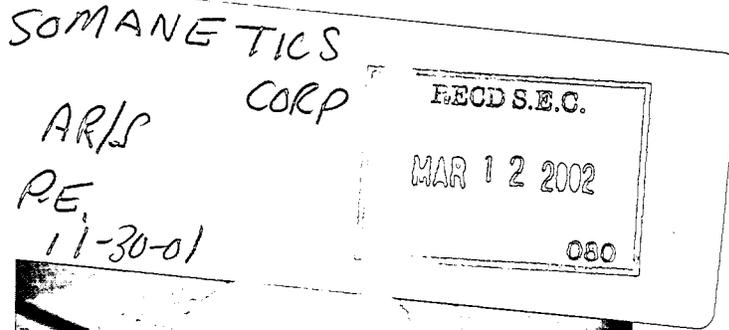




ANNUAL REPORT

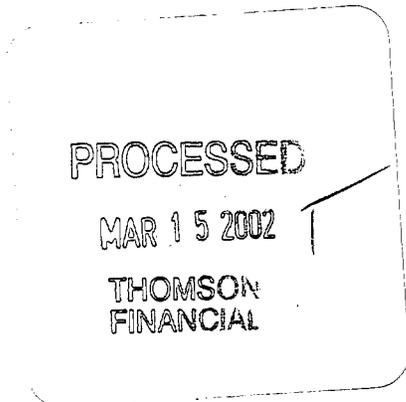
2001



COMPSTORE™ SYSTEM



INVOS® SYSTEM



SOMANETICS®

Clinical Research Shows Benefits of SVR

The results of a 13-center and 662-patient study evaluating the safety and effectiveness of SVR demonstrated that SVR is a safe and effective treatment for certain types of CHF. Most of the patients in the study were severe Class IV CHF patients. Among the 355 patients in whom functional class was reported at last follow up, 91 percent of the patients were functionally improved from congestive heart failure, with 61 percent classified as Class I and 30 percent as Class II.

Readmission data was obtained on 658 patients. Freedom from readmission to the hospital for CHF at three years was 88.7 percent. By comparison, the annual hospital admission rate for Class III and IV heart failure patients is more than 40 percent and 24 percent are admitted two or more times each year.

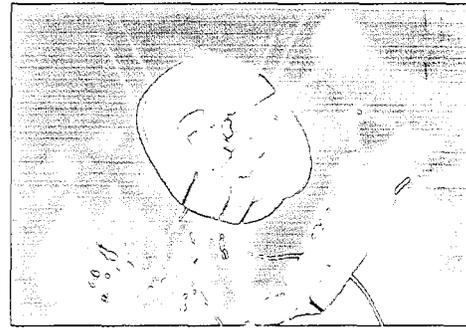
The study was presented at the opening scientific session of the American Association for Thoracic Surgery meeting in May 2001. The presentation of 36-month research data updated the 18-month results of a study of 439 SVR patients that was published in a peer-reviewed article in the April 2001 issue of the *Journal of the American College of Cardiology*. The study reporting the most recent data was published in the October 2001 issue of *Seminars in Thoracic and Cardiovascular Surgery*, distributed in early 2002.

We understand the important role clinical research plays in establishing a medical device and are pleased to be launching our CorRestore System with the availability of such strong research data supporting the safety and effectiveness of the SVR procedure.

Benefits of the CorRestore System

Before the availability of the CorRestore System, surgeons performing the SVR procedure had to fabricate an implant by hand using off-the-shelf materials at the time of surgery. The process is time-consuming and results in an implant of variable quality that can leak around its perimeter.

The CorRestore System provides the surgeon with a ready-made bovine pericardial patch that is easier to implant and provides a better seal against leaks at the perimeter than existing patches.



The CorRestore Patch, being inserted into the patient's left ventricle during SVR, is a ready-made bovine pericardial patch that is easier to implant and provides a better seal against leaks at the perimeter than existing patches.

2002 Off to a Positive Start

Already in 2002 we have attended a medical conference with presentations related to both of our products, the INVOS Cerebral Oximeter and the CorRestore System. In addition, the CorRestore System was used for the first time in an SVR procedure that was performed in January 2002.

A live satellite transmission of a patient undergoing coronary artery bypass graft surgery with the "off-pump" beating-heart technique and monitored with the INVOS system was broadcast to approximately one thousand cardiothoracic and vascular surgeons attending the Cardiothoracic Techniques and Technologies international symposium in January 2002.

The surgery was performed by Yvon Baribeau, M.D., cardiac surgeon, Catholic Medical Center, Manchester N.H., to update attending physicians to developments in cardiothoracic surgical techniques and technologies.

The off-pump technique for coronary artery bypass grafting eliminates the need to place patients on the heart-lung machine. However, beating-heart surgery can be associated with significant blood pressure changes during heart mobilization and stabilization. Large fluctuations in blood pressure can reduce organ blood flow, potentially causing brain damage, kidney failure, and various other poor outcomes. With the INVOS system, the surgeon is able to assess the patient's ability to tolerate such fluctuations and, if needed, the surgeon can intervene and potentially greatly reduce the chance of inadequate cerebral brain blood oxygenation.

The INVOS Cerebral Oximeter is a standard of care for beating-heart surgery for this surgeon's practice.

EVENTS OF 2001

January - Clinical study results and a workshop on using cerebral oximetry to monitor blood brain oxygen levels during a new bypass management technique for infant heart surgery patients were presented at the Society of Thoracic Surgeons.

March - Somanetics reported 36 percent U.S. sales growth for the first quarter.

April - The *Journal of the American College of Cardiology* published a study highlighting Surgical Ventricular Restoration as an effective treatment for certain types of CHF.

April - Somanetics completed a private placement of common shares for net proceeds of \$2.2 million.

May - A Weill Medical College of Cornell University study demonstrated that maintaining regional brain oxygen saturation during cardiac surgery, as monitored with the INVOS system, and making interventions as needed, shortened average ICU and hospital stays. Presented at the Society of Cardiovascular Anesthesiologists.

May - Results of a 13-center, 662-patient study demonstrated the safety and effectiveness of SVR. Presented at the opening scientific session of the American Association for Thoracic Surgery.

May - An intervention outcome study from Hackensack University Medical Center indicated that when cerebral oximetry is used to guide management of brain blood oxygen saturation during cardiac surgery, neurological complications decreased by 55 percent, renal failure, which can be a significant and costly complication of cardiac surgery, decreased by 45 percent and average hospital length of stay was reduced. Presented at 2001 Outcomes, Cardiac and Vascular Surgery: Neuro-behavioral Assessment, Physiological Monitoring and Cerebral Protective Strategies.

May - Somanetics submitted a 510(k) pre-market notification to the FDA to apply for clearance to market the CorRestore Patch in the U.S.

June - Somanetics reported a record quarter for U.S. sales for the second quarter.

September - Somanetics reported record U.S. SomaSensor sales for the third quarter, which grew 61 percent over the third quarter of 2000.

October - A 286-patient study reported that maintaining adequate brain blood oxygen saturation by monitoring with the INVOS system, and making interventions as needed, significantly decreased the incidence of stroke and coma in these patients. Released at the American Society of Anesthesiologists by Cornell University.

November - Somanetics received FDA clearance to market the CorRestore Patch in the U.S.

Despite available therapies, the prognosis for patients with the most severe New York Hospital Association Class III and Class IV CHF is dismal. Nearly 40 percent of these heart failure patients will die within 12 months of their initial hospital admission for heart failure.

The quality of life of the survivors is poor and deteriorates, characterized by problems with physical strength and stamina, shortness of breath and fluid retention.

The progressive disease of CHF is generally treated with drugs, cardiac assist devices or transplantation. However, such treatments are expensive and do not address the causes of CHF. As a result, even if these treatments help CHF patients for a time, the long-term prognosis is poor as the disease progresses.

SVR with the CorRestore System is focused on correcting the enlarged, poorly functioning left ventricle associated with CHF in certain patients, thereby correcting the problem, as opposed to treating the symptoms.

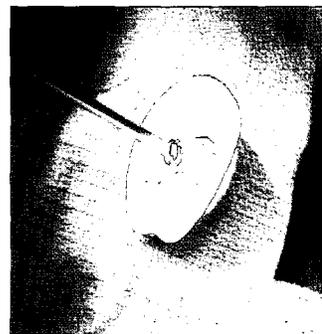
The SVR procedure is typically performed immediately after coronary artery bypass graft surgery, and mitral valve replacement or repair, if needed.

SVR Treats Problem, Not Symptoms

A type of heart attack called anterior infarction can result in changes to the ventricle's shape and size, impairing its ability to pump blood. To compensate, other parts of the heart enlarge, often leading to congestive heart failure.

The initial target market for the SVR procedure is patients with the most serious NYHA Class III and Class IV CHF, where a heart attack has resulted in changes to the left ventricle's shape and size, impairing its ability to pump blood and leading to CHF.

During SVR, the surgeon restores the enlarged, poorly functioning left ventricle to more normal size and function by inserting an implant, in most instances, or by direct closure.



The CorRestore Patch prepared for implantation in an SVR procedure.

TO OUR SHAREHOLDERS

We are very pleased to report that Somanetics accomplished the two primary objectives we set for fiscal 2001. We moved the INVOS® Cerebral Oximetry business toward profitability, reporting our first quarter of net income in our history in the fourth quarter of fiscal 2001, and we secured Food and Drug Administration clearance to market the CorRestore™ System in the United States.

On the financial front, we achieved profitability in the fourth quarter through a combination of increased revenues, improved gross margin and cost containment.

Revenues in fiscal 2001 increased 11 percent over fiscal 2000, including a 43 percent increase in the U.S. Gross margin improved to 63 percent for 2001 from 54 percent for 2000 as a result of increased average selling prices for SomaSensors®, related in part to a price increase, manufacturing cost reductions for the SomaSensors, and a change in sales mix between sales in the U.S. and sales to international distributors.

The growth in the U.S. INVOS cerebral oximetry business was marked by increased use of the INVOS system in cardiac and cardiovascular surgery programs. This was, in part, driven by new intervention outcomes data supporting the use of the INVOS Cerebral Oximeter in cardiac surgery.

The growth in the U.S. cerebral oximetry business in fiscal 2001 was marked by increased use of the INVOS system in cardiac and cardiovascular surgery programs.

In addition, early in the year, a study conducted at Duke University Medical Center and published in *The New England Journal of Medicine* (in the February 8, 2001 issue) confirmed the prevalence and persistence of cognitive decline related to coronary artery bypass graft surgery.

The study concluded that interventions to prevent or reduce long- and short-term cognitive decline are warranted to preserve long-term cognitive function and quality of life after cardiac surgery. The research performed using cerebral oximetry demonstrates that our monitoring system can play an important role in preventing brain injuries and other adverse outcomes related to cardiac surgery.



The INVOS Cerebral Oximeter is used to monitor an infant heart repair surgery patient by Richard Ohye, M.D. (left), pediatric cardiac surgeon at the University of Michigan's Mott Children's Hospital, Ann Arbor, MI.

Milestone Achieved - FDA Clearance for the CorRestore Patch

Our second product platform, also focusing on the cardiovascular marketplace, is the CorRestore System. We are developing the CorRestore System for use in cardiac repair and reconstruction, including a procedure called Surgical Ventricular Restoration, or SVR, a treatment for certain types of congestive heart failure.

We submitted our 510(k) pre-market notification to the U.S. Food and Drug Administration to apply for clearance to market the CorRestore Patch in the U.S. in May 2001, and received 510(k) clearance in November 2001.

Congestive Heart Failure Affects Many

Congestive heart failure (CHF) occurs when the heart loses its ability to pump enough blood through the body. An estimated five million people in the U. S. are currently diagnosed with CHF.

Each year, an additional 550,000 people are diagnosed with CHF, and about 250,000 deaths are attributed to CHF and related causes in the U.S. CHF cases have increased in the past few decades, with experts predicting that the trend will continue as the population ages. CHF is the most common cause of hospital admissions for people over age 65. Each admission is costly to the hospital, which loses an average of \$3,100 per patient.

First CorRestore Patch Implanted

The CorRestore System was used for the first time in an SVR procedure performed at Carraway Methodist Medical Center in Birmingham, AL in January 2002.

The patient was a 56-year-old male who had two heart attacks prior to 1992 and coronary artery bypass graft and carotid operations in 1992. In mid-2001, the patient began to notice shortness of breath. He returned to Carraway Methodist Medical Center with end-stage congestive heart failure.

Upon arrival, without SVR, the patient had a very poor prognosis and his clinical condition was associated with a very poor quality of life, high likelihood of mortality and expensive, repetitive hospitalizations.

The patient's prognosis is excellent with a vastly improved quality of life and a reduced chance of repeated hospitalizations for heart failure.

Repeat coronary artery bypass grafting and mitral valve replacement were required, but would not have corrected the heart failure that was caused by his enlarged left ventricle.

Also, he most likely would have required additional temporary cardiac support devices to help him recover from surgery, which are associated with many complications as well as a long intensive care unit stay.

Repeat coronary artery bypass grafting, mitral valve replacement and SVR with the CorRestore System were performed and the patient progressed through a normal, uneventful recovery. He has more endurance now, just shortly after his surgery, and his prognosis is excellent with a vastly improved quality of life and a reduced chance of repeated hospitalizations for heart failure.

CorRestore System Meets the Challenges of Performing SVR

The patient we just described had a ventricle that is typical of an SVR candidate; fragile with an uneven interior surface. Past use of off-the-shelf material for patching the ventricle usually left the surgeon needing to address leaks around the patch, because it did not readily seal the uneven interior surface of the ventricle.

The CorRestore System offers surgeons an out-of-the-box repair device of a material and design specifically suited for the challenges they face in performing SVR.

The CorRestore Patch, made from bovine pericardium, is designed to be more hemostatic (leak-proof) and easier to work with than other materials used to improvise a patch in the operating room. Surgeons prefer to suture tissue-to-tissue (bovine pericardium to heart muscle) as opposed to synthetic material-to-tissue. The CorRestore System worked well in our initial experience and we expect continued success with it.

We showed the CorRestore System to the public for the first time at the Society of Thoracic Surgeons annual meeting in late January, where the product was met with interest from cardiac surgeons who attended the meeting.

Shipments of CorRestore Systems to customers began in February. Our other activities related to the marketing launch of the CorRestore System, including training and educational programs and plans for our attendance at a variety of medical conferences, are underway and will unfold as the year progresses.

A Look Ahead

We described several exciting activities that have already occurred in 2002. In addition, in January 2002 we completed a public offering of 1,000,000 common shares at \$4.25 a share, raising net proceeds of approximately \$3,725,000. In February we expanded our international distribution when we signed an exclusive distribution agreement with Tyco Healthcare Group Canada under which Tyco will market and sell the INVOS Cerebral Oximeter system throughout Canada.

Our goals for the remainder of the year include continuing to increase revenues and to become profitable for the year in our INVOS Cerebral Oximeter business, and conducting a successful launch of the CorRestore System. With a healthy INVOS Cerebral Oximeter business, the launch of the CorRestore System now occurring, and sufficient financial resources to execute our business plans, we are excited about our future. Thank you for your continued interest and support.

Sincerely,



Bruce J. Barrett
President and Chief Executive Officer

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

(Mark One)

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

For the fiscal year ended November 30, 2001 or

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

For the transition period from ___ to ___

Commission File No. 0-19095

SOMANETICS CORPORATION

(Exact name of Registrant as specified in its charter)

MICHIGAN

(State or other jurisdiction of incorporation or organization)

38-2394784

(I.R.S. Employer Identification No.)

1653 East Maple Road, Troy, Michigan

(Address of principal executive offices)

48083-4208

(Zip Code)

Registrant's telephone number, including area code: (248) 689-3050

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

Securities registered pursuant to Section 12(g) of the Act:

Common Shares, par value \$.01 per share

(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.

The aggregate market value of the common shares held by non-affiliates of the Registrant as of February 13, 2002, computed by reference to the closing sale price as reported by Nasdaq on such date, was approximately \$33,702,000.

The number of the Registrant's common shares outstanding as of February 13, 2002 was 9,075,055

Documents Incorporated by Reference

Portions of the Proxy Statement for the 2002 Annual Meeting of Shareholders, scheduled to be held April 17, 2002, are incorporated by reference in Part III, if the Proxy Statement is filed no later than March 30, 2002.

SOMANETICS CORPORATION
 ANNUAL REPORT ON FORM 10-K
 FOR THE FISCAL YEAR ENDED NOVEMBER 30, 2001

TABLE OF CONTENTS

		<u>PAGE</u>
PART I		
Item 1.	Business	2
Item 2.	Properties.....	21
Item 3.	Legal Proceedings	21
Item 4.	Submission of Matters to a Vote of Security Holders.....	21
Supplemental Item.	Executive Officers of the Registrant.....	22
PART II		
Item 5.	Market for Registrant's Common Equity and Related Shareholder Matters.....	24
Item 6.	Selected Financial Data	25
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	26
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk.....	33
Item 8.	Financial Statements and Supplementary Data.....	34
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure....	49
PART III		
Item 10.	Directors and Executive Officers of Registrant	50
Item 11.	Executive Compensation.....	50
Item 12.	Security Ownership of Certain Beneficial Owners and Management.....	50
Item 13.	Certain Relationships and Related Transactions.....	50
PART IV		
Item 14.	Exhibits, Financial Statement Schedules and Reports on Form 8-K.....	51

PART I

ITEM 1. BUSINESS

The Company

We were incorporated in 1982, and we develop, manufacture and market the INVOS® Cerebral Oximeter, the only non-invasive patient monitoring system commercially available in the United States that continuously measures changes in the blood oxygen level in the brain. We are also developing the CorRestore™ System for use in cardiac repair and reconstruction, including heart surgeries called surgical ventricular restoration, or SVR. We developed the Cerebral Oximeter to meet the need for information about oxygen in the brain, the organ least tolerant of oxygen deprivation. Without sufficient oxygen, brain damage may occur within a few minutes, which can result in paralysis, severe and complex disabilities or death. Brain oxygen information, therefore, is important, especially in surgical procedures requiring general anesthesia and in other critical care situations with a high risk of the brain getting less oxygen than it needs. We target surgical procedures with a high risk of brain oxygen imbalances, such as heart surgeries, heart blood vessel surgeries, other blood vessel surgeries and surgeries involving elderly patients. Surgeons, anesthesiologists and other medical professionals use the Cerebral Oximeter to identify brain oxygen imbalances and take corrective action, potentially improving patient outcome and reducing the cost of care.

The Cerebral Oximeter is a relatively inexpensive, portable and easy-to-use monitoring system placed at a patient's bedside in hospital critical care areas, especially operating rooms, recovery rooms, intensive care units and emergency rooms. It is comprised of

- a portable unit including a computer and a display monitor,
- dual single-use, disposable sensors, called SomaSensors®,
- proprietary software, and
- a preamplifier cable.

SomaSensors can be placed on both sides of a patient's forehead to offer bi-lateral monitoring and are connected to the computer through the preamplifier cable. The computer uses our proprietary software to analyze information received from the SomaSensors and provides a continuous digital and trend display on the monitor of an index of the oxygen saturation in the area of the brain under the SomaSensors. Users of the Cerebral Oximeter will be required to purchase disposable SomaSensors on a regular basis because of their single-use nature. We began shipping the model 4100 Cerebral Oximeter in the first quarter of fiscal 1998. During the third quarter of fiscal 1999, we introduced our new model 5100 Cerebral Oximeter at an international trade show, and began international shipments of the model 5100 in August 1999. The model 5100 Cerebral Oximeter has the added capability of being able to monitor pediatric patients. In September 2000, we received clearance from the FDA to market the model 5100 Cerebral Oximeter in the United States.

Our objective is to establish the Cerebral Oximeter as a standard of care in surgical procedures requiring general anesthesia and in other critical care situations.

We are developing the CorRestore System, which includes a new cardiac implant designed by CorRestore LLC, for use in cardiac repair and reconstruction, including heart surgeries called surgical ventricular restoration, or SVR. During SVR, the surgeon restores an enlarged, poorly functioning left ventricle to more normal size and function by inserting an implant, in most instances, or closing the defect directly. We entered into a License Agreement as of June 2, 2000 giving us worldwide, royalty-bearing licenses to specified rights relating to the CorRestore System, subject to the terms and conditions of the license agreement. In November 2001 we received clearance from the FDA to market the CorRestore patch in the United States. Our objective is to obtain regulatory clearances or approvals necessary to market the CorRestore System outside the United States and to have the system used in SVR surgeries. Our initial target market is SVR surgeries on patients with dilated ischemic cardiomyopathy due to a previous myocardial infarction involving the anterior wall of the ventricle. Ischemic cardiomyopathy is a damaged heart muscle caused by the obstruction of the inflow of blood from the arteries, resulting in an enlarged ventricle. Myocardial infarction is the death of an area of the middle muscle layer in the heart wall.

Market Overview

Industry Background

The brain is the human organ least tolerant of oxygen deprivation. Without sufficient oxygen, brain damage may occur within a few minutes, which can result in paralysis, severe and complex disabilities, or death. Undetected brain hypoxia, which is the insufficiency of oxygen delivery, and ischemia, which is tissue oxygen starvation due to the obstruction of the inflow of arterial blood, are common causes of brain damage and death during and after many surgical procedures and in other critical care situations. A December 1996 article in *The New England Journal of Medicine* and a March 1998 article in *The Lancet* reported separately on the results of multi-center studies involving surgeries. *The New England Journal of Medicine* article concluded that adverse cerebral outcomes after coronary artery bypass graft surgery are relatively common and serious and are associated with substantial increases in death, length of hospitalization and use of intermediate- or long-term care facilities. Adverse cerebral outcomes occurred in 6.1% of the patients included in the study. *The Lancet* article reported that approximately 26% of patients over age 60 who had major abdominal or orthopedic surgery under general anesthesia experienced a neurological injury. Additional studies have estimated that a higher percentage of patients experience some neurological decline after heart surgery and that insufficient oxygen delivery to the brain is a frequent cause of this problem. *The Lancet* article reported that injured patients require more assistance with everyday actions, and *The New England Journal of Medicine* article further concluded that new diagnostic and therapeutic strategies must be developed to lessen these injuries.

Oxygen is carried to the brain by hemoglobin in the blood. Hemoglobin passes through the lungs, bonds with oxygen and is pumped by the heart through arteries and capillaries to the brain. Brain cells extract the oxygen and the blood carries away carbon dioxide through the capillaries and veins back to the lungs. Brain oxygen imbalances can be caused by several factors, including changes in oxygen saturation, which is the percentage of hemoglobin contained in a given amount of blood which carries oxygen, in the arteries, blood flow to the brain, hemoglobin concentration and oxygen consumption by the brain.

Brain oxygen information is important in surgical procedures requiring general anesthesia, in other critical care situations with a high risk of brain oxygen imbalances, as well as in the treatment of patients with head injuries or strokes. These procedures include

- heart surgeries,
- heart blood vessel surgeries,
- other blood vessel surgeries,
- surgeries involving elderly patients,
- any neurosurgery,
- major surgeries involving the neck,
- transplant surgeries,
- treatment of patients with diseases resulting from high blood pressure,
- lung problems,
- head, organ or heart injuries, and
- treatment of patients suffering from strokes.

These patients are most commonly found in operating rooms as well as in the other critical care areas of hospitals, especially recovery rooms, intensive care units and emergency rooms. We believe that medical professionals need immediate and continuous information about changes in the oxygen levels in the blood in the brain to identify brain oxygen imbalances. After they are alerted to these imbalances, medical professionals have the information to take corrective action through the introduction of medications, anesthetic agents or mechanical intervention, potentially improving patient outcome and reducing the costs of care. Immediate and continuous information about changes in brain oxygen levels also provides immediate feedback regarding the adequacy of the selected therapy. Equally important, without information about brain oxygen levels, therapy that may not be necessary might be initiated to assure adequate brain oxygen levels. Unnecessary therapy can have an adverse impact on patient safety and increase hospital costs.

A 1999 independent industry report estimates that there are approximately 60,000 operating rooms worldwide performing approximately 50 million surgeries involving general anesthesia every year. Industry sources estimate that, in 1993, there were more than 4.4 million surgeries involving the heart or the blood vessels around the heart in the United States. Such surgeries include more than 600,000 open heart surgeries and 89,000 carotid endarterectomies, which is the removal of blockage in the artery.

Currently, several different methods are used to detect one or more of the factors affecting brain oxygen levels or the effects of brain oxygen imbalances. These methods include

- invasive jugular bulb catheter monitoring,
- transcranial Doppler,
- electroencephalograms, or EEGs,
- intracranial pressure monitoring, and
- neurological examination.

These methods have not been widely adopted to monitor brain oxygen levels in critical care situations for a variety of reasons. The use of any of these methods is limited because it is either

- expensive,
- difficult or impractical to use as a brain monitor,
- invasive,
- not available under some circumstances, such as when the patient is unconscious or has suppressed neural activity,
- not able to measure all of the factors that may affect brain oxygen imbalances,
- not organ specific,
- not able to provide continuous information, or
- able to measure only the effects of brain oxygen imbalances.

Arterial oxygen saturation is only one of the factors that can affect oxygen imbalances in the brain. Pulse oximetry measures oxygen saturation in the arteries. It is non-invasive, uses optical spectroscopy and has become a standard of care for measuring arterial oxygen saturation in critical care situations. However, pulse oximeters require a strong pulse, making them unavailable during bypass surgeries, surgeries involving induced hypothermia or any other time the patient does not have a strong peripheral pulse. Pulse oximeters provide information about the oxygen saturation of the arteries in a finger or earlobe, not oxygen imbalances in the brain. Changes in the oxygen balance in the brain may not have any affect on the oxygen levels in a finger or earlobe. For example, a blocked artery to the brain would affect oxygen in the brain, but would not affect the amount of oxygen in the arteries in the finger.

The Cerebral Oximeter is the only non-invasive monitoring system commercially available in the United States that provides continuous information about changes in the blood oxygen level in the brain. It is easy to use and relatively inexpensive and provides medical professionals with new information to help them identify brain oxygen imbalances. This information may help medical professionals intervene in a timely manner to correct brain oxygen imbalances, provide feedback regarding the adequacy of the selected therapy and provide medical professionals with additional assurance when they make decisions regarding the need for therapy, thereby potentially improving patient outcome and reducing the cost of care.

Market Trends

We believe the market for our products is driven by the following market trends:

Less Invasive Medical Procedures. We believe there is a trend toward less invasive medical procedures. Notable examples include laparoscopic procedures in general surgery and arthroscopic procedures in orthopedic surgery. Such procedures are designed to reduce trauma, thereby decreasing complications, reducing pain and suffering, speeding recovery and decreasing costs associated with patient care. We also believe that there is a trend

to minimize invasive procedures relating to the brain to increase the safety of patients and medical professionals, reduce recovery time and minimize costs.

Demand to Reduce Health Care Costs. Hospitals in the United States are increasingly faced with direct economic incentives to control health care costs through improved labor productivity, shortened hospital stays and more selective performance of medical procedures and use of facilities and equipment. Hospitals often receive a fixed fee from Medicare, managed care organizations and private insurers based on the disease diagnosed, rather than based on the services actually performed. Therefore, hospitals are increasingly focused on avoiding unexpected costs, such as those associated with increased hospital stays resulting from patients with brain damage or other adverse outcomes following surgery. This focus on avoiding unexpected costs is especially pronounced in the operating room and other hospital critical care areas due to their high operating costs. The economic and human costs of brain damage can be tremendous. Even short extensions of hospital stays resulting from brain damage can be expensive. In addition, over-treating a patient as a result of lack of knowledge about brain oxygen levels can result in unnecessary costs.

Organ-Specific Monitoring; Current Emphasis on the Brain. We believe that physicians and hospitals are increasingly interested in monitoring the status of specific organs in the body, especially the brain. We also believe there is an increased interest in understanding how the brain functions and in finding ways to prevent injury to the brain and finding cures to diseases affecting the brain. We believe that this interest has led to a greater focus on monitoring the brain, both to determine how it functions and to monitor the effects of various actions on the brain.

Aging Population. According to the Administration on Aging, United States Department of Health and Human Services, approximately 33.5 million persons in the United States were age 65 or older in 1995, representing 13% of the population. The number of Americans age 65 or older increased by approximately 2.3 million, or 7%, between 1990 and 1995, compared to an increase of 5% for the under-65 population. The Administration on Aging predicts that the number of Americans age 65 or older will increase to approximately 39.4 million by the year 2010 and to approximately 69.4 million by the year 2030. We believe that older patients require a higher level of medical care using more procedures in which the patient or the procedure involves a risk of brain oxygen imbalances.

Business Strategy

Our objective is to establish the Cerebral Oximeter as a standard of care in surgical procedures requiring general anesthesia and in other critical care situations. Key elements of our strategy are as follows:

Target Surgical Procedures With a High Risk of Brain Oxygen Imbalances. We target surgical procedures with a high risk of brain oxygen imbalances, such as heart surgeries, heart blood vessel surgeries, other blood vessel surgeries and surgeries involving elderly patients. We believe that the medical professionals involved in these surgeries are the most aware of the risks of brain damage resulting from brain oxygen imbalances. Therefore, we believe that it will be easier to demonstrate the clinical benefits of the Cerebral Oximeter and potentially gain market acceptance for our products in connection with these surgeries.

Demonstrate Clinical Benefits and Promote Acceptance of the Cerebral Oximeter. We sponsor clinical studies using the Cerebral Oximeter to provide additional evidence of its benefits. We use the resulting publication of any favorable peer-reviewed papers to help convince the medical community of the clinical benefits of the Cerebral Oximeter. We also promote acceptance of the Cerebral Oximeter in the medical community by encouraging surgeons, anesthesiologists and nurses in leading hospitals, whose opinions and practices we believe are valued by other hospitals and physicians, to use the Cerebral Oximeter on a trial basis. We believe that successful evaluations of the Cerebral Oximeter by these medical professionals will accelerate the acceptance of the Cerebral Oximeter by other medical professionals. We are sponsoring discussions among physicians who have used the Cerebral Oximeter about its clinical benefits.

Invest in Marketing and Sales Activities. We have established a distribution network consisting of our direct sales employees, independent sales representatives and distributors. We invest in our marketing and sales efforts to increase the medical community's exposure to our INVOS technology and the Cerebral Oximeter, including continued participation in trade shows and medical conferences, and ongoing product evaluations. We are marketing our products through our existing sales force and independent sales representatives and we leverage our

sales resources through the use of our distributors, including Tyco Healthcare AG, formerly Nellcor Puritan Bennett Export, Inc., in Europe and Baxter Limited in Japan.

Develop Additional Applications of the Cerebral Oximeter. In September 2000, we received clearance from the FDA to market the model 5100 Cerebral Oximeter in the United States. The model 5100 Cerebral Oximeter has the added capability of being able to monitor pediatric patients. Over the longer term, we expect to focus efforts on developing product-line extensions of the Cerebral Oximeter for use on newborns and in other non-brain tissue applications. We believe that these natural extensions of our existing products will increase the market for the Cerebral Oximeter without the more significant development efforts required for entirely new products. Research conducted on children has resulted in a SomaSensor that can fit smaller heads. We believe that non-invasive monitoring is especially important in this patient population, as they generally have lower oxygen reserves than adults, have less blood volume from which to make invasive blood gas measurements and are less tolerant of painful skin punctures and infections.

License Our Technology to Medical Device Manufacturers. We plan to license our Cerebral Oximeter technology to other medical device manufacturers to expand the installed base of Cerebral Oximeters and increase the demand for SomaSensors. Such a license might be made to a company interested in incorporating the Cerebral Oximeter into a multi-function monitor. We believe that such an arrangement could provide another distribution channel for our Cerebral Oximeter. We, however, have no current commitments for any such licenses.

Products and Technology

The Cerebral Oximeter

Our Cerebral Oximeter is the only non-invasive patient monitoring system commercially available in the United States that provides continuous information about changes in the blood oxygen level in the brain. It is a portable and easy-to-use monitoring system that is placed at a patient's bedside in hospital critical care areas, especially operating rooms, recovery rooms, ICUs and emergency rooms. Surgeons, anesthesiologists and other medical professionals use the information provided by the Cerebral Oximeter to identify brain oxygen imbalances and take corrective action, potentially improving patient outcome and reducing the cost of care. Once the cause of a cerebral oxygen imbalance is identified and therapy is initiated, the Cerebral Oximeter provides immediate feedback regarding the adequacy of the selected therapy. It can also provide medical professionals with an additional level of assurance when they make decisions regarding the need for therapy.

Unlike some existing monitoring methods, the Cerebral Oximeter functions even when the patient is unconscious, lacks a strong peripheral pulse or has suppressed neural activity. The measurement made by the Cerebral Oximeter is dominated by the blood in the veins. Therefore, it responds to the changes in factors that affect the balance between cerebral oxygen supply and demand, including changes in arterial oxygen saturation, cerebral blood flow, hemoglobin concentration and cerebral oxygen consumption. The Cerebral Oximeter responds to global changes in brain oxygen levels and to events that affect the brain oxygen levels in the region beneath the SomaSensor.

The Cerebral Oximeter monitoring system is comprised of

- a portable unit including a computer and a display monitor,
- dual single-use, disposable sensors, called SomaSensors,
- proprietary software, and
- a preamplifier cable.

SomaSensors can be placed on both sides of a patient's forehead to offer bi-lateral monitoring and are connected to the computer through the preamplifier cable. The SomaSensors continuously transmit and receive predetermined wavelengths of light sent through the scalp, muscle and skull into the brain tissue. The computer receives the information about the intensity of the light scattered by the blood and tissue in the area being monitored. The computer uses our proprietary software to analyze this information and provide a continuous digital and trend display on the monitor of an index of the oxygen saturation in the area of the brain under the SomaSensors.

The portable unit includes menus that make it easy for users to set high and low audible alarms, customize the display and retrieve data. Single-function keys provide a convenient means to turn on the Cerebral Oximeter, silence alarms, mark important events and print results that can be stored for up to 24 hours and retrieved by a variety of standard, commercially-available printers. The model 4100 Cerebral Oximeter measures approximately 9 inches wide, 8 inches high, and 8 inches deep and weighs approximately 15 pounds; the model 5100 has the same dimensions.

The suggested list price in the United States for the model 4100 Cerebral Oximeter is \$16,995, for the model 5100 Cerebral Oximeter is \$24,000, for the model 4100 SomaSensor is \$50.00, and for the model 5100 SomaSensor is \$75.00. Users of the Cerebral Oximeter will be required to purchase disposable SomaSensors on a regular basis. The SomaSensor may only be used once because after one use it may become contaminated and we do not warrant its effectiveness after one use. We provide a one-year warranty on the Cerebral Oximeter, which we will satisfy by repairing or exchanging those units in need of repair. We also offer maintenance agreements and service for the Cerebral Oximeter for a fee after the warranty expires.

The following table summarizes the principal features and related benefits of the Cerebral Oximeter:

<u>Features</u>	<u>Benefits</u>
FDA-cleared Non-invasive	<ul style="list-style-type: none"> ◦ Access to United States and certain foreign markets ◦ Consistent with market trend toward less invasive medical procedures ◦ No risk to patients and medical professionals ◦ No added patient recovery costs
Continuous Information	<ul style="list-style-type: none"> ◦ Immediate information regarding brain oxygen imbalances ◦ Real-time guide to therapeutic interventions
New Organ-Specific Information	<ul style="list-style-type: none"> ◦ Provides information about oxygen imbalances in both sides of the brain
Relatively Inexpensive	<ul style="list-style-type: none"> ◦ Low cost relative to other brain monitors and medical devices ◦ Small portion of the cost of the procedures in which it is used ◦ New information can potentially improve patient outcome and reduce the cost of care
Easy-to-Use	<ul style="list-style-type: none"> ◦ Does not require a trained technician to operate or interpret ◦ Automatic SomaSensor calibration ◦ Simple user interface and controls ◦ Audible alarm limits
Effective in Difficult Circumstances	<ul style="list-style-type: none"> ◦ Provides information when the patient is unconscious, lacks a strong peripheral pulse or has suppressed neural activity, specifically during cardiac arrest, hypothermia, hypertension, hypotension and hypovolemia ◦ Indicates oxygen imbalances in the brain, not just blood flow, oxygenation of the arteries or the effects of imbalances
Portable	<ul style="list-style-type: none"> ◦ Placed at patient's bedside

Optical Spectroscopy Technology

Our proprietary In Vivo Optical Spectroscopy, or INVOS, technology is based primarily on the physics of optical spectroscopy. Optical spectroscopy is the interpretation of the interaction between matter and light. Spectrometers and spectrophotometers function primarily by shining light through matter and measuring the extent to which the light is transmitted through, or scattered or absorbed by, the matter. Physicians and scientists can use spectrophotometers to examine human blood and tissue. Although most human tissue is opaque to ordinary light, some wavelengths penetrate tissue more easily than others. Therefore, by shining appropriate wavelengths of light into the body and measuring its transmission, scattering and absorption, or a combination, physicians can obtain information about the matter under analysis. Optical spectroscopy generates no ionizing radiation and produces no known hazardous effects.

Optical spectroscopy was first used clinically in the 1940s at the Sloan-Kettering Institute for cancer research. The pulse oximeter uses optical spectroscopy to determine the oxygen saturation of the blood in the arteries in peripheral tissue, such as in a finger or an earlobe. By identifying the hemoglobin and the oxygenated hemoglobin and measuring the relative amounts of each, oxygen saturation of hemoglobin can be measured. However, optical spectroscopy was generally not useful when the substances to be measured were surrounded by, were behind, or were near bone, muscle or other tissue, because they produce extraneous data that interferes with analysis of the data from the area being examined.

INVOS Technology

The Cerebral Oximeter is based on our INVOS technology. In 1982, we began developing a spectroscopic instrument to measure breast tissue abnormalities. Our first product, the Somanetics INVOS 2100 System, used the same INVOS technology as the Cerebral Oximeter. Later, we began analyzing the use of INVOS technology to measure changes in cellular metabolism in the brain. Early studies conducted with the Henry Ford Neurosurgical Institute demonstrated the ability of our INVOS technology to make measurements that were highly correlated to controlled changes in animal brain cell metabolism. In 1988, we began clinical studies of the Cerebral Oximeter on human patients in operating rooms, emergency rooms and intensive care units at Henry Ford Hospital and later at Bowman Gray School of Medicine and Mount Sinai Medical Center.

Like other applications of optical spectroscopy, INVOS analyzes various characteristics of human blood and tissue by measuring and analyzing low-intensity visible and near-infrared light transmitted into portions of the body. It measures the composition of substances by detecting the effect they have on light. The INVOS technology measurement is made by transmitting low-intensity visible and near-infrared light through a portion of the body and detecting the manner in which the molecules of the exposed substance interact with light at specific wavelengths. INVOS technology detects this interaction by measuring the intensity of the various wavelengths of light received by light sensors. By measuring the effect on specific wavelengths of light caused by oxygenated hemoglobin contained in blood in the region of the brain being monitored, the Cerebral Oximeter can monitor changes in the approximate oxygen saturation of the hemoglobin in that region of the brain.

We have developed a method of reducing extraneous spectroscopic data caused by surrounding bone, muscle and other tissue. This method allows us to gather information about portions of the body that previously could not be analyzed using traditional optical spectroscopy. The dual detector design of the SomaSensor enables us to measure scattered light intensities from the intermediate tissues of skin, muscle and skull in a separate process. Each SomaSensor contains two light detectors and a light source. While both detectors receive similar information about the tissue outside the brain, the detector further from the light source detects light that has penetrated deeper into the brain, and, therefore, receives more information specific to the brain than does the detector closer to the light source. By subtracting the two measurements, INVOS technology is able to suppress the influence of the tissues outside the brain to provide a measurement of changes in brain oxygen saturation.

Research and Development

We are currently focusing our research and development efforts on the advancement of the design and production processes of the Cerebral Oximeter and SomaSensor. Over the longer term, we expect to focus efforts on developing product-line extensions of the Cerebral Oximeter for use on newborns, other non-brain tissue applications, and advancement of the design and production processes of the Cerebral Oximeter and SomaSensor. In September 2000, we received clearance from the FDA to market the model 5100 Cerebral Oximeter in the United States. The model 5100 Cerebral Oximeter has the added capability of being able to monitor pediatric patients. We have redesigned the SomaSensor for use on smaller heads. We believe that non-invasive monitoring is especially important in this patient population, as they generally have lower oxygen reserves than adults, have less blood volume from which to make invasive blood gas measurements, and are less tolerant of painful skin punctures and infections.

We spent \$777,974 during fiscal 2001 on research, development and engineering, \$513,816 during fiscal 2000, and \$598,348 during fiscal 1999.

Marketing, Sales and Distribution

Marketing

The Cerebral Oximeter is for use on patients at risk of brain oxygen imbalances. These patients are most commonly found in operating rooms undergoing general anesthesia for various surgical procedures as well as in the other critical care areas of hospitals, especially recovery rooms, intensive care units and emergency rooms. After the Cerebral Oximeter is accepted in hospitals, future markets might include free-standing operating rooms, clinics, ambulances and nursing homes.

We market the Cerebral Oximeter primarily to cardiac, cardiovascular and vascular surgeons, neurosurgeons and anesthesiologists. We believe that these specialists are the medical professionals most aware of the risks of brain damage resulting from brain oxygen imbalances. We and our distributors have concentrated our sales efforts on the major teaching hospitals in the United States and selected foreign markets in which we have commenced commercial sales and on other large United States hospitals, especially those we consider opinion leaders. In addition, we sponsor discussions among physicians who have used the Cerebral Oximeter about its clinical benefits.

We believe that favorable peer review is a key element to a product's success in the medical equipment industry. Accordingly, we support clinical research programs with third-party clinicians and researchers intended to demonstrate the need for the Cerebral Oximeter and its clinical benefits with the specific objective of publishing the results in peer-reviewed journals. The research primarily consists of studies comparing cerebral oximetry measurements with objective measures of patient outcome and hospital costs, including patient length of stay, length of time on the ventilator, and incidence of stroke. In addition, fully randomized studies are being pursued that investigate the ability of clinicians to improve patient outcomes and reduce hospital costs by managing patients based on information provided by the Cerebral Oximeter. We attend trade shows and medical conferences to introduce and promote the Cerebral Oximeter and to meet medical professionals with an interest in performing research and reporting their results in peer-reviewed medical journals and at major international meetings. For example, a number of intervention outcome studies were presented in 2001 demonstrating the relationship between monitoring changes in regional brain blood oxygen saturation and reductions in neurological complications and hospital length of stay:

- a 286-patient intervention outcome study conducted by Dr. Fun-Sun Yao, M.D., Professor of Anesthesia, the Weill Medical College of Cornell University demonstrated that maintaining adequate regional brain blood oxygen saturation levels during cardiac surgery, by monitoring with the Cerebral Oximeter and intervening as needed, resulted in significantly reduced strokes and comas in these patients. The intervention outcome study results were presented at the 2001 annual meeting of the American Society of Anesthesiologists in October 2001. The American Society of Anesthesiologists considered these results important, and issued a news release discussing the potential improvements in outcome through intervention based on information provided by cerebral oximetry.
- a 340-patient intervention outcome study from the Weill Medical College of Cornell University demonstrated that maintaining regional brain blood oxygen saturation at adequate levels during cardiac surgery, as monitored with the Cerebral Oximeter and intervening as needed, shortened intensive care unit and hospital stays on average for these patients. The intervention group had fewer and, on average, shorter brain blood oxygen desaturation events and had significantly shorter average ICU and hospital stays than the control group. On average, ICU stays were shortened by one and a half days and hospital length of stay was reduced by about two days. The intervention outcome study results were presented in May 2001 at the annual meeting of the Society of Cardiovascular Anesthesiologists in Vancouver.
- a 306-patient intervention outcome study performed at Hackensack University Medical Center demonstrated that using the Cerebral Oximeter to guide the management of brain blood oxygen saturation during cardiac surgery reduced neurological complications, renal failure and patient hospital length of stay on average for these patients. Neurological complications were 55 percent lower, and renal failure, which can be a significant and costly complication of cardiac surgery, was 45 percent

lower in these patients compared to the control group. In addition, overall hospital average length of stay of monitored patients was 1.37 days shorter compared to a control group of cardiac surgery patients operated on at the same time at the facility. These findings suggest that inadequate brain oxygenation may be responsible for neurological complications that are preventable, and preventing these complications could result in reduced length of stay. The study was presented at the 2001 Outcomes, Cardiac and Vascular Surgery: Neurobehavioral Assessment, Physiological Monitoring and Cerebral Protective Strategies meeting.

- o a 56-patient study performed at the University of Louisville Health Science Center reported that brain blood oxygenation, as monitored by the Cerebral Oximeter, may decline during cardiopulmonary bypass surgery, even when blood pressure is considered to be adequate. In one-third of the cases, clinically significant declines in brain blood oxygenation occurred despite an apparently adequate blood pressure (mean arterial pressure above 70 mm Hg). Frequent, temporary decreases in oxygen saturation of the blood in the brain, as monitored by the Cerebral Oximeter and confirmed by transcranial Doppler, occurred despite presumably adequate blood pressure. This suggests that blood pressure is an incomplete indicator of brain blood oxygenation during cardiopulmonary bypass surgery. This observation may help explain the inconsistent association between blood pressure during an operation and neurological complications after the operation. These results were presented at the 2001 Annual Meeting of the American Society of Anesthesiologists.

Sales and Distribution

We sell the Cerebral Oximeter through our direct sales force, independent sales representatives and independent distributors. In the United States, we sell the Cerebral Oximeter through our eight direct salespersons, one clinical specialist and 11 independent sales representatives. Our sales compensation and incentive plans are designed to motivate our direct sales force by making half of their targeted compensation dependent on meeting targeted sales levels. We believe that the minimum selling cycle for new medical devices is approximately six to nine months.

Internationally, we have distribution agreements with six independent distributors covering 59 countries for the model 4100 Cerebral Oximeter, and our distribution agreements with four of those distributors cover 57 countries for the model 5100 Cerebral Oximeter. Our distributors include Tyco Healthcare AG, formerly Nellcor Puritan Bennett Export, Inc., part of Tyco International Ltd., in Europe, and Baxter Limited in Japan. Our agreement with Tyco Healthcare AG covers 40 countries for the model 4100 and model 5100 Cerebral Oximeters. In March 1995, we engaged Baxter Limited as our exclusive distributor in Japan. In January 1999, the Japanese Ministry of Health and Welfare licensed Baxter Limited to market the INVOS 4100 Cerebral Oximeter in Japan.

During fiscal 1998, we began a no-cap sales program whereby we ship the model 4100 Cerebral Oximeter to the customer at no charge, and the customer agrees to purchase a minimum quantity of SomaSensors, on a monthly basis, at a premium, for a stated period of time.

We did not have any backlog of firm orders as of January 10, 2002 or as of January 2, 2001. We generally do not have a backlog of firm orders.

For a description of sales to major customers, see Note 10 of Notes to Financial Statements included in Item 8 of this Report. Tyco Healthcare AG, formerly Nellcor Puritan Bennett Export, Inc., was our largest customer in fiscal 2001 and fiscal 2000, and our distributor in Japan was our largest customer in fiscal 1999. We are dependent on our sales to Tyco Healthcare AG in Europe, and the loss of them as a customer would have an adverse effect on our business, financial condition and results of operations.

Our export sales were approximately \$1,595,000 for the fiscal year ended November 30, 2001, \$2,265,000 for the fiscal year ended November 30, 2000, and \$1,632,000 for the fiscal year ended November 30, 1999. See Note 10 of Notes to Financial Statements. For a description of the breakdown of sales between model 5100 Cerebral Oximeters, model 4100 Cerebral Oximeters, model 4100 exchanges, and SomaSensors, see "Management's Discussion and Analysis of Financial Condition and Results of Operations — Results of Operations."

Manufacturing

We assemble the Cerebral Oximeter in our facilities in Troy, Michigan, from components purchased from outside suppliers. We assemble the Cerebral Oximeter to control its quality and costs and to permit us to make changes to the Cerebral Oximeter faster than we could if third-parties assembled it. We believe that each component is generally available from several potential suppliers. The SomaSensor, the printed circuit boards, other mechanical components and the unit enclosure are the primary components that must be manufactured according to specifications provided by us. Although we are currently dependent on one manufacturer of the SomaSensor, we believe that several potential suppliers are available to assemble the components of the Cerebral Oximeter. We would, however, require approximately three to four months to change SomaSensor suppliers. We do not currently intend to manufacture on a commercial scale the disposable SomaSensor or the components of the Cerebral Oximeter.

On June 11, 1998, we received ISO 9001 certification and met the requirements under the European Medical Device Directive to use the CE Mark, thereby allowing us to continue to market our products in the European Economic Community. Our most recent ISO 9001 compliance surveillance audit occurred in July 2001.

Competition

We do not believe there is currently any direct commercial competition for the Cerebral Oximeter. We believe, however, that the market for cerebral oximetry products is in the early stages of its development and, if it develops, might become highly competitive. We are aware of foreign companies that have sold products relating to cerebral metabolism monitoring for research or evaluation.

The medical products industry is characterized by intense competition and extensive research and development. Other companies and individuals are engaged in research and development of non-invasive cerebral oximeters, and we believe there are many other potential entrants into the market. Some of these potential competitors have well established reputations, customer relationships and marketing, distribution and service networks, and have substantially longer histories in the medical products industry, larger product lines and greater financial, technical, manufacturing, research and development and management resources than ours. Many of these potential competitors have long-term product supply relationships with our potential customers. These potential competitors might develop products that are at least as reliable and effective as our products, that make additional measurements, or that are less costly than our products. These potential competitors might be more successful than we are in manufacturing and marketing their products and might be able to take advantage of the significant time and effort we have invested to gain medical acceptance of cerebral oximetry. In addition, two patents issued to an unaffiliated third party and relating to cerebral oximetry expired in 2000, one patent issued to an unaffiliated third party and relating to cerebral oximetry expired in 1999, and two patents issued to an unaffiliated third party and relating to cerebral oximetry expired in 1998. These expiring patents will make that technology generally available and potentially help the development of competing products. See "Market Overview."

We also compete indirectly with the numerous companies that sell various types of medical equipment to hospitals for the limited amount of funding allocated to capital equipment in hospital budgets. The market for medical products is subject to rapid change due to an increasingly competitive, cost-conscious environment and to government programs intended to reduce the cost of medical care. Many of these manufacturers of medical equipment are large, well-established companies whose resources, reputations and ability to leverage existing customer relationships might give them a competitive advantage over us. Our products and technology also compete indirectly with many other methods currently used to measure blood oxygen levels or the effects of low blood oxygen levels.

We believe that a manufacturer's reputation for producing accurate, reliable and technically advanced products, references from users, features (speed, safety, ease of use, patient convenience and range of applicability), product effectiveness and price are the principal competitive factors in the medical products industry.

Proprietary Rights Information

We have fifteen United States patents and fifteen patents in various foreign countries. Our patents basically cover methods and apparatus for introducing light into a body part and receiving, measuring and analyzing the resulting light and its interaction with tissue. These methods also involve receiving, measuring and analyzing the light transmissivity of various body parts of a single subject, as well as of body parts of different subjects, which provides a standard against which a single subject can be compared. Although we believe that one or more of our issued patents cover some of the underlying technology used in the Cerebral Oximeter, only ten of the issued patents expressly refer to examination of the brain or developments involving the Cerebral Oximeter.

Our initial United States patent, covering the in vivo tissue examination technology developed in conjunction with the INVOS 2100 and its predecessor, the SOMA 100, was allowed and issued in 1986 and will expire on October 14, 2003. The corresponding Canadian patent was issued in 1987, the corresponding European Community patent was issued in 1990, with related patents issued in the ten Western European countries that were then member states, and the corresponding Japanese patent was issued in 1991. Our fourteen additional United States patents expire on various dates from February 2005 to December 2014. We also have one patent application pending in the United States and a number of patent applications in various foreign countries with respect to other aspects of our technology relating to the interaction of light with tissue.

Many other patents have previously been issued to third parties involving optical spectroscopy and the interaction of light with tissue, some of which relate to the use of optical spectroscopy in the area of brain metabolism monitoring, the primary use of the Cerebral Oximeter. No patent infringement claims have been asserted against us.

In addition to our patent rights, we have obtained United States Trademark registrations for our trademarks "SOMANETICS," "SOMAGRAM," "INVOS," "SOMASENSOR" and "WINDOW TO THE BRAIN." We have also obtained registrations of our basic mark, "SOMANETICS," in eleven foreign countries.

We also rely on trade secret, copyright and other laws and on confidentiality agreements to protect our technology, but we believe that neither our patents nor other legal rights will necessarily prevent third parties from developing or using similar or related technology to compete against our products. Moreover, our technology primarily represents improvements or adaptations of known optical spectroscopy technology, which might be duplicated or discovered through our patents, reverse engineering or both.

Government Regulation

The testing, manufacture and sale of our products are subject to regulation by numerous governmental authorities, principally the FDA and corresponding state and foreign agencies. Pursuant to the Federal Food, Drug, and Cosmetic Act, and the related regulations, the FDA regulates the preclinical and clinical testing, manufacture, labeling, distribution and promotion of medical devices. If we do not comply with applicable requirements, we can be subject to, among other things,

- o fines,
- o injunctions,
- o civil penalties,
- o recall or seizure of products,
- o total or partial suspension of production,
- o failure of the government to grant premarket clearance or premarket approval for devices,
- o withdrawal of marketing clearances or approvals and
- o criminal prosecution.

A medical device may be marketed in the United States only if the FDA gives prior authorization, unless it is subject to a specific exemption. Devices classified by the FDA as posing less risk than class III devices are categorized as class I or II and are eligible to seek "510(k) clearance." 510(k) clearance generally is granted when

submitted information establishes that a proposed device is “substantially equivalent” in intended use and other factors, such as technological characteristics, to a class I or II device already legally on the market or to a “preamendment” class III device, which is one that has been in commercial distribution since before May 28, 1976, for which the FDA has not called for PMA applications, which are defined below. In recent years, the FDA has been requiring a more rigorous demonstration of substantial equivalence than in the past, including requiring clinical trial data in many cases. For any devices that are cleared through the 510(k) process, modifications or enhancements that could significantly affect safety or effectiveness, or constitute a major change in the intended use of the device, will require new 510(k) submissions. We believe that it now usually takes from three to six months from the date of submission to obtain 510(k) clearance, but it can take substantially longer. We cannot assure you that any of our devices or device modifications will receive 510(k) clearance in a timely fashion, or at all. The Cerebral Oximeter has been categorized as a class II device. The CorRestore patch has been categorized as a class II device.

A device requiring prior marketing authorization that does not qualify for 510(k) clearance is categorized as class III, which is reserved for devices classified by the FDA as posing the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices that are not substantially equivalent to a legally marketed class I or class II device. A class III device generally must receive approval of a premarket approval, or PMA, application, which requires proving the safety and effectiveness of the device to the FDA. The process of obtaining PMA approval is expensive and uncertain. We believe that it usually takes from one to three years after filing, but it can take longer.

If human clinical trials of a device are required, whether for a 510(k) or a PMA application, and the device presents a “significant risk,” the sponsor of the trial, which is usually the manufacturer or the distributor of the device, will have to file an investigational device exemption, or IDE, application before beginning human clinical trials. The IDE application must be supported by data, typically including the results of animal and laboratory testing. If the IDE application is approved by the FDA and one or more appropriate Institutional Review Boards, or IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a “nonsignificant risk” to the patient, a sponsor may begin the clinical trial after obtaining approval for the study by the IRB at each clinical site without the need for FDA approval.

In June 1992, we received 510(k) clearance from the FDA to market the Cerebral Oximeter in the United States for use on adults. We began commercial shipments of Cerebral Oximeters and SomaSensors in May 1993. In November 1993, we received notification that the FDA had rescinded our 510(k) clearance to market the Cerebral Oximeter. As a result, all commercial sales of our product were suspended. In February 1994, we resumed marketing our product in several foreign countries. In June 1996, we received 510(k) clearance from the FDA to market the Cerebral Oximeter, including the SomaSensor, in the United States. In October 1997, we obtained FDA clearance for new advances in our INVOS technology that are incorporated in our model 4100 Cerebral Oximeter. We introduced the model 4100 Cerebral Oximeter in October 1997 and began shipments in the first quarter of fiscal 1998. In September 2000, we received 510(k) clearance from the FDA to market the model 5100 Cerebral Oximeter in the United States. The model 5100 Cerebral Oximeter has the added capability of being able to monitor pediatric patients.

In October 1997, we obtained FDA clearance for advances in our INVOS technology that are incorporated in our model 4100 Cerebral Oximeter. We made additional minor changes to the model 3100A Cerebral Oximeter that resulted in the model 4100 Cerebral Oximeter and we have made additional minor changes to the SomaSensor. We do not believe that these changes could significantly affect the safety or efficacy of the Cerebral Oximeter or the SomaSensor and, therefore, we believe that these changes do not require the submission of a new 510(k) notice. The FDA, however, could disagree with our determination not to submit a new 510(k) notice for the model 4100 Cerebral Oximeter or SomaSensor and could require us to submit a new 510(k) notice for any changes made to the device. If the FDA requires us to submit a new 510(k) notice for our model 4100 Cerebral Oximeter or SomaSensor or for any device modification, we might be prohibited from marketing the modified device until the 510(k) notice is cleared by the FDA.

In November 2001 we received clearance from the FDA to market the CorRestore patch in the United States.

Any devices we manufacture or distribute pursuant to FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA and some state agencies. Manufacturers of medical devices marketed in the United States must comply with detailed Quality System Regulation, or QSR, requirements, which include testing, control, documentation and other quality assurance procedures. Manufacturers must also comply with Medical Device Reporting requirements. These requirements require a manufacturer to report to the FDA any incident in which its product may have caused or contributed to a death or serious injury, or in which its product malfunctioned and, if the malfunction were to recur, it would likely cause or contribute to a death or serious injury. Labeling and promotional activities are subject to scrutiny by the FDA and, in some circumstances, by the Federal Trade Commission. Current FDA enforcement policy prohibits marketing approved medical devices for unapproved uses.

We are subject to routine inspection by the FDA and some state agencies for compliance with QSR requirements and other applicable regulations. Our most recent FDA QSR inspection occurred in October 2001. We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances.

If any of our current or future FDA clearances or approvals are rescinded or denied, sales of our applicable products in the United States would be prohibited during the period we do not have such clearances or approvals. In such cases we would consider shipping the product internationally and/or assembling it overseas if permissible and if we determine such product to be ready for commercial shipment. The FDA's current policy is that a medical device that is not in commercial distribution in the United States, but which needs 510(k) clearance to be commercially distributed in the United States, can be exported without submitting an export request and prior FDA clearance provided that

- the company believes the device can be found to be substantially equivalent through a 510(k) submission,
- the device is labeled and intended for export only,
- the device meets the specifications of the foreign purchaser, and
- other conditions of the export provisions of the Federal Food, Drug, and Cosmetic Act and the Export Reform Act have been met.

Seasonality

Our business is seasonal. Our third quarter sales have typically been lower, compared to other fiscal quarters, principally because the fiscal quarter coincides with the summer vacation season, especially in Europe, the United States and Japan.

The CorRestore System

Market Overview

Congestive heart failure is when the heart is unable to pump enough blood to meet the circulation needs of the body. It is the number one cause of death for persons over age 65. Approximately 5,000,000 persons in the United States have been diagnosed with congestive heart failure, and each year an estimated 550,000 additional persons in the United States are diagnosed with this condition. An estimated 30% of those with congestive heart failure are in Class III or IV, based on the New York Heart Association classifications. These classifications divide patients into four classes based on how debilitating their condition is. Of these patients in Classes III and IV, only approximately 61% survive one year after they are diagnosed with congestive heart failure, and, for all classes, there is a 40% annualized rate of admission to the hospital for congestive heart failure.

One of the many causes of congestive heart failure is dilated cardiomyopathy, which is generally a disease that damages the heart muscle, resulting in an enlarged ventricle. The left ventricle is the chamber of the heart that pumps the blood through the body. Most cases of congestive heart failure result from the failure of the left ventricle and the resulting backup of fluid in the lungs. As a result of dilated cardiomyopathy, the muscles in the ventricle become thinner and weaker, the ventricle becomes enlarged, and it is not able to pump blood through the body with enough force. Often the body reacts with short-term solutions that further damage the muscle. Drug therapies can

be used to treat congestive heart failure, but they often only relieve symptoms or reduce the body's reactions to the problem with the pump.

Ventricular restoration is a surgical technique that can be used to treat some patients suffering from congestive heart failure. It involves reducing the size of the ventricle to restore more normal function. During SVR, the surgeon restores an enlarged, poorly functioning left ventricle to more normal size and function by inserting an implant, in most instances, or closing the defect directly. Two heart surgeons and their company, CorRestore LLC, have designed and patented a patch for use in SVR that they believe is easier to implant and provides a better seal against leaks at the perimeter than existing patches, which are formed by the surgeon during the surgery out of dacron or bovine pericardium tissue. These existing patches take time for the surgeon to form, can be difficult to insert, and can leak around the edges. One study of SVR surgeries using existing dacron patches indicates a higher 12-month and 18-month survival rate and a lower hospital re-admission rate for patients undergoing SVR.

We believe that the trends in aging of the population and the demand to reduce health care costs, and the increased survival rate after initial heart problems, will increase the number of persons diagnosed with congestive heart failure and will increase the demand for procedures that can increase the survival rate and decrease the hospital re-admission rate for these patients.

Business Strategy

Our objective is to obtain regulatory clearance or approval to sell the CorRestore System and to have the system used in SVR surgeries. Key elements of our strategy are as follows:

Obtain Regulatory Clearance or Approval for the CorRestore System. We are currently working to obtain regulatory approvals for the CorRestore System, including CE certification, and to begin marketing the CorRestore System in the United States. In November 2001 we received clearance from the FDA to market the CorRestore patch in the United States.

Target Surgical Procedures Where Benefits Have Been Demonstrated. Our initial target market is SVR surgeries on Class III and IV congestive heart failure patients with dilated ischemic cardiomyopathy due to a previous myocardial infarction in the anterior wall of the left ventricle. Dilated ischemic cardiomyopathy is a damaged heart muscle caused by the obstruction of the inflow of blood from the arteries and resulting in an enlarged ventricle. Myocardial infarction is death of an area of the middle muscle layer in the heart wall. One study of SVR surgeries on these patients, using patches that were formed by the surgeon during the surgery out of dacron, indicates a higher 12-month and 18-month survival rate and a lower hospital re-admission rate for patients undergoing SVR. These existing patches take time for the surgeon to form, can be difficult to insert, and can leak around the edges. Therefore, we believe it will be possible to demonstrate the clinical benefits of the CorRestore System and to gain market acceptance for this product in connection with these surgeries.

Demonstrate the Clinical Benefits and Promote Acceptance of the CorRestore System. We intend to sponsor clinical studies using the CorRestore System to provide additional evidence of its benefits. The resulting publication of any favorable papers can be used to help convince the medical community of the clinical benefits of the CorRestore System. We also expect to promote the acceptance of the CorRestore System in the medical community by encouraging cardiac surgeons in leading hospitals, whose opinions and practices we believe are valued by other hospitals and physicians, to use the CorRestore System. We believe that the successful evaluations of the CorRestore System by these medical professionals will accelerate the acceptance of the CorRestore System by other medical professionals.

Invest in Marketing and Sales Activities. We expect to use a distribution network of direct sales employees and independent sales representatives to distribute the product in the United States. We expect to be dependent on international distributors for international sales of the CorRestore System. We also expect to invest in marketing and sales efforts to increase the medical community's exposure to the CorRestore System, including participation in trade shows, conducting seminars and direct advertising. We expect to realize some synergies with our Cerebral Oximeter selling efforts because our sales personnel will be calling on some of the same customers to sell both products.

Establish an Insurance Reimbursement Code for SVR. We desire to obtain a reimbursement code for SVR from private and government insurers. These codes permit medical insurance reimbursement for this procedure. We believe reimbursement would increase use of the procedure and the CorRestore System. We might not be able to get a reimbursement code for SVR, and sales of the CorRestore System could be harmed if we fail to obtain these codes.

Product

We are developing the CorRestore System for use in cardiac repair and reconstruction, including heart surgeries called surgical ventricular restoration, or SVR. During SVR, the surgeon restores an enlarged, poorly functioning left ventricle to more normal size and function by inserting an implant, in most instances, or closing the defect directly. SVR is currently generally performed using a patch that is formed by the surgeon during the surgery out of dacron or bovine pericardium tissue. These existing patches take time for the surgeon to form, can be difficult to insert, and can leak around the edges.

As a result of these problems, the inventors developed a non-circular bovine pericardium, or cow heart-sac, tissue patch with an integrated soft dacron suture ring. It is being developed to make SVR easier for the surgeon and to provide a better seal on the edges of the patch to minimize leaking. The inventors and their company, CorRestore LLC, filed for a patent with respect to their patch, which was issued in part in February 2000 and expires in May 2018. Other claims under the patent application are still pending. The claims allowed relate primarily to the product design of a soft suture ring integrated with a patch. In addition, other United States and foreign patent applications are pending.

We plan to offer the CorRestore System, which is a kit containing the patches, needles, strips of pericardium, sizers, holders and sutures, to hospitals performing SVR. We currently expect the retail price of these kits to be \$3,500 to \$4,000, although we have done only preliminary market research regarding our proposed pricing. See "Competition." Prices to distributors will be significantly discounted from the retail price. Because of the requirements for sterility and pursuant to our license agreement, the patches and kits will be manufactured for us by PM Devices, Inc. We are dependent on PM Devices, Inc. to manufacture our entire requirements for the patches and the kits. We have already entered into a Contract Development and Manufacturing Agreement with PM Devices, Inc. Although we are currently dependent on PM Devices, Inc. as a manufacturer, we believe that several potential suppliers are available. However, we are uncertain as to the length of time it would take to change suppliers.

Marketing

We believe that favorable peer review is a key element to a product's success in the medical equipment industry. In May 2001, the results of a 13-center, 662-patient study evaluating the safety and effectiveness of SVR reported improvement in patient function based on New York Heart Association classification criteria, improvement in readmission and survival rates, and improvement in ejection fraction for SVR patients. Most of the patients in the study were severe New York Hospital Association Class III and Class IV congestive heart failure patients. Of the 355 patients for whom New York Heart Association classifications were reported at the last follow up, 91 percent improved functionally, with 61 percent classified as Class I and 30 percent as Class II. Readmission data was obtained on 658 patients. Of these patients, 88.7 percent were not readmitted to the hospital for congestive heart failure during the three years after their SVR surgery. By comparison, the annual hospital admission rate for Class III and IV heart failure patients is more than 40 percent and 24 percent are admitted two or more times each year.

The overall survival rate for the study group was 89.4 percent at three years. In addition, post-operatively, the ejection fraction of these patients increased from 29.7 % to 40% and the left ventricular end systolic volume index decreased from 96 ml/m² to 62 ml/m². These results were presented at the May 2001 meeting of the American Association for Thoracic Surgery, and published in the October 2001 issue of *Seminars in Thoracic and Cardiovascular Surgery*. They updated the 18-month results of a study of 439 SVR patients that was published in a peer-reviewed article in the April 2001 issue of the *Journal of the American College of Cardiology*.

Sales and Distribution

In the first quarter of fiscal 2002, we expect to execute the initial phase of the CorRestore System market launch plan, including gaining our initial customer experience and obtaining feedback that will be used to evaluate and finalize our marketing and training programs and materials. In January 2002, we performed the first implantation of our CorRestore System, and we expect to start our broader market launch in the second quarter of 2002.

We expect that the target market for the CorRestore System will be cardiac centers. In the United States, we expect to use a distribution network of direct sales employees and independent sales representatives to distribute the CorRestore System. Internationally, we intend to sell the CorRestore System through independent distributors.

License Agreement

We entered into a license agreement as of June 2, 2000 with the inventors and their company, CorRestore LLC. The license grants us worldwide, royalty-bearing licenses to specified rights relating to the CorRestore System and related products and accessories for SVR, subject to the terms and conditions of the license agreement. The license also grants us the right to use the names of the inventors and CorRestore on CorRestore System products, as trademarks and in advertising, as long as they do not object to such use within 20 days after the proposed use is submitted to them. We also have specified rights to future developments relating to the CorRestore System products if we incorporate the developments in the system products, begin testing them, receive clearances to market them and actually begin marketing them within specified time periods. Transfer and sublicensing of our licenses are restricted by the license agreement.

Pursuant to the license agreement, CorRestore LLC has agreed to provide us with various consulting services for up to 10 days during each of our fiscal years during the term of the licenses. These services include the following relating to the CorRestore System:

- assisting us in designing and executing the clinical tests necessary to demonstrate the safety and efficacy of the CorRestore System or to obtain regulatory approvals;
- assisting us in preparing and defending applications for regulatory approvals and patent and other intellectual property applications;
- training our personnel and customers in the use of the CorRestore System;
- providing ongoing technical and general consulting and advice;
- assisting with product designs; and
- consulting with us in connection with regulatory applications, marketing efforts and efforts to obtain insurance reimbursement codes.

We have agreed to pay all of the expenses of such consultation, of clinical testing of the CorRestore System and of the existing patent and future patent applications or registrations after the date of the license. We are dependent on the inventors for further development of the CorRestore System, training doctors in SVR and training our personnel and customers in the use of the CorRestore System.

In exchange for the licenses and consulting services, we agreed to the following compensation for CorRestore LLC and its agent, Wolfe & Company:

- A royalty of 10% of our net sales of products subject to the licenses, for the term of the patent relating to the CorRestore System, or for 10 years from the date of the first commercial sale if the patent is determined to be invalid.
- Five-year warrants to purchase up to 400,000 common shares at \$3.00 a share. The warrants became exercisable to purchase 300,000 shares immediately and became exercisable to purchase an additional 50,000 shares when we received clearance from the FDA to market the CorRestore patch in the United States and become exercisable to purchase another 50,000 shares when we receive CE certification for the CorRestore System. The warrant expires when the license terminates, except that the vested

portion of the warrant remains exercisable for an additional 90 days or, if the licenses terminate because of specified breaches by us, for the remaining term of the warrant.

- Five-year warrants to purchase 2,100,000 common shares at \$3.00 a share, granted when we received clearance from the FDA to market the CorRestore patch in the United States. The warrants will become exercisable based on our cumulative net sales of the CorRestore System products as follows:

<u>Net Sales</u>	<u>Additional Portion of Shares</u>
\$5,000,000	233,330
\$10,000,000	233,330
\$20,000,000	233,340
\$35,000,000	350,000
\$55,000,000	466,000
\$80,000,000	584,000

The warrant expires when the license terminates, except that the vested portion of the warrant remains exercisable for an additional 90 days or, if the licenses terminate because of specified breaches by us, for the remaining term of the warrant.

- A consulting fee of \$25,000 a year to each of the inventors until we sell 1,000 CorRestore patches.

We have also agreed to increase the size of our Board of Directors and add CorRestore LLC's designee as a director. Joe B. Wolfe is CorRestore LLC's designee and he has been added as a Class I director. We have also agreed to cooperate with CorRestore LLC to establish a mutually acceptable medical advisory board to provide us with information and advice regarding the CorRestore System. The inventors and CorRestore LLC also agreed to specified confidentiality, non-competition and non-solicitation provisions in the license agreement and we agreed to specified confidentiality provisions in the license agreement.

CorRestore LLC and the inventors may terminate the licenses as follows:

- In their sole discretion, within 120 days after we consummate specified types of business combination transactions with another entity and the holders of our common shares immediately before the transaction hold less than 50% of the surviving entity's or its ultimate parent's outstanding voting securities immediately after the transaction, but only if (1) the transaction is consummated before June 2, 2002, and (2) the consideration received by our shareholders in the transaction has a fair market value of less than \$10.00 a share.
- In their sole discretion, if Bruce J. Barrett ceases to be our chief executive officer or ceases to be responsible for our activities relating to the licenses, but only if (1) one of these events happens before June 2, 2005, and (2) CorRestore LLC or either of the inventors exercises the right to terminate within 120 days after the event occurs.
- In their sole discretion, if we materially breach specified covenants in the license agreement and fail to cure the breach within 90 days (30 days for payment obligations) after CorRestore LLC notifies us of the breach, but only if CorRestore LLC exercises its right to terminate within 120 days after the 90-day cure period expires.
- In their sole discretion, if our common shares are delisted from The Nasdaq Stock Market and are not re-listed within 90 days, but only if CorRestore LLC exercises its right to terminate within 120 days after the 90-day period expires.
- In their sole discretion, if we make an assignment for the benefit of our creditors or voluntarily commence any bankruptcy, receivership, insolvency or liquidation proceedings and the action is not reversed or terminated within 90 days, but only if CorRestore LLC exercises its right to terminate within 120 days after the 90-day period expires.

CorRestore LLC and the inventors may limit the licenses as follows:

- CorRestore LLC may exclude specified countries from the geographic scope of the license if we have not begun marketing the CorRestore System products or begun the process of obtaining necessary

regulatory approval to sell CorRestore System products in that country within one year after the date we file a 510(k) clearance application or PMA approval application with the FDA with respect to the CorRestore patch products. The countries may be excluded from the license only if we fail to cure the breach of this provision within 90 days after CorRestore LLC notifies us of the breach.

- CorRestore LLC may change our licenses to be non-exclusive for developments that we do not incorporate in the CorRestore System products, begin marketing or testing, receive clearances to market or IDE approvals and actually begin marketing within specified time periods.
- Our licenses become non-exclusive for products that we do not begin marketing and selling in the United States within 30 days after we receive 510(k) clearance or approval of a PMA application from the FDA to market the applicable product in the United States.

We may terminate the licenses as follows:

- In our sole discretion, within 120 days after we sign a definitive agreement for specified types of business combination transactions with another entity and the holders of our common shares immediately before the transaction hold less than 50% of the surviving entity's or its ultimate parent's outstanding voting securities immediately after the transaction. If we use this provision to terminate the licenses, we must pay \$1,000,000 to CorRestore LLC and the inventors.
- In our sole discretion, if CorRestore LLC or either of the inventors materially breaches specified covenants in the license agreement and fails to cure such breach within 90 days after we notify the applicable party of the breach, but only if we exercise our right to terminate within 120 days after the 90-day cure period expires.

Competition

The CorRestore System will compete against existing patches, which are formed by the surgeon during SVR surgeries out of dacron or bovine pericardium tissue. These existing patches take time for the surgeon to form, can be difficult to insert, and can leak around the edges. Although we believe the CorRestore System has important advantages over patches that are currently used, including its ease of use and better seal against leaks at the edge, existing patches are significantly less expensive. In addition to promoting SVR in general as a treatment for congestive heart failure, we will have to convince users that the advantages of the CorRestore System outweigh its additional cost. At least one study using dacron patches indicates that they are effective. SVR is in the early stages of its development and, if it develops, the market for patches used in SVR might become highly competitive. There are many larger companies in this industry that have significantly larger research and development budgets than ours. Competitors may be able to develop additional or better treatments for congestive heart failure.

We believe that a manufacturer's reputation for producing effective, sterile, reliable and technically advanced and patented products, clinical literature, association with leaders in the field, references from users, surgeon convenience and price are the principal competitive factors in the medical supply industry.

Insurance

Because the Cerebral Oximeter and the CorRestore System are intended to be used in hospital critical care units with patients who may be seriously ill or may be undergoing dangerous procedures, we might be exposed to serious potential products liability claims. We have obtained products liability insurance with a liability limit of \$5,000,000. We expect to increase this coverage when we begin recognizing revenues from the CorRestore System because of the higher risk associated with this product. We also maintain coverage for property damage or loss, general liability, business interruption, travel-accident, directors' and officers' liability and workers' compensation. We do not maintain key-man life insurance.

Employees

As of February 5, 2002, we employed 28 full-time individuals, including 10 in sales and marketing, four in research and development, six in general and administration and eight in manufacturing, quality and service. We also use two consultants. We believe that our future success is dependent, in large part, on our ability to attract and retain highly qualified managerial, marketing and technical personnel. We expect to add additional sales and

marketing employees for the CorRestore System when we begin our broader market launch in the second quarter of 2002. Our employees are not represented by a union or subject to a collective bargaining agreement. We believe that our relations with our current employees are good.

Financial Information about Foreign and Domestic Operations and Export Sales

We are located in Troy, Michigan and have no other locations. Our export sales were approximately \$1,595,000 for the fiscal year ended November 30, 2001, \$2,265,000 for the fiscal year ended November 30, 2000 and \$1,632,000 for the fiscal year ended November 30, 1999, including \$369,000 in fiscal 2001, \$582,000 in fiscal 2000, and \$923,000 in fiscal 1999 to Baxter Limited, our distributor in Japan, and \$939,000 in fiscal 2001 and \$1,190,000 in fiscal 2000 to Tyco Healthcare AG, formerly Nellcor Puritan Bennett Export, Inc., our distributor in Europe. See Note 10 of Notes to Financial Statements included in Item 8 of this Report.

ITEM 2. PROPERTIES

We lease 23,392 square feet of office, manufacturing and warehouse space in Troy, Michigan. Approximately 12,000 square feet is office space for sales and marketing, engineering, accounting and other administrative activities. The lease agreement was extended in fiscal 2000, with the extension commencing January 1, 2001 and expiring December 31, 2003. The minimum monthly lease payment is approximately \$16,200 for fiscal 2001, \$16,500 for fiscal 2002, and \$16,800 for fiscal 2003, excluding other occupancy costs. We believe that, depending on sales of the Cerebral Oximeter and the CorRestore System, our current facility is more than suitable and adequate for our current needs, including our assembly of the Cerebral Oximeter, storing inventories of CorRestore System products and conducting our operations in compliance with prescribed FDA QSR guidelines, and will allow for substantial expansion of our business and number of employees.

ITEM 3. LEGAL PROCEEDINGS

We are not a party to any pending legal proceedings.

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

No matter was submitted to a vote of security holders during the fourth quarter of the fiscal year ended November 30, 2001.

SUPPLEMENTAL ITEM. EXECUTIVE OFFICERS OF THE REGISTRANT

Our current executive officers and the positions held by them are as follows:

<u>Name</u>	<u>Executive Officer Since</u>	<u>Age</u>	<u>Position</u>
Bruce J. Barrett	6/94	42	President and Chief Executive Officer
William M. Iacona	12/00	31	Vice President, Finance, Controller, and Treasurer
Richard S. Scheuing	1/98	46	Vice President, Research and Development
Mary Ann Victor	1/98	44	Vice President, Communications and Administration, and Secretary
Ronald A. Widman	1/98	51	Vice President, Medical Affairs
Pamela A. Winters	1/98	43	Vice President, Operations

Our officers serve at the discretion of the Board of Directors.

BIOGRAPHICAL INFORMATION

Mr. Bruce J. Barrett has served as our President and Chief Executive Officer and as one of our directors since June 1994. Mr. Barrett previously served, from June 1993 until May 1994, as the Director, Hospital Products Division for Abbott Laboratories, Ltd., a health care equipment manufacturer and distributor, and from September 1989 until May 1993, as the Director, Sales and Marketing for Abbott Critical Care Systems, a division of Abbott Laboratories, Inc., a health care equipment manufacturer and distributor. While at Abbott Critical Care Systems, Mr. Barrett managed Abbott's invasive oximetry products for approximately four years. From September 1981 until June 1987, he served as the group product manager of hemodynamic monitoring products of Baxter Edwards Critical Care, an affiliate of Baxter International, Inc., another health care equipment manufacturer and distributor. Mr. Barrett received a B.S. degree in marketing from Indiana State University and an M.B.A. degree from Arizona State University. Mr. Barrett is a party to an employment agreement with us that requires us to elect him to the offices he currently holds.

Mr. William M. Iacona has served as our Vice President, Finance since December 2000, as our Treasurer since February 2000 and as our Controller since April 1997. Before joining us, he was in the Finance Department of Ameritech Advertising Services, a telephone directory company and a division of Ameritech Corporation (now SBC Communications), from November 1994 until April 1997, and was on the audit staff of Deloitte & Touche LLP, independent auditors, from September 1992 until October 1994. He is a certified public accountant and received a B.S. degree in accounting from the University of Detroit.

Mr. Richard S. Scheuing has served as our Vice President, Research and Development since January 1998. From March 1993 to January 1998, he served as our Director of Research and Development. He joined us in 1991 as our Director of Mechanical Engineering. He is an inventor on four of our issued patents, and one patent that is pending. Before joining us, he was Director of Mechanical Engineering for Irwin Magnetic Systems, Inc. from 1987 until 1991 and was a Development Engineer with the Sarns division of Minnesota Mining and Manufacturing Company, or 3M, from 1982 to 1987. He received a B.S. degree in mechanical engineering from the University of Michigan.

Ms. Mary Ann Victor has served as our Vice President, Communications and Administration and Secretary since January 1998. From July 1997 until January 1998, she served as our Director, Communications and Administration and was our consultant from September 1996 until July 1997. She also served as our Director of Corporate Communications from July 1991 until February 1994. Prior experience includes serving as Director of Investor Relations with the Taubman Company from February to May 1994, legal assistant from June 1994 to November 1994 and then attorney from November 1994 to September 1995 with Varnum Riddering Schmidt & Howlett, and Human Resources Consultant in the Actuarial Benefits and Compensation Consulting Group of Deloitte & Touche LLP from September 1995 to September 1996. Ms. Victor received a B.S. in political science from the University of Michigan and a J.D. from the University of Detroit.

Mr. Ronald A. Widman has served as our Vice President, Medical Affairs since January 1998. From August 1994 to January 1998, he served as our Director of Medical Affairs. Before joining us as Marketing Manager in 1991, he was employed by Mennen Medical, Inc., a manufacturer and marketer of medical monitoring and diagnostic devices, for 12 years, where he held various positions in domestic and international medical product marketing, including Senior Product Manager from 1982 until 1991. He is the author of several papers and articles related to medical care and monitoring devices.

Ms. Pamela A. Winters has served as our Vice President, Operations since January 1998. From February 1996 to January 1998, she served as our Director of Operations. From May 1992 to February 1996, she served as our Manager of Quality Assurance. From October 1991 to May 1992, Ms. Winters served as our Quality Assurance Supervisor. Ms. Winters received a B.S. degree in management from the University of Phoenix.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED SHAREHOLDER MATTERS

Our common shares trade on The Nasdaq SmallCap Market under the trading symbol "SMTS." The following table sets forth, for the periods indicated, the range of high and low closing sales prices as reported by Nasdaq.

	<u>High</u>	<u>Low</u>
Fiscal Year Ended November 30, 2000		
First Quarter.....	\$ 4.13	\$ 1.19
Second Quarter.....	6.88	2.50
Third Quarter.....	4.38	2.63
Fourth Quarter.....	3.75	1.81
Fiscal Year Ended November 30, 2001		
First Quarter.....	\$ 2.75	\$ 1.13
Second Quarter.....	4.07	1.88
Third Quarter.....	3.90	2.62
Fourth Quarter.....	3.95	1.91

As of February 5, 2002, we had 679 shareholders of record.

We have never paid cash dividends on our common shares and do not expect to pay such dividends in the foreseeable future. We currently intend to retain any future earnings for use in our business. The payment of any future dividends will be determined by the Board in light of the conditions then existing, including our financial condition and requirements, future prospects, restrictions in financing agreements, business conditions and other factors deemed relevant by the Board.

Pursuant to the CorRestore license agreement, effective November 21, 2001 we issued to CorRestore LLC and Wolfe & Company additional five-year warrants to purchase an aggregate of 2,100,000 common shares at \$3.00 a share, as a result of our receipt of clearance from the FDA to market the CorRestore patch in the United States. The warrants will become exercisable based on our cumulative net sales of the CorRestore System products. All of the warrants become exercisable if our cumulative net sales of the CorRestore System products are at least \$80 million. The warrants expire when the license terminates, except that the vested portion of the warrant remains exercisable for an additional 90 days or, if termination is a result of specified breaches by us, for the remaining term of the warrants. The warrants are not registered, but were issued in reliance upon the exemptions from registration contained in Sections 4(2) and 4(6) of the Securities Act.

In connection with our public offering of securities that closed on January 16, 2002, we issued to the placement agent, Brean Murray & Co., Inc. warrants to purchase 100,000 common shares at \$5.10 per share exercisable during the four-year period beginning January 11, 2003. The common shares were not registered, but were issued in reliance upon the exemptions from registration contained in Sections 4(2) and 4(6) of the Securities Act.

ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data as of November 30, 2001, 2000, 1999, 1998 and 1997, and for each of the years in the five-year period ended November 30, 2001 have been derived from our audited financial statements, some of which appear in Item 8 of this Report together with the report of Deloitte & Touche LLP, independent auditors. This selected financial data might not be a good indicator of our expected results for fiscal 2002. You should read the selected financial data together with the Financial Statements and Notes to Financial Statements included in Item 8 of this Report and with "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Item 7 of this Report. In June 2000, we entered into the CorRestore license. In November 2001 we received clearance from the FDA to market the CorRestore patch in the United States. See Item 1. "Business – The CorRestore System."

	<u>Fiscal Year Ended November 30,</u>				
	<u>2001</u>	<u>2000</u>	<u>1999</u>	<u>1998</u>	<u>1997</u>
	(in thousands, except per share data)				
Statement of Operations Data:					
Net revenues (1).....	\$ 5,656	\$ 5,103	\$ 4,001	\$ 2,491	\$ 1,212
Cost of sales.....	2,094	2,370	1,906	1,326	631
Gross margin.....	3,561	2,733	2,095	1,165	580
Research, development and engineering expenses.....	778	514	598	665	736
Selling, general, and administrative expenses	5,133	5,722	6,436	6,347	6,238
Net loss	(2,331)	(3,622)	(4,665)	(5,470)	(6,155)
Net loss per common share-basic and diluted (2).....	(.31)	(.57)	(.77)	(1.01)	(1.88)
Weighted average number of common shares outstanding—basic and diluted(2)	7,606	6,310	6,036	5,422	3,272

	<u>At November 30,</u>				
	<u>2001</u>	<u>2000</u>	<u>1999</u>	<u>1998</u>	<u>1997</u>
	(in thousands)				
Balance Sheet Data:					
Cash and marketable securities	\$ 168	\$ 122	\$ 2,257	\$ 6,894	\$ 4,603
Working capital.....	1,724	1,393	2,960	7,633	4,511
Total assets.....	3,587	3,659	4,444	9,047	5,677
Total liabilities	575	776	762	629	788
Accumulated deficit (4).....	(52,455)	(50,124)	(46,502)	(41,836)	(36,367)
Shareholders' equity (3) (4).....	3,013	2,883	3,682	8,418	4,889

- (1) Net revenues recorded in fiscal years 2001, 2000, 1999, 1998 and 1997 relate primarily to the sale of Cerebral Oximeters and SomaSensors for commercial use.
- (2) See Note 4 of Notes to Financial Statements included in Item 8 of this Report for information with respect to the calculation of per share data. The net loss per common share data and weighted average number of common shares outstanding data have been adjusted to give retroactive effect to the 1-for-10 reverse stock split effected April 10, 1997.
- (3) See Statements of Shareholders' Equity of the Financial Statements included in Item 8 of this Report for an analysis of common share transactions for the period from December 1, 1998 through November 30, 2001.
- (4) We believe our accumulated deficit has increased since November 30, 2001. We also believe our shareholders' equity has increased since November 30, 2001, as a result of our offering of common shares that closed on January 16, 2002. Our net proceeds from that offering were approximately \$3,725,000.

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

Some of the statements in this report are forward-looking statements. These forward-looking statements include statements relating to our performance in this Management's Discussion and Analysis of Financial Condition and Results of Operations. In addition, we may make forward-looking statements in future filings with the Securities and Exchange Commission and in written material, press releases and oral statements issued by us or on our behalf. Forward-looking statements include statements regarding the intent, belief or current expectations of us or our officers, including statements preceded by, followed by or including forward-looking terminology such as "may," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "predict" or similar expressions, with respect to various matters.

It is important to note that our actual results could differ materially from those anticipated from the forward-looking statements depending on various important factors. These important factors include our history of losses and ability to continue as a going concern, our current dependence on the Cerebral Oximeter and SomaSensor, the challenges associated with developing new products, the uncertainty of acceptance of our products by the medical community, the lengthy sales cycle for our products, competition in our markets, our dependence on our distributors, and the other factors discussed under the caption "Risk Factors" and elsewhere in our Registration Statement on Form S-1 (file no. 333-74788) effective January 11, 2002 and elsewhere in this report.

All forward-looking statements in this report are based on information available to us on the date of this report. We do not undertake to update any forward-looking statements that may be made by us or on our behalf in this report or otherwise. In addition, please note that matters set forth under the caption "Risk Factors" in our registration statement constitute cautionary statements identifying important factors with respect to the forward-looking statements, including certain risks and uncertainties, that could cause actual results to differ materially from those in such forward-looking statements.

Results of Operations

Overview

We develop, manufacture and market the INVOS Cerebral Oximeter, the only non-invasive patient monitoring system commercially available in the United States that continuously measures changes in the blood oxygen level in the brain. We are also developing the CorRestore System for use in cardiac repair and reconstruction, including heart surgeries called surgical ventricular restoration, or SVR. During the third quarter of fiscal 1999, we introduced our new model 5100 Cerebral Oximeter at an international trade show, and began international shipments of the model 5100 in August 1999. The model 5100 has the added capability of being able to monitor pediatric patients. In September 2000, we received clearance from the FDA to market the model 5100 Cerebral Oximeter in the United States. In June 2000, we entered into a license agreement for the CorRestore System. In November 2001 we received clearance from the FDA to market the CorRestore patch in the United States.

During fiscal 1999, 2000 and 2001, our primary activities consisted of sales and marketing of the Cerebral Oximeter and related disposable SomaSensor. We had an accumulated deficit of \$52,454,657 through November 30, 2001.

We derive our revenues from sales of Cerebral Oximeters and SomaSensors to our distributors and to hospitals in the United States through our direct sales employees and independent sales representatives. We recognize revenue when there is persuasive evidence of an arrangement with the customer, the product has been delivered, the sales price is fixed or determinable, and collectibility is reasonably assured. The product is considered delivered to the customer once we have shipped it, as this is when title and risk of loss have transferred. Payment terms are generally net 30 days for United States sales and net 60 days or longer for international sales. Our primary expenses, excluding the cost of our products, are selling, general and administrative and research, development and engineering.

Fiscal Year Ended November 30, 2001 Compared to Fiscal Year Ended November 30, 2000

Our net revenues increased approximately \$552,000, or 11%, from \$5,103,098 in the fiscal year ended November 30, 2000 to \$5,655,532 in the fiscal year ended November 30, 2001. The increase in net revenues is primarily attributable to

- an increase in United States sales of approximately \$1,223,000, from approximately \$2,838,000 in fiscal 2000 to approximately \$4,061,000 in fiscal 2001, primarily due to increased sales of the disposable SomaSensor and initial purchases of demonstration equipment by independent sales representatives, and
- a 12% increase in the average selling price of SomaSensors primarily as a result of the 25% increase from the prior year in the suggested retail price of the SomaSensor effective September 1, 2001, and a change in the sales mix between sales in the United States, which have higher average selling prices, and sales to international distributors, and
- a 10% increase in the average selling price of Cerebral Oximeters, primarily as a result of a change in the sales mix between sales in the United States and sales to international distributors, and increased sales of the model 5100 Cerebral Oximeter in the United States in fiscal 2001.

The increase in net revenues was achieved despite a decrease in international sales of approximately \$670,000, from approximately \$2,265,000 in fiscal 2000 to approximately \$1,595,000 in fiscal 2001. This decrease is primarily attributable to

- stocking orders for model 4100 and model 5100 Cerebral Oximeters and SomaSensors by Tyco Healthcare AG, formerly Nellcor Puritan Bennett Export Inc., in fiscal 2000, and delays in marketing the Cerebral Oximeter in 39 markets, including Europe, in fiscal 2001, and
- decreased purchases by Baxter Limited in Japan in fiscal 2001 attributable to a change in product focus by Edwards Lifesciences Corporation since being spun-off by Baxter International, Inc. Baxter Limited in Japan is now part of Edwards Lifesciences Corporation.

Approximately 28% of our net revenues in fiscal 2001 were export sales, compared to approximately 44% of our net revenues in fiscal 2000. Sales of SomaSensors, model 4100 Cerebral Oximeters, model 5100 Cerebral Oximeters, and model 4100 exchanges as a percentage of net revenues were as follows:

<u>Product</u>	<u>Percent of Net Revenue</u>	
	<u>Fiscal Year Ended November 30,</u> <u>2001</u>	<u>2000</u>
SomaSensors.....	60%	49%
Model 4100 Cerebral Oximeters.....	28%	30%
Model 5100 Cerebral Oximeters.....	12%	20%
Model 4100 Exchanges.....	0%	1%
Total	<u>100%</u>	<u>100%</u>

One international distributor accounted for approximately 17% of net revenues for the fiscal year ended November 30, 2001, and two international distributors accounted for approximately 23% and 11%, respectively, of net revenues for the fiscal year ended November 30, 2000.

Gross margin as a percentage of net revenues was approximately 63% for the fiscal year ended November 30, 2001 and approximately 54% for the fiscal year ended November 30, 2000. The increase in gross margin as a percentage of net revenues is primarily attributable to a 12% increase in the average selling price of SomaSensors and a 10% increase in the average selling price of Cerebral Oximeters described above, and increased sales of our latest model SomaSensor, launched in May 2001, which is less costly to manufacture than the prior model SomaSensor.

Our research, development and engineering expenses increased approximately \$264,000, or 51%, from \$513,816 in fiscal 2000 to \$777,974 in fiscal 2001. The increase is primarily attributable to a \$328,000 increase in costs associated with the development of the CorRestore System. This increase was partially offset by

- o a \$36,000 decrease in costs associated with the development of the latest model SomaSensor, and
- o a \$19,000 decrease in engineering salaries as a result of one less engineer.

Selling, general and administrative expenses decreased approximately \$589,000, or 10%, from \$5,722,409 for the fiscal year ended November 30, 2000 to \$5,133,473 for the fiscal year ended November 30, 2001. The decrease in selling, general and administrative expense is primarily attributable to

- o a \$541,000 decrease in salaries, wages, commissions and related expenses, primarily as a result of a reduction in the number of employees, principally sales and marketing (from an average of 40 employees for the fiscal year ended November 30, 2000 to an average of 31 employees for the fiscal year ended November 30, 2001),
- o a \$256,000 decrease in travel and selling-related expenses primarily related to reduced trade show and travel expenses as a result of the reduction in sales personnel, and reduced marketing expenses as a result of promotional materials, travel and training for Tyco Healthcare AG in fiscal 2000,
- o a \$124,000 decrease in office-related expenses primarily as a result of the reduced number of employees and our focus on cost containment,
- o a \$106,000 decrease in clinical research expenses, primarily related to the model 5100 Cerebral Oximeter, and
- o a \$90,000 decrease in incentive compensation expense primarily due to our executive officers not participating in the 2001 Employee Incentive Compensation Plan in exchange for a grant of stock options,

These decreases were partially offset by

- o \$259,000 in commissions paid to our independent sales representatives engaged in fiscal 2001,
- o a \$200,000 termination fee related to the Kingsbridge Capital Limited Private Equity Line, and
- o a \$110,000 increase in intangible amortization expense related to the amortization of license acquisition costs.

We expect our selling, general and administrative expenses to increase in fiscal 2002 as a result of marketing and selling the CorRestore System.

We realized a \$212,000 loss on the sale of marketable securities in fiscal 2000.

Fiscal Year Ended November 30, 2000 Compared to Fiscal Year Ended November 30, 1999

Our net revenues increased approximately \$1,102,000, or 28%, from \$4,000,972 in the fiscal year ended November 30, 1999 to \$5,103,098 in the fiscal year ended November 30, 2000. The increase in net revenues is primarily attributable to

- o an increase in international sales of approximately \$633,000, from approximately \$1,632,000 in fiscal 1999 to approximately \$2,265,000 in fiscal 2000, primarily due to the stocking orders for model 4100 and model 5100 Cerebral Oximeters and SomaSensors by Nellcor Puritan Bennett Export, Inc., and
- o an increase in United States sales of approximately \$469,000, from approximately \$2,369,000 in fiscal 1999 to approximately \$2,838,000 in fiscal 2000, primarily due to increased purchases of the disposable SomaSensor.

The increase in net revenues was achieved despite

- o decreased purchases of the model 4100 by Baxter Limited in Japan attributable to the initial stocking purchases and exchange purchases made in fiscal 1999. In the third quarter of fiscal 1999, we offered to exchange model 4100 Cerebral Oximeters for model 3100A Cerebral Oximeters (which we then scrapped) and cash equal to the difference in sales prices of the two models to Baxter Limited in Japan, as a result of

the Japanese Ministry of Health and Welfare approval in the first quarter of fiscal 1999 to market the model 4100 in Japan,

- o a 15% decrease in the average selling price of Cerebral Oximeters primarily as a result of the stocking orders from Nellcor Puritan Bennett Export, Inc., at lower per unit prices, for use as demonstration equipment by its sales personnel, and a change in the sales mix in the United States between direct purchases of the model 4100 and no-cap placements of the model 4100. During fiscal 1998, we began a no-cap sales program whereby we ship the model 4100 Cerebral Oximeter to the customer at no charge, in exchange for the customer agreeing to purchase at a premium a minimum monthly quantity of SomaSensors, and
- o a 7% decrease in the average selling price of SomaSensors primarily as a result of the initial stocking orders from Nellcor Puritan Bennett Export, Inc., at lower per unit prices, for use as demonstration equipment by its sales personnel.

Approximately 44% of our net revenues in fiscal 2000 were export sales, compared to approximately 41% of our net revenues in fiscal 1999. Sales of SomaSensors, model 4100 Cerebral Oximeters, model 5100 Cerebral Oximeters, and model 4100 exchanges as a percentage of net revenues were as follows:

Product	Percent of Net Revenue	
	Fiscal Year Ended November 30, 2000	1999
SomaSensors.....	49%	42%
Model 4100 Cerebral Oximeters.....	30%	52%
Model 5100 Cerebral Oximeters.....	20%	3%
Model 4100 Exchanges.....	1%	3%
Total	100%	100%

Two international distributors accounted for approximately 23% and 11%, respectively, of net revenues for the fiscal year ended November 30, 2000, and one international distributor accounted for approximately 23% of net revenues for the fiscal year ended November 30, 1999.

Gross margin as a percentage of net revenues was approximately 54% for the fiscal year ended November 30, 2000 and approximately 52% for the fiscal year ended November 30, 1999. Although we realized a lower average selling price for Cerebral Oximeters and SomaSensors in fiscal 2000, gross margin as a percentage of net revenues increased primarily due to shipments of our new model SomaSensor in fiscal 2000, which is less costly to manufacture than the old model SomaSensors. The new model SomaSensor was sold for the entire year in fiscal 2000, as compared to fiscal 1999 when it was launched and was sold primarily in the second half of the year.

Our research, development and engineering expenses decreased approximately \$85,000, or 14%, from \$598,348 in fiscal 1999 to \$513,816 in fiscal 2000. The decrease is primarily attributable to:

- o a \$123,000 decrease in consulting fees associated with the termination of our consulting order with NeuroPhysics Corporation, and
- o a \$72,000 decrease in costs associated with enhancements to the design of the disposable SomaSensor.

These decreases were achieved despite:

- o a \$71,000 increase in costs associated with the development of the CorRestore System, and
- o a \$37,000 increase in engineering salaries.

Selling, general and administrative expenses decreased approximately \$713,000, or 11%, from \$6,435,628 for the fiscal year ended November 30, 1999 to \$5,722,409 for the fiscal year ended November 30, 2000. The decrease in selling, general and administrative expense is primarily attributable to

- o a \$700,000 decrease in salaries, wages, commissions and related expenses, primarily as a result of a reduction in the number of employees, principally sales and marketing, (from an average of 47 employees for the fiscal year ended November 30, 1999 to an average of 40 employees for the fiscal year ended November 30, 2000) and reduced sales commissions,
- o a \$157,000 decrease in trade show expenditures during fiscal 2000,
- o a \$107,000 decrease in professional service fees primarily as a result of decreased business consulting fees during fiscal 2000, and
- o a \$40,000 decrease in employee severance during fiscal 2000.

These decreases were incurred despite

- o a \$116,000 increase in selling-related expenses, primarily related to marketing and promotional materials, travel, and training related to our new distribution agreement with Nellcor Puritan Bennett Export, Inc., and other employee travel expenses,
- o a \$110,000 increase in intangible amortization expense related to the amortization of license acquisition costs, and
- o a \$47,000 increase in clinical research expenses, primarily related to the model 5100 Cerebral Oximeter.

We realized a \$212,000 loss on the sale of marketable securities in fiscal 2000.

Effects of Inflation

We do not believe that inflation has had a significant impact on our financial position or results of operations in the past three years.

Liquidity and Capital Resources

Net cash used in operations during fiscal 2001 was approximately \$2,126,000. Cash was used primarily to

- o fund our net loss, including selling, general and administrative expenses and research, development and engineering expenses, totaling approximately \$1,833,000, before depreciation and amortization expense,
- o increase inventory by approximately \$180,000, primarily due to the purchase of components related to our new generation SomaSensor,
- o decrease accrued liabilities by approximately \$175,000 and accounts payable by \$26,000, primarily as a result of payments made in fiscal 2001.

These uses of cash were partially offset by an \$87,000 decrease in accounts receivable, primarily as a result of more timely collections in fiscal 2001.

We expect to increase our inventory in fiscal 2002, as a result of our fourth quarter 2001 sales, and our expected sales of the Cerebral Oximeter, SomaSensor and CorRestore System in fiscal 2002.

We expect our working capital requirements to increase if sales increase. We capitalized approximately \$115,000 of costs for model 4100 and model 5100 Cerebral Oximeters being used as demonstration units and no-cap units during fiscal 2001, compared to approximately \$114,000 in fiscal 2000. We expect to depreciate these costs over three years.

Capital expenditures in fiscal 2001 were approximately \$167,000. These expenditures were primarily for the costs for model 4100 and model 5100 demonstration and no-cap Cerebral Oximeters described above, and for approximately \$52,000 in tooling costs associated with our new model SomaSensor. We expect our capital requirements to increase as a result of the costs of developing and marketing the CorRestore System.

Our principal sources of operating funds have been the proceeds of equity investments from sales of our common shares. See Statements of Shareholders' Equity of our Financial Statements included in Item 8 of this Report.

On March 6, 2000, we entered into the Private Equity Line Agreement with Kingsbridge Capital Limited, a private institutional investor. We completed the sales of 714,484 common shares under the Private Equity Line Agreement, for gross proceeds of \$2,000,000. Our net proceeds, after deducting the commissions and the estimated expenses of the offerings, were approximately \$1,793,000. Effective March 5, 2001, we de-registered the remaining shares originally registered for resale by Kingsbridge under the Private Equity Line Agreement, because we no longer intend to sell any more shares to Kingsbridge, except upon any exercise of its warrant, and Kingsbridge is no longer publicly offering for resale the shares subject to the warrant we granted to them. On April 10, 2001, we mutually agreed with Kingsbridge to terminate the Private Equity Line Agreement, the related Registration Rights Agreement, and Kingsbridge's right to the discount on any unsold shares, in exchange for our payment of \$200,000 to Kingsbridge.

On February 13, 2001, we entered into a Loan and Security Agreement with Crestmark Bank for a working capital line of credit for up to \$750,000, collateralized by all of our assets. Under the Agreement, Crestmark Bank may, but is not obligated to, lend us amounts we request from time to time, up to \$750,000, if no default exists. The loans are limited by a borrowing base based on qualifying accounts receivable and lender reserves. The loan is payable on demand, and collections of our receivables are directed to Crestmark Bank in payment of any outstanding balance of the loan.

The principal amount outstanding bears interest, payable monthly, at the prime rate (4.75% at February 5, 2002) plus 2% plus a 2.4% service fee, and we paid a \$45,000 commitment fee for the loan. Through November 30, 2001, we have borrowed an aggregate of \$920,050 under the agreement and repaid \$920,050 in principal amount through Crestmark's collection of our receivables and by using some of the proceeds from our April 9, 2001 offering. As of November 30, 2001, \$750,000 was available for borrowing, at Crestmark's discretion, under the facility. We have agreed to use the proceeds of the loans solely as working capital. The line of credit requires us to maintain minimum tangible net worth of \$500,000 and a ratio of total liabilities to tangible net worth not to exceed 3:1. The line of credit terminates upon Crestmark's demand.

On April 9, 2001, we completed the private placement of 1,325,000 newly-issued common shares at a price of \$1.75 per share, for gross proceeds of \$2,318,750. Our estimated net proceeds, after deducting the placement agent's commission and the expenses of the offering, were approximately \$2,152,000. Brean Murray & Co., Inc. was our exclusive placement agent for the offering and received for its services (1) \$104,363 as a placement agent fee, and (2) warrants to purchase 25,000 common shares at \$2.10 per share exercisable during the four-year period beginning April 9, 2002. A. Brean Murray, one of our directors, and his wife control Brean Murray & Co., Inc. In addition, the Brean Murray & Co., Inc. Profit Sharing Plan purchased 32,285 common shares in the offering, and Robert R. Henry, one of our directors, purchased 100,000 common shares in the offering.

As of November 30, 2001, we had working capital of \$1,724,358, cash and cash equivalents of \$167,873, total current liabilities of \$574,566 and shareholders' equity of \$3,012,547.

From December 1, 2001 through February 5, 2002, we have borrowed \$375,000 under the Loan and Security Agreement with Crestmark Bank. We have repaid \$326,632 in principal amount under the agreement through Crestmark's collection of our receivables, and have repaid \$48,368 in principal amount under the agreement from the proceeds of our January 16, 2002 offering described below. As of February 5, 2002, we had no outstanding principal loan balance, and \$548,468 was available for borrowing, at Crestmark's discretion, under the facility.

On January 16, 2002, we completed the public offering of 1,000,000 newly-issued common shares at a price of \$4.25 per share, for gross proceeds of \$4,250,000. Our estimated net proceeds, after deducting the placement agent's commission and the estimated expenses of the offering, were approximately \$3,725,000. Brean Murray & Co., Inc. was our exclusive placement agent for the offering and received for its services (1) \$340,000 as a placement agent fee, and (2) warrants to purchase 100,000 common shares at \$5.10 per share exercisable during the four-year period beginning January 11, 2003. A. Brean Murray, one of our directors, and his wife control Brean Murray & Co., Inc.

We expect that our primary needs for liquidity in fiscal 2002 will be

- to fund our losses and sustain our operations, including funding

- marketing costs for the Cerebral Oximeter and the CorRestore System; and
- research and development efforts related to product-line extensions of the Cerebral Oximeter for use on newborns, other non-brain tissue applications, and enhancements to the Cerebral Oximeter and SomaSensor; and
- for working capital, including increased accounts receivable and inventories of components and sales units to satisfy expected sales orders.

In addition, we have budgeted approximately \$200,000 for capital expenditures during fiscal 2002, primarily for new demonstration and no-cap equipment and manufacturing tooling for the Cerebral Oximeter, SomaSensor, and CorRestore System.

We believe that the cash and cash equivalents on hand at November 30, 2001, together with the net proceeds of our public offering of 1,000,000 common shares that closed on January 16, 2002 described above and the estimated net borrowings available under the Crestmark Bank Loan and Security Agreement described above, will be adequate to satisfy our operating and capital requirements for more than the next twelve months.

The estimated length of time current cash, cash equivalents and available borrowings will sustain our operations is based on estimates and assumptions we have made. These estimates and assumptions are subject to change as a result of actual experience. Actual capital requirements necessary to market the Cerebral Oximeter and SomaSensor, to develop and market the CorRestore System, to undertake other product development activities, and for working capital might be substantially greater than current estimates.

Our ability to use our accumulated net operating loss carryforwards to offset future income, if any, for income tax purposes, is limited due to the initial public offering of our securities in March 1991. See Note 6 of Notes to Financial Statements included in Item 8 of this Report.

New Accounting Pronouncements

Effective December 1, 2000, we adopted Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities." This statement establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities. This statement had no impact on our financial statements.

In June 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets." This Statement is effective for fiscal years beginning after December 15, 2001, and establishes accounting and reporting standards for goodwill and other intangible assets. This Statement is effective for our financial statements for the fiscal year ending November 30, 2003. We expect to adopt this Statement early, for our first quarter of fiscal 2002. The effect of adopting this Statement will be to discontinue amortizing our license acquisition costs related to our acquisition of worldwide, royalty-bearing licenses to specified rights relating to the CorRestore System and related products and accessories because we believe these licenses have an indefinite life. Amortization expense related to these licenses was approximately \$219,000 for the year ended November 30, 2001.

In October 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." This Statement is effective for fiscal years beginning after December 15, 2001, and replaces Statement No. 121 and provisions of APB Opinion No. 30 for the disposal of segments of a business. The statement creates one accounting model, based on the framework established in Statement No. 121, to be applied to all long-lived assets including discontinued operations. This Statement is effective for our financial statements for the fiscal year ending November 30, 2003. We have not yet determined the impact of this Statement on our financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Independent Auditors' Report

To the Board of Directors and Shareholders of
Somanetics Corporation
Troy, Michigan

We have audited the accompanying balance sheets of Somanetics Corporation (the "Company") as of November 30, 2001 and 2000, and the related statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended November 30, 2001. Our audits also included the financial statement schedule listed in the index at Item 14. These financial statements and the financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and the financial statement schedule 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, such financial statements present fairly, in all material respects, the financial position of the Company at November 30, 2001 and 2000, and the results of its operations and its cash flows for each of the three years in the period ended November 30, 2001 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ DELOITTE & TOUCHE LLP

Detroit, Michigan
January 21, 2002

SOMANETICS CORPORATION

BALANCE SHEETS

	November 30,	
	<u>2001</u>	<u>2000</u>
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents (Note 4)	\$ 167,873	\$ 122,299
Accounts receivable	1,263,039	1,349,726
Inventory (Note 4)	793,757	613,930
Prepaid expenses	74,255	83,100
Total current assets	<u>2,298,924</u>	<u>2,169,055</u>
PROPERTY AND EQUIPMENT: (Note 4)		
Machinery and equipment	1,615,009	1,471,114
Furniture and fixtures	183,497	183,497
Leasehold improvements	165,642	165,642
Total	1,964,148	1,820,253
Less accumulated depreciation and amortization	<u>(1,631,907)</u>	<u>(1,384,000)</u>
Net property and equipment	<u>332,241</u>	<u>436,253</u>
OTHER ASSETS:		
Intangible assets, net (Note 4)	928,870	1,038,688
Other	27,078	15,000
Total other assets	<u>955,948</u>	<u>1,053,688</u>
TOTAL ASSETS	<u>\$ 3,587,113</u>	<u>\$ 3,658,996</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 482,137	\$ 508,647
Accrued liabilities (Notes 5 and 7)	<u>92,429</u>	<u>267,184</u>
Total current liabilities	<u>574,566</u>	<u>775,831</u>
COMMITMENTS AND CONTINGENCIES (Note 7)		
SHAREHOLDERS' EQUITY: (Notes 3 and 11)		
Preferred shares; authorized, 1,000,000 shares of \$.01 par value; no shares issued or outstanding	--	--
Common shares; authorized, 20,000,000 shares of \$.01 par value; issued and outstanding, 8,075,055 shares at November 30, 2001, and 6,637,087 shares at November 30, 2000	80,751	66,371
Additional paid-in capital	55,386,453	52,940,540
Accumulated deficit	<u>(52,454,657)</u>	<u>(50,123,746)</u>
Total shareholders' equity	<u>3,012,547</u>	<u>2,883,165</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>\$ 3,587,113</u>	<u>\$ 3,658,996</u>

See notes to financial statements

SOMANETICS CORPORATION
STATEMENTS OF OPERATIONS

	For the Years Ended November 30,		
	2001	2000	1999
NET REVENUES (Notes 4 and 10).....	\$ 5,655,532	\$ 5,103,098	\$ 4,000,972
COST OF SALES.....	<u>2,094,472</u>	<u>2,370,205</u>	<u>1,905,541</u>
Gross margin.....	<u>3,561,060</u>	<u>2,732,893</u>	<u>2,095,431</u>
 OPERATING EXPENSES:			
Research, development and engineering (Note 4).....	777,974	513,816	598,348
Selling, general and administrative (Note 9).....	<u>5,133,473</u>	<u>5,722,409</u>	<u>6,435,628</u>
Total operating expenses.....	<u>5,911,447</u>	<u>6,236,225</u>	<u>7,033,976</u>
 OPERATING LOSS.....	 <u>(2,350,387)</u>	 <u>(3,503,332)</u>	 <u>(4,938,545)</u>
 OTHER INCOME (EXPENSE):			
Loss on sale of securities.....	--	(211,560)	--
Interest income.....	22,177	92,805	273,254
Interest expense and other.....	<u>(2,701)</u>	<u>--</u>	<u>--</u>
Total other income (expense).....	<u>19,476</u>	<u>(118,755)</u>	<u>273,254</u>
NET LOSS.....	<u>\$ (2,330,911)</u>	<u>\$ (3,622,087)</u>	<u>\$ (4,665,291)</u>
 NET LOSS PER COMMON SHARE --			
BASIC AND DILUTED (Note 4).....	<u>\$ (.31)</u>	<u>\$ (.57)</u>	<u>\$ (.77)</u>
 WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING --			
BASIC AND DILUTED (Note 4).....	<u>7,605,865</u>	<u>6,310,109</u>	<u>6,035,597</u>

See notes to financial statements

SOMANETICS CORPORATION

STATEMENTS OF SHAREHOLDERS' EQUITY

	Share Value	Additional Paid-In Capital	Accumulated Deficit	Accumulated Unrealized Losses on Investments	Total Shareholders' Equity	Comprehensive Income
Balance at December 1, 1998.....	60,356	50,290,067	(41,836,368)	(96,262)	8,417,793	
Net loss			(4,665,291)		(4,665,291)	(4,665,291)
Unrealized losses on investments.....				(70,008)	(70,008)	(70,008)
Comprehensive income						<u>\$ (4,735,299)</u>
Balance at November 30, 1999	<u>\$ 60,356</u>	<u>\$ 50,290,067</u>	<u>\$ (46,501,659)</u>	<u>\$ (166,270)</u>	<u>\$ 3,682,494</u>	
For cash, less issuance costs of \$193,619.....	6,015	1,600,366			1,606,381	
Warrants issued to acquire license, less acquisition costs of \$46,791		1,050,107			1,050,107	
Net loss			(3,622,087)		(3,622,087)	(3,622,087)
Unrealized losses on investments.....				(45,290)	(45,290)	(45,290)
Reclassification of unrealized losses				211,560	211,560	211,560
Comprehensive income						<u>\$ (3,455,817)</u>
Balance at November 30, 2000	<u>\$ 66,371</u>	<u>\$ 52,940,540</u>	<u>\$ (50,123,746)</u>	<u>\$ --</u>	<u>\$ 2,883,165</u>	
For cash, less issuance costs of \$13,000.....	1,130	185,870			187,000	
For cash, less issuance costs of \$166,488.....	13,250	2,138,587			2,151,837	
Warrants issued to acquire license.....		116,472			116,472	
Stock options issued to consultant.....		4,984			4,984	
Net loss and comprehensive income.....			(2,330,911)		(2,330,911)	(2,330,911)
Balance at November 30, 2001	<u>\$ 80,751</u>	<u>\$ 55,386,453</u>	<u>\$ (52,454,657)</u>	<u>\$ --</u>	<u>\$ 3,012,547</u>	

See notes to financial statements

SOMANETICS CORPORATION
STATEMENTS OF CASH FLOWS

	For the Years Ended November 30,		
	2001	2000	1999
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	\$ (2,330,911)	\$ (3,622,087)	\$ (4,665,291)
Adjustments to reconcile net loss to net cash used in operations:			
Depreciation and amortization	497,640	446,962	295,598
Realized losses on sales of marketable securities	--	210,724	--
Compensation expense for consultant stock options ...	4,984	--	--
Changes in assets and liabilities:			
Accounts receivable (increase) decrease	86,687	(585,573)	(148,471)
Inventory (increase) decrease	(179,827)	(2,598)	49,632
Prepaid expenses decrease	8,845	6,602	2,348
Other assets (increase)	(12,078)	(46,789)	--
Accounts payable increase (decrease)	(26,510)	10,639	235,076
Accrued liabilities increase (decrease)	(174,755)	3,289	(102,327)
Net cash (used in) operating activities	<u>(2,125,925)</u>	<u>(3,578,831)</u>	<u>(4,333,435)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:			
Proceeds from sale of marketable securities	--	789,282	4,013,198
Acquisition of property and equipment (net)	<u>(167,338)</u>	<u>(117,956)</u>	<u>(233,169)</u>
Net cash provided by (used in) investing activities	<u>(167,338)</u>	<u>671,326</u>	<u>3,780,029</u>
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from issuance of Common Shares	<u>2,338,837</u>	<u>1,606,381</u>	--
Net cash provided by financing activities	<u>2,338,837</u>	<u>1,606,381</u>	--
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	45,574	(1,301,124)	(533,406)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	<u>122,299</u>	<u>1,423,423</u>	<u>1,976,829</u>
CASH AND CASH EQUIVALENTS, END OF PERIOD	<u>\$ 167,873</u>	<u>\$ 122,299</u>	<u>\$ 1,423,423</u>
Supplemental Disclosure of Non cash investing activities:			
Issuance of warrants and stock options in connection with license acquisition (Note 4)	\$ 116,472	\$ 1,050,107	

See notes to financial statements

SOMANETICS CORPORATION

NOTES TO FINANCIAL STATEMENTS

1. Organization and Operations

We are a Michigan corporation that was formed in 1982. We develop, manufacture and market the INVOS® Cerebral Oximeter, the only non-invasive patient monitoring system commercially available in the United States that continuously measures changes in the blood oxygen level in the brain. The principal markets for our products are the United States, Europe, and Japan. The Cerebral Oximeter is based on our proprietary In Vivo Optical Spectroscopy, or INVOS, technology. INVOS analyzes various characteristics of human blood and tissue by measuring and analyzing low-intensity visible and near-infrared light transmitted into portions of the body.

We are also developing the CorRestore™ System for use in cardiac repair and reconstruction, including heart surgeries called surgical ventricular restoration, or SVR. We entered into a License Agreement as of June 2, 2000 with the inventors and their company, CorRestore LLC. The license grants us worldwide, royalty-bearing licenses to specified rights relating to the CorRestore System and related products and accessories for SVR, subject to the terms and conditions of the license agreement (Note 4). In November 2001 we received clearance from the FDA to market the CorRestore patch in the United States.

2. Financial Statement Presentation

We have incurred an accumulated deficit of \$52,454,657 through November 30, 2001. We had working capital of \$1,724,358, cash and cash equivalents of \$167,873, total current liabilities of \$574,566 and shareholders' equity of \$3,012,547, as of November 30, 2001.

On June 6, 1996, we received clearance from the FDA to market our model 3100A Cerebral Oximeter in the United States, and on October 13, 1997, we received clearance from the FDA to market enhancements to our Cerebral Oximeter in the United States. On September 15, 2000, we received FDA clearance to market our model 5100 Cerebral Oximeter in the United States. The model 5100 has the added capability of being able to monitor pediatric patients. In November 2001, we received clearance from the FDA to market the CorRestore patch in the United States. Our current financial condition and results of operations and the status of our product marketing efforts and sales have been affected by the process of obtaining such clearances.

As of February 5, 2002, we had six international distributors for the model 4100 Cerebral Oximeter, four international distributors for the model 5100 Cerebral Oximeter, eight direct sales personnel, one clinical specialist, one international sales consultant, and 11 independent sales representatives. During fiscal 2001, we devoted most of our marketing to continuing to introduce cerebral oximetry patient monitoring into the operating rooms of hospitals. There can be no assurance that we will be successful or profitable in marketing the Cerebral Oximeter, the related SomaSensor and the CorRestore System.

We believe that markets exist for the products we have developed and are developing; however, whether our products will be successful is uncertain. The following factors could impact the likelihood of our success: our limited resources and current financial condition, the problems and expenses frequently encountered by companies forming a new business, our ability to develop, apply and market new technology, and our industry and competitive environment.

We believe that the cash and cash equivalents on hand at November 30, 2001, together with the net proceeds of approximately \$3,725,000 from our public offering of 1,000,000 common shares on January 16, 2002 (Note 12) and the estimated net borrowings available under the Crestmark Bank Loan and Security Agreement (Note 11), will be adequate to satisfy our operating and capital requirements for more than the next twelve months.

The estimated length of time current cash and cash equivalents will sustain our operations is based on estimates and assumptions we have made. These estimates and assumptions are subject to change as a result of actual experience. Actual capital requirements necessary to market the Cerebral Oximeter and SomaSensor, to develop and market the CorRestore System, to undertake other product development activities, and for working capital might be substantially greater than current estimates.

SOMANETICS CORPORATION

NOTES TO FINANCIAL STATEMENTS – (Continued)

3. Stock Offerings and Common Shares

The underwriter of the June 1997 public offering and its transferees received warrants to purchase 200,000 common shares exercisable at \$4.80 per share until May 29, 2002. In addition, Kingsbridge Capital Limited has warrants to purchase 203,108 common shares exercisable at \$4.29 per share until September 3, 2005 pursuant to the Private Equity Line Agreement described below. Also, CorRestore, LLC and its agent, Wolfe & Company, received warrants to purchase 400,000 common shares exercisable at \$3.00 per share until June 2, 2005 pursuant to the CorRestore license agreement, and received warrants to purchase an additional 2,100,000 common shares exercisable at \$3.00 per share until November 21, 2006 pursuant to the CorRestore license agreement. Also, as described below, the placement agent in the April 9, 2001 private placement received warrants to purchase 25,000 common shares exercisable at \$2.10 per share until April 9, 2006.

On March 6, 2000, we entered into the Private Equity Line Agreement with Kingsbridge Capital Limited, a private institutional investor. In consideration for Kingsbridge's commitment under the Private Equity Line Agreement, we issued a warrant to Kingsbridge on March 6, 2000. The warrant entitles the holder to purchase 203,108 common shares, after adjustment for the April 2001 private placement, at a purchase price of \$4.29 per share. The warrant is exercisable at any time until September 3, 2005. The warrant contains standard provisions that protect the holder against dilution by adjustment of the exercise price and the number of shares issuable pursuant to the warrant if various events occur. The exercise price of the warrant is payable either in cash or by a cashless exercise.

Pursuant to the Private Equity Line Agreement, we completed the sales of 714,484 common shares under the Private Equity Line Agreement, for gross proceeds of \$2,000,000. Our net proceeds, after deducting the commissions and the estimated expenses of the offerings, were approximately \$1,793,000. Effective March 5, 2001, we de-registered the remaining shares originally registered for resale by Kingsbridge under the Private Equity Line Agreement, because we no longer intend to sell any more shares to Kingsbridge, except upon any exercise of its warrant, and Kingsbridge is no longer publicly offering for resale the shares subject to the warrant we granted to them. On April 10, 2001, we mutually agreed with Kingsbridge to terminate the Private Equity Line Agreement, the related Registration Rights Agreement, and Kingsbridge's right to the discount on any unsold shares, in exchange for our payment of \$200,000 to Kingsbridge.

On April 9, 2001, we completed the private placement of 1,325,000 newly-issued common shares at a price of \$1.75 per share, for gross proceeds of \$2,318,750. Our net proceeds, after deducting the placement agent's commission and the expenses of the offering, were approximately \$2,152,000. Brean Murray & Co., Inc. was our exclusive placement agent for the offering and received for its services (1) \$104,363 as a placement agent fee, and (2) warrants to purchase 25,000 common shares at \$2.10 per share exercisable during the four-year period beginning April 9, 2002. A. Brean Murray, one of our directors, and his wife control Brean Murray & Co., Inc. In addition, the Brean Murray & Co., Inc. Profit Sharing Plan purchased 32,285 common shares in the offering, and Robert R. Henry, one of our directors, purchased 100,000 common shares in the offering.

Common shares reserved for future issuance upon exercise of stock options and warrants as discussed above at November 30, 2001, are as follows:

1991 Incentive Stock Option Plan.....	88,089
1993 Director Stock Option Plan	2,498
1997 Stock Option Plan	1,659,800
Options Granted Independent of Option Plans.....	158,678
Underwriter Warrants.....	200,000
Kingsbridge Capital Limited Warrants	203,108
Placement Agent Warrants.....	25,000
License Acquisition Warrants	2,500,000
Total reserved for future issuance.....	<u>4,837,173</u>

SOMANETICS CORPORATION

NOTES TO FINANCIAL STATEMENTS – (Continued)

4. Summary of Significant Accounting Policies

Cash Equivalents consist of short-term, interest-bearing investments maturing within three months of our acquisition of them.

Inventory is stated at the lower of cost or market on a first-in, first-out (FIFO) basis. Inventory consists of:

	<u>November 30,</u>	
	<u>2001</u>	<u>2000</u>
Finished goods.....	\$ 50,314	\$ 36,374
Work in process.....	215,313	124,127
Purchased components.....	<u>528,130</u>	<u>453,429</u>
Total.....	<u>\$ 793,757</u>	<u>\$ 613,930</u>

Property and Equipment are stated at cost. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the assets, which range from two to five years.

Intangible Assets consist of patents and trademarks, and license acquisition costs. Patents and trademarks are recorded at cost and are being amortized on the straight-line method over 17 years. License acquisition costs are related to our acquisition of worldwide, royalty-bearing licenses to specified rights relating to the CorRestore System and related products and accessories.

We entered into a License Agreement as of June 2, 2000 with the inventors and their company, CorRestore LLC. The license grants us worldwide, royalty-bearing licenses to specified rights relating to the CorRestore System and related products and accessories for SVR, subject to the terms and conditions of the license agreement. Pursuant to the license agreement, CorRestore LLC has agreed to provide various consulting services to us. We have agreed to pay all of the expenses of such consultation, of clinical testing of the CorRestore System, training doctors in SVR and training our personnel and customers in the use of the CorRestore System.

In exchange for the licenses and consulting services, we agreed to the following compensation for CorRestore LLC and its agent, Wolfe & Company: (1) a royalty of 10% of our “net sales” of products subject to the licenses, (2) five-year warrants to purchase up to 400,000 common shares at \$3.00 a share, exercisable to purchase 300,000 shares immediately and to purchase an additional 50,000 shares upon our receipt of clearance or approval from the FDA to market the CorRestore patch in the United States and another 50,000 shares upon our receipt of CE certification for the CorRestore System, (3) additional five-year warrants to purchase up to 2,100,000 common shares at \$3.00 a share, granted when we received clearance from the FDA to market the CorRestore patch in the United States, exercisable based on our cumulative net sales of the CorRestore System products, and (4) a consulting fee of \$25,000 a year to each of the inventors until we sell 1,000 CorRestore patches.

License acquisition costs consist of professional service fees recorded at cost, our estimate of the fair value of the ten-year vested stock options to purchase 50,000 common shares at \$3.00 a share granted to one of our directors in connection with negotiating and assisting us in completing the transaction, and our estimate of the fair value of the 350,000 common share vested portion of the five-year warrants to purchase up to 400,000 common shares at \$3.00 a share issued in the transaction.

We estimated the value of the stock options to purchase 50,000 common shares using the Black-Scholes valuation model with the following assumptions: expected volatility (the measure by which the stock price has fluctuated or is expected to fluctuate during the period) 111.16%, risk-free interest rate of 7.5%, expected life of 4 years and dividend yield of 0%. We estimated the value of the warrants to purchase 300,000 common shares that vested immediately in this transaction using the Black-Scholes valuation model with the following assumptions: expected volatility (the measure by which the stock price has fluctuated or is expected to fluctuate during the period) 111.16%, risk-free interest rate of 7.5%, expected life of 5 years and dividend yield of 0%. We estimated the value

SOMANETICS CORPORATION

NOTES TO FINANCIAL STATEMENTS – (Continued)

of the warrants to purchase 50,000 common shares that vested upon receipt of FDA clearance in November 2001 using the Black-Scholes valuation model with the following assumptions: expected volatility (the measure by which the stock price has fluctuated or is expected to fluctuate during the period) 100.68%, risk-free interest rate of 4.0%, expected life of 42 months and dividend yield of 0%.

These costs are being amortized on the straight-line method over 5 years. Intangible assets consist of:

	November 30,	
	2001	2000
License acquisition costs	\$ 1,213,370	\$ 1,096,898
Patents and trademarks	<u>111,733</u>	<u>111,733</u>
Sub-total	1,325,103	1,208,631
Less accumulated amortization	<u>(396,233)</u>	<u>(169,943)</u>
Total	<u>\$ 928,870</u>	<u>\$ 1,038,688</u>

Amortization expense was \$226,290 for the fiscal year ended November 30, 2001, \$116,602 for the fiscal year ended November 30, 2000, and \$6,912 for the fiscal year ended November 30, 1999.

Intangible assets are reviewed periodically for impairment whenever events or changes in circumstances indicate that the carrying value of the asset may not be recovered.

In June 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets." This Statement is effective for fiscal years beginning after December 15, 2001, and establishes accounting and reporting standards for goodwill and other intangible assets. This Statement is effective for our financial statements for the fiscal year ending November 30, 2003. We expect to early adopt this Statement for our first quarter of fiscal 2002. The effect of adopting this Statement will be to discontinue amortizing our license acquisition costs related to our acquisition of worldwide, royalty-bearing licenses to specified rights relating to the CorRestore System and related products and accessories described above because we believe these licenses have an indefinite life. Amortization expense related to these licenses was approximately \$219,000 for the year ended November 30, 2001.

Revenue Recognition occurs when there is persuasive evidence of an arrangement with the customer, the product has been delivered, the sales price is fixed or determinable, and collectibility is reasonably assured. The product is considered delivered to the customer once we have shipped it, as this is when title and risk of loss have transferred.

Research, Development and Engineering costs are expensed as incurred.

Loss Per Common Share – basic and diluted is computed using the weighted average number of common shares outstanding during each period. Common shares issuable under stock options and warrants have not been included in the computation of net loss per common share – diluted, because such inclusion would be antidilutive. As of November 30, 2001, we had outstanding 4,774,228 warrants and options to purchase common shares, and as of November 30, 2000, we had outstanding 2,261,081 warrants and options to purchase common shares.

Accounting Pronouncements Effective December 1, 2000, we adopted Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities." This statement establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities. This statement had no impact on our financial statements.

In June 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets." This Statement is discussed above. See *Intangible Assets*.

In October 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting

SOMANETICS CORPORATION

NOTES TO FINANCIAL STATEMENTS - (Continued)

Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." This Statement is effective for fiscal years beginning after December 15, 2001, and replaces Statement No. 121 and provisions of APB Opinion No. 30 for the disposal of segments of a business. The statement creates one accounting model, based on the framework established in Statement No. 121, to be applied to all long-lived assets including discontinued operations. This Statement is effective for our financial statements for the fiscal year ending November 30, 2003. We have not yet determined the impact of this Statement on our financial statements.

Use Of Estimates The preparation of financial statements in conformity with generally accepted accounting principles requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities, and the reported amounts of revenues and expenses for each fiscal period. Actual results could differ from those estimated.

Reclassifications - Certain reclassifications have been made to the financial statements for 2000 and 1999 to conform to the 2001 presentation.

5. Accrued Liabilities

Accrued liabilities consist of the following:

	November 30,	
	2001	2000
Accrued Sales Commissions.....	\$ 60,109	\$ 117,045
Professional Fees	--	94,000
Accrued Insurance	24,570	24,361
Accrued Warranty.....	7,750	7,000
Accrued Incentive.....	--	17,500
Other	--	7,278
Total.....	\$ 92,429	\$ 267,184

6. Income Tax

Deferred income taxes reflect the estimated future tax effect of (1) temporary differences between the amount of assets and liabilities for financial reporting purposes and such amounts as measured by tax laws and regulations and (2) net operating loss and tax credit carryforwards. Our deferred tax assets primarily represent the tax benefit of net operating loss carryforwards and research and general business tax credit carryforwards. We had deferred tax assets of approximately \$17,100,000 and \$16,734,000 for the years ended November 30, 2001 and 2000, respectively, which were entirely offset by valuation allowances, due to the uncertainty of utilizing such assets against future earnings, prior to their expiration. The components of deferred income tax assets as of November 30, 2001 and 2000 were as follows:

	November 30,	
	2001	2000
	(in thousands)	
Net operating loss carryforwards.....	\$ 16,557	\$ 16,401
Other.....	79	36
Basis difference of fixed assets and intangibles.....	55	(90)
Research and general business tax credit carryforwards	409	387
Subtotal	17,100	16,734
Valuation allowance	(17,100)	(16,734)
Deferred tax asset.....	\$ —	\$ —

As of November 30, 2001, net operating loss carryforwards of approximately \$48.7 million were available for Federal income tax purposes. Our ability to use the net operating loss carryforwards incurred on or before

SOMANETICS CORPORATION

NOTES TO FINANCIAL STATEMENTS – (Continued)

March 27, 1991 (the date we completed our initial public offering) is limited to approximately \$296,000 per year. Research and business general tax credits of \$408,973 are also available to offset future taxes. These losses and credits expire, if unused, at various dates from 2001 through 2021.

Use of our net operating loss carryforwards, tax credit carryforwards and certain future deductions could be restricted, in the event of future changes in our equity structure, by provisions contained in the Tax Reform Act of 1986.

7. Commitments and Contingencies

We have a lease agreement for a 23,392 square foot, stand-alone office, assembly and warehouse facility. The current lease, as amended, expires December 31, 2003.

Operating lease expense for the years ended November 30, 2001, 2000 and 1999 was approximately \$196,000, \$182,000, and \$184,000, respectively. Approximate future minimum lease commitments are as follows:

<u>Year ended November 30,</u>	
2002	\$ 197,700
2003	\$ 201,700
2004	<u>16,800</u>
Total	<u>\$ 416,200</u>

In December 1991, we amended and restated our profit sharing plan to include a 401(k) plan covering substantially all employees. Under provisions of the plan, participants may contribute, annually, between 1% and 15% of their compensation. At the discretion of our Board of Directors, we may contribute matching contributions or make other annual discretionary contributions to the plan, all of which, together with the participants' contributions, cannot exceed 15% of the total compensation we pay to eligible employees. We did not make any matching or discretionary contributions to the plan for the years ended November 30, 2001, 2000 or 1999.

As of November 30, 2001, we had an employment agreement with Bruce J. Barrett, our President and Chief Executive Officer. Mr. Barrett's employment agreement, as amended, expires April 30, 2003 unless earlier terminated as provided in the agreement. Mr. Barrett is entitled to receive an annual base salary, plus potential discretionary bonuses. Mr. Barrett has agreed not to compete with us during specified periods.

We may become subject to products liability claims by patients or physicians, and may become a defendant in products liability or malpractice litigation. We have obtained products liability insurance and an umbrella policy; however, we might not be able to maintain such insurance or such insurance might not be sufficient to protect us against products liability.

8. Stock Option Plans

In February 1991 and January 1997, we adopted stock option plans for our key management employees, directors, consultants and advisors. The plans provide for our issuance of options to purchase a maximum of 115,000 common shares under the 1991 plan and 1,660,000 common shares under the 1997 plan. In addition, we granted options to employees independent of the plans. Options granted generally have a 10-year life, and vest over a three-year period. Awards and expirations under the 1991 plan, 1997 plan, and independent of the plans during the years ended November 30, 2001, 2000 and 1999 are listed below.

At November 30, 2001, no additional options may be granted under the 1991 plan, and 62,945 common shares were available for options to be granted under the 1997 plan.

In January 1993, we adopted the Somanetics Corporation 1993 Director Stock Option Plan. The directors plan provided up to 24,000 common shares for the grant of options to each director who was not one of our officers or employees. In January 1998, our Board of Directors terminated the directors plan, except as to options previously granted under the directors plan. Therefore, no additional options may be granted under the directors plan.

SOMANETICS CORPORATION

NOTES TO FINANCIAL STATEMENTS – (Continued)

In October 1995, SFAS No. 123, "Accounting for Stock-Based Compensation," was issued. We have chosen to continue to account for stock-based compensation of employees using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. Accordingly, compensation costs for stock options granted to employees are measured as the excess, if any, of the market price of our stock at the date of the grant over the amount an employee must pay to acquire the stock. No compensation expense has been charged against income for stock option grants to employees. Stock-based compensation of consultants and advisors is determined based on the fair value of the options or warrants on the grant date pursuant to the methodology of SFAS No. 123, estimated using the Black-Scholes model with the assumptions described in the next paragraph. The resulting amount is recognized as compensation expense and an increase in additional paid-in capital over the vesting period of the option or warrant. As a result, we recorded \$4,984 of compensation expense, and an equal increase in additional paid in capital, for stock options issued to a consultant in fiscal 2001.

Had compensation expense for our stock options granted to employees been determined based on the fair value of the options on the grant date pursuant to the methodology of SFAS No. 123, our net loss on a pro forma basis would have

- o increased by approximately \$752,000 to \$(3,083,000), or \$(.41) per common share, for fiscal 2001,
- o increased by approximately \$495,000 to \$(4,117,000), or \$(.65) per common share, for fiscal 2000, and
- o increased by approximately \$571,000 to \$(5,236,000), or \$(.87) per common share, for fiscal 1999.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions used for 2001, 2000 and 1999: expected volatility (the measure by which the stock price has fluctuated or is expected to fluctuate during the period) 100.68% for 2001 (109.94% for 2000 and 95.05% for 1999), risk-free interest rate of 4.0% for 2001 (6.0% for 2000 and 6.5% for 1999), expected lives of 4 years and dividend yield of 0%.

A summary of our stock option activity and related information for years ended November 30, 2001, 2000 and 1999 is as follows:

	2001		2000		1999	
	Common Shares	Weighted Average Exercise Price	Common Shares	Weighted Average Exercise Price	Common Shares	Weighted Average Exercise Price
Options outstanding						
December 1,	1,394,537	\$ 5.74	1,226,537	\$ 6.16	998,737	\$ 6.81
Options granted.....	529,800	2.00	236,000	3.24	242,900	3.38
Options exercised.....	--	--	--	--	--	--
Options canceled.....	<u>(78,217)</u>	<u>9.25</u>	<u>(68,000)</u>	<u>4.65</u>	<u>(15,100)</u>	<u>4.62</u>
Options outstanding						
November 30, (1) (2) ..	<u>1,846,120</u>	<u>4.52</u>	<u>1,394,537</u>	<u>5.74</u>	<u>1,226,537</u>	<u>6.16</u>
Options exercisable						
November 30,	<u>1,267,849</u>	<u>\$ 5.63</u>	<u>958,152</u>	<u>\$ 6.66</u>	<u>585,952</u>	<u>\$ 8.03</u>

(1) Exercise dates range from May 4, 1992 to November 19, 2011.

(2) As of November 30, 2001, options outstanding have exercise prices between \$1.44 and \$32.50, and a weighted-average remaining contractual life of 6.98 years.

SOMANETICS CORPORATION

NOTES TO FINANCIAL STATEMENTS – (Continued)

9. Related Party Transactions

We received legal services from certain shareholders. Services from such parties amounted to approximately \$197,000 during the year ended November 30, 2001, \$211,600 during the year ended November 30, 2000, and \$160,400 during the year ended November 30, 1999.

We paid a non-refundable fee of \$50,000 to Brean Murray & Co., Inc. during fiscal 1999 for financial advisory services. A. Brean Murray, one of our directors, and his wife control Brean Murray & Co., Inc.

Pursuant to an engagement letter between us and Brean Murray & Co., Inc., dated March 1, 2000, we agreed to pay Brean Murray & Co., Inc. a commission of 3.5% on proceeds of specified securities sales, including sales pursuant to the Kingsbridge Capital Limited Private Equity Line Agreement. During fiscal 2000, we paid Brean Murray & Co., Inc. \$63,000 in commissions pursuant to this engagement letter. During fiscal 2001, we paid Brean Murray & Co., Inc. \$7,000 in commissions pursuant to this engagement letter.

Also, during fiscal 2000, we granted A. Brean Murray (1) a 10-year option to purchase 50,000 common shares on May 31, 2000, exercisable at \$3.00 a share, which was more than the fair market value of the common shares on the date of grant, in connection with negotiating and assisting us in completing our CorRestore licenses, and (2) a 10-year option to purchase 50,000 common shares on May 31, 2000, exercisable at \$4.36 a share, which was more than the fair market value of the common shares on the date of grant, in connection with the Kingsbridge Capital Limited Private Equity Line Agreement.

In connection with our April 2001 private placement of common shares, Brean Murray & Co., Inc. was our exclusive placement agent and received for its services (1) \$104,363 as a placement agent fee, and (2) warrants to purchase 25,000 common shares at \$2.10 per share exercisable during the four-year period beginning April 9, 2002. In addition, the Brean Murray & Co., Inc. Profit Sharing Plan purchased 32,285 common shares in the offering, and Robert R. Henry, one of our directors, purchased 100,000 common shares in the offering.

In connection with our CorRestore license, effective June 2, 2000, we granted Wolfe & Company a five-year warrant to purchase 20,000 common shares, exercisable at \$3.00 a share. These warrants were granted before Mr. Joe B. Wolfe became one of our directors. Also, in connection with our CorRestore license, effective November 21, 2001, we granted Wolfe & Company a five-year warrant to purchase 180,000 common shares, exercisable at \$3.00 a share.

10. Major Customers and Foreign Sales

One international distributor accounted for approximately 17% (Europe) of net revenues for the fiscal year ended November 30, 2001, two international distributors accounted for approximately 23% (Europe) and 11% (Japan), respectively, of net revenues for the fiscal year ended November 30, 2000, and one international distributor accounted for approximately 23% (Japan) of net revenues for the fiscal year ended November 30, 1999.

Additionally, net revenues from foreign customers for the fiscal year ended November 30, 2001 were approximately \$1,595,000, for the fiscal year ended November 30, 2000 were approximately \$2,265,000, and for the fiscal year ended November 30, 1999 were approximately \$1,632,000.

11. Notes Payable – Bank Line of Credit

On February 13, 2001, we entered into a Loan and Security Agreement with Crestmark Bank for a working capital line of credit for up to \$750,000, collateralized by all of our assets. Under the Agreement, Crestmark Bank may, but is not obligated to, lend us amounts we request from time to time, up to \$750,000, if no default exists. The loans are limited by a borrowing base based on qualifying accounts receivable and lender reserves. The loan is payable on demand, and collections of our receivables are directed to Crestmark Bank in payment of any outstanding balance of the loan.

SOMANETICS CORPORATION

NOTES TO FINANCIAL STATEMENTS – (Continued)

The principal amount outstanding bears interest, payable monthly, at the prime rate (5.00% at November 30, 2001) plus 2% plus a 2.4% service fee, and we paid a \$45,000 commitment fee for the loan. Through November 30, 2001, we have borrowed an aggregate of \$920,050 under the agreement and repaid \$920,050 in principal amount through Crestmark's collection of our receivables and by using some of the proceeds from our April 9, 2001 offering. As of November 30, 2001, \$750,000 was available for borrowing, at Crestmark's discretion, under the facility. We have agreed to use the proceeds of the loans solely as working capital. The line of credit requires us to maintain minimum tangible net worth of \$500,000 and a ratio of total liabilities to tangible net worth not to exceed 3:1. The line of credit terminates upon Crestmark's demand.

12. Subsequent Events

On January 16, 2002, we completed a public offering of 1,000,000 newly-issued common shares at a price of \$4.25 per share, for gross proceeds of \$4,250,000. Our estimated net proceeds, after deducting the placement agent's commission and the estimated expenses of the offering, were approximately \$3,725,000. Brean Murray & Co., Inc. was our exclusive placement agent for the offering and received for its services (1) \$340,000 as a placement agent fee, and (2) warrants to purchase 100,000 common shares at \$5.10 per share exercisable during the four-year period beginning January 11, 2003. A. Brean Murray, one of our directors, and his wife control Brean Murray & Co., Inc. As a result of this offering, Kingsbridge Capital Limited's warrant has been adjusted, and Kingsbridge is now entitled to purchase 205,097 common shares at a purchase price of \$4.25 per share.

QUARTERLY INFORMATION (unaudited)

The following is a summary of our quarterly operating results for the fiscal years ended November 30, 2001 and 2000:

	Quarter			
	First	Second	Third	Fourth
(in thousands, except per share data)				
<u>Year Ended November 30, 2001</u>				
Net revenues	\$1,437,492	\$1,261,513	\$1,110,721	\$1,845,806
Gross margin.....	837,333	843,834	720,106	1,159,787
Net income (loss).....	(711,156)	(849,775)	(820,475)	50,495
Net income (loss) per common share - basic and diluted	\$(0.11)	\$(0.11)	\$(0.10)	\$ 0.01
<u>Year Ended November 30, 2000</u>				
Net revenues	\$1,037,615	\$1,430,066	\$1,006,408	\$1,629,009
Gross margin.....	544,256	711,597	584,929	892,111
Net loss	(885,928)	(922,885)	(995,187)	(818,087)
Net loss per common share -basic and diluted	\$(0.15)	\$(0.15)	\$(0.15)	\$(0.12)

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS
ON ACCOUNTING AND FINANCIAL DISCLOSURE

NONE

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required by this Item 10 regarding our executive officers is included in the Supplemental Item in Part I of this Report, and is incorporated in this Item 10 by reference. The information required by this Item 10 regarding our directors will be set forth under the caption "Election of Directors" in our Proxy Statement in connection with the 2002 Annual Meeting of Shareholders scheduled to be held April 17, 2002, and is incorporated in this Item 10 by reference. The information required by this Item 10 concerning compliance with Section 16(a) of the Securities Exchange Act of 1934 will be set forth under the caption "Section 16(a) Beneficial Ownership Reporting Compliance" in our Proxy Statement in connection with the 2002 Annual Meeting of Shareholders scheduled to be held April 17, 2002, and is incorporated in this Item 10 by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 concerning executive compensation will be set forth under the caption "Executive Compensation" in our Proxy Statement in connection with the 2002 Annual Meeting of Shareholders scheduled to be held April 17, 2002, and is incorporated in this Item 11 by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information required by this Item 12 concerning security ownership of certain beneficial owners and management will be set forth under the captions "Voting Securities and Principal Holders" and "Election of Directors" in our Proxy Statement in connection with the 2002 Annual Meeting of Shareholders scheduled to be held April 17, 2002, and is incorporated in this Item 12 by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this Item 13 concerning certain relationships and related transactions, if any, will be set forth under the caption "Certain Transactions" or "Compensation Committee Interlocks and Insider Participation" in our Proxy Statement in connection with the 2002 Annual Meeting of Shareholders scheduled to be held April 17, 2002, and is incorporated in this Item 13 by reference.

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a) (1) Financial Statements

Our financial statements for the following years are included in response to Item 8 of this Report:

Independent Auditors' Report

Balance Sheets - November 30, 2001 and 2000

Statements of Operations - For Each of the Three Years in the Period Ended November 30, 2001

Statements of Shareholders' Equity - For Each of the Three Years in the Period Ended November 30, 2001

Statements of Cash Flows - For Each of the Three Years in the Period Ended November 30, 2001

Notes to Financial Statements

(2) Financial Statement Schedule

The following financial statement schedule is included in response to Item 8 of this Report:

Schedule II - Valuation and Qualifying Accounts and Reserves for the Years Ended November 30, 2001, 2000 and 1999.

(3) Exhibits

The Exhibits to this Report are as set forth in the "Index to Exhibits" on pages 54 to 57 of this Report. Each management contract or compensatory plan or arrangement filed as an exhibit to this Report is identified in the "Index to Exhibits" with an asterisk before the exhibit number.

(b) Reports on Form 8-K

No reports on Form 8-K were filed by us during the fourth quarter of the fiscal year ended November 30, 2001.

SCHEDULE II -- VALUATION AND QUALIFYING ACCOUNTS AND RESERVES
for the years ended November 30, 2001, 2000 and 1999

	<u>Column B</u>	<u>Column C</u>		<u>Column D</u>	<u>Column E</u>
		<u>Additions</u>			
	Balance at Beginning of Period	Charged to Costs and Expenses	Charged to Other Accounts, Describe	(1)(2) Deductions, Describe	Balance at End of Period
Allowance for doubtful accounts:					
Year ended November 30, 2001	\$ --	\$--	--	\$ --	\$--
Year ended November 30, 2000	--	--	--	--	--
Year ended November 30, 1999	152,602	--	--	152,602	--
Note: (1) Write-off uncollectible accounts, net of recoveries					
Inventory reserve for obsolescence:					
Year ended November 30, 2001	\$ --	\$ --	--	\$ --	\$--
Year ended November 30, 2000	--	--	--	--	--
Year ended November 30, 1999	138,224	1,199	--	139,423	--

Note: (2) Write-off obsolete, excess inventory, net of recoveries

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.

Date: February 12, 2002

Somanetics Corporation
 By: /s/ Bruce J. Barrett
 Bruce J. Barrett
 President & 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 and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Bruce J. Barrett</u> Bruce J. Barrett	President and Chief Executive Officer and a Director (Principal Executive Officer)	February 12, 2002
<u>H. Raymond Wallace</u>	Chairman of the Board of Directors	February __, 2002
<u>/s/ William M. Iacona</u> William M. Iacona	Vice President, Finance, Controller, and Treasurer (Principal Financial Officer and Principal Accounting Officer)	February 12, 2002
<u>/s/ Daniel S. Follis</u> Daniel S. Follis	Director	February 8, 2002
<u>/s/ James I. Ausman</u> James I. Ausman, M.D., Ph.D.	Director	February 11, 2002
<u>/s/ Robert R. Henry</u> Robert R. Henry	Director	February 11, 2002
<u>/s/ A. Brean Murray</u> A. Brean Murray	Director	February 11, 2002
<u>/s/ Joe B. Wolfe</u> Joe B. Wolfe	Director	February 12, 2002

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
3(i)	Restated Articles of Incorporation of Somanetics Corporation, incorporated by reference to Exhibit 3(i) to the Company's Quarterly Report on Form 10-Q for the quarter ended February 28, 1998.
3(ii)	Amended and Restated Bylaws of Somanetics Corporation, incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 16, 1995.
10.1	Lease Agreement, dated September 10, 1991, between Somanetics Corporation and WS Development Company, incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended August 31, 1991.
10.2	Extension of Lease, between Somanetics Corporation and WS Development Company, dated July 22, 1994, incorporated by reference to Exhibit 10.11 to the Company's Quarterly Report on Form 10-Q for the quarter ended August 31, 1994.
10.3	Change in ownership of Lease Agreement for 1653 E. Maple Road, Troy, MI 48083, dated September 12, 1994, between Somanetics Corporation and First Industrial, L.P., incorporated by reference to Exhibit 10.12 to the Company's Quarterly Report on Form 10-Q for the quarter ended August 31, 1994.
10.4	Second Addendum, between Somanetics Corporation and First Industrial Mortgage Partnership, L.P., dated April 14, 1997, incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended May 31, 1997.
10.5	Third Amendment, between Somanetics Corporation and First Industrial Mortgage Partnership, L.P., dated April 23, 1999, incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended May 31, 1999.
10.6	Fourth Amendment, between Somanetics Corporation and First Industrial Mortgage Partnership, L.P., dated April 13, 2000, incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended May 31, 2000.
*10.7	Somanetics Corporation Amended and Restated 1991 Incentive Stock Option Plan, incorporated by reference to Exhibit 10.5 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1991.
*10.8	Fourth Amendment to Somanetics Corporation 1991 Incentive Stock Option Plan, incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1992.
*10.9	Amended and Restated Fifth Amendment to Somanetics Corporation 1991 Incentive Stock Option Plan, incorporated by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1995.
*10.10	Somanetics Corporation 1993 Director Stock Option Plan, incorporated by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1992.
*10.11	Somanetics Corporation 1997 Stock Option Plan, incorporated by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1996.
*10.12	First Amendment to Somanetics Corporation 1997 Stock Option Plan, incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1997.
*10.13	Second Amendment to Somanetics Corporation 1997 Stock Option Plan, incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1998.
*10.14	Third Amendment to Somanetics Corporation 1997 Stock Option Plan, incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1999.
*10.15	Fourth Amendment to Somanetics Corporation 1997 Stock Option Plan, incorporated by referenced to Exhibit 10.16 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 2000.

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
*10.16	Restated Somanetics Corporation 2001 Employee Incentive Compensation Plan, dated as of March 5, 2001, incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended February 28, 2001.
*10.17	Employment Agreement, dated as of December 1, 1992, between Somanetics Corporation and Raymond W. Gunn, incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1992.
*10.18	Employment Agreement, dated May 13, 1994, between Somanetics Corporation and Bruce J. Barrett, incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended May 31, 1994.
*10.19	Amendment to Employment Agreement, dated as of February 23, 1994, between Somanetics Corporation and Raymond W. Gunn, incorporated by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1993.
*10.20	Amendment to Employment Agreement, dated as of July 21, 1994, between Somanetics Corporation and Bruce J. Barrett, incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended August 31, 1994.
*10.21	Amendment to Employment Agreement, dated as of July 21, 1994, between Somanetics Corporation and Raymond W. Gunn, incorporated by reference to Exhibit 10.3 to the Company's Quarterly report on Form 10-Q for the quarter ended August 31, 1994.
*10.22	Amendment to Employment Agreement, dated as of December 1, 1995, between Somanetics Corporation and Raymond W. Gunn, incorporated by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1995.
*10.23	Amendment to Employment Agreement, dated as of November 18, 1996, between Somanetics Corporation and Raymond W. Gunn, incorporated by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1996.
*10.24	Amendment to Employment Agreement, dated as of April 24, 1997, between Somanetics Corporation and Bruce J. Barrett, incorporated by reference to Exhibit 10.21 to Amendment No. 1 to the Registration Statement on Form S-1 (file no. 333-25275), filed with the Securities and Exchange Commission on May 30, 1997.
*10.25	Amendment to Employment Agreement, dated as of April 24, 1997, between Somanetics Corporation and Raymond W. Gunn, incorporated by reference to Exhibit 10.22 to Amendment No. 1 to the Registration Statement on Form S-1 (file no. 333-25275), filed with the Securities and Exchange Commission on May 30, 1997.
*10.26	Amendment to Employment Agreement, dated as of April 18, 2000, between Somanetics Corporation and Bruce J. Barrett, incorporated by reference to Exhibit 10.3 to the Company's Quarterly report on Form 10-Q for the quarter ended May 31, 2000.
*10.27	Amendment to Employment Agreement, dated as of March 5, 2001, between Somanetics Corporation and Bruce J. Barrett, incorporated by reference to Exhibit 10.2 to the Company's Quarterly report on Form 10-Q for the quarter ended February 28, 2001.
*10.28	Change in Control, Invention, Confidentiality, Non-Compete and Non-Solicitation Agreement, dated January 11, 2002, between Somanetics Corporation and Richard S. Scheuing.
*10.29	Stock Option Agreement, dated May 16, 1994, between Somanetics Corporation and Bruce J. Barrett, incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q for the quarter ended August 31, 1994.
*10.30	Stock Option Agreement, dated July 21, 1994, between Somanetics Corporation and Bruce J. Barrett, incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended August 31, 1994.
*10.31	Stock Option Agreement, dated July 21, 1994, between Somanetics Corporation and Gary D. Lewis, incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended August 31, 1994.
*10.32	Stock Option Agreement, dated July 21, 1994, between Somanetics Corporation and Raymond W. Gunn, incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q for the quarter ended August 31, 1994.
*10.33	Stock Option Agreements, dated July 20, 1995, between Somanetics Corporation and Richard Farkas, incorporated by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1995.

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
*10.34	Form of Stock Option Agreement, dated December 22, 1995, between Somanetics Corporation and various employees, incorporated by reference to Exhibit 10.29 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1995.
*10.35	Form of Stock Option Agreement, dated December 22, 1995, between Somanetics Corporation and various officers, incorporated by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1995.
*10.36	Form of new Stock Option agreement, dated December 22, 1995, between Somanetics Corporation and various employees, incorporated by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1995.
*10.37	Form of Stock Option Agreement, dated January 5, 1996, between Somanetics Corporation and two officers, incorporated by reference to Exhibit 10.32 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1995.
*10.38	Form of Stock Option Agreement, dated as of April 24, 1997, between Somanetics Corporation and twenty-three employees, incorporated by reference to Exhibit 10.32 to Amendment No. 1 to the Registration Statement on Form S-1 (file no. 333-25275), filed with the Securities and Exchange Commission on May 30, 1997.
*10.39	Amendment to Stock Option Agreement, dated as of February 1, 1995, between Somanetics Corporation and Gary D. Lewis, amending July 21, 1994 Stock Option Agreement, incorporated by reference to Exhibit 10.31 to Post-Effective Amendment No. 5 to the Company's Registration Statement on Form S-1 (file no. 33-38438) filed with the Securities and Exchange Commission on March 30, 1995.
*10.40	Consulting Agreement, dated February 28, 1983, as amended, between Somanetics Corporation and Hugh F. Stoddart, incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1991.
10.41	Current Form of Somanetics Corporation Confidentiality Agreement used for testing hospitals and clinics, incorporated by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1992.
10.42	Current Form of Somanetics Corporation Confidentiality Agreement used for the Company's employees and agents, incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended August 31, 1992.
10.43	Assignments, dated October 6, 1983, January 23, 1986, February 11, 1986 and February 11, 1986, from Gary D. Lewis to Somanetics Corporation in connection with the Company's INVOS technology, incorporated by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1 (file no. 33-38438).
10.44	Assignments, dated October 5, 1983, August 28, 1985, February 11, 1986, February 12, 1986, and September 24, 1986, from Hugh F. Stoddart to Somanetics Corporation in connection with the Company's INVOS technology, incorporated by reference to Exhibit 10.18 to the Company's Registration Statement on Form S-1 (file no. 33-38438).
10.45	Private Equity Line Agreement, dated as of March 6, 2000, between Somanetics Corporation and Kingsbridge Capital Limited, incorporated by reference to Exhibit 10.42 to the Company's Registration Statement on Form S-1 (file no. 333-33262) filed on March 24, 2000 and effective March 31, 2000.
10.46	Warrant, dated as of March 6, 2000, from Somanetics Corporation to Kingsbridge Capital Limited, incorporated by reference to Exhibit 10.43 to the Company's Registration Statement on Form S-1 (file no. 333-33262) filed on March 24, 2000 and effective March 31, 2000.
10.47	Registration Rights Agreement, dated as of March 6, 2000, between Somanetics Corporation and Kingsbridge Capital Limited, incorporated by reference to Exhibit 10.44 to the Company's Registration Statement on Form S-1 (file no. 333-33262) filed on March 24, 2000 and effective March 31, 2000.

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
10.48	Termination Agreement, dated as of March 29, 2001, between Somanetics Corporation and Kingsbridge Capital Limited, incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended February 28, 2001.
10.49	Form of Warrant Agreement and Warrant, dated June 4, 1997, between Somanetics Corporation and Brean Murray & Co., Inc., incorporated by reference to Exhibit 10.60 to Amendment No. 1 to the Registration Statement on Form S-1 (file no. 333-25275), filed with the Securities and Exchange Commission on May 30, 1997.
10.50	Engagement Letter, dated as of March 29, 2001, between Somanetics Corporation and Brean Murray & Co., Inc., incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended February 28, 2001.
10.51	Registration Rights Agreement, dated as of April 9, 2001, among Somanetics Corporation and the selling shareholders, incorporated by reference to Exhibit 4.3 to the Somanetics Corporation Registration Statement on Form S-3 (file no. 333-59376) filed April 23, 2001 and effective May 3, 2001.
10.52	Form of Warrant Agreement, dated April 9, 2001, between Somanetics Corporation and Brean Murray & Co., Inc., incorporated by reference to Exhibit 4.4 to the Somanetics Corporation Registration Statement on Form S-3 (file no. 333-59376) filed April 23, 2001 and effective May 3, 2001.
10.53	Amendment to Warrant Agreement, dated December 6, 2001, between Somanetics Corporation and Brean Murray & Co., Inc., incorporated by reference to Exhibit 10.53 to the Somanetics Corporation Registration Statement on Form S-1 (file no. 333-74788) filed December 7, 2001 and effective January 11, 2002.
10.54	Form of Placement Agency Agreement, dated as of January 11, 2002, between Somanetics Corporation and Brean Murray & Co., Inc., incorporated by reference to Exhibit 1.1 to the Somanetics Corporation Registration Statement on Form S-1 (file no. 333-74788) filed December 7, 2001 and effective January 11, 2002.
10.55	Form of Warrant Agreement and Warrant, dated January 16, 2002, between Brean Murray & Co., Inc. and Somanetics Corporation, incorporated by reference to Exhibit 1.3 to the Somanetics Corporation Registration Statement on Form S-1 (file no. 333-74788) filed December 7, 2001 and effective January 11, 2002.
10.56	Loan and Security Agreement, dated as of February 13, 2001, between Somanetics Corporation and Crestmark Bank, incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended February 28, 2001.
10.57	License Agreement, dated as of June 2, 2000, among Somanetics Corporation, CorRestore LLC, Constantine L. Athanasuleas, M.D. and Gerald D. Buckberg, M.D., including forms of warrants from Somanetics Corporation to CorRestore LLC and Wolfe & Company, incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended May 31, 2000.
23.1	Consent of Deloitte & Touche LLP.

BOARD OF DIRECTORS

H. RAYMOND WALLACE
Chairman of the Board
Somanetics Corporation

BRUCE J. BARRETT
President and Chief Executive Officer
Somanetics Corporation

JAMES I. AUSMAN, M.D., Ph.D.
Professor, Department of Neurosurgery
College of Medicine
University of Illinois at Chicago

DANIEL S. FOLLIS
President, Verschuren & Follis, Inc.
Investment Fund Management
President, Follis Corporation
Sales and Marketing Company

ROBERT R. HENRY
President, Robert R. Henry & Co., Inc.
Financial Consulting and Investment Firm

A. BREAN MURRAY
Chairman, President and Chief Executive Officer
Brean Murray & Co., Inc.
Investment Banking Firm

JOE B. WOLFE
President, Wolfe & Company
Financial Advisory Company

OFFICERS

BRUCE J. BARRETT
President and Chief Executive Officer

WILLIAM M. IACONA
Vice President, Finance, Controller and Treasurer

RICHARD S. SCHEUING
Vice President, Research & Development

MARY ANN VICTOR
Vice President, Communications and Administration
and Secretary

RONALD A. WIDMAN
Vice President, Medical Affairs

PAMELA A. WINTERS
Vice President, Operations

CORPORATE INFORMATION

SOMANETICS' COMMON SHARES: Somanetics' common shares are traded on The Nasdaq SmallCap Market under the symbol SMTS.

REGISTRAR AND TRANSFER AGENT: American Stock Transfer & Trust Company,
59 Maiden Lane, New York, NY 10007

AUDITORS: Deloitte & Touche LLP, Detroit, MI

GENERAL COUNSEL: Honigman Miller Schwartz and Cohn LLP, Detroit, MI

FORM 10-K: Additional copies of Somanetics' Annual Report to the Securities and Exchange Commission on Form 10-K for the fiscal year ended November 30, 2001 are available without charge to shareholders, on request, and may be obtained by contacting Somanetics' Investor Relations Department.

INVESTOR RELATIONS: 1653 East Maple Road, Troy, MI 48063-4208
(248) 689-3050 ext. 204
E-mail: info@somanetics.net

CORPORATE WEB SITE: www.somanetics.net



SOMANETICS®

Window to the Brain®

ABOUT SOMANETICS

Nasdaq: SMTS

Somanetics manufactures and markets the INVOS® Cerebral Oximeter system, the only noninvasive and continuous monitor of changes in regional oxygen saturation of a patient's blood in the brain commercially available in the U.S. Use of the patient monitoring system helps medical professionals, such as surgeons and anesthesiologists, identify regional brain blood oxygen imbalances and take corrective action. Such action can prevent or reduce neurological injuries related to adverse events during surgery or in the critical care unit and reduce the associated cost of care.

Somanetics also is developing the CorRestore™ System for use in cardiac repair and reconstruction, including a procedure called Surgical Ventricular Restoration, or SVR, a treatment for patients with certain types of congestive heart failure. During SVR, the surgeon restores an enlarged, poorly functioning left ventricle to more normal size and function by inserting an implant, in most instances, or by direct closure.

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