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SOMANETICS CORP

Form 10-K

January 12, 2001

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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, 2000 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

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(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 ☐  
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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

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Registrant as of January 11, 2001, computed by reference to the closing sale price as reported by Nasdaq on such date, was approximately \$10,147,000.

The number of the Registrant's common shares outstanding as of January 11, 2001 was 6,750,081

### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the 2001 Annual Meeting of Shareholders, scheduled to be held February 22, 2001, are incorporated by reference in Part III, if the Proxy Statement is filed no later than March 30, 2001.

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### SOMANETICS CORPORATION

### ANNUAL REPORT ON FORM 10-K

FOR THE FISCAL YEAR ENDED NOVEMBER 30, 2000

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PART I

ITEM 1. BUSINESS

THE COMPANY

We were incorporated in 1982, and we develop, manufacture and market the INVOS(R) 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(TM) patch, which is being developed for use in heart surgeries called surgical anterior ventricular restoration, or SAVR. 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(TM) patch, a new cardiac implant

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designed by CorRestore LLC, for use in heart surgeries called surgical anterior ventricular restoration, or SAVR. During SAVR, the surgeon restores, or remodels, an enlarged, poor 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 exclusive, worldwide, royalty-bearing licenses to specified rights relating to the CorRestore(TM) patch, subject to the terms and conditions of the license agreement. Our objective is to obtain regulatory clearance or approval to sell the CorRestore(TM) patch and other regulatory approvals necessary to market outside the United States and to have the patch used in SAVR surgeries. Our initial target market is SAVR 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,

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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

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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

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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,

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- 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

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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**

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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 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

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trade shows and medical conferences, and ongoing product evaluations. We are marketing our products through our existing sales force and we leverage our sales resources through the use of our distributors, including 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. We are also in the process of 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



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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 \$15,995, for the model 5100 Cerebral Oximeter is \$23,000, 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

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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:

FEATURES	BENEFITS
FDA-cleared	- Access to United States and certain foreign markets
Non-invasive	- Consistent with market trend toward less invasive procedures
	- No risk to patients and medical professionals
	- No added patient recovery costs
Continuous Information	- Immediate information regarding brain oxygen imbalance
	- Real-time guide to therapeutic interventions
New Organ-Specific Information	- Provides information about oxygen imbalances in both sides of the brain
Relatively Inexpensive	- Low cost relative to other brain monitors and medical procedures
	- 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	- Does not require a trained technician to operate or maintain
	- Automatic SomaSensor calibration
	- Simple user interface and controls
	- Audible alarm limits
Effective in Difficult Circumstances	- Provides information when the patient is unconscious, has no 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 oxygenation of the arteries or the effects of imbalance on the brain
Portable	- 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 product-line extensions of the Cerebral Oximeter for use on newborns, other non-brain tissue applications, and enhancements to the Cerebral Oximeter and SomaSensor. In September 2000, we received clearance from the FDA to market the

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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 \$513,816 during fiscal 2000 on research, development and engineering, \$598,348 during fiscal 1999, and \$664,874 during fiscal 1998. Effective April 28, 1999, we terminated our consulting order with NeuroPhysics Corporation, except for general consulting which terminated in February 2000. We terminated the consulting order and general consulting because of our cost to pursue their new products.

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### 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 consists primarily of comparing the measurements obtained from the Cerebral Oximeter to the data obtained from existing diagnostic methods, including EEG, transcranial Doppler and invasive jugular bulb catheter monitoring, or reports of the results of the use of the Cerebral Oximeter in various procedures. We attend trade shows and medical conferences to introduce and promote the Cerebral Oximeter and to meet medical professionals with an interest in submitting peer-reviewed papers to appropriate medical journals and to major national meetings. In fiscal year 2000, a total of 60 presentations concerning the Cerebral Oximeter were made at 22 meetings, 22 articles mentioning the Cerebral Oximeter were published in peer-reviewed journals, and 13 abstracts mentioning the Cerebral Oximeter were published. Some of these

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presentations contained the same subject matter as other presentations, articles or abstracts. Also, in May 1999, at the University of Chicago Charles Huggins Annual Research Conference, a researcher received the first place award for research related to cerebral oximetry.

### SALES AND DISTRIBUTION

We sell the Cerebral Oximeter through our direct sales force and independent distributors. In the United States, we sell the Cerebral Oximeter through our 12 direct salespersons and four clinical specialists. 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 seven independent distributors covering 45 countries for the model 4100 Cerebral Oximeter, and our distribution agreements with three of those distributors cover 41 countries for the model 5100 Cerebral Oximeter. Our distributors include Nellcor Puritan Bennett Export, Inc., part of Tyco International Ltd., in Europe, and Baxter Limited in Japan. Our agreement with Nellcor Puritan Bennett Export, Inc. covers 39 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 2, 2001 or as of January 20, 2000.

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

Our export sales were approximately \$2,265,000 for the fiscal year ended November 30, 2000, \$1,632,000 for the fiscal year ended November 30, 1999, and \$959,000 for the fiscal year ended November 30, 1998. 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 3100A Cerebral Oximeters, model 4100 exchanges and refurbished model 3100 Cerebral Oximeters, 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,

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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.

### 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,

- fines,
- injunctions,
- civil penalties,
- recall or seizure of products,
- total or partial suspension of production,
- failure of the government to grant premarket clearance or premarket approval for devices,
- withdrawal of marketing clearances or approvals and
- 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." Such clearance generally is granted when submitted information establishes that a proposed device is "substantially equivalent" in intended use 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.

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 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



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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

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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 changes to the model 3100A Cerebral Oximeter that resulted in the model 4100 Cerebral Oximeter and we have made additional changes to the SomaSensor. We do not believe that these changes 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.

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

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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 May 1997. 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.

Congress enacted the FDA Modernization Act of 1997. This law, which is intended to make the regulatory process more consistent and efficient, makes changes to the device provisions of the Food, Drug, and Cosmetic Act and other provisions in this act affecting the regulation of devices. Among other things, the changes will affect the IDE, 510(k) and PMA processes, and also will affect device standards and data requirements, procedures relating to humanitarian and breakthrough devices, tracking and postmarket surveillance, accredited third party review, and the dissemination of off label information. We cannot predict how or when these changes will be implemented or what effect the changes will have on the regulation of our products.

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### 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(TM) PATCH

### 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

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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 remodeling 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 SAVR, the surgeon restores, or remodels, an enlarged, poor 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 SAVR 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 SAVR 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 SAVR.

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(TM) patch and to have the patch used in SAVR surgeries. Key elements of our strategy are as follows:

Obtain Regulatory Clearance or Approval for the CorRestore(TM) Patch. We are currently working with the inventors to design and execute the preliminary and definitive clinical tests necessary to obtain regulatory approvals for the CorRestore(TM) patch, including FDA clearance and CE certification. We currently believe that the CorRestore(TM) patch is eligible to seek 510(k) clearance to market the product in the United States. If human clinical trials are required by the FDA, we will have to file IDE applications with the FDA before beginning the human clinical trials. However, the FDA could require a PMA application, which would require significantly more time and expense. Assuming the FDA requires 510(k) clearance and not PMA approval, and human clinical trials are not

required, we expect the process of development, testing, application, clearance and preparing to manufacture the product to take approximately one year and to cost us approximately \$1,000,000. If the 510(k) process requires human clinical trials, we expect the process of development, testing, application, clearance and preparing to manufacture the product to take approximately two years and to cost us approximately \$2,000,000 to \$3,000,000. If PMA approval is required, the time and cost of development, testing, application, clearance and preparing to manufacture the product could be significantly greater. These expenditures will require us to raise additional capital.

Target Surgical Procedures Where Benefits Have Been Demonstrated. Our initial target market is SAVR 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 SAVR 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 SAVR. 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(TM) patch and to gain market acceptance for this product in connection with these surgeries.

Demonstrate the Clinical Benefits and Promote Acceptance of the CorRestore(TM) Patch. We intend to sponsor clinical studies using the CorRestore(TM) patch 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(TM) patch. We also expect to promote the acceptance of the CorRestore(TM) patch 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(TM) patch. We believe that the successful evaluations of the CorRestore(TM) patch by these medical professionals will accelerate the acceptance of the CorRestore(TM) patch by other medical professionals.

Invest in Marketing and Sales Activities. Once the CorRestore(TM) patch may be marketed and sold in the United States, we expect to use our existing distribution network of direct sales employees to distribute the product in the United States. We expect to be dependent on international distributors for international sales of the CorRestore(TM) patch products. We also expect to invest in marketing and sales efforts to increase the medical community's exposure to the CorRestore(TM) patch, 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 SAVR. We desire to obtain a reimbursement code for SAVR 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(TM) patch.

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We might not be able to get a reimbursement code for SAVR, and sales of CorRestore(TM) patches could be harmed if we fail to obtain these codes.

### PRODUCT

We are developing the CorRestore(TM) patch for use in SAVR surgeries. During SAVR, the surgeon restores, or remodels, an enlarged, poor functioning left ventricle to more normal size and function by inserting an implant, in most instances, or closing the defect directly. SAVR 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 SAVR 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.

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We plan to offer kits containing the patches, needles, strips of pericardium, sizers, holders and sutures to hospitals performing SAVR. We currently expect the retail price of these kits to be \$3,500 to \$5,000, 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 will be dependent on PM Devices, Inc. to develop and conduct the in vitro and animal testing required for FDA clearance or approval of the CorRestore(TM) patch and to manufacture our entire requirements for the patches. We have already entered into a Contract Development and Manufacturing Agreement with PM Devices, Inc.

### 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 exclusive, worldwide, royalty-bearing licenses to specified rights relating to the CorRestore(TM) patch and related products and accessories for SAVR, 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(TM) on patch 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 patch products if we incorporate the developments in the patch 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.

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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(TM) patch:

- assisting us in designing and executing the clinical tests necessary to demonstrate the safety and efficacy of the CorRestore(TM) patch 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(TM) patch;
- 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(TM) patch 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(TM) patch, training doctors in SAVR and training our personnel and customers in the use of the CorRestore(TM) patch.

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(TM) patch, 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 become exercisable to purchase an additional 50,000 shares when we receive clearance or approval from the FDA to market the CorRestore(TM) patch in the United States and another 50,000 shares when we receive CE certification for the CorRestore(TM) patch. 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.

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- Subject to shareholder approval, five-year warrants to purchase 2,100,000 common shares at \$3.00 a share, to be granted when we receive clearance or approval from the FDA to market the CorRestore(TM) patch in the United States. The warrants will become exercisable based on our cumulative net sales of the CorRestore(TM) patch products as follows:

Additional Portion

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Net Sales -----	of Shares -----
\$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. CorRestore LLC may terminate our licenses if we do not obtain shareholder approval for the issuance of this warrant. We are seeking this approval at our 2001 Annual Meeting of Shareholders.

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

We have also agreed to increase the size of our Board of Directors and add CorRestore LLC's designee as a director, if CorRestore LLC designates a person by June 2, 2001. 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(TM) patch. 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 we do not obtain shareholder approval of the issuance of the warrants to purchase 2,100,000 Common Shares on or before the date we must issue the warrants.
- 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

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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 may exclude specified countries from the geographic scope of the license if we have not begun marketing the CorRestore(TM) patch products or begun the process of obtaining necessary

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regulatory approval to sell CorRestore(TM) patch 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(TM) 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 patch 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(TM) patch will compete against existing patches, which are formed by the surgeon during SAVR 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(TM) patch 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



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promoting SAVR in general as a treatment for congestive heart failure, we will have to convince users that the advantages of the CorRestore(TM) patch outweigh its additional cost. At least one study using dacron patches indicates that they are effective. SAVR is in the early stages of its development and, if it develops, the market for patches used in SAVR 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(TM) patch 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 \$2,000,000. We expect to increase this coverage when we begin human clinical trials, if they are required, or when we begin selling the CorRestore(TM) patches 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 January 2, 2001, we employed 35 full-time individuals, including 17 in sales and marketing, five in research and development, seven in general and administration and six in manufacturing, quality and service, and one part-time employee. 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. 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 \$2,265,000 for the fiscal year ended November 30, 2000, \$1,632,000 for the fiscal year ended November 30, 1999, and \$959,000 for the fiscal year ended November 30, 1998, including \$582,000 in fiscal 2000, \$923,000 in fiscal 1999, and \$103,000 in fiscal 1998 to Baxter Limited, our distributor in Japan and \$1,190,000 in fiscal 2000 to Nellcor Puritan Bennett Export, Inc., our distributor in Europe. See Note 10 of Notes to Financial Statements included in Item 8 of this Report.

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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 \$14,700 for fiscal 2000, \$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, our current facility is more than suitable and adequate for our current needs, including our assembly of the Cerebral Oximeter, storing inventories of CorRestore(TM) patch 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

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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, 2000.

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### SUPPLEMENTAL ITEM. EXECUTIVE OFFICERS OF THE REGISTRANT

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

Name ----	Executive Officer Since -----	Age ---	Position -----
Bruce J. Barrett	6/94	41	President and Chief Executive Officer
William M. Iacona	12/00	30	Vice President, Finance, Controller, and
Richard S. Scheuing	1/98	45	Vice President, Research and Development
Mary Ann Victor	1/98	43	Vice President, Communications and Admin
Ronald A. Widman	1/98	50	Vice President, Medical Affairs
Pamela A. Winters	1/98	42	Vice President, Operations

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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

The 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.

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	HIGH ----	LOW ---
Fiscal Year Ended November 30, 1999		
First Quarter.....	\$ 3.50	\$ 1.25
Second Quarter.....	4.69	1.63
Third Quarter.....	4.69	2.00
Fourth Quarter.....	2.69	1.38
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

As of January 2, 2001, we had 641 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 Private Equity Line Agreement, on November 3, 2000, we issued and sold 108,696 common shares, par value \$0.01 a share, to Kingsbridge Capital Limited for \$1.84 a share. The purchase price paid by Kingsbridge was 86% of an average market price of the common shares. We paid \$7,000 in commissions to Brean Murray & Co., Inc. in connection with this sale. The common shares were sold to Kingsbridge in reliance on the exemptions from registration contained in Sections 4(2) and 4(6) of the Securities Act. We have filed a registration statement under the Securities Act of 1933 to permit Kingsbridge to resell these shares to the public.

Pursuant to the Private Equity Line Agreement, on December 4, 2000, we issued and sold 112,994 common shares, par value \$0.01 a share, to Kingsbridge Capital Limited for \$1.77 a share. The purchase price paid by Kingsbridge was 86% of an average market price of the common shares. We paid \$7,000 in commissions to Brean Murray & Co., Inc. in connection with this sale. The common shares were sold to Kingsbridge in reliance on the exemptions from registration contained in Sections 4(2) and 4(6) of the Securities Act. We have filed a registration statement under the Securities Act of 1933 to permit Kingsbridge to resell these shares to the public.

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## ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data as of November 30, 2000, 1999, 1998, 1997 and 1996, and for each of the years in the five-year period ended November 30, 2000 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, whose report includes an explanatory paragraph relating to an uncertainty concerning our ability to continue as a going concern. 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(TM) license. See Item 1. "Business -- The CorRestore(TM) Patch." Thus, this selected financial data might not be a good indicator of our expected results for fiscal 2001.

	FISCAL YEAR ENDED NOVEMBER 30			
	2000	1999	1998	
	(in thousands, except per share d			
STATEMENT OF OPERATIONS DATA:				
Net revenues (1).....	\$ 5,103	\$ 4,001	\$ 2,491	\$
Cost of sales.....	2,370	1,906	1,326	
Gross margin.....	2,733	2,095	1,165	
Research, development and engineering expenses.....	514	598	665	
Selling, general, and administrative expenses	5,934	6,436	6,347	
Net loss.....	(3,622)	(4,665)	(5,470)	(
Net loss per common share - basic and diluted (2).....	(.57)	(.77)	(1.01)	
Weighted average number of common shares outstanding (2).....	6,310	6,036	5,422	
	NOVEMBER 30,			
	2000	1999	1998	19
	----	----	----	----
	(in thousands)			
BALANCE SHEET DATA:				
Cash and marketable securities.....	\$ 122	\$ 2,257	\$ 6,894	\$ 4,
Working capital.....	1,393	2,960	7,633	4,
Total assets.....	3,659	4,444	9,047	5,
Total liabilities.....	776	762	629	
Accumulated deficit (4).....	(50,124)	(46,502)	(41,836)	(36,
Shareholders' equity (3) (4).....	2,883	3,682	8,418	4,

- (1) Net revenues recorded in fiscal years 2000, 1999, 1998, 1997 and 1996 relate primarily to the sale of Cerebral Oximeters and SomaSensors for commercial use. For a description of our loss of, and regaining, FDA clearance to market the Cerebral Oximeter in the United States, see

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"Business -- Government Regulation."

- (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, 1997 through November 30, 2000.
- (4) We believe our accumulated deficit has increased and shareholders' equity has decreased since November 30, 2000.

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### 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 need for additional financing, 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. 333-33262) effective March 31, 2000 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.



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### 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(TM) patch, which is being developed for use in heart surgeries called surgical anterior ventricular restoration, or SAVR. In October 1997, we obtained FDA clearance for new advances in our INVOS technology that are incorporated in our model 4100 Cerebral Oximeter. The model 4100 Cerebral Oximeter was introduced in October 1997 and we began shipping the model 4100 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 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(TM) patch, which requires testing and FDA clearance or approval before we can sell it in the United States.

During fiscal 1998, 1999, and 2000, our primary activities consisted of sales and marketing of the Cerebral Oximeter and related disposable SomaSensor. We had an accumulated deficit of \$50,123,746 through November 30, 2000. We believe that our accumulated deficit will continue to increase for the foreseeable future.

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. We recognize revenues when we ship our products to distributors or to hospitals. 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, which we generally expense as incurred. From May 1994 through the first quarter of fiscal 1998, we exchanged model 3100A Cerebral Oximeters for our model 3100

Cerebral Oximeters. Until shipments of the model 4100 Cerebral Oximeter began in the first quarter of fiscal 1998, we refurbished the model 3100 Cerebral Oximeters we received and sold them approximately at cost in countries that do not require compliance with the standards met by the model 3100A. During fiscal 1998, 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. Beginning in the third quarter of fiscal 1999, we offered the same exchange of model 4100 Cerebral Oximeters for model 3100A Cerebral Oximeters 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. Such sales reduce our average unit sales price and overall gross margin. Also, 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.

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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

- 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
- 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

- decreased purchases of the model 4100 by Baxter Limited in Japan attributable to the initial stocking purchases and exchange purchases made in fiscal 1999 as a result of Japanese Ministry of Health and Welfare approval in fiscal 1999 to market the model 4100 in Japan,
- an 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, and
- 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

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for the fiscal year ended November 30, 1999. Effective January 1, 2001, we increased the price of the model 4100 SomaSensor by 25%. This price increase does not apply to any existing sales quotations which were issued before

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January 1, 2001. In addition, the suggested retail price of the model 5100 Cerebral Oximeter is approximately 44% higher than the model 4100.

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:

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

These decreases were achieved despite:

- a \$71,000 increase in costs associated with the development of the CorRestore(TM) patch, and
- a \$37,000 increase in engineering salaries.

We expect our research, development and engineering expenses to increase significantly in connection with development and clinical testing of the CorRestore(TM) patch in fiscal 2001.

Selling, general and administrative expenses decreased approximately \$502,000, or 8%, from \$6,435,628 for the fiscal year ended November 30, 1999 to \$5,933,969 for the fiscal year ended November 30, 2000. The decrease in selling, general and administrative expense is primarily attributable to

- 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,
- a \$157,000 decrease in trade show expenditures during fiscal 2000,
- a \$107,000 decrease in professional service fees primarily as a result of decreased business consulting fees during fiscal 2000, and
- a \$40,000 decrease in employee severance during fiscal 2000.

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These decreases were incurred despite

- a \$212,000 realized loss on the sale of marketable securities in fiscal 2000,
- 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,
- a \$110,000 increase in intangible amortization expense related to the amortization of license acquisition costs, and
- a \$47,000 increase in clinical research expenses, primarily related to the model 5100 Cerebral Oximeter.

FISCAL YEAR ENDED NOVEMBER 30, 1999 COMPARED TO FISCAL YEAR ENDED NOVEMBER 30, 1998

Our net revenues increased approximately \$1,510,000, or 61%, from \$2,490,851 in the fiscal year ended November 30, 1998 to \$4,000,972 in the fiscal year ended November 30, 1999. The increase in net revenues is primarily due to

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- an approximately \$837,000 (55%) increase in United States sales, from approximately \$1,532,000 in fiscal 1998 to approximately \$2,369,000 in fiscal 1999, and
- an approximately \$673,000 (70%) increase in international sales, from approximately \$959,000 in fiscal 1998 to approximately \$1,632,000 in fiscal 1999.

These increases are primarily due to

- increased purchases of the disposable SomaSensor,
- purchases of the model 4100 Cerebral Oximeter by Baxter Limited as a result of Japanese Ministry of Health and Welfare approval in the first quarter of fiscal 1999 to market the model 4100 in Japan,
- a 17% increase in the average selling price of Cerebral Oximeters, primarily due to the March 1, 1999 increase in the price of the Cerebral Oximeter and fewer no-cap and exchange unit sales in fiscal 1999, and
- an 8% increase in the average selling price of the disposable SomaSensor, due to the effects of no-cap sales and the March 1, 1999 increase in SomaSensor prices.

Approximately 41% of our net revenues in fiscal 1999 were export sales, compared to approximately 39% in fiscal 1998. Sales of model 4100 Cerebral Oximeters, SomaSensors, model 4100 exchanges, model 5100 Cerebral Oximeters, and model 3100A Cerebral Oximeters as a percent of net revenues were as follows:

PERCENT OF NET REVENUES

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PRODUCT -----	1999 -----	1998 -----
Model 4100 Cerebral Oximeters.....	52%	61%
SomaSensors.....	42%	28%
Model 4100 Exchanges.....	3%	8%
Model 5100 Cerebral Oximeters.....	3%	0%
Model 3100A Cerebral Oximeters.....	0%	3%
	-----	-----
Total.....	100%	100%
	=====	=====

One international distributor accounted for approximately 23% of net revenues in fiscal 1999, and one United States distributor accounted for approximately 10% of net revenues for fiscal year 1998.

Gross margin as a percentage of net revenues was approximately 52% for the fiscal year ended November 30, 1999 and approximately 47% for the fiscal year ended November 30, 1998. Gross margin as a percentage of net revenues increased in fiscal 1999 from fiscal 1998 primarily due to

- the higher average selling prices we realized for the model 4100 Cerebral Oximeter and the SomaSensor,
- increased shipments of our new model SomaSensor, which is less costly to manufacture than old model SomaSensors, and
- a smaller percentage of model 4100 exchanges in fiscal 1999.

These increases were partially offset by a higher percentage of our net revenues derived from the sale of SomaSensors in fiscal 1999, which still have lower margins than Cerebral Oximeters.

Our research, development and engineering expenses decreased approximately \$67,000, or 10%, from \$664,874 for the fiscal year ended November 30, 1998 to \$598,348 for the fiscal year ended November 30, 1999. The decrease is primarily due to

- approximately \$84,000 in decreased costs associated with enhancements to the model 4100, and
- \$35,000 in decreased consulting fees.

These decreases were partially offset by a \$45,000 increase in costs associated with enhancements to the design of the disposable SomaSensor.

Selling, general and administrative expenses increased approximately \$89,000, or 1%, from \$6,346,595 for the fiscal year ended November 30, 1998 to \$6,435,628 for the fiscal year ended November 30, 1999. The increase in selling, general and administrative expenses for fiscal 1999 is primarily due to

- a \$144,000 increase in salaries, wages, commissions and related expenses, primarily as a result of increased sales commissions we paid to our sales force during fiscal 1999, and

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- a \$69,000 increase in professional service and investor relations fees.

These increases were partially offset by

- a \$73,000 decrease in selling-related expenses, primarily attributable to employee travel, industry trade shows, marketing and advertising, and
- a \$49,000 decrease in bad debts expense for fiscal 1999.

### 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 2000 was approximately \$3,790,000. Cash was used primarily to

- fund our net loss, including selling, general and administrative expenses and research, development and engineering expenses, totaling approximately \$3,175,000, before depreciation and amortization expense,
- increase accounts receivable by approximately \$586,000, primarily due to higher sales in the fourth quarter of fiscal 2000 than in the fourth quarter of fiscal 1999, and
- increase other assets by approximately \$47,000 as a result of professional service fees capitalized as part of our license acquisition costs.

We expect our working capital requirements to increase if sales increase. We capitalized approximately \$114,000 of costs for model 4100 and model 5100 Cerebral Oximeters being used as demonstration units and no-cap units during fiscal 2000, compared to approximately \$179,000 in fiscal 1999. We expect to depreciate these costs over three years.

Capital expenditures in fiscal 2000 were approximately \$118,000. These expenditures were primarily for the costs for model 4100 and model 5100 demonstration and no-cap Cerebral Oximeters described above. We expect our capital requirements to increase as a result of the costs of developing and testing the CorRestore(TM) patch.

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 April 8, 1998, we completed the public offering of 1,750,000 newly-issued common shares, at a price of \$5.75 per share, for gross proceeds of \$10,062,500, through an offering underwritten by Brean Murray & Co., Inc. Our net proceeds, after deducting the underwriting discount and the expenses of the offering, were approximately \$9,100,000.

On March 6, 2000, we entered into the Private Equity Line Agreement with Kingsbridge Capital Limited, a private institutional investor. Pursuant to the Private Equity Line Agreement we may issue and sell, from time to time, common shares for cash consideration up to an aggregate of \$15 million. As required by the Private Equity Line Agreement, we have filed a registration

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statement to permit Kingsbridge to resell to the public 1,000,000 of the shares that we sell to it pursuant to the Private Equity Line Agreement. Until March 31, 2002, we may sell, or "put," common shares to Kingsbridge from time to time in amounts and at times we select at our discretion, subject to specific restrictions set forth in the Private Equity Line Agreement. The price for these sales is between 86% and

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90% of the then current average market price of our common shares. The actual percentage will depend on an average market price of our common shares. In addition, we must pay Brean Murray & Co., Inc. a 3.5% commission in connection with these sales. We must also pay additional expenses in connection with these sales. We are not permitted to sell more than 19.9% of our outstanding common shares pursuant to this arrangement unless we first obtain shareholder approval under The Nasdaq SmallCap Market rules. We are seeking shareholder approval at the 2001 Annual Meeting of Shareholders to issue up to 3,000,000 common shares pursuant to the arrangement, including the common shares already issued.

Puts can be made every 15 trading days in amounts ranging from a minimum of \$10,000 to a maximum of \$1,000,000. The amounts depend on the then current trading volume and average market price of our common shares at the time of each put. We are required to put at least \$7,500,000 of our common shares to Kingsbridge over the life of the Private Equity Line Agreement or pay Kingsbridge the discount on the unsold shares. As of November 30, 2000, we had issued 601,490 common shares under the Private Equity Line Agreement. Under the Private Equity Line Agreement, the average market price of our common shares for purposes of calculating the purchase price to be paid by Kingsbridge is the average of the lowest trade prices of the common shares as reported by Bloomberg L.P. on each of five days on which The Nasdaq SmallCap Market is open for trading. The five days are the two trading days before the day on which we deliver notice to Kingsbridge that we are exercising a put, the trading day on which we deliver the put notice, and the two trading days after the trading day on which we deliver the put notice.

The Private Equity Line Agreement provides that we may not put our common shares to Kingsbridge unless the following conditions are satisfied or waived (none of which is within Kingsbridge's control):

- the registration statement must have been declared effective by the SEC and must remain effective;
- the representations and warranties made by us in the Private Equity Line Agreement must be accurate in all material respects as of the date of each put and as of the date of the closing of the sale. One of our representations is that since November 30, 1999 there has been no material adverse change in our business, operations, properties, prospects or financial condition, except as disclosed in the registration statement or specified periodic reports filed with the SEC pursuant to the Securities Exchange Act of 1934;
- we must have performed and complied with in all material respects all obligations under the Private Equity Line Agreement, the warrant and the Registration Rights Agreement entered into between us and Kingsbridge in connection with the Private Equity Line Agreement that are required to be performed as of the date of each put and as of the date of the closing of the sale;
- no statute, rule, regulation, executive order, decree, ruling or

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injunction may be in effect that prohibits or directly and adversely affects any of the transactions contemplated by the Private Equity Line Agreement;

- our common shares must not have been delisted from The Nasdaq SmallCap Market nor suspended from trading;
- the issuance of the common shares must not violate the shareholder approval requirements of The Nasdaq SmallCap Market;
- the number of shares to be put to Kingsbridge, together with any shares then held by Kingsbridge, must not exceed 9.9% of our common shares that would be outstanding upon completion of the put; and
- the average trading volume of our common shares for 26 of the 30 consecutive trading days immediately preceding a put must be at least 30,000 shares a day. The two highest and the two lowest trading volume days are excluded.

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 200,000 common shares at a purchase price of \$4.36 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 any of the following occurs:

- stock split

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- reverse stock split,
- stock dividend,
- reclassification,
- merger,
- statutory share exchange,
- similar transactions affecting our common shares, or
- specified issuances of common shares, convertible or exchangeable securities, options and warrants at less than the market price of the common shares, as defined in the Private Equity Line Agreement.

The warrant also provides for adjustments if we pay liquidating dividends. No adjustments are required for instruments or benefits issued under any of our stock option plans or in consideration of our acquisition of all or any part of the assets of another person. The exercise price of the warrant is payable either in cash or by a cashless exercise in which the number of common shares underlying the warrant having an aggregate fair market value at the time of exercise equal to the aggregate exercise price are cancelled as payment of the exercise price.

We have completed the following sales of common shares under the Private Equity Line Agreement:

- On April 13, 2000, we completed the sale of 167,131 common shares to Kingsbridge, at a price of \$3.59 per share, for gross proceeds of \$600,000.



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- On May 11, 2000, we completed the sale of 148,148 common shares to Kingsbridge, at a price of \$2.70 per share, for gross proceeds of \$400,000.
- On June 22, 2000, we completed the sale of 177,515 common shares to Kingsbridge, at a price of \$3.38 per share, for gross proceeds of \$600,000.
- On November 3, 2000, we completed the sale of 108,696 common shares to Kingsbridge, at a price of \$1.84 per share, for gross proceeds of \$200,000.

Our net proceeds, after deducting the commissions and the estimated expenses of the offerings, were approximately \$1,606,000.

As of November 30, 2000, we had working capital of \$1,393,224, cash and cash equivalents of \$122,299, total current liabilities of \$775,831 and shareholders' equity of \$2,883,165.

We expect that our primary needs for liquidity in fiscal 2001 will be

- to fund our losses and sustain our operations, including funding
  - marketing costs for the Cerebral Oximeter; and
  - research and development efforts related to development and testing of the CorRestore(TM) patch, 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 2001, primarily for new demonstration and no-cap equipment and manufacturing tooling for the Cerebral Oximeter and SomaSensor.

We are currently working with the inventors to design and execute the preliminary and definitive clinical test necessary to obtain regulatory approvals for the CorRestore(TM) patch, including FDA clearance and CE certification. We currently believe that the CorRestore(TM) patch is eligible to seek 510(k) clearance to market the product in the United States. If human clinical trials are required by the FDA, we will have to file IDE applications with the FDA before beginning the human clinical trials. However, the FDA could require a PMA application, which would require significantly more time and expense. Assuming the FDA requires 510(k) clearance and not PMA approval, and human clinical trials are not required, we expect the process of development, testing, application, clearance and preparing to manufacture the product to take approximately one year and to cost us approximately \$1,000,000. If the 510(k) process requires human clinical trials, we expect the process of development, testing, application, clearance and preparing to manufacture the product to take approximately two

years and to cost us approximately \$2,000,000 to \$3,000,000. If PMA approval is required, the time and cost of development, testing, application, clearance and preparing to manufacture the product could be significantly greater. These expenditures will require us to raise additional capital.

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We believe that the cash and cash equivalents on hand at November 30, 2000, together with the estimated net proceeds from the sales of the then remaining 398,510 common shares over time to Kingsbridge Capital Limited pursuant to the Private Equity Line Agreement based on current market prices, will be adequate to satisfy our operating and capital requirements through February 2001. By that time we will be required to raise additional cash either through additional sales of our products, through sales of securities, by incurring indebtedness or by some combination of these alternatives. If we are unable to raise additional cash by that time, we will be required to reduce or discontinue our operations.

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. Changes in the market price or trading volume of our common shares could reduce the proceeds we receive for selling those common shares under the Private Equity Line Agreement, decrease the number of shares we can sell in a particular period or both. Actual capital requirements necessary to market the Cerebral Oximeter and SomaSensor, to develop and test the CorRestore(TM) patch, to undertake other product development activities, and for working capital might be substantially greater than current estimates.

We do not believe that product sales will be sufficient to fund our operations in fiscal 2001.

As of November 30, 2000, we had 55,120 redeemable warrants outstanding exercisable at \$17.50 per share until April 1, 2001. These warrants were issued in our April 1996 Regulation S securities offering. The conditions permitting us to redeem these warrants have not been met as of January 2, 2001. In addition, the placement agents in that offering and their transferees hold warrants to purchase 11,424 common shares exercisable at \$12.50 per share until April 1, 2001. Also, 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 received warrants to purchase 200,000 common shares exercisable at \$4.36 per share until September 3, 2005 pursuant to the Private Equity Line Agreement described above. 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(TM) license agreement, and, subject to shareholder approval, when specified events occur we agreed to issue them five-year warrants to purchase an additional 2,100,000 common shares exercisable at \$3.00 per share pursuant to the CorRestore(TM) license agreement; we are seeking shareholder approval for the issuance of these warrants and shares at our 2001 Annual Meeting of Shareholders. It is unlikely that these warrants will be exercised if the exercise price exceeds the market price of the common shares.

We are also party to the Private Equity Line Agreement described above. On December 4, 2000, we completed the sale of 112,994 common shares to Kingsbridge, at a price of \$1.77 per share, for gross proceeds of \$200,000 under the Private Equity Line Agreement. We may sell up to an aggregate of \$13,000,000 more of our common shares under the Private Equity Line Agreement. However, we must obtain shareholder approval and register under the Securities Act of 1933 any common shares we sell pursuant to the Private Equity Line Agreement beyond the remaining 285,516 already registered common shares. We are seeking shareholder approval at the 2001 Annual Meeting of Shareholders to issue up to 3,000,000 common shares pursuant to this arrangement, including the common shares already issued.

We are considering various capital-raising alternatives, including a private placement or public offering of newly-issued debt or equity securities. Final terms and conditions of any offering may be subject to, among other

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things, the satisfactory completion by an underwriter or placement agent of such inquiry and investigation of the transaction and of us as they may deem appropriate, and a determination that there has been no material adverse change in the conditions in the markets for the offering or the financial markets generally. In addition, the type and amount of securities, if any, that might ultimately be issued in any such offering have not yet been determined and will be dependent on negotiations with the underwriter, any private placement investor, market conditions and our then current estimate of the proceeds necessary or desired to sustain our operations. There can be no assurance that such offering will occur or that we will be able to raise any capital or capital in amounts we desire, or on terms and conditions acceptable to us.

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We have no loan commitments.

Even if we receive additional capital, we might not be able to achieve the level of sales necessary to sustain our operations, and we will incur the costs of developing and testing the CorRestore(TM) patch before we realize any revenues from the patch. We might not be able to obtain any funds on terms acceptable to us and at times required by us through sales of our products, sales of securities or loans in sufficient quantities. Our Independent Auditors' Report contains an explanatory paragraph relating to the uncertainty concerning our ability to continue as a going concern. See "Independent Auditors Report" accompanying the Financial Statements in Item 8 of this Report.

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

In June 1998, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities." This statement, as amended, is effective for fiscal years beginning after June 15, 2000. This statement establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities. This statement is effective for our financial statements for the year ending November 30, 2001. We have evaluated all contractual agreements and purchase order commitments and determined that the adoption of this statement will have no material impact on our financial statements.

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ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The tables below provide information about our financial instruments that are sensitive to changes in interest rates, consisting of investments in corporate bonds and other fixed income securities. For these financial instruments, the tables present principal cash flows and related weighted average interest rates by expected maturity dates. Weighted average variable rates are based on current rates for the applicable period. Weighted average fixed rates are based on the contract rates. The actual cash flows of all instruments are denominated in U.S. dollars. We invest our cash on hand not needed in current operations in fixed income securities generally maturing within one year from the date of acquisition.

NOVEMBER 30, 2000						
EXPECTED MATURITY DATES						
2001	2002	2003	2004	2005	THEREAFTER	
----	----	----	----	----	-----	
MARKETABLE SECURITIES:						
-----						
Short-term Debt:						
Variable Rate (\$)	--	--	--	--	--	
Average interest rate...	N/A	N/A	N/A	N/A	N/A	

NOVEMBER 30, 1999					
EXPECTED MATURITY DATES					
2000	2001	2002	2003	2004	THEREAFTER
----	----	----	----	----	-----
MARKETABLE SECURITIES:					

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### Short-term Debt:

Variable Rate (\$)	..... \$1,000,006	--	--	--	--	--
Average interest rate...	9.09%	N/A	N/A	N/A	N/A	N/A

During fiscal 2000, we liquidated our investments in corporate bonds and other fixed income securities to provide cash to finance our operations.

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### 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, 2000 and 1999, and the related statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended November 30, 2000. 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, 2000 and 1999, and the results of its operations and its cash flows for each of the three years in the period ended November 30, 2000 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

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statements taken as a whole, presents fairly in all material respects the information set forth therein.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, conditions exist which raise substantial doubt about the Company's ability to continue as a going concern. Management's plans concerning these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

/s/ DELOITTE & TOUCHE LLP

DELOITTE & TOUCHE LLP

Detroit, Michigan  
January 4, 2001

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### SOMANETICS CORPORATION

#### BALANCE SHEETS

	No
	----- 2000 -----
ASSETS	
CURRENT ASSETS:	
Cash and cash equivalents (Note 4).....	\$ 122,299
Marketable Securities (Note 4).....	--
Accounts receivable, net of allowance for doubtful accounts of \$0 and \$0 at November 30, 2000 and November 30, 1999, respectively.....	1,349,726
Inventory (Note 4).....	613,930
Prepaid expenses.....	83,100
Total current assets.....	----- 2,169,055 -----
PROPERTY AND EQUIPMENT: (Note 4)	
Machinery and equipment.....	1,471,114
Furniture and fixtures.....	183,497
Leasehold improvements.....	165,642
Total.....	----- 1,820,253 -----
Less accumulated depreciation and amortization.....	(1,384,000)
Net property and equipment.....	----- 436,253 -----
OTHER ASSETS:	
Intangible assets, net (Note 4).....	1,038,688
Other.....	15,000

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Total other assets.....	1,053,688
TOTAL ASSETS.....	\$ 3,658,996
=====	
LIABILITIES AND SHAREHOLDERS' EQUITY	
CURRENT LIABILITIES:	
Accounts payable.....	\$ 508,647
Accrued liabilities (Notes 5 and 7).....	267,184
Total current liabilities.....	775,831
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, 6,637,087 shares at November 30, 2000, and 6,035,597 shares at November 30, 1999.....	66,371
Additional paid-in capital.....	52,940,540
Accumulated unrealized losses on investments.....	--
Accumulated deficit.....	(50,123,746)
Total shareholders' equity.....	2,883,165
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY.....	\$ 3,658,996
=====	

See notes to financial statements

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SOMANETICS CORPORATION

STATEMENTS OF OPERATIONS

	For the Years Ended November 3	
	2000	1999
NET REVENUES (Notes 4 and 10).....	\$ 5,103,098	\$ 4,000,972
COST OF SALES.....	2,370,205	1,905,541
Gross margin.....	2,732,893	2,095,431
OPERATING EXPENSES:		
Research, development and engineering (Note 4).....	513,816	598,348
Selling, general and administrative (Note 9).....	5,933,969	6,435,628
Total operating expenses.....	6,447,785	7,033,976

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OPERATING LOSS.....	(3,714,892)	(4,938,545)
	-----	-----
OTHER INCOME:		
Interest income.....	92,805	273,254
Other.....	--	--
	-----	-----
Total other income.....	92,805	273,254
	-----	-----
NET LOSS.....	\$ (3,622,087)	\$ (4,665,291)
	=====	=====
NET LOSS PER COMMON SHARE --		
BASIC AND DILUTED (Note 4).....	\$ (.57)	\$ (.77)
	=====	=====
WEIGHTED AVERAGE NUMBER OF		
COMMON SHARES OUTSTANDING		
(Note 4).....	6,310,109	6,035,597
	=====	=====

See notes to financial statements

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## SOMANETICS CORPORATION

### STATEMENTS OF SHAREHOLDERS' EQUITY

	SHARE VALUE	ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT
	-----	-----	-----
Balance at December 1, 1997.....	42,853	41,212,639	(36,366,536)
Exercise of stock options for cash.....	3	1,345	
For cash, less issuance costs of \$968,917...	17,500	9,076,083	
Net loss.....			(5,469,832)
Unrealized losses on investments.....			
Comprehensive income.....			
	-----	-----	-----
Balance at November 30, 1998.....	60,356	50,290,067	(41,836,368)
Net loss.....			(4,665,291)
Unrealized losses on investments.....			



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Comprehensive income.....	-----	-----	-----
Balance at November 30, 1999.....	\$ 60,356	\$ 50,290,067	\$ (46,501,659)
For cash, less issuance costs of \$193,619...	6,015	1,600,366	
Warrants issued to acquire license, less...			
acquisition costs of \$46,791.....		1,050,107	
Net loss.....			(3,622,087)
Unrealized losses on investments.....			
Reclassification of unrealized losses.....			
Comprehensive income.....	-----	-----	-----
Balance at November 30, 2000.....	\$ 66,371	\$ 52,940,540	\$ (50,123,746)
	=====	=====	=====

	TOTAL SHAREHOLDERS' EQUITY	COMPREHENSIVE INCOME
	-----	-----
Balance at December 1, 1997.....	4,888,956	
Exercise of stock options for cash.....	1,348	
For cash, less issuance costs of \$968,917...	9,093,583	
Net loss.....	(5,469,832)	(5,469,832)
Unrealized losses on investments.....	(96,262)	(96,262)
Comprehensive income.....		\$ (5,566,094)
	-----	=====
Balance at November 30, 1998.....	8,417,793	
Net loss.....	(4,665,291)	(4,665,291)
Unrealized losses on investments.....	(70,008)	(70,008)
Comprehensive income.....		\$ (4,735,299)
	-----	=====
Balance at November 30, 1999.....	\$ 3,682,494	
For cash, less issuance costs of \$193,619...	1,606,381	
Warrants issued to acquire license, less...		
acquisition costs of \$46,791.....	1,050,107	
Net loss.....	(3,622,087)	(3,622,087)
Unrealized losses on investments.....	(45,290)	(45,290)
Reclassification of unrealized losses.....	211,560	211,560
Comprehensive income.....		\$ (3,455,817)
	-----	=====
Balance at November 30, 2000.....	\$ 2,883,165	
	=====	

See notes to financial statements

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## SOMANETICS CORPORATION

### STATEMENTS OF CASH FLOWS

	For the Years End	
	2000	1999
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss.....	\$ (3,622,087)	\$ (4,665,
Adjustments to reconcile net loss to net cash used in operations:		
Depreciation and amortization.....	446,962	295,
Realized losses on sales of marketable securities.....	210,724	
Changes in assets and liabilities:		
Accounts receivable (increase).....	(585,573)	(148,
Inventory (increase) decrease.....	(2,598)	49,
Prepaid expenses (increase) decrease.....	6,602	2,
Other assets (increase) decrease.....	(46,789)	
Accounts payable increase (decrease).....	10,639	235,
Accrued liabilities increase (decrease).....	3,289	(102,
Net cash (used in) operations.....	(3,578,831)	(4,333,
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of marketable securities.....	--	
Proceeds from sale of marketable securities.....	789,282	4,013,
Acquisition of property and equipment (net).....	(117,956)	(233,
Net cash provided by (used in) investing activities...	671,326	3,780,
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of Common Shares.....	1,606,381	
Net cash provided by financing activities.....	1,606,381	
NET (DECREASE) IN CASH AND CASH EQUIVALENTS.....	(1,301,124)	(553,
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD.....	1,423,423	1,976,
CASH AND CASH EQUIVALENTS, END OF PERIOD.....	\$ 122,299	\$ 1,423,
Supplemental Disclosure of Non cash investing activities:		
Issuance of warrants and stock options in connection with license acquisition (Note 4).....	\$ 1,050,107	

See notes to financial statements

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SOMANETICS CORPORATION

NOTES TO FINANCIAL STATEMENTS

1. ORGANIZATION AND OPERATIONS

We are a Michigan corporation that was formed in January 1982. We develop, manufacture and market the INVOS(R) 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 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(TM) patch, which is being developed for use in heart surgeries called surgical anterior ventricular restoration, or SAVR. We entered into a License Agreement as of June 2, 2000 with the inventors and their company, CorRestore LLC. The license grants us exclusive, worldwide, royalty-bearing licenses to specified rights relating to the CorRestore(TM) patch and related products and accessories for SAVR, subject to the terms and conditions of the license agreement (Note 4).

We have incurred expenses in designing, developing, marketing and selling our products, and in raising capital for our business.

2. FINANCIAL STATEMENT PRESENTATION

We have incurred an accumulated deficit of \$50,123,746 through November 30, 2000. We had working capital of \$1,393,224, cash and cash equivalents of \$122,299, total current liabilities of \$775,831 and shareholders' equity of \$2,883,165, as of November 30, 2000.

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. 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 January 2, 2001, we had seven international distributors for the model 4100 Cerebral Oximeter, three international distributors for the model 5100 Cerebral Oximeter, 12 direct sales personnel, four clinical specialists, and one international sales consultant. During fiscal 2000, we sold our product to 19 of our international distributors and 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 and the related SomaSensor.

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We believe that markets exist for the products we have developed and are developing; however, whether our products will be successful is uncertain. You should consider the following factors in evaluating 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.

The net proceeds from our public offering of common shares in April 1998 (Note 3) and the net proceeds from the sales of common shares to Kingsbridge Capital Limited during fiscal 2000 (Note 3) were sufficient to fund our working capital requirements for the fiscal year ended November 30, 2000.

We believe that the cash and cash equivalents on hand at November 30, 2000, together with the estimated net proceeds from the sales of the then remaining 398,510 common shares over time to Kingsbridge Capital Limited pursuant to the Private Equity Line Agreement (Note 3) based on current market prices, will be adequate to satisfy our operating and capital requirements through February 2001. By that time we will be required to raise additional cash either through additional sales of our products, through sales of securities, by incurring indebtedness or by some combination of these alternatives. If we are unable to raise additional cash by that time, we will be required to reduce or discontinue our operations.

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### SOMANETICS CORPORATION

#### NOTES TO FINANCIAL STATEMENTS - (CONTINUED)

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. Changes in the market price or trading volume of our common shares could reduce the proceeds we receive for selling those common shares under the Private Equity Line Agreement, decrease the number of shares we can sell in a particular period or both. Actual capital requirements necessary to market the Cerebral Oximeter and SomaSensor, to develop and test the CorRestore(TM) patch, to undertake other product development activities, and for working capital might be substantially greater than current estimates.

We do not believe that product sales will be sufficient to fund our operations in fiscal 2001.

We are a party to the Private Equity Line Agreement described in Note 3. As of November 30, 2000, we may sell up to an aggregate of \$13,200,000 more of our common shares under the Private Equity Line Agreement. However, we must obtain shareholder approval and register under the Securities Act of 1933 any common shares we sell pursuant to the Private Equity Line Agreement beyond the then remaining 398,510 already registered common shares. We are seeking shareholder approval at the 2001 Annual Meeting of Shareholders to issue up to 3,000,000 common shares pursuant to this arrangement, including the common shares already issued.

We are considering various capital-raising alternatives, including a private placement or public offering of newly-issued debt or equity securities. Final terms and conditions of any offering may be subject to, among other things, the satisfactory completion by an underwriter or placement agent of such

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inquiry and investigation of the transaction and of us as they may deem appropriate, and a determination that there has been no material adverse change in the conditions in the markets for the offering or the financial markets generally. In addition, the type and amount of securities, if any, that might ultimately be issued in any such offering have not yet been determined and will be dependent on negotiations with the underwriter, any private placement investor, market conditions and our then current estimate of the proceeds necessary or desired to sustain our operations. There can be no assurance that such offering will occur or that we will be able to raise any capital or capital in amounts we desire, or on terms and conditions acceptable to us.

We have no loan commitments.

Even if we receive additional capital, we might not be able to achieve the level of sales necessary to sustain our operations, and we will incur the costs of developing and testing the CorRestore(TM) patch before we realize any revenues from the patch. We might not be able to obtain any funds on terms acceptable to us and at times required by us through sales of our products, sales of securities or loans in sufficient quantities.

These factors, among others, raise substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments relating to the recoverability and classification of asset carrying amounts or the amount and classification of liabilities that might be necessary should we be unable to continue as a going concern.

### 3. STOCK OFFERINGS AND COMMON SHARES

As of November 30, 2000, we had 55,120 redeemable warrants outstanding exercisable at \$17.50 per share until April 1, 2001. These warrants were issued in our April 1996 Regulation S securities offering. The conditions permitting us to redeem these warrants have not been met as of January 2, 2001. In addition, the placement agents in that offering and their transferees hold warrants to purchase 11,424 common shares exercisable at \$12.50 per share until April 1, 2001. Also, 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 received warrants to purchase 200,000 common shares exercisable at \$4.36 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(TM) license agreement, and, subject to shareholder approval, when specified events occur we agreed to issue them five-year warrants to purchase an additional 2,100,000 common shares

#### NOTES TO FINANCIAL STATEMENTS - (CONTINUED)

exercisable at \$3.00 per share pursuant to the CorRestore(TM) license agreement. It is unlikely that these warrants will be exercised if the exercise price exceeds the market price of the common shares.

On April 8, 1998, we completed the public offering of 1,750,000 newly-issued common shares at a price of \$5.75 per share, for gross proceeds of \$10,062,500, through an offering underwritten by Brean Murray & Co., Inc. Our

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net proceeds, after deducting the underwriting discount and the estimated expenses of the offering, were approximately \$9,100,000.

On March 6, 2000, we entered into the Private Equity Line Agreement with Kingsbridge Capital Limited, a private institutional investor. Pursuant to the Private Equity Line Agreement we may issue and sell, from time to time, common shares for cash consideration up to an aggregate of \$15 million. As required by the Private Equity Line Agreement, we have filed a registration statement to permit Kingsbridge to resell to the public 1,000,000 of the shares that we sell to it pursuant to the Private Equity Line Agreement. Until March 31, 2002, we may sell, or "put," common shares to Kingsbridge from time to time in amounts and at times we select at our discretion, subject to specific restrictions set forth in the Private Equity Line Agreement. The price for these sales is between 86% and 90% of the then current average market price of our common shares. The actual percentage will depend on an average market price of our common shares. In addition, we must pay Brean Murray & Co., Inc. a 3.5% commission in connection with these sales. We must also pay additional expenses in connection with these sales. We are not permitted to sell more than 19.9% of our outstanding common shares pursuant to this arrangement unless we first obtain shareholder approval under The Nasdaq SmallCap Market rules.

As of November 30, 2000, we may sell up to an aggregate of \$13,200,000 more of our common shares under the Private Equity Line Agreement. However, we must obtain shareholder approval and register under the Securities Act of 1933 any common shares we sell pursuant to the Private Equity Line Agreement beyond the then remaining 398,510 already registered common shares.

We have completed the following sales of common shares under the Private Equity Line Agreement:

- On April 13, 2000, we completed the sale of 167,131 common shares to Kingsbridge, at a price of \$3.59 per share, for gross proceeds of \$600,000.
- On May 11, 2000, we completed the sale of 148,148 common shares to Kingsbridge, at a price of \$2.70 per share, for gross proceeds of \$400,000.
- On June 22, 2000, we completed the sale of 177,515 common shares to Kingsbridge, at a price of \$3.38 per share, for gross proceeds of \$600,000.
- On November 3, 2000, we completed the sale of 108,696 common shares to Kingsbridge, at a price of \$1.84 per share, for gross proceeds of \$200,000.

Our net proceeds, after deducting the commissions and the estimated expenses of the offerings, were approximately \$1,606,000.

Common shares reserved for future issuance upon exercise of stock options and warrants as discussed above at November 30, 2000, are as follows:

1983 Stock Option Plan.....	9,317
1991 Incentive Stock Option Plan.....	110,289
1993 Director Stock Option Plan.....	2,498
1997 Stock Option Plan.....	1,334,800
Options Granted Independent of Option Plans.....	163,578
Placement Agent Warrants.....	11,424
Regulation S Warrants.....	55,120
Underwriter Warrants.....	200,000
Kingsbridge Capital Limited Warrants.....	200,000
License Acquisition Warrants.....	400,000
	-----

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Total reserved for future issuance.....

2,487,026

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## 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.

Marketable Securities consist of lower rated, fixed income securities, classified as available for sale, maturing approximately six months to one year from the date of acquisition and are stated at fair market value.

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

	NOVEMBER 30,	
	2000	
	-----	-----
Finished goods.....	\$ 36,374	\$
Work in process.....	124,127	
Purchased components.....	453,429	
	-----	-----
Total.....	\$ 613,930	\$
	=====	=====

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 exclusive, worldwide, royalty-bearing licenses to specified rights relating to the CorRestore(TM) patch and related products and accessories and consulting services.

We entered into a License Agreement as of June 2, 2000 with the inventors and their company, CorRestore LLC. The license grants us exclusive, worldwide, royalty-bearing licenses to specified rights relating to the CorRestore(TM) patch and related products and accessories for SAVR, 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(TM) patch, training doctors in SAVR and training our personnel and customers in the use of the CorRestore(TM) patch.

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)

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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(TM) patch in the United States and another 50,000 shares upon our receipt of CE certification for the CorRestore(TM) patch, (3) additional five-year warrants to purchase up to 2,100,000 common shares at \$3.00 a share, to be granted, subject to shareholder approval, when we receive clearance or approval from the FDA to market the CorRestore(TM) patch in the United States, exercisable based on our cumulative net sales of the CorRestore(TM) patch products, and (4) a consulting fee of \$25,000 a year to each of the inventors until we sell 1,000 CorRestore(TM) patches.

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### SOMANETICS CORPORATION

#### NOTES TO FINANCIAL STATEMENTS - (CONTINUED)

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 the transaction, and our estimate of the fair value of the 300,000 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. These costs are being amortized on the straight-line method over 5 years. Intangible assets consist of:

	NOVEMBER 30,	
	2000	
License acquisition costs.....	\$ 1,096,898	\$
Patents and trademarks.....	111,733	
Sub-total.....	1,208,631	
Less accumulated amortization.....	(169,943)	
Total.....	\$ 1,038,688	\$

Amortization expense was \$116,602 for the fiscal year ended November 30, 2000, \$6,912 for the fiscal year ended November 30, 1999, and \$6,912 for the fiscal year ended November 30, 1998.

Revenue Recognition occurs upon shipment to customers.

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



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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, 2000, we had outstanding 2,261,081 warrants and options to purchase common shares, and as of November 30, 1999, we had outstanding 1,568,481 warrants and options to purchase common shares.

Accounting Pronouncements In June 1998, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities." This statement, as amended, is effective for fiscal years beginning after June 15, 2000. This statement establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities. This statement is effective for our financial statements for the year ending November 30, 2001. We have evaluated all contractual agreements and purchase order commitments and determined that the adoption of this statement will have no material impact 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 1999 and 1998 to conform to the 2000 presentation.

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### SOMANETICS CORPORATION

#### NOTES TO FINANCIAL STATEMENTS - (CONTINUED)

##### 5. ACCRUED LIABILITIES

Accrued liabilities consist of the following:

	NOVEMBER 30,	
	2000	
Accrued Sales Commissions.....	\$ 117,045	\$
Professional Fees.....	94,000	
Accrued Insurance.....	24,361	
Accrued Warranty.....	7,000	
Accrued Incentive.....	17,500	
Other.....	7,278	
	-----	-----
Total.....	\$ 267,184	\$
	=====	=====

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## 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 \$16,734,000 and \$15,646,000 for the years ended November 30, 2000 and 1999, 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, 2000 and 1999 were as follows:

	NOVEMBER 30,	
	2000	
	(IN THOUSANDS)	
Net operating loss carryforwards.....	\$ 16,401	\$
Accrued liabilities.....	36	
Basis difference of fixed assets.....	(90)	
Research and general business tax credit carryforwards.....	387	
Subtotal.....	16,734	
Valuation allowance.....	(16,734)	
Deferred tax asset.....	\$ --	\$

As of November 30, 2000, net operating loss carryforwards of approximately \$48.0 million were available for Federal income tax purposes. Our ability to use the net operating loss carryforwards incurred on or before 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 \$387,000 are also available to offset future taxes. These losses and credits expire, if unused, at various dates from 2000 through 2020.

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

On September 10, 1991 we entered into 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.

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### NOTES TO FINANCIAL STATEMENTS - (CONTINUED)

Operating and building lease expense for the years ended November 30, 2000, 1999 and 1998 was approximately \$182,000, \$184,000, and \$184,600, respectively. Approximate future minimum lease commitments are as follows:

#### YEAR ENDED NOVEMBER 30,

2001.....	\$	192,700
2002.....	\$	197,700
2003.....	\$	201,700
2004.....		16,800
-----		
Total.....	\$	608,900
=====		

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, 2000, 1999 or 1998.

As of November 30, 2000, 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 January 1983, 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 15,668 common shares under the 1983 plan, 115,000 common shares under the 1991 plan, and 1,335,000 common shares under the 1997 plan. In addition, we granted options to employees independent of the plans. Awards and expirations under the 1983 plan, 1991 plan, 1997 plan, and independent of the plans during the years ended November 30, 2000, 1999 and 1998 are listed below.

At November 30, 2000, no additional options may be granted under the 1983 plan, 14,667 common shares were available for options to be granted under the 1991 plan, and 211,278 common shares were available 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

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plan, except as to options previously granted under the directors plan. Therefore, no additional options may be granted under the directors plan.

In October 1995, SFAS No. 123, "Accounting for Stock-Based Compensation," was issued. We have chosen to continue to account for stock-based compensation 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 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.

Had compensation expense for our stock options 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 increased

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### SOMANETICS CORPORATION

#### NOTES TO FINANCIAL STATEMENTS - (CONTINUED)

by approximately \$495,000 to \$(4,117,000), or \$(.65) per common share, for fiscal 2000, increased by approximately \$571,000 to \$(5,236,000), or \$(.87) per common share, for fiscal 1999, and increased by approximately \$1,589,000 to \$(7,059,000), or \$(1.30) per common share, for fiscal 1998. 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 2000, 1999 and 1998: expected volatility (the measure by which the stock price has fluctuated or is expected to fluctuate during the period) 109.94% for 2000 (95.05% for 1999 and 72.34% for 1998), risk-free interest rate of 6.0% for 2000 (6.5% for 1999 and 5% for 1998), 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, 2000, 1999 and 1998 follows:

	2000		1999		
	COMMON SHARES	WEIGHTED AVERAGE EXERCISE PRICE	COMMON SHARES	WEIGHTED AVERAGE EXERCISE PRICE	COMMON SHARES
Options outstanding					
December 1, .....	1,226,537	\$ 6.16	998,737	\$ 6.81	554,9
Options granted.....	236,000	3.24	242,900	3.38	476,1
Options exercised.....	--	--	--	--	(2
Options canceled.....	(68,000)	4.65	(15,100)	4.62	(32,0
Options outstanding					
November 30, (1) (2)...	1,394,537	5.74	1,226,537	6.16	998,7
Options exercisable					
November 30, .....	958,152	\$ 6.66	585,952	\$ 8.03	356,5

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- 
- (1) Exercise dates range from February 21, 1991 to May 31, 2010.
  - (2) As of November 30, 2000, options outstanding have exercise prices between \$1.44 and \$42.50, and a weighted average remaining contractual life of 7.05 years.

Also, see Note 11 for approval of an amendment to the 1997 plan.

### 9. RELATED PARTY TRANSACTIONS

We received legal services from certain shareholders. Services from such parties amounted to approximately \$211,600 during the year ended November 30, 2000, \$160,400 during the year ended November 30, 1999, and \$195,500 during the year ended November 30, 1998.

Brean Murray & Co., Inc. was the underwriter of our public offering of common shares in April 1998.

We paid a non-refundable fee of \$50,000 to Brean Murray & Co., Inc. during fiscal 1999 for financial advisory services.

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.

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 our CorRestore(TM) 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

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### SOMANETICS CORPORATION

#### NOTES TO FINANCIAL STATEMENTS - (CONTINUED)

the common shares on the date of grant, in connection with the Kingsbridge Capital Limited Private Equity Line Agreement.

### 10. MAJOR CUSTOMERS AND FOREIGN SALES

Two international distributors accounted for approximately 23% (Europe) and 11% (Japan), respectively, of net revenues for the fiscal year ended November 30, 2000, one international distributor accounted for approximately 23% (Japan) of net revenues for the fiscal year ended November 30, 1999, and one United States distributor accounted for approximately 10% of net revenues for the fiscal year ended November 30, 1998 (this relationship was terminated in the third quarter of fiscal 1998 as part of our planned expansion of the direct sales force within the United States).

Additionally, net revenues from foreign customers for the fiscal year ended November 30, 2000 was approximately \$2,265,000, for the fiscal year ended

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November 30, 1999 was approximately \$1,632,000, and for the fiscal year ended November 30, 1998 was approximately \$959,000.

### 11. SUBSEQUENT EVENTS

Effective December 4, 2000, we granted 10-year options under the 1997 Stock Option Plan to purchase 195,000 common shares to 27 of our key employees (including officers) and one of our consultants at an exercise price of \$1.97 per share (the closing sale price of the common shares as of the date of grant).

On December 4, 2000, our Board of Directors approved an amendment to the Somanetics Corporation 1997 Stock Option Plan to increase the number of common shares reserved for issuance pursuant to the exercise of options granted under the 1997 plan by 325,000 shares, from 1,335,000 to 1,660,000 shares, subject to shareholder approval at the 2001 Annual Meeting of Shareholders.

Also on December 4, 2000, our Board of Directors authorized us to seek shareholder approval at the 2001 Annual Meeting of Shareholders to issue up to 3,000,000 common shares pursuant to the Private Equity Line Agreement, including the common shares already issued. Our Board of Directors also authorized us to seek shareholder approval at our 2001 Annual Meeting of Shareholders for the issuance of warrants to purchase 2,100,000 common shares to CorRestore LLC under specified circumstances pursuant to our CorRestore(TM) license agreement and to issue the underlying shares upon exercise of those warrants.

On December 4, 2000, we completed the sale of 112,994 common shares to Kingsbridge, at a price of \$1.77 per share, for gross proceeds of \$200,000.

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### QUARTERLY INFORMATION (UNAUDITED)

The following is a summary of our quarterly operating results for the fiscal years ended November 30, 2000 and 1999:

	QUARTER		
	FIRST	SECOND	THIRD
	-----	-----	-----
	(IN THOUSANDS, EXCEPT PER SHARE DATA)		
YEAR ENDED NOVEMBER 30, 2000			
-----			
Net revenues.....	\$1,037,615	\$1,430,066	\$1,006,408
Gross margin.....	544,256	711,597	584,929
Net loss.....	(885,928)	(922,885)	(995,187)
Net loss per common share -basic and diluted.....	\$ (0.15)	\$ (0.15)	\$ (0.15)
YEAR ENDED NOVEMBER 30, 1999			
-----			
Net revenues.....	\$910,739	\$1,041,479	\$877,346

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Gross margin.....	463,650	522,620	419,251
Net loss.....	(1,184,328)	(1,265,587)	(1,035,091)
Net loss per common share -basic and diluted.....	\$ (0.20)	\$ (0.21)	\$ (0.17)

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

NONE

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PART III

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### 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 2001 Annual Meeting of Shareholders scheduled to be held February 22, 2001, 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 2001 Annual Meeting of Shareholders scheduled to be held February 22, 2001, 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 2001 Annual Meeting of Shareholders scheduled to be held February 22, 2001, 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 2001 Annual Meeting of Shareholders scheduled to be held February 22, 2001, 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 2001 Annual Meeting of Shareholders scheduled to be held February 22, 2001, and is incorporated in this Item 13 by reference.

### 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



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Balance Sheets - November 30, 2000 and 1999

Statements of Operations - For Each of the Three Years in the Period Ended November 30, 2000

Statements of Shareholders' Equity - For Each of the Three Years in the Period Ended November 30, 2000

Statements of Cash Flows - For Each of the Three Years in the Period Ended November 30, 2000

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, 2000, 1999 and 1998.

(3) Exhibits

The Exhibits to this Report are as set forth in the "Index to Exhibits" on pages 55 to 58 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, 2000.

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		ADDITIONS		
	BALANCE AT BEGINNING OF PERIOD	(2) CHARGED TO COSTS AND EXPENSES	CHARGED TO OTHER ACCOUNTS, DESCRIBE	(1) (3) DEDUCTION DESCRIBE
Allowance for doubtful accounts:				
Year ended November 30, 2000	\$ --	\$ --	--	\$ --
Year ended November 30, 1999	152,602	--	--	152,602
Year ended November 30, 1998	165,990	4,319	--	17,700
Note: (1) Write-off uncollectible accounts, net of recoveries				
Note: (2) Reserve of additional uncollectible accounts, net of recoveries				
Inventory reserve for obsolescence:				
Year ended November 30, 2000	\$ --	\$ --	--	\$ --
Year ended November 30, 1999	138,224	1,199	--	139,423
Year ended November 30, 1998	356,298	40,817	--	258,890
Note: (3) Write-off obsolete, excess inventory, net of recoveries				

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## 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: January 12, 2001

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.

Signature	Title	Date
-----	-----	----
/s/ Bruce J. Barrett	President and Chief Executive Officer and a Director (Principal Executive	January
-----		

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Bruce J. Barrett	Officer)	
 /s/ H. Raymond Wallace ----- H. Raymond Wallace	Chairman of the Board of Directors	January
 /s/ William M. Iacona ----- William M. Iacona	Vice President, Finance, Controller, and Treasurer (Principal Financial Officer and Principal Accounting Officer)	January
 /s/ Daniel S. Follis ----- Daniel S. Follis	Director	January
 /s/ James I. Ausman ----- James I. Ausman, M.D., Ph.D.	Director	January
 /s/ Robert R. Henry ----- Robert R. Henry	Director	January
 /s/ A. Brean Murray ----- A. Brean Murray	Director	January

## EXHIBIT INDEX

EXHIBIT	DESCRIPTION
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

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- 10.1 Securities and Exchange Commission on June 16, 1995. 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 1983 Stock Option Plan, incorporated by reference to Exhibit 10.4 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1991.
- \*10.8 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.
- \*10.9 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.
- \*10.10 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.
- \*10.11 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.
- \*10.12 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.
- \*10.13 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.
- \*10.14 Second Amendment to Somanetics Corporation 1997 Stock

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	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.
*10.15	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.
*10.16	Fourth Amendment to Somanetics Corporation 1997 Stock Option Plan.

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### EXHIBIT INDEX

EXHIBIT	DESCRIPTION
*10.17	Somanetics Corporation 2000 Employee Incentive Compensation Plan, incorporated by reference to Exhibit 10.16 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1999.
*10.18	Somanetics Corporation 2001 Employee Incentive Compensation Plan.
*10.19	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.
*10.20	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.
*10.21	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.
*10.22	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.
*10.23	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.
*10.24	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.
*10.25	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.
*10.26	Amendment to Employment Agreement, dated as of April 24,

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- 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.
- \*10.27 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.
- \*10.28 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.
- \*10.29 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.
- \*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.

### EXHIBIT INDEX

EXHIBIT	DESCRIPTION
*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

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- 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,

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- 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.
- 10.48 Form of Warrant between Somanetics Corporation and purchasers of Units in the April 1996 Regulation S Offering, incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended February 29, 1996.
- 10.49 Warrant Agreement, dated as of April 2, 1996, between Somanetics Corporation and Rauscher Pierce & Clark Limited, incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended February 29, 1996.
- 10.50 Warrant to Purchase Common Stock of Somanetics Corporation, dated as of April 2, 1996, between Somanetics Corporation and Rauscher Pierce & Clark Limited, incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended February 29, 1996.

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EXHIBIT	DESCRIPTION
10.51	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.
10.52	Revolving Note from Somanetics Corporation to Fifth Third Bank of Northwestern Ohio, N.A., dated April 1, 1999, incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended May 31, 1999.
10.53	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.



