003, the Company granted 25,000 fully vested options to certain non-employees for past services. The fair value of the options approximated $54,000, as determined using the Black-Scholes options pricing model assuming no dividends, 90% volatility, risk-free interest rate of 2.4%, and an expected life of five years. This expense was recognized in 2003 and is included in selling, general, and administrative expenses in the accompanying consolidated statement of operations and other comprehensive income (loss).

During 2002 and 2001, the Company granted 25,000 and 70,000 options to non-employees for consulting services with a combined value of $168,000. The value in 2002 and 2001 was determined using the Black-Scholes options pricing model with the following assumptions: 91% and 98% volatility, risk-free interest rate of 2.7% and 3.0%, no dividend yield, and an expected life of three to seven years, respectively. The total value of the options is being amortized to expense on a straight-line basis over the vesting period through October 2006. The expense recognized was $55,000, $36,000, and $40,000 during the years ended December 31, 2003, 2002, and 2001, respectively, and is included in selling, general and administrative expenses in the accompanying consolidated statements of operations and other comprehensive income (loss).

(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 151,690, 107,231, and 162,525 in 2003, 2002, and 2001, 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 2003, 2002, and 2001 was $1.83, $0.84, and $1.43, respectively, per right, which was estimated using the Black-Scholes model with the following assumptions:

	2003	2002	2001
Risk free interest rate	0.9%	1.2%	1.7%
Expected life	6 months	6 months	6 months
Expected volatility	166.9%	89.0%	94.0%
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 accrued contributions of $126,000 and $108,000 to the plan in 2003 and 2002, respectively, based on a match of 25% of the first 4% of each employee's contribution. The Company made no matching contributions to the plan for the year ended December 31, 2001.

(8) 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, 2003, 2002, and 2001 were 1,355,317, 3,683,533, and 3,812,068 because their effect would have been antidilutive.

	2003	2002	2001
		(In thousands)	
Net income (loss)	$ 929	$(1,561)	$ 590
Common shares outstanding:			
Historical common shares outstanding at beginning of year	23,878	23,599	23,426
Weighted average common shares issued	376	210	121
Weighted average common shares outstanding — basic	24,254	23,809	23,547
Effect of dilution from stock options	1,189	—	614
Weighted average common shares outstanding — diluted	25,443	23,809	24,161

	2003	2002	2001
Net income (loss) per share, basic	$0.04	$(0.07)	$0.03
Net income (loss) per share, diluted	0.04	(0.07)	0.02

(9) Leases

The Company leases office space, furniture and equipment under noncancelable operating leases with initial terms that expire at various dates through 2008. All assets held under capital leases were fully depreciated at December 31, 2003 and 2002.

The future minimum payments under noncancelable operating leases as of December 31, 2003, are as follows:

	Operating Leases (In thousands)
Years ending December 31:	
2004	$ 495
2005	376
2006	83
2007	54
2008	16
Total minimum lease payments	$1,024

Rent expense under operating leases totaled approximately $538,000, $495,000, and $525,000 for the years ended December 31, 2003, 2002, and 2001, respectively.

(10) Income Taxes

At December 31, 2003, the Company has net operating loss carryforwards for United States federal income tax purposes of approximately $53 million, which are available to offset future federal taxable income, if any, and expire at varying dates from 2004 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 $298,000 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, 2003, 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 2023. The annual use of portions of the research and experimentation credit carryforwards is also limited under Section 382.

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

	2003	2002
	(In thousands)	
Current:		
Royalty reserve, due to accrual for financial reporting purposes	$ 569	$ 548
Warranty reserve, due to accrual for financial reporting purposes	51	147
Accrued liabilities, not deducted until paid for tax purposes	341	510
Inventories, principally due to accrual for obsolescence for financial reporting purposes, net of additional costs inventoried for tax purposes	36	16
Deferred revenue, due to deferral for financial reporting purposes	664	414
Noncurrent:		
Net operating loss carryforwards — U.S. and related states	20,508	21,146
Foreign net operating loss carryforwards	14,292	10,074
Research and experimentation tax credit	2,928	2,947
Equipment, primarily due to differences in cost basis and depreciation methods	277	44
Alternative minimum tax credit	298	253
Other	—	38
Total net deferred tax assets	39,964	36,137
Less valuation allowance	(39,964)	(36,137)
Net deferred tax assets	$ —	$ —

The Company has recorded a valuation allowance equal to the gross deferred tax asset at December 31, 2003 and 2002, 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 expense (benefit) attributable to income (loss) before income taxes differed from the amounts computed by applying the U.S. federal income tax rate of 34% to income (loss) before income taxes as a result of the following (in thousands):

	2003	2002	2001
Computed expected tax expense (benefit)	$ 316	$(531)	$ 201
Increase (reduction) in income taxes resulting from:			
State and local income taxes, net of federal impact	49	(32)	42
Permanent differences	(25)	141	144
Change in valuation allowance	3,827	223	(8,379)
Change in or utilization of net operating loss carryforward	—	—	8,100
Foreign operations	(4,218)	16	(108)
Change in the beginning of the year balance of the valuation allowance for deferred tax assets allocated to income tax expense	(114)	—	—
Other, net	165	183	—
	$ —	$ —	$ —

(11) 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, 2003.

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

(12) 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, 2003, FDA-approved products were used in conjunction with coronary atherectomy as well as the removal of nonfunctioning 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, 2003, 2002, and 2001 cost allocations of these functions to Europe Medical have not been performed.

Revenue associated with intersegment transfers to Europe Medical was $1,439,000, $1,338,000, and $1,074,000 for the years ended December 31, 2003, 2002, and 2001, 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, 2003, 2002, and 2001, intersegment revenue and intercompany profits are not included in the segment information in the table shown below.

(b) Europe Medical

The Europe Medical segment is a marketing and sales subsidiary located in the Netherlands that serves Europe as well as the Middle East. Products offered by this reportable segment are the same as those offered by U.S. Medical. The Company has received CE mark approval for products that relate to 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 segment operations is shown below. Intersegment transfers as well as intercompany assets and liabilities are excluded from the information provided (in thousands):

	2003	2002	2001
Revenue:			
Equipment	$ 2,508	$ 4,744	$ 4,429
Disposables	18,787	17,098	17,396
Service	3,783	3,597	3,440
Other, net of provision for sales returns	(55)	41	319
Subtotal — U.S. Medical	25,023	25,480	25,584
Equipment	316	338	113
Disposables	2,340	2,063	1,825
Service	190	216	286
Subtotal — Europe Medical	2,846	2,617	2,224
Total revenue	$27,869	$28,097	$27,808

In 2003, 2002, and 2001, no individual customer represented 10% or more of consolidated revenue.

	2003	2002	2001
Interest income:			
U.S. Medical	$ 93	$ 469	$ 574
Europe Medical	11	11	20
Total interest income	$ 104	$ 480	$ 594
Interest expense:			
U.S. Medical	$ —	$ 129	$ 132
Europe Medical	17	28	18
Total interest expense	$ 17	$ 157	$ 150
Depreciation expense:			
U.S. Medical	$ 1,168	$ 1,302	$ 1,419
Europe Medical	83	104	28
Total depreciation	$ 1,251	$ 1,406	$ 1,447
Amortization expense:			
U.S. Medical	$ 290	$ 272	$ 342
Europe Medical	15	15	43
Total amortization	$ 305	$ 287	$ 385
Segment net income (loss):			
U.S. Medical	$ 807	$(1,800)	$ 445
Europe Medical	122	239	145
Total net income (loss)	$ 929	$(1,561)	$ 590
Capital expenditures:			
U.S. Medical	$ 357	$ 187	$ 290
Europe Medical	12	11	—
Total capital expenditures	$ 369	$ 198	$ 290
Segment assets:			
U.S. Medical	$23,363	$21,636	
Europe Medical	2,719	2,200	
Total assets	$26,082	$23,836	

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

	2003	2002	2001
U.S. Medical	$ 140	$ 267	$ 746
Europe Medical	2,846	2,617	2,224
Total foreign revenue	$2,986	$2,884	$2,970

There were no individual countries, other than the United States, that represented at least 10% of consolidated revenue in 2003, 2002, or 2001. Long-lived assets located in foreign countries are concentrated in Europe, and totaled $863,000 and $658,000 as of December 31, 2003 and 2002, respectively.

(13) Reorganization Costs

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

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

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

(14) 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.

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. As of December 31, 2003, two new directors have been appointed.
- 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		Adjustments 2003	Accrued Costs as of December 31, 2003
		2002	2003		
Termination and severance costs	$ 570	$ 336	$215	$(19)	$—
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	11	144	—
Total	$1,781	$1,555	$226	$ —	$—

Additional costs of $56,000 relate primarily to costs associated with extending the vesting period of stock options of terminated executives. All settlement costs have been paid at December 31, 2003.

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

The Company has received inquiries from two of its licensors regarding the level of past royalty payments. The Company has settled one dispute and has recently engaged in discussions with the other regarding their inquiries. The disagreement over past royalty payments centers on the treatment of certain service-based

revenue, including repair and maintenance, and physician and clinical training services. Management believes that these are beyond the scope of the license agreement. If the Company's discussions do not resolve the dispute, the license agreement with the licensor provides for arbitration proceedings to settle this matter, which would streamline a resolution compared with proceedings in a federal or state court. The Company has accrued costs of approximately $1,300,000 associated with the resolution of this matter, which represents management's best estimate of costs to resolve the matter based on the status of ongoing negotiations. If the matter is referred to arbitration proceedings, the Company will vigorously defend its position that royalties are not owed on the service-based revenues in dispute.

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

(16) Valuation and Qualifying Accounts

Description	Balance at Beginning of Year	Additions	Deductions	Balance at End of Year
		(In thousands)		
Year ended December 31, 2001:				
Accrued warranty liability	$ 295	$ 240	$ 211	$ 324
Accrued royalty liability	3,578	1,419	2,578	2,419(a)
Allowance for doubtful accounts and sales returns	398	332	88	642
Accrued litigation and reorganization reserves	1,714	—	1,220	494
Inventory obsolescence reserves	41	35	13	63
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
Inventory obsolescence reserves	63	61	63	61
Year ended December 31, 2003:				
Accrued warranty liability	$ 435	56	285	206
Accrued royalty liability	1,405	1,099	1,044	1,460
Allowance for doubtful accounts and sales returns	555	2	97	460
Accrued litigation and reorganization reserves	233	—	182	51
Accrued proxy contest and settlement costs	226	—	226	—
Inventory obsolescence reserves	61	9	40	30

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

(17) Selected Quarterly Financial Data (Unaudited)

	2003				2002			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
	(In thousands, except per share amounts)							
Net sales	$6,977	$6,545	$6,901	$7,446	$7,059	$ 6,463	$7,157	$7,418
Gross profit	4,869	4,754	4,947	5,399	4,791	4,434	4,794	5,095
Net income (loss)	141	53	357	378	(17)	(2,259)	227	488
Net income (loss) per share:								
Basic	0.01	0.00	0.01	0.02	(0.00)	(0.09)	0.01	0.02
Diluted	0.01	0.00	0.01	0.01	(0.00)	(0.09)	0.01	0.02

EXHIBIT INDEX

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

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

Exhibit Number	Description
10.26	Agreement of Settlement and Compromise dated June 6, 2002, (the "Settlement Agreement") by and among the Company, on the one hand, and Steven Sweet, Joseph Largey, Paul Samek, Lawrence McKinley, acting solely in his individual capacity, and Sharon Sweet, on the other hand, including the exhibits thereto.(26)
10.27	Separation Agreement between the Company and Joseph Largey, dated as of June 6, 2002, filed as exhibit E to the Settlement Agreement referenced in Exhibit 10.26.(28)
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.(28)
10.29	Form of Indemnification Agreement entered into between the Company and each of its directors as of May 10, 2002.(27)
10.30	Fourth Amendment to the 1997 Equity Participation Plan.(27)
10.31	Fifth Amendment to the 1997 Equity Participation Plan.(27)
10.32	Letter agreement dated January 20, 2003 between the Company and John G. Schulte.(29)
10.33	Asset purchase agreement between the Company and LaTIS, Inc.(30)
10.34	Settlement Agreement between the Company and Interlase Limited Partnership dated November 19, 2003.
21.1	Subsidiary of the Company.(25)
23.1	Consent of Independent Auditors.
31.1	Rule 13(a)-14(a)/15d-14(a) Certifications.
32.1	Section 1350 Certifications.

(1) Incorporated by reference to the Company's 1993 Annual Report on Form 10-K filed on March 31, 1994.

(2) Incorporated by reference to exhibits previously filed by the Company with its Registration Statement on Form S-4 filed May 18, 1994 (File No. 33-79106).

(3) Incorporated by reference to exhibits previously filed by the Company with its Registration Statement on Form S-1, filed December 5, 1991 (File No. 33-44367).

(4) Incorporated by reference to exhibits previously filed by the Company with its Amendment No. 2 to the Registration Statement, filed January 24, 1992 (File No. 33-44367).

(5) Incorporated by reference to exhibits previously filed by LAIS with its Registration Statement on Form S-1 filed August 30, 1991 (File No. 33-42457).

(6) Incorporated by reference to exhibits previously filed by the Company with its Amendment No. 1 to the Registration Statement on Form S-1, filed January 10, 1992 (File No. 33-44367).

(7) Incorporated by reference to exhibits previously filed by the Company with its Annual Report for 1992 on Form 10-K filed March 31, 1993.

(8) Incorporated by reference to exhibits previously filed by the Company with its Registration Statement on Form S-8 filed April 1, 1992 (File No. 33-46725).

(9) Incorporated by reference to exhibits previously filed by the Company with its Registration Statement on Form S-8 filed December 30, 1994 (File No. 33-88088).

(10) Incorporated by reference to exhibits previously filed by the Company with its Registration Statement on Form S-8 filed November 16, 1995 (File No. 33-99406).

(11) Incorporated by reference to exhibits previously filed by the Company with its Registration Statement on Form S-8 filed October 6, 1994 (File No. 33-85198).

(12) Incorporated by reference to exhibits previously filed by the Company with its 1994 Annual Report on Form 10-K filed on March 31, 1995.

(13) Incorporated by reference to the Company's 1995 Annual Report on Form 10-K filed on April 29, 1996.

(14) Incorporated by reference to exhibits previously filed by the Company with its Current Report on Form 8-K filed on May 6, 1996.

(15) Incorporated by reference to exhibits previously filed by the Company with its Form 10-Q for the quarter ended on March 31, 1997.

(16) Incorporated by reference to exhibits previously filed by the Company with its Form 10-Q for the quarter ended on September 30, 1997.

(17) Incorporated by reference to exhibits previously filed by the Company with its Registration Statement on Form S-8 filed July 19, 1996.

(18) Incorporated by reference to exhibits previously filed by the Company with its Form 10-Q for the quarter ended on June 30, 1998.

(19) Incorporated by reference to exhibits previously filed by the Company with its 1997 Annual Report on Form 10-K filed on March 30, 1998.

(20) Incorporated by reference to exhibits previously filed by the Company with its Current Report on Form 8-K filed on June 8, 1999.

(21) Incorporated by reference to exhibits previously filed by the Company with its Registration Statement on Form S-8 filed June 17, 1998 (File No. 333-57015).

(22) Incorporated by reference to exhibits previously filed by the Company with its Form 10-Q for the quarter ended March 31, 1999.

(23) Incorporated by reference to exhibit previously filed by the Company with its Registration Statement on Form S-8 filed on November 22, 2000.

(24) Incorporated by reference to exhibit previously filed by the Company with its 2000 Annual Report on Form 10-K filed on March 30, 2001.

(25) Incorporated by reference to exhibit previously filed by the Company with its 2001 Annual Report on Form 10-K filed on March 30, 2002.

(26) Incorporated by reference to exhibits previously filed by the Company with its Current Report on Form 8-K filed on June 7, 2002.

(27) Incorporated by reference to exhibits previously filed by the Company with its Quarterly Report on Form 10-Q for the quarter ended June 30, 2002.

(28) Incorporated by reference to exhibit previously filed by the Company with its 2002 Annual Report on Form 10-K filed on March 30, 2003.

(29) Incorporated by reference to exhibits previously filed by the Company with its Quarterly Report on Form 10-Q for the quarter ended March 31, 2003.

(30) Incorporated by reference to exhibits previously filed by the Company with its Quarterly Report on Form 10-Q for the quarter ended June 30, 2003.

Corporate Information

Board of Directors

David G. Blackburn
Principal
TRG Cardiovascular

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. Hart [2]
Self-employed, Investor

Joseph M. Ruggio, MD [1]
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

Design: Barker Design. **Front and back cover illustrations:** Howe Creative.

Corporate Headquarters

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

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

Product Information

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

Stock Data

NASDAQ: SPNC

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

As of March 12, 2004, there were 728 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

Annual Meeting

Date: Tuesday, June 22, 2004
Time: 10:00 am Mountain Daylight Time
Location: Antlers Adam's Mark Hotel
Address: 4 South Cascade
City/State: Colorado Springs, CO 80903

The Spectranetics Corporation

96 Talamine Court
Colorado Springs, CO 80907-5186

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or
800-633-0960

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