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SOMANETICS CORP  
Form 10-K  
January 30, 2004

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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, 2003 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 38-2394784  
(State or other jurisdiction of (I.R.S. Employer Identification No.)  
incorporation or organization)

1653 EAST MAPLE ROAD, TROY, MICHIGAN 48083-4208  
(Address of principal executive offices) (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

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

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes  No

The aggregate market value of the common shares held by non-affiliates of the Registrant as of May 30, 2003 (the last business day of the Registrant's most recently completed second fiscal quarter), computed by reference to the closing sale price as reported by Nasdaq on such date, was approximately \$25,991,000.

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The number of the Registrant's common shares outstanding as of January 30, 2004 was 9,312,680

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the 2004 Annual Meeting of Shareholders, scheduled to be held March 31, 2004, are incorporated by reference in Part III, if the Proxy Statement is filed no later than March 29, 2004.

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## SOMANETICS CORPORATION

### ANNUAL REPORT ON FORM 10-K

FOR THE FISCAL YEAR ENDED NOVEMBER 30, 2003

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## PART I

### ITEM 1. BUSINESS

#### THE COMPANY

We were incorporated in 1982. We develop, manufacture and market the INVOS(R) Cerebral Oximeter, the only non-invasive patient monitoring system

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commercially available in the United States that continuously measures changes in the blood oxygen level in the brain. We also develop and market the CorRestore(TM) System for use in cardiac repair and reconstruction, including heart surgeries called surgical ventricular restoration, or SVR.

We developed the Cerebral Oximeter to meet the need for information about oxygen in the brain, the organ least tolerant of oxygen deprivation. Without sufficient oxygen, brain damage may occur within a few minutes, which can result in paralysis, severe and complex disabilities or death. Brain oxygen information, therefore, is important, especially in surgical procedures requiring general anesthesia and in other critical care situations with a high risk of the brain getting less oxygen than it needs. We target surgical procedures with a high risk of brain oxygen imbalances, primarily cardiac surgeries, as well as other blood vessel surgeries, such as carotid artery surgeries, and surgeries involving elderly patients. Surgeons, anesthesiologists, perfusionists 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(R),
- 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 are 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. We began international shipments of the model 5100 Cerebral Oximeter 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 and began shipping 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 develop and market the CorRestore System, which includes a cardiac implant designed by CorRestore LLC, for use in cardiac repair and reconstruction, including heart surgeries called surgical ventricular restoration, or SVR. During SVR, the surgeon restores an enlarged, poorly-functioning left ventricle to more normal size and function by inserting an implant, in most instances, or closing the defect

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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 System, subject to the terms and conditions of the license agreement. In November 2001 we received clearance from the FDA to market the CorRestore patch in the United States. The first surgical procedure using the CorRestore System was performed in January 2002. We began shipping the CorRestore System in the United States in the first quarter of fiscal 2002. In April 2003, we met the requirements under the European Medical Device Directive to use the CE Mark, thereby allowing us to market the CorRestore System in the European Economic Community. In October 2003, we began shipping the CorRestore System in Europe. Our objective is to have the CorRestore System used in SVR surgeries in the United States and Europe. Our initial target market is SVR surgeries on patients with dilated ischemic cardiomyopathy due to a previous myocardial infarction involving the anterior wall of the ventricle. Ischemic cardiomyopathy is a damaged heart muscle caused by the obstruction of the inflow of blood from the arteries, resulting in an enlarged ventricle. Myocardial infarction is the death of an area of the middle muscle layer in the heart wall.

### MARKET OVERVIEW

#### Industry Background

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

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

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

- heart surgeries,

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- heart blood vessel surgeries,
- other blood vessel surgeries,

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

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

A 1999 independent industry report estimates that there are approximately 60,000 operating rooms worldwide performing approximately 50 million surgeries involving general anesthesia every year. Industry sources estimate that, in the United States in 2003, there were approximately 4.6 million surgeries involving patients that, due to the type of surgery, age of the patient, or other factors, represent a higher risk for post-operative neurological complications. Such surgeries include open heart surgeries, carotid endarterectomies, which is the removal of blockage in the artery, major abdominal surgeries, orthopedic surgeries, and other major general surgeries involving elderly patients.

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

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

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- 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.

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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 information to help them identify brain oxygen imbalances. This information may help medical professionals intervene in a timely manner to correct brain oxygen imbalances, provide feedback regarding the adequacy of the selected therapy and provide medical professionals with additional assurance when they make decisions regarding the need for therapy, thereby potentially improving patient outcome and reducing the cost of care.

### Market Trends

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

**Less Invasive Medical Procedures.** We believe there is a trend toward less invasive medical procedures. Notable examples include laparoscopic procedures in general surgery and arthroscopic procedures in orthopedic surgery. Such procedures are designed to reduce trauma, thereby decreasing complications,

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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.

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**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, primarily cardiac surgeries, as well as other blood vessel surgeries, such as carotid artery 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.

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

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

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.

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

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

### PRODUCTS AND TECHNOLOGY

#### The Cerebral Oximeter

Our Cerebral Oximeter is the only non-invasive patient monitoring system commercially available in the United States that provides continuous information about changes in the blood oxygen level in the brain. It is a portable and easy-to-use monitoring system that is placed at a patient's bedside



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in hospital critical care areas, especially operating rooms, recovery rooms, ICUs and emergency rooms. Surgeons, anesthesiologists, perfusionists 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

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hours and retrieved by a variety of standard, commercially-available printers. The Cerebral Oximeter measures approximately 9 inches wide, 8 inches high, and 8 inches deep and weighs approximately 14 pounds.

Our suggested retail list prices in the United States are as follows: the Cerebral Oximeter \$25,000, the pediatric SomaSensor \$140.00, the adult SomaSensor \$110.00, and the small adult SomaSensor, launched in 2003 and designed for use on patients with smaller foreheads or lower hairlines, \$125.00. Users of the Cerebral Oximeter are required to purchase disposable SomaSensors on a regular basis. The SomaSensor may only be used once because after one use it may become contaminated and we do not warrant its effectiveness after one use. We provide a one-year warranty on the Cerebral Oximeter, which we will

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satisfy by repairing or exchanging those units in need of repair, and we offer 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<br>-----                    | Benefits<br>-----   |
|--------------------------------------|---|
| FDA-cleared                          | - Access to United States and certain foreign markets   |
| Non-invasive                         | - Consistent with market trend toward less invasive medical procedures<br><br>- No risk to patients and medical professionals<br><br>- No added patient recovery costs  |
| Continuous Information               | - Immediate information regarding brain oxygen imbalance<br><br>- Real-time guide to therapeutic interventions  |
| 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 equipment used<br><br>- Small portion of the cost of the procedures in which it is used<br><br>- New information can potentially improve patient outcomes and reduce the cost of care   |
| Easy to Use                          | - Does not require a trained technician to operate or install<br><br>- Automatic SomaSensor calibration<br><br>- Simple user interface and controls<br><br>- 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<br><br>- Indicates oxygen imbalances in the brain, not just blood flow, oxygenation of the arteries or the effects of other imbalances |
| 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

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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

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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

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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.

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### RESEARCH AND DEVELOPMENT

We are currently focusing our research and development efforts on the advancement of the design and production processes of the Cerebral Oximeter and SomaSensor. Over the longer term, we expect to focus efforts on developing product-line extensions of the Cerebral Oximeter for use on newborns, other non-brain tissue applications, and advancement of the design and production processes of the Cerebral Oximeter and SomaSensor.

We spent \$412,953 during fiscal 2003 on research, development and engineering, \$571,126 during fiscal 2002, and \$777,974 during fiscal 2001.

### 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, anesthesiologists and perfusionists. 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 larger hospitals in the United States and selected foreign markets in which we have commenced commercial sales, because these hospitals have a larger volume of surgical procedures and we consider them to be opinion leaders in the medical community. In addition, we sponsor discussions among physicians who have used the Cerebral Oximeter about its clinical benefits.

We believe that favorable peer review is a key element to a product's success in the medical equipment industry. Accordingly, we support clinical research programs with third-party clinicians and researchers intended to demonstrate the need for the Cerebral Oximeter and its clinical benefits with the specific objective of publishing the results in peer-reviewed journals. The research primarily consists of studies comparing patients managed based on information provided by cerebral oximetry with other patients, based on measures of patient outcome and hospital costs, including patient length of stay, length of time on the ventilator, cognitive dysfunction and incidence of stroke. During fiscal 2003, the results of the first prospective, randomized, blinded, intervention trial were presented, reporting a statistically significant reduction in average length of hospital stay for cardiac surgery patients who were monitored and managed with the INVOS Cerebral Oximeter. This trial is ongoing, and other fully randomized studies are being pursued that investigate the ability of clinicians to improve patient outcomes and reduce hospital costs by managing patients based on information provided by the Cerebral Oximeter. We attend trade shows and medical conferences to introduce and promote the Cerebral Oximeter and to meet medical professionals with an interest in performing

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research and reporting their results in peer-reviewed medical journals and at major international meetings.

### Sales and Distribution

We sell the Cerebral Oximeter through our direct sales force, independent sales representative firms and, in international markets, independent distributors. In the United States, we sell the Cerebral

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Oximeter through our seven direct salespersons, two clinical specialists and 12 independent sales representative firms. 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 three independent distributors covering 56 countries for the Cerebral Oximeter. Our distributors for the Cerebral Oximeter include Tyco Healthcare, part of Tyco International Ltd., in Europe and Canada, and Edwards Lifesciences Ltd., formerly Baxter Limited, in Japan.

During fiscal 1998, we began a no-cap sales program in the United States whereby we ship the Cerebral Oximeter to the customer at no charge, and the customer agrees to purchase at a premium a minimum monthly quantity of SomaSensors. It has been our experience that the larger hospitals in the United States prefer to use this method to acquire Cerebral Oximeters.

We did not have any backlog of firm orders as of January 10, 2004 or as of January 10, 2003. We generally do not have a backlog of firm orders.

For a description of sales to major customers, see Note 10 of Notes to Financial Statements included in Item 8 of this Report. Tyco Healthcare was our largest customer in fiscal 2003, 2002 and 2001. We are dependent on our sales to Tyco Healthcare, and the loss of them as a customer would have an adverse effect on our business, financial condition and results of operations.

Our export sales were approximately \$1,945,000 for the fiscal year ended November 30, 2003, \$1,348,000 for the fiscal year ended November 30, 2002, and \$1,595,000 for the fiscal year ended November 30, 2001. See Note 10 of Notes to Financial Statements. For a description of the breakdown of sales between Cerebral Oximeters, SomaSensors, and CorRestore Systems, see "Management's Discussion and Analysis of Financial Condition and Results of Operations -- Results of Operations."

### MANUFACTURING

We assemble the Cerebral Oximeter in our facilities in Troy, Michigan, from components purchased from outside suppliers. We assemble the Cerebral Oximeter to control its quality and costs and to permit us to make changes to the Cerebral Oximeter faster than we could if third-parties assembled it. We believe that each component is generally available from several potential suppliers. The SomaSensor, the printed circuit boards, other mechanical components and the unit enclosure are the primary components that must be manufactured according to specifications provided by us. Although we are currently dependent on one manufacturer of the SomaSensor, we believe that several potential suppliers are available to assemble the components of the Cerebral Oximeter. We would, however, require approximately three to four months

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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 Cerebral Oximeter and SomaSensor in the European Economic Community. Our most recent ISO 9001 compliance surveillance audit occurred in April 2003.

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### 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. Our initial United States patent, covering in vivo tissue examination technology, was allowed and issued in 1986 and expired in October 2003. We do not expect the expiration of this patent to have a material effect on our business. We are aware of patents issued to unaffiliated third parties and relating to cerebral oximetry that have expired. These expired patents make that technology generally available and potentially help the development of competing products. In addition, 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. 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

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medical products industry.

### PROPRIETARY RIGHTS INFORMATION

We have fifteen United States patents and four patents in various foreign countries. In September 2003, we were issued a new patent by the U.S. Patent and Trademark Office, titled "Multi-Channel, Noninvasive, Tissue Oximeter," covering the application of non-invasive, near-infrared spectroscopy to measure continuously and substantially concurrently a blood metabolite (oxygen saturation) in at least two separate internal regions of the brain. This patent will expire in October 2019. The corresponding Australian patent for "Multi-Channel, Noninvasive, Tissue Oximeter" issued in December 2003, and also expires in October 2019. Our other 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

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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 eleven 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 expired in October 2003. We do not expect the expiration of this patent to have a material effect on our business. The corresponding Canadian patent was issued in 1987 and expires in October 2004. 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. These European patents and this Japanese patent have now expired. We do not expect the expiration of these patents to have a material effect on our business. Our fifteen additional United States patents, and the corresponding four foreign patents, expire on various dates from February 2005 to October 2019. We currently do not have any patent applications pending in the United States, although we do have patent applications in various foreign countries with respect to 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

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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

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

A device requiring prior marketing authorization that does not qualify for 510(k) clearance is categorized as class III, which is reserved for devices classified by the FDA as posing the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices that are not substantially equivalent to a legally marketed class I or class II device. A class III device generally must receive approval of a premarket approval, or PMA, application,



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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, and some are never approved.

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

In June 1992, we received 510(k) clearance from the FDA to market the Cerebral Oximeter in the United States for use on adults. We began commercial shipments of Cerebral Oximeters and SomaSensors in May 1993. In November 1993, we received notification that the FDA had rescinded our 510(k) clearance to market the Cerebral Oximeter. As a result, all commercial sales of our product were suspended. In February 1994, we resumed marketing our product in several foreign countries. In June 1996, we received 510(k) clearance from the FDA to market the Cerebral Oximeter, including the SomaSensor, in the United States. In October 1997, we obtained FDA clearance for new advances in our INVOS technology that are incorporated in our model 4100 Cerebral Oximeter. We made additional minor changes to the model 3100A Cerebral Oximeter which resulted in the model 4100. We also made additional minor changes to the SomaSensor. 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. We have made additional minor changes to the model 5100. We do not believe that these changes could significantly affect the safety or efficacy of

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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 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 Cerebral Oximeter or SomaSensor or for any device modification, we might be prohibited from marketing the modified device until the 510(k) notice is cleared by the FDA.

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

Any devices we manufacture or distribute pursuant to FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA and some state agencies. Manufacturers of medical devices marketed in the United States must comply with detailed Quality System Regulation, or QSR, requirements, which include design, 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

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were to recur, it would likely cause or contribute to a death or serious injury. Labeling and promotional activities are subject to scrutiny by the FDA and, in some circumstances, by the Federal Trade Commission. Current FDA enforcement policy prohibits promoting approved medical devices for unapproved uses.

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

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

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

Rules for export of PMA devices are more stringent.

Congress has enacted the Medical Device User Fee Modernization Act of 2002. Among other things, this law has provisions which permit the assessment of user fees for product approvals and clearances. Given the recent enactment of this law, the effect of the law as it relates to us and our products is still unknown, other than that we will have to pay the FDA to review our 510(k) submissions.

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For fiscal 2003, our fees for 510(k) reviews were approximately \$2,000, and for fiscal 2004 our fees for a 510(k) review will be approximately \$3,000.

### SEASONALITY

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

### THE CORRESTORE SYSTEM

Market Overview

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

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

Surgical ventricular restoration is a surgical technique that can be used to treat some patients suffering from congestive heart failure. It involves reducing the size of the ventricle to restore more normal function. During SVR, the surgeon restores an enlarged, poorly functioning left ventricle to more normal size and function by inserting an implant, in most instances, or closing the defect directly. One study of SVR surgeries using existing dacron patches indicates a higher 12-month, 18-month and 36-month survival rate and a lower hospital re-admission rate for patients undergoing SVR. These existing patches take time for the surgeon to form, can be difficult to insert, and can leak around the edges. Two heart surgeons and their company, CorRestore LLC, have designed and patented a patch for use in SVR that they believe is easier to implant and provides a better seal against leaks at the perimeter than existing patches, which are formed by the surgeon during the surgery out of dacron or bovine pericardium tissue. Therefore, we believe it will be possible to demonstrate the clinical benefits of the CorRestore System and to gain market acceptance for this product in connection with these surgeries.

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.

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### Business Strategy

Our objective is to have the CorRestore System used in SVR surgeries in the United States and Europe. Key elements of our strategy are as follows:

Target and Promote Surgical Procedures Where Benefits Have Been Demonstrated. Our initial target market is SVR surgeries on Class III and IV congestive heart failure patients with dilated ischemic cardiomyopathy due to a previous myocardial infarction in the anterior wall of the left ventricle. Dilated ischemic cardiomyopathy is a damaged heart muscle caused by the

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obstruction of the inflow of blood from the arteries and resulting in an enlarged ventricle. Myocardial infarction is death of an area of the middle muscle layer in the heart wall. One study of SVR surgeries on these patients, using patches that were formed by the surgeon during the surgery out of dacron, indicates a higher 12-month, 18-month and 36-month survival rate and a lower hospital re-admission rate for patients undergoing SVR. We promote SVR by sponsoring education programs teaching SVR with the CorRestore System. Existing patches used in SVR take time for the surgeon to form, can be difficult to insert, and can leak around the edges. Therefore, we believe it will be possible to demonstrate the clinical benefits of the CorRestore System and to gain market acceptance for this product in connection with these surgeries.

Demonstrate the Clinical Benefits and Promote Acceptance of the CorRestore System. We expect to promote the acceptance of the CorRestore System in the medical community by encouraging cardiac surgeons in leading hospitals, whose opinions and practices we believe are valued by other hospitals and physicians, to use the CorRestore System. We believe that the successful evaluations of the CorRestore System by these medical professionals will accelerate the acceptance of the CorRestore System by other medical professionals.

Invest in Marketing and Sales Activities. We sell the CorRestore System through our direct sales force and independent sales representative firms in the United States. We are dependent on international distributors for international sales of the CorRestore System. We have distribution agreements with two independent distributors covering two countries for the CorRestore System. We invest in marketing and sales efforts to increase the medical community's exposure to SVR and the CorRestore System, including participation in trade shows and conducting training seminars. We have realized some synergies with our Cerebral Oximeter selling efforts because our sales personnel call on some of the same customers to sell both products. In addition, our SVR training programs have enabled us to establish relationships that benefit both the CorRestore System and the Cerebral Oximeter.

### Product

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

As a result of these problems, the inventors developed a non-circular bovine pericardium, or cow heart-sac, tissue patch with an integrated pericardial suture ring. It was developed to make SVR easier for the surgeon and to provide a better seal on the edges of the patch to minimize leaking. The inventors and their company, CorRestore LLC, filed for a patent with respect to their patch, which was issued in the United States in February 2000 and expires in May 2018. The claims allowed relate primarily to the product design of a soft suture ring integrated with a patch. Subsequently, two other United States patents

have been issued to the inventors, also with the claims allowed relating primarily to the product design of a soft suture ring integrated with a patch,

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and they also expire in May 2018. In addition, other United States and foreign patent applications are pending. We have also obtained United States Trademark registration for the trademark "CorRestore."

We offer the CorRestore System, which contains the patch and the accessories for aiding the implantation of the patch, to hospitals performing SVR. The retail price of the CorRestore System is approximately \$4,000. See "Competition." Prices to distributors are significantly discounted from the retail price. Because of the requirements for sterility and pursuant to our license agreement, the patches and accessories are being manufactured for us by PM Devices, Inc. We are dependent on PM Devices, Inc. to manufacture our entire requirements for the patches and the accessories. We entered into a Contract Development and Manufacturing Agreement with PM Devices, Inc. in September 2000. Although we are currently dependent on PM Devices, Inc. as a manufacturer, we believe that several potential suppliers are available. However, we are uncertain as to the length of time it would take to change suppliers.

### Marketing

We believe that favorable peer review is a key element to a product's success in the medical equipment industry. In November 2002, the results of a 13-center, 1,113-patient study evaluating the safety and effectiveness of SVR reported improvement in patient function based on New York Heart Association classification criteria, improvement in readmission and survival rates, and improvement in ejection fraction for SVR patients. Most of the patients in the study were severe New York Hospital Association Class III and Class IV congestive heart failure patients. For those patients whose New York Hospital Association Class was reported at last follow-up, 89 percent were functionally Class I or Class II. In addition, 89 percent of the patients were not readmitted to the hospital for congestive heart failure during the three years after their SVR surgery. By comparison, the annual hospital admission rate for Class III and IV heart failure patients is more than 40 percent and 24 percent are admitted two or more times each year.

The overall survival rate for the study group was 83 percent at three years. In addition, post-operatively, the ejection fraction of these patients increased from 28% to 40% and the left ventricular end systolic volume index decreased from 96 ml/m<sup>2</sup> to 62 ml/m<sup>2</sup>. These results were presented at the November 2002 meeting of the American Heart Association. These results updated the three-year results of a study of 662 SVR patients that were presented at the May 2001 meeting of the American Association for Thoracic Surgery, and were published in the October 2001 issue of *Seminars in Thoracic and Cardiovascular Surgery*. The initial three-year results had updated the 18-month results of a study of 439 SVR patients that was published in a peer-reviewed article in the April 2001 issue of the *Journal of the American College of Cardiology*.

### Sales and Distribution

We sell the CorRestore System through our seven direct salespersons, two clinical specialists and eight independent sales representative firms in the United States. Internationally, we met the requirements under the European Medical Device Directive to use the CE Mark in April 2003. We sell the CorRestore System through independent distributors in international markets. We have distribution agreements with two independent distributors covering two countries for the CorRestore System.

### License Agreement

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

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

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

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

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

- A royalty of 10% of our net sales of products subject to the licenses, for the term of the patent relating to the CorRestore System, or for 10 years from the date of the first commercial sale if the patent is determined to be invalid.
- Five-year warrants to purchase up to 400,000 common shares at \$3.00 a share. The warrants became exercisable to purchase 300,000 shares immediately, became exercisable to purchase an additional 50,000 shares when we received clearance from the FDA to market the CorRestore patch in the United States, and became exercisable to purchase another 50,000 shares when we received CE certification for the CorRestore System. The warrants expire when the licenses terminate, except that the vested portion of the warrants remain exercisable for an additional 90 days or, if the licenses terminate because of

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specified breaches by us, for the remaining term of the warrants.

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

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| Net Sales<br>----- | Additional Portion<br>of Shares<br>----- |
|--------------------|--|
| \$ 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 warrants expire when the licenses terminate, except that the vested portion of the warrants remain exercisable for an additional 90 days or, if the licenses terminate because of specified breaches by us, for the remaining term of the warrants.

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

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

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

- In their sole discretion, within 120 days after we consummate specified types of business combination transactions with another entity and the holders of our common shares immediately before the transaction hold less than 50% of the surviving entity's or its ultimate parent's outstanding voting securities immediately after the transaction, but only if (1) the transaction is consummated before June 2, 2004, 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

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these events happens before June 2, 2005, and (2) CorRestore LLC or either of the inventors exercises the right to terminate within 120 days after the event occurs.

- In their sole discretion, if we materially breach specified covenants in the license agreement and fail to cure the breach within 90 days (30 days for payment obligations) after CorRestore LLC notifies us of the breach, but only if CorRestore LLC exercises its right to terminate within 120 days after the 90-day cure period expires.
- In their sole discretion, if our common shares are delisted from The Nasdaq Stock Market and are not re-listed within 90 days, but only if CorRestore LLC exercises its right to terminate within 120 days after the 90-day period expires.
- In their sole discretion, if we make an assignment for the benefit of our creditors or voluntarily commence any bankruptcy, receivership, insolvency or liquidation proceedings and the action is not reversed or terminated within 90 days, but only if CorRestore LLC exercises its right to terminate within 120 days after the 90-day period expires.

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

- CorRestore LLC may exclude specified countries from the geographic scope of the license if we have not begun marketing the CorRestore System products or begun the process of obtaining necessary regulatory approval to sell CorRestore System products in that country within one year after the date we file a 510(k) clearance application or PMA approval application with the FDA with respect to the CorRestore patch products. We filed a 510(k) clearance application with the FDA with respect to the CorRestore patch products on May 15, 2001. 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. We have not received any such notice.
- CorRestore LLC may change our licenses to be non-exclusive for developments that we do not incorporate in the CorRestore System products, begin marketing or testing, receive clearances to market or IDE approvals and actually begin marketing within specified time periods.

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



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inventors materially breaches specified covenants in the license agreement and fails to cure such breach within 90 days after we notify the applicable party of the breach, but only if we exercise our right to terminate within 120 days after the 90-day cure period expires.

### Competition

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

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

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### INSURANCE

Because the Cerebral Oximeter and the CorRestore System are intended to be used in hospital critical care units with patients who may be seriously ill or may be undergoing dangerous procedures, we might be exposed to serious potential products liability claims. We have obtained products liability insurance with a liability limit of \$5,000,000. We 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 28, 2004, we employed 27 full-time individuals, including 11 in sales and marketing, four in research and development, five in general and administration and seven in manufacturing, quality and service. We also employed one part-time individual, in general and administration. In addition, we use two contract manufacturing employees, and we use two consultants. We believe that our future success is dependent, in large part, on our ability to attract and retain highly qualified managerial, marketing and technical personnel. We expect to add additional sales and marketing employees in fiscal 2004. Our employees are not represented by a union or subject to a collective bargaining agreement. We believe that our relations with our current employees are good.

### FINANCIAL INFORMATION ABOUT FOREIGN AND DOMESTIC OPERATIONS AND EXPORT SALES

We are located in Troy, Michigan and have no other locations. Our export sales were approximately \$1,945,000 for the fiscal year ended November

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30, 2003, \$1,348,000 for the fiscal year ended November 30, 2002 and \$1,595,000 for the fiscal year ended November 30, 2001, including approximately \$1,166,000 in fiscal 2003, \$820,000 in fiscal 2002 and \$939,000 in fiscal 2001 to Tyco Healthcare, our distributor in Europe and Canada, and approximately \$616,000 in fiscal 2003, \$352,000 in fiscal 2002, and \$369,000 in fiscal 2001 to Edwards Lifesciences Ltd., our distributor in Japan. See Note 10 of Notes to Financial Statements included in Item 8 of this Report.

### WHERE YOU CAN GET INFORMATION WE FILE WITH THE SEC

We file annual, quarterly and special reports, proxy statements and other information with the SEC. You can read and copy any materials we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers, such as us, that file electronically with the SEC. The address of the SEC's Web site is <http://www.sec.gov>.

We also maintain a Web site at <http://www.somanetics.com>. We make available free of charge on or through our Web site, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. We will voluntarily provide electronic or paper copies of our filings free of charge upon request.

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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 January 2003, with the extension commencing January 1, 2004 and expiring December 31, 2004. The minimum monthly lease payment was approximately \$16,200 for fiscal 2001, \$16,500 for fiscal 2002, \$16,800 for fiscal 2003, and is approximately \$16,800 for fiscal 2004 excluding other occupancy costs. We believe that, depending on sales of the Cerebral Oximeter and the CorRestore System, our current facility is more than suitable and adequate for our current needs, including our assembly of the Cerebral Oximeter, storing inventories of CorRestore System products and conducting our operations in compliance with prescribed FDA QSR guidelines, and will allow for substantial expansion of our business and number of employees.

### ITEM 3. LEGAL PROCEEDINGS

We are not a party to any pending legal proceedings.

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

No matter was submitted to a vote of security holders during the fourth quarter of the fiscal year ended November 30, 2003.

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### SUPPLEMENTAL ITEM. EXECUTIVE OFFICERS OF THE REGISTRANT

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

| Name<br>-----        | Executive<br>Officer<br>Since<br>----- | Age<br>-- | Position<br>-----                        |
|----------------------|--|-----------|--|
| Bruce J. Barrett     | 6/94                                   | 44        | President and Chief Executive Officer    |
| William M. Iacona    | 12/00                                  | 33        | Vice President, Finance, Controller, and |
| Richard S. Scheuing  | 1/98                                   | 48        | Vice President, Research and Development |
| Dominic J. Spadafore | 8/02                                   | 44        | Vice President, Sales and Marketing      |
| Mary Ann Victor      | 1/98                                   | 46        | Vice President, Communications and Admin |
| Ronald A. Widman     | 1/98                                   | 53        | Vice President, Medical Affairs          |
| Pamela A. Winters    | 1/98                                   | 45        | Vice President, Operations               |

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

### BIOGRAPHICAL INFORMATION

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

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

Mr. Richard S. Scheuing has served as our Vice President, Research and Development since January 1998. From March 1993 to January 1998, he served as our Director of Research and Development. He joined us in 1991 as our Director of Mechanical Engineering. He is an inventor on five of our issued patents. 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.

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Mr. Dominic J. Spadafore has served as our Vice President, Sales and Marketing since August 2002. Mr. Spadafore previously served, from July 2000 until July 2002, as National Sales and Clinical Director of the Cardiac Assist Division of Datascope Corporation, a medical device company that manufactures and markets healthcare products including medical devices used in high-risk cardiac patients. In this position, Mr. Spadafore supervised approximately 50 sales and clinical personnel, and approximately \$80 million in domestic revenues. From July 1997 until July 2000 he served as Western Area Manager of the Patient Monitoring Division of Datascope Corporation, and from January 1990 until July 1997 held field sales representative and regional manager positions with progressive responsibilities with Datascope Corporation. From May 1983 to January 1984 Mr. Spadafore was a sales representative with the Upjohn Company, a pharmaceutical manufacturer, and from January 1984 until January 1990 was a sales representative with White and White Incorporated, a medical supply distributor. He received a BA degree in pre-medicine from Oakland University. Mr. Spadafore is a party to an employment agreement with us that requires us to elect him to the office he currently holds.

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.

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## PART II

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

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

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|                                     | HIGH    | LOW     |
|-------------------------------------|---------|---------|
|                                     | ----    | ---     |
| Fiscal Year Ended November 30, 2002 |         |         |
| First Quarter.....                  | \$ 4.95 | \$ 3.65 |
| Second Quarter.....                 | 4.10    | 2.38    |
| Third Quarter.....                  | 2.84    | 1.40    |
| Fourth Quarter.....                 | 2.10    | 1.43    |
| Fiscal Year Ended November 30, 2003 |         |         |
| First Quarter.....                  | \$ 2.15 | \$ 1.55 |
| Second Quarter .....                | 3.48    | 1.54    |
| Third Quarter .....                 | 5.75    | 3.08    |
| Fourth Quarter .....                | 9.17    | 5.70    |

As of January 28, 2004, we had 590 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.

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ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data as of November 30, 2003, 2002, 2001, 2000 and 1999, and for each of the years in the five-year period ended November 30, 2003 have been derived from our audited financial statements, some of which appear in Item 8 of this Report. In fiscal 2002 we began selling the CorRestore System in the United States, and in fiscal 2003 we began selling the CorRestore System in Europe. See Item 1. "Business - The CorRestore System."

This selected financial data might not be a good indicator of our expected results for fiscal 2004. 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.

|  | FISCAL YEAR ENDED     |          |          |
|--|-----------------------|----------|----------|
|  | 2003                  | 2002     | 2001     |
|  | -----                 | ----     | ----     |
|  | (in thousands, except |          |          |
| STATEMENT OF OPERATIONS DATA:                        |                       |          |          |
| Net revenues (1) .....                               | \$ 9,361              | \$ 6,706 | \$ 5,656 |
| Cost of sales .....                                  | 2,140                 | 2,049    | 2,094    |
| Gross margin .....                                   | 7,221                 | 4,657    | 3,561    |
| Research, development and engineering expenses ..... | 413                   | 571      | 778      |
| Selling, general, and administrative expenses .....  | 6,759                 | 5,344    | 5,133    |
| Net income (loss) .....                              | 73                    | (1,207)  | (2,331)  |
| Net income (loss) per common share - basic           |                       |          |          |

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|  |       |       |       |
|--|-------|-------|-------|
| and diluted (2) .....                    | .01   | (.13) | (.31) |
| Weighted average number of common shares |       |       |       |
| outstanding - basic (2) .....            | 9,114 | 8,951 | 7,606 |
| Weighted average number of common shares |       |       |       |
| outstanding - diluted (2) .....          | 9,467 | 8,951 | 7,606 |

AT NOVEMBER 30,

|                                      | 2003           | 2002     | 2001     | 2000 |
|--------------------------------------|----------------|----------|----------|------|
|                                      | ----           | ----     | ----     | ---- |
|                                      | (in thousands) |          |          |      |
| <b>BALANCE SHEET DATA:</b>           |                |          |          |      |
| Cash and marketable securities ..... | \$ 2,239       | \$ 2,382 | \$ 168   | \$   |
| Working capital .....                | 4,480          | 4,047    | 1,724    | 1,   |
| Total assets .....                   | 7,156          | 6,164    | 3,587    | 3,   |
| Total liabilities .....              | 991            | 664      | 575      |      |
| Accumulated deficit .....            | (53,589)       | (53,661) | (52,455) | (50, |
| Shareholders' equity (3) .....       | 6,165          | 5,501    | 3,013    | 2,   |

- (1) Net revenues recorded in fiscal years 2001, 2000, and 1999 relate primarily to the sale of Cerebral Oximeters and SomaSensors for commercial use. Fiscal years 2003 and 2002 net revenues include sales of CorRestore Systems.
- (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.
- (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, 2000 through November 30, 2003.

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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.

Our actual results might differ materially from those projected in the forward-looking statements depending on various important factors. These important factors include our history of losses, our current dependence on the Cerebral Oximeter and SomaSensor, the challenges associated with developing new products, the uncertainty of acceptance of our products by the medical community, the lengthy sales cycle for our products, competition in our markets, our dependence on our distributors, and the other factors discussed under the

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caption "Risk Factors" and elsewhere in our Registration Statement on Form S-1 (file no. 333-74788) effective January 11, 2002 and elsewhere in this report, all of which 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.

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.

### 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 also develop and market the CorRestore System for use in cardiac repair and reconstruction, including heart surgeries called surgical ventricular restoration, or SVR. In June 2000, we entered into a license agreement for the CorRestore System. In November 2001 we received clearance from the FDA to market the CorRestore patch in the United States, and in April 2003 we met the requirements under the European Medical Device Directive to use the CE Mark, thereby allowing us to market the product in the European Economic Community.

During fiscal 2001, our primary activities consisted of sales and marketing of the Cerebral Oximeter and related disposable SomaSensor. During fiscal 2002 and 2003, our primary activities consisted of sales and marketing of the Cerebral Oximeter, the related disposable SomaSensor, and the CorRestore System.

We derive our revenues from sales of Cerebral Oximeters, SomaSensors and CorRestore Systems to our distributors and to hospitals in the United States through our direct sales employees and independent sales representative firms. We offer to our customers in the United States a no-cap sales program whereby we ship the 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. We recognize revenue when there is persuasive evidence of an arrangement with the customer, the product

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has been delivered, the sales price is fixed or determinable, and collectibility is reasonably assured. The product is considered delivered to the customer once we have shipped it, as this is when title and risk of loss have transferred. Payment terms are generally net 30 days for United States sales and net 60 days or longer for international sales. Our primary expenses, excluding the cost of our products, are selling, general and administrative and research, development and engineering.

As described in more detail below, we achieved our first year of profitability in fiscal 2003, with net income of \$.01 per common share. Our net income was primarily a result of a 40% increase in net revenues, an 8% increase in gross margin percentage, and the control of our operating expenses. We have projected an increase in net revenues for fiscal 2004 of approximately 30% to 40%, and have projected net income per basic common share of approximately \$.12 to \$.15. We also expect our gross margin percentage to increase in fiscal 2004.

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Fiscal Year Ended November 30, 2003 Compared to Fiscal Year Ended November 30, 2002

Our net revenues increased approximately \$2,655,000, or 40%, from \$6,705,647 in the fiscal year ended November 30, 2002 to \$9,360,893 in the fiscal year ended November 30, 2003. The increase in net revenues is primarily attributable to

- an increase in United States sales of approximately \$2,059,000, or 38%, from approximately \$5,357,000 in fiscal 2002 to approximately \$7,416,000 in fiscal 2003, primarily due to an increase in sales of the disposable SomaSensor of approximately \$1,648,000, or 38%, and an increase in CorRestore System revenues of approximately \$430,000, or 160%,
- an increase in international sales of approximately \$596,000, or 44%, from approximately \$1,348,000 in fiscal 2002 to approximately \$1,945,000 in fiscal 2003, primarily due to increased purchases of the Cerebral Oximeter and disposable SomaSensor by Tyco Healthcare in Europe and Edwards Lifesciences in Japan, and
- a 16% increase in the average selling price of SomaSensors in the United States, primarily as a result of the increase in the suggested retail price of the SomaSensor effective December 1, 2002, the addition of new customers during 2003 at the higher suggested retail prices, and increased sales of SomaSensors to larger U.S. hospitals at a premium price pursuant to our no-cap sales program. This increase was partially offset by increased SomaSensor sales to international distributors, which have lower average selling prices.

Sales of our products as a percentage of net revenues were as follows:

| PRODUCT<br>-----         | PERCENT OF NET REVENUE    |                      |
|--------------------------|---------------------------|----------------------|
|                          | FISCAL YEAR ENDED<br>2003 | NOVEMBER 30,<br>2002 |
|                          | ----                      | ----                 |
| SomaSensors .....        | 71%                       | 72%                  |
| Cerebral Oximeters ..... | 21%                       | 24%                  |
| CorRestore Systems ..... | 8%                        | 4%                   |
|                          | ---                       | ---                  |
| Total .....              | 100%                      | 100%                 |
|                          | ===                       | ===                  |

Approximately 21% of our net revenues in fiscal 2003 were export sales, compared to approximately 20% of our net revenues in fiscal 2002. One international distributor accounted for approximately 12% of net revenues for each of the fiscal years ended November 30, 2003 and November 30, 2002.

Effective September 1, 2003, we increased the suggested list price for the adult SomaSensor and the pediatric SomaSensor in the United States to \$110.00 and \$140.00, respectively. In addition, we



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launched our new small adult SomaSensor, designed for use on patients with smaller foreheads or lower hairlines, with a suggested list price of \$125.00.

Although these prices may not apply to existing customers or to any existing sales quotations issued before September 1, 2003, we expect that the average selling price of SomaSensors in the United States will increase by approximately 15% in fiscal 2004, primarily as a result of

- the addition of new customers at our suggested retail prices,
- the preference of larger U.S. hospitals to acquire the Cerebral Oximeter using our no-cap sales program and, thereby, pay a premium price for the disposable SomaSensor,
- increased sales of our pediatric SomaSensor, which has a higher retail price than our adult SomaSensor, and
- increased sales of our new small adult SomaSensor.

Gross margin as a percentage of net revenues was approximately 77% for the fiscal year ended November 30, 2003 and approximately 69% for the fiscal year ended November 30, 2002. The increase in gross margin as a percentage of net revenues is primarily attributable to

- the increase in the average selling price of SomaSensors in the United States described above,
- increased sales of our latest model SomaSensor, which is less costly to manufacture than the prior model SomaSensor sold in fiscal 2002,
- sales of our latest model Cerebral Oximeter, which was launched in 2003, and is less costly to manufacture than the model sold in fiscal 2002, and
- increased sales of the CorRestore system in fiscal 2003.

We expect gross margins to increase in fiscal 2004 primarily as a result of increased average selling prices of the SomaSensor in the United States and expected reduced costs of manufacturing the SomaSensor.

Our research, development and engineering expenses decreased approximately \$158,000, or 28%, from \$571,126 in fiscal 2002 to \$412,953 in fiscal 2003. The decrease is primarily attributable to approximately \$124,000 in decreased costs associated with the development of the CorRestore System and approximately \$47,000 in decreased costs associated with the development of the Cerebral Oximeter.

Selling, general and administrative expenses increased approximately \$1,415,000, or 26%, from \$5,343,513 for the fiscal year ended November 30, 2002 to \$6,758,637 for the fiscal year ended November 30, 2003. The increase in selling, general and administrative expense is primarily attributable to

- a \$477,000 increase in commissions paid to our independent sales representative firms as a result of increased sales and additional independent representative firms,
- a \$305,000 increase in incentive compensation expense due to

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increased sales, net income, and our executive officers receiving awards under the 2003 Incentive Compensation Plan after forgoing awards under the 2002 Incentive Compensation Plan,

- a \$278,000 increase in salaries, wages, commissions and related expenses, primarily as a result of increased salaries, principally sales and marketing, and increased employee insurance costs,
- a \$216,000 increase in trade show, promotional, and selling-related expenses as a result of our increased sales and marketing activities, and
- a \$44,000 increase in royalty expense due to increased sales of the CorRestore System.

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We expect our selling, general and administrative expenses to increase in fiscal 2004 as a result of marketing and selling the Cerebral Oximeter and the CorRestore System.

Fiscal Year Ended November 30, 2002 Compared to Fiscal Year Ended November 30, 2001

Our net revenues increased approximately \$1,050,000, or 19%, from \$5,655,532 in the fiscal year ended November 30, 2001 to \$6,705,647 in the fiscal year ended November 30, 2002. The increase in net revenues is primarily attributable to

- an increase in United States sales of approximately \$1,296,000, or 32%, from approximately \$4,061,000 in fiscal 2001 to approximately \$5,357,000 in fiscal 2002, primarily due to a 45% increase in sales of the disposable SomaSensor, and approximately \$268,000 in CorRestore System revenues in fiscal 2002, partially offset by a 33% decrease in sales of the Cerebral Oximeter primarily as a result of approximately \$210,000 in stocking orders to independent representatives in fiscal 2001, and also partly as a result of a preference by larger U.S. hospitals to acquire Cerebral Oximeters using our no-cap sales program, and
- a 10% increase in the average selling price of SomaSensors primarily as a result of the 25% increase from the prior year in the suggested retail price of the SomaSensor effective September 1, 2001, and a change in the sales mix between sales in the United States, which have higher average selling prices, and sales to international distributors.

The increase in net revenues was achieved despite a decrease in international sales of approximately \$246,000, or 15%, from approximately \$1,595,000 in fiscal 2001 to approximately \$1,348,000 in fiscal 2002. This decrease is primarily attributable to decreased purchases by Tyco Healthcare in fiscal 2002.

Sales of our products as a percentage of net revenues were as follows:

PERCENT OF NET REVENUE

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| PRODUCT<br>-----        | FISCAL YEAR ENDED NOVEMBER 30,<br>2002<br>---- | 2001<br>---- |
|-------------------------|--|--------------|
| SomaSensors.....        | 72%  | 60%          |
| Cerebral Oximeters..... | 24%  | 40%          |
| CorRestore Systems..... | 4%   | 0%           |
|                         | ---  | ---          |
| Total.....              | 100%   | 100%         |
|                         | ===  | ===          |

Approximately 20% of our net revenues in fiscal 2002 were export sales, compared to approximately 28% of our net revenues in fiscal 2001. One international distributor accounted for approximately 12% of net revenues for the fiscal year ended November 30, 2002, and approximately 17% of net revenues for the fiscal year ended November 30, 2001.

Effective December 1, 2002, we increased the suggested list price for the adult SomaSensor and the pediatric SomaSensor in the United States to \$95.00 and \$125.00, respectively.

Gross margin as a percentage of net revenues was approximately 69% for the fiscal year ended November 30, 2002 and approximately 63% for the fiscal year ended November 30, 2001. The increase in gross margin as a percentage of net revenues is primarily attributable to

- a 10% increase in the average selling price of SomaSensors, described above,
- increased sales of our latest model SomaSensor, which is less costly to manufacture than the prior model SomaSensor,

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- sales of the CorRestore system in fiscal 2002, and
- a change in sales mix with increased sales in the United States and decreased sales to international distributors which have lower average selling prices.

Our research, development and engineering expenses decreased approximately \$207,000, or 27%, from \$777,974 in fiscal 2001 to \$571,126 in fiscal 2002. The decrease is primarily attributable to approximately \$222,000 in decreased costs associated with the development of the CorRestore System and a \$35,000 decrease in engineering salaries as a result of one less engineer, partially offset by approximately \$64,000 in increased costs associated with the development of our next generation Cerebral Oximeter.

Selling, general and administrative expenses increased approximately \$210,000, or 4%, from \$5,133,473 for the fiscal year ended November 30, 2001 to \$5,343,513 for the fiscal year ended November 30, 2002. The increase in selling, general and administrative expense is primarily attributable to

- a \$248,000 increase in commissions paid to our independent sales representative firms,
- \$234,000 in customer education expenses for the CorRestore System in fiscal 2002,

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- a \$141,000 increase in trade show expenditures for the Cerebral Oximeter and CorRestore System as a result of our increased sales and marketing activities,
- a \$74,000 increase in insurance expense, primarily due to increased products liability insurance coverage since we began marketing the CorRestore System, and
- a \$73,000 increase in professional service fees, primarily due to the timing of auditing and tax service expenses.

These increases were partially offset by

- a \$219,000 decrease in intangible amortization expense as a result of discontinued amortization of license acquisition costs in connection with our adoption of Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets,"
- a \$200,000 termination fee paid in fiscal 2001 related to the Kingsbridge Capital Limited Private Equity Line,
- a \$129,000 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 31 employees for the fiscal year ended November 30, 2001 to an average of 28 employees for the fiscal year ended November 30, 2002) and reduced employee sales commissions, and
- \$45,000 paid in fiscal 2001 in connection with the Loan and Security Agreement with Crestmark Bank.

### 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 2003 was approximately \$260,000. Cash was used primarily to

- increase accounts receivable by approximately \$791,000, primarily as a result of higher fourth quarter 2003 sales than fourth quarter 2002 sales, and

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- increase inventory by approximately \$86,000, primarily due to the acquisition of components associated with our SomaSensor and Cerebral Oximeter due to anticipated sales, partially offset by a reduction in CorRestore inventory.

These uses of cash were partially offset by

- our net income, approximately \$308,000 before depreciation and amortization expense,
- a \$170,000 increase in accounts payable, primarily due to

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increased inventories and the increased sales commissions payable to our independent sales representative firms described above, and

- a \$157,000 increase in accrued liabilities, primarily as a result of the increased accrued incentive compensation described above and increased sales commissions to our direct sales employees as a result of higher sales, partially offset by a reduction in accrued training and clinical research expenses from 2002.

We expect our working capital requirements to increase as sales increase.

We capitalized approximately \$371,000 of costs for Cerebral Oximeters being used as demonstration units and no-cap units during fiscal 2003, compared to approximately \$239,000 in fiscal 2002. As of November 30, 2003, we have capitalized approximately \$1,309,000 in costs for Cerebral Oximeters being used as demonstration and no-cap units, and these assets have a net book value of approximately \$530,000. We depreciate these costs over five years.

Capital expenditures in fiscal 2003 were approximately \$421,000. These expenditures were primarily

- approximately \$371,000 for Cerebral Oximeters being used as demonstration units and no-cap units, and
- approximately \$33,000 in tooling costs, primarily for the SomaSensor.

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

On March 6, 2000, we entered into the Private Equity Line Agreement with Kingsbridge Capital Limited, a private institutional investor. We completed the sales of 714,484 common shares under the Private Equity Line Agreement, for gross proceeds of \$2,000,000 through December 4, 2000. Our net proceeds, after deducting the commissions and the estimated expenses of the offerings, were approximately \$1,793,000. On April 10, 2001, we mutually agreed with Kingsbridge to terminate the Private Equity Line Agreement, the related Registration Rights Agreement, and Kingsbridge's right to the discount on any unsold shares, in exchange for our payment of \$200,000 to Kingsbridge.

In connection with the Private Equity Line Agreement, we issued to Kingsbridge Capital warrants which entitled the holder to purchase 205,097 common shares, after adjustment for the April 2001 private placement and the January 2002 public offering, at a purchase price of \$4.25 per share. The warrants are exercisable at any time until September 3, 2005. The warrants contain standard provisions that protect the holder against dilution by adjustment of the exercise price and the number of shares issuable pursuant to the warrants if various events occur. The exercise price of the warrants is payable either in cash or by a cashless exercise. In November 2003, Kingsbridge purchased 100,000 common shares under the warrants by a cashless exercise. As a result of this cashless exercise, we issued 53,603 common shares to

Kingsbridge, retaining 46,397 common shares in payment of the exercise price,

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and Kingsbridge's warrants now entitle it to purchase 105,097 more common shares.

On February 13, 2001, we entered into a Loan and Security Agreement with Crestmark Bank for a working capital line of credit for up to \$750,000, collateralized by all of our assets. We paid a \$45,000 commitment fee for the loan. As of April 24, 2003, we amended our Loan and Security Agreement with Crestmark Bank. Pursuant to the amendment, we paid a \$5,000 renewal commitment fee to continue our lending relationship for the remainder of 2003. Through November 30, 2003, we had borrowed an aggregate of \$1,295,050 under the agreement and repaid \$1,295,050 in principal amount through Crestmark's collection of our receivables and by using some of the proceeds from our April 9, 2001 and January 16, 2002 offerings. No amounts were borrowed under this facility in fiscal 2003. Effective December 31, 2003, our Loan and Security Agreement with Crestmark Bank expired. We do not intend to renew this lending agreement.

On April 9, 2001, we completed the private placement of 1,325,000 newly-issued common shares at a price of \$1.75 per share, for gross proceeds of \$2,318,750. Our estimated net proceeds, after deducting the placement agent's commission and the expenses of the offering, were approximately \$2,152,000. Brean Murray & Co., Inc. was our exclusive placement agent for the offering and received for its services (1) \$104,363 as a placement agent fee, and (2) warrants to purchase 25,000 common shares at \$2.10 per share exercisable during the four-year period beginning April 9, 2002, with the exercise price of the warrants payable either in cash or by a cashless exercise. In addition, the Brean Murray & Co., Inc. Profit Sharing Plan purchased 32,285 common shares in the offering, and Robert R. Henry, one of our directors, purchased 100,000 common shares in the offering. In October 2003, Brean Murray & Co., Inc. transferred the 25,000 warrants to persons who are or were employees of Brean Murray & Co., Inc., and in November 2003, those persons exercised the warrants to purchase all 25,000 common shares under the warrants by a cashless exercise. As a result of this cashless exercise, we issued 18,832 restricted common shares to those individuals, retaining 6,168 common shares in payment of the exercise price, and no more common shares remain subject to these warrants.

On January 16, 2002, we completed the public offering of 1,000,000 newly-issued common shares at a price of \$4.25 per share, for gross proceeds of \$4,250,000. Our estimated net proceeds, after deducting the placement agent's commission and the estimated expenses of the offering, were approximately \$3,680,000. Brean Murray & Co., Inc. was our exclusive placement agent for the offering and received for its services (1) \$340,000 as a placement agent fee, and (2) warrants to purchase 100,000 common shares at \$5.10 per share exercisable during the four-year period beginning January 11, 2003.

During fiscal 2003, we issued 148,371 common shares as a result of stock option exercises by employees, directors and former employees, for proceeds of approximately \$539,000.

As of November 30, 2003, we had working capital of \$4,480,492, cash and cash equivalents of \$2,239,192, total current liabilities of \$990,779 and shareholders' equity of \$6,165,068. We had an accumulated deficit of \$53,588,723 through November 30, 2003.

We expect that our primary needs for liquidity in fiscal 2004 will be

- to fund our operations, including funding for
  - marketing costs for the Cerebral Oximeter and the CorRestore System, and
  - research and development efforts related to the

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advancement of the design and production processes of the Cerebral Oximeter and SomaSensor, and

- for working capital, primarily accounts receivable, as our sales increase.

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In addition, we have budgeted approximately \$300,000 for capital expenditures during fiscal 2004, primarily for new demonstration and no-cap equipment.

We believe that the cash and cash equivalents on hand at November 30, 2003 will be adequate to satisfy our operating and capital requirements for more than the next twelve months.

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

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

### NEW ACCOUNTING PRONOUNCEMENTS

In December 2002, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure." This Statement, which is effective for fiscal years ending after December 15, 2002, amends Statement No. 123, "Accounting for Stock-Based Compensation," and provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based compensation. In addition, Statement No. 148 amends the disclosure requirements of Statement No. 123 regardless of the accounting method used to account for stock-based compensation. We have chosen to continue to account for stock-based compensation of employees using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. However, we adopted the enhanced disclosure provisions as defined by Statement No. 148 beginning with our fiscal quarter ended February 28, 2003.

During the first quarter of fiscal 2003, we adopted Financial Accounting Standards Board Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." The adoption of this interpretation had no impact on our financial statements.

During the fourth quarter of fiscal 2003, we adopted Emerging Issues Task Force Issue 00-21, "Revenue Arrangements with Multiple Deliverables." The adoption of EITF 00-21 had no impact on our financial statements.

### CRITICAL ACCOUNTING POLICIES

We believe our most significant accounting policies relate to the recording of an intangible asset for license acquisition costs related to our acquisition of exclusive, worldwide, royalty-bearing licenses to specified

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rights relating to the CorRestore System and related products and accessories, and our accounting treatment of stock options issued to employees.

In fiscal years 2000, 2001, and 2003, we recorded an intangible asset related to our acquisition of exclusive, worldwide, royalty-bearing licenses to specified rights relating to the CorRestore System and related products and accessories. License acquisition costs include our estimate of the fair value of ten-year vested stock options to purchase common shares granted to one of our then current directors in connection

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with negotiating and assisting us in completing the transaction, and our estimate of the fair value of the vested portion of five-year warrants to purchase common shares issued in the transaction.

We estimated the value of the stock options to purchase common shares and the warrants to purchase common shares using the Black-Scholes valuation model. The Black-Scholes valuation model requires the following assumptions: expected life period of the security, expected volatility of our stock price during the period, risk-free interest rate, and dividend yield. Given the assumptions inherent in the Black-Scholes valuation model, it is possible to calculate a different value for our intangible asset by changing one or more of the valuation model variables or by using a different valuation model. However, we believe that the model is appropriate, that the judgments and assumptions that we have made at the time of valuation were also appropriate, and that the reported results would not be materially different had one or more of the variables been different or had a different valuation model been used.

In addition, effective December 1, 2001, we adopted Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets." The effect of adopting this Statement has been to discontinue amortizing our license acquisition costs related to our acquisition of exclusive, worldwide, royalty-bearing licenses to specified rights relating to the CorRestore System and related products and accessories described above because we believe these licenses have an indefinite life. Therefore, we recorded no amortization expense related to these license acquisition costs in fiscal 2003 or 2002. For fiscal 2001, we incurred amortization expense of approximately \$219,000 associated with these license acquisition costs. Our net loss for fiscal 2001, excluding the effect of amortizing our license acquisition costs, would have been reduced to approximately \$2,112,000, or \$(.28) per common share. It is possible to determine a different life for these licenses, and if they had a definite life we would amortize the intangible asset over the remaining useful life. However, we believe it is appropriate to use an indefinite life for these licenses.

In October 1995, Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation," was issued by the Financial Accounting Standards Board. In addition, as described above, in December 2002, Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure," was issued by the Financial Accounting Standards Board, and amends Statement No. 123. We have chosen to continue to account for stock-based compensation of employees using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. Accordingly, compensation costs for stock options granted to employees are measured as the excess, if any, of the market price of our stock at the date of the grant over the amount an employee must pay to acquire the stock. No compensation expense has been charged against income for stock option grants to employees because our stock option grants are priced at the market value as of the date of grant. During fiscal 2003, we granted 471,000 stock options to our



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employees and directors, in fiscal 2002 we granted 509,500 stock options to our employees and directors, and in fiscal 2001 we granted 529,800 stock options to our employees and directors.

Had we recognized compensation expense for our stock options granted to employees in fiscal 2003, based on the fair value of the options on the grant date pursuant to the methodology of SFAS No. 123, we would have recorded approximately \$962,000 in compensation expense and incurred a pro forma net loss of approximately \$889,000, or \$.09 per fully diluted common share. Had we recognized compensation expense for stock options granted to employees in fiscal 2002 and 2001, our net loss, on a pro forma basis, would have

- increased by approximately \$760,000, or \$.08 per common share, in fiscal 2002, and
- increased by approximately \$606,000, or \$.08 per common share, in fiscal 2001.

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### CONTRACTUAL OBLIGATIONS

The following information is provided as of November 30, 2003 with respect to our known contractual obligations specified in the following table, aggregated by type of contractual obligation:

| Contractual Obligations           | Payments due |                        |              |
|-----------------------------------|--------------|------------------------|--------------|
|                                   | Total        | Less<br>than 1<br>year | 1-3<br>years |
| Long-term debt obligations .....  | \$ 0         | \$ 0                   | \$           |
| Capital lease obligations .....   | \$ 0         | \$ 0                   | \$           |
| Operating lease obligations ..... | \$ 218,500   | \$ 201,700             | \$ 16,       |
| Purchase obligations .....        | \$1,854,300  | \$1,854,300            | \$           |
| Other long-term liabilities ..... | \$ 0         | \$ 0                   | \$           |

Purchase obligations consist primarily of purchase orders executed for inventory components.

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### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

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ITEM 8 FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Independent Auditors' Report

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, 2003 and 2002, and the related statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended November 30, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such financial statements present fairly, in all material respects, the financial position of the Company at November 30, 2003 and 2002, and the results of its operations and its cash flows for each of the three years in the period ended November 30, 2003 in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 3 to the financial statements, the Company changed its method of accounting for intangible assets in fiscal 2002.

/s/ DELOITTE & TOUCHE LLP  
-----

Detroit, Michigan  
January 12, 2004

SOMANETICS CORPORATION

BALANCE SHEETS

|  | Nov 30, 2003           |
|--|------------------------|
|  | -----<br>2003<br>----- |
| ASSETS                                   |                        |
| CURRENT ASSETS:                          |                        |
| Cash and cash equivalents (Note 3) ..... | \$ 2,239,192           |
| Accounts receivable .....                | 2,018,615              |
| Inventory (Note 3) .....                 | 1,090,261              |

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|   |              |
|---|--------------|
| Prepaid expenses .....  | 123,203      |
|   | -----        |
| Total current assets .....  | 5,471,271    |
|   | -----        |
| PROPERTY AND EQUIPMENT: (Note 3)  |              |
| Machinery and equipment .....   | 2,071,758    |
| Furniture and fixtures .....  | 248,657      |
| Leasehold improvements .....  | 171,882      |
|   | -----        |
| Total .....   | 2,492,297    |
| Less accumulated depreciation and amortization .....  | (1,782,559)  |
|   | -----        |
| Net property and equipment .....  | 709,738      |
|   | -----        |
| OTHER ASSETS:   |              |
| Intangible assets, net (Note 3) .....   | 959,838      |
| Other .....   | 15,000       |
|   | -----        |
| Total other assets .....  | 974,838      |
|   | -----        |
| TOTAL ASSETS .....  | \$ 7,155,847 |
|   | =====        |
| LIABILITIES AND SHAREHOLDERS' EQUITY  |              |
| CURRENT LIABILITIES:  |              |
| Accounts payable .....  | \$ 641,232   |
| Accrued liabilities (Notes 5 and 7) .....   | 349,547      |
|   | -----        |
| Total current liabilities .....   | 990,779      |
|   | -----        |
| COMMITMENTS AND CONTINGENCIES (Note 7)  |              |
| SHAREHOLDERS' EQUITY: (Note 4)  |              |
| Preferred shares; authorized, 1,000,000 shares of \$.01 par<br>value; no shares issued or outstanding .....   | --           |
| Common shares; authorized, 20,000,000 shares of \$.01 par<br>value; issued and outstanding, 9,298,669 shares at November 30, 2003,<br>and 9,077,863 shares at November 30, 2002 ..... | 92,987       |
| Additional paid-in capital .....  | 59,660,804   |
| Accumulated deficit .....   | (53,588,723) |
|   | -----        |
| Total shareholders' equity .....  | 6,165,068    |
|   | -----        |
| TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY .....  | \$ 7,155,847 |
|   | =====        |

See notes to financial statements

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SOMANETICS CORPORATION

STATEMENTS OF OPERATIONS

For the Years Ended November 30

| 2003 | 2002 |
|------|------|
| ---- | ---- |

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|   |              |                |        |
|---|--------------|----------------|--------|
| NET REVENUES (Notes 3 and 10) .....     | \$ 9,360,893 | \$ 6,705,647   | \$ 5,  |
| COST OF SALES .....                     | 2,139,827    | 2,048,758      | 2,     |
|   | -----        | -----          | -----  |
| Gross margin .....                      | 7,221,066    | 4,656,889      | 3,     |
|   | -----        | -----          | -----  |
| OPERATING EXPENSES:                     |              |                |        |
| Research, development and engineering   |              |                |        |
| (Note 3) .....                          | 412,953      | 571,126        |        |
| Selling, general and administrative     |              |                |        |
| (Note 9) .....                          | 6,758,637    | 5,343,513      | 5,     |
|   | -----        | -----          | -----  |
| Total operating expenses .....          | 7,171,590    | 5,914,639      | 5,     |
|   | -----        | -----          | -----  |
| OPERATING INCOME (LOSS) .....           | 49,476       | (1,257,750)    | (2,    |
|   | -----        | -----          | -----  |
| OTHER INCOME (EXPENSE):                 |              |                |        |
| Interest income .....                   | 23,110       | 51,892         |        |
| Interest expense and other .....        | --           | (794)          |        |
|   | -----        | -----          | -----  |
| Total other income (expense) .....      | 23,110       | 51,098         |        |
|   | -----        | -----          | -----  |
| NET INCOME (LOSS) .....                 | \$ 72,586    | \$ (1,206,652) | \$ (2, |
|   | =====        | =====          | =====  |
| NET INCOME (LOSS) PER COMMON            |              |                |        |
| SHARE -BASIC AND DILUTED (Note 3) ..... | \$ .01       | \$ (.13)       | \$     |
|   | =====        | =====          | =====  |
| WEIGHTED AVERAGE NUMBER OF              |              |                |        |
| COMMON SHARES OUTSTANDING --            |              |                |        |
| BASIC (Note 3) .....                    | 9,113,854    | 8,951,266      | 7,     |
|   | =====        | =====          | =====  |
| WEIGHTED AVERAGE NUMBER OF              |              |                |        |
| COMMON SHARES OUTSTANDING --            |              |                |        |
| DILUTED (Note 3) .....                  | 9,466,838    | 8,951,266      | 7,     |
|   | =====        | =====          | =====  |

See notes to financial statements

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SOMANETICS CORPORATION  
STATEMENTS OF SHAREHOLDERS' EQUITY

|  | SHARE<br>VALUE | ADDITIONAL<br>PAID-IN<br>CAPITAL | ACCUMULATED<br>DEFICIT |
|--|----------------|----------------------------------|------------------------|
|  | -----          | -----                            | -----                  |
| Balance at December 1, 2000 .....                | \$ 66,371      | \$ 52,940,540                    | \$ (50,123,746)        |
| For cash, less issuance costs of \$13,000 .....  | 1,130          | 185,870                          |                        |
| For cash, less issuance costs of \$166,488 ..... | 13,250         | 2,138,587                        |                        |

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|  |           |               |                 |
|--|-----------|---------------|-----------------|
| Warrants issued to acquire license .....         |           | 116,472       |                 |
| Stock options issued to consultant .....         |           | 4,984         |                 |
| Net loss and comprehensive loss .....            |           |               | (2,330,911)     |
| Balance at November 30, 2001 .....               | \$ 80,751 | \$ 55,386,453 | \$ (52,454,657) |
| For cash, less issuance costs of \$570,418 ..... | 10,000    | 3,669,582     |                 |
| For cash, exercise of stock options .....        | 28        | 9,490         |                 |
| Stock options issued to non-employees .....      |           | 5,597         |                 |
| Net loss and comprehensive loss .....            |           |               | (1,206,652)     |
| Balance at November 30, 2002 .....               | \$ 90,779 | \$ 59,071,122 | \$ (53,661,309) |
| For cash, exercise of stock options .....        | 1,484     | 537,142       |                 |
| Warrants issued to acquire license .....         |           | 44,793        |                 |
| Stock options issued to non-employees .....      |           | 8,471         |                 |
| Cashless exercise of warrants .....              | 724       | (724)         |                 |
| Net income and comprehensive income .....        |           |               | 72,586          |
| Balance at November 30, 2003 .....               | \$ 92,987 | \$ 59,660,804 | \$ (53,588,723) |

See notes to financial statements

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SOMANETICS CORPORATION

STATEMENTS OF CASH FLOWS

|  | For the Y |
|--|-----------|
|  | 2003      |
|  | -----     |
| CASH FLOWS FROM OPERATING ACTIVITIES:                                      |           |
| Net income (loss) .....  | \$ 72,586 |
| Adjustments to reconcile net income (loss) to net cash used in operations: |           |
| Depreciation and amortization .....  | 235,537   |
| Compensation expense for non-employee stock options .....                  | 8,471     |
| Changes in assets and liabilities:   |           |
| Accounts receivable (increase) decrease .....                              | (790,830) |
| Inventory (increase) .....   | (85,956)  |
| Prepaid expenses (increase) decrease .....                                 | (26,895)  |
| Other assets (increase) decrease .....                                     | --        |
| Accounts payable increase (decrease) .....                                 | 170,352   |
| Accrued liabilities increase (decrease) .....                              | 156,781   |
| Net cash (used in) operating activities .....                              | (259,954) |
| CASH FLOWS FROM INVESTING ACTIVITIES:                                      |           |
| Acquisition of property and equipment (net) .....                          | (421,288) |
| Net cash (used in) investing activities .....                              | (421,288) |

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|   |                       |
|---|-----------------------|
| CASH FLOWS FROM FINANCING ACTIVITIES:   |                       |
| Proceeds from issuance of Common Shares .....   | 538,626<br>-----      |
| Net cash provided by financing activities .....   | 538,626<br>-----      |
|   |                       |
| NET INCREASE (DECREASE) IN CASH AND<br>CASH EQUIVALENTS .....                                   | (142,616)             |
| CASH AND CASH EQUIVALENTS,<br>BEGINNING OF PERIOD .....   | 2,381,808<br>-----    |
| CASH AND CASH EQUIVALENTS,<br>END OF PERIOD .....   | \$ 2,239,192<br>===== |
|   |                       |
| Supplemental Disclosure of Non cash investing activities:                                       |                       |
| Issuance of warrants and stock options in connection<br>with license acquisition (Note 3) ..... | \$ 44,793             |

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 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 principal markets for our products are the United States, Europe, and Japan. The Cerebral Oximeter is based on our proprietary In Vivo Optical Spectroscopy, or INVOS, technology. INVOS analyzes various characteristics of human blood and tissue by measuring and analyzing low-intensity visible and near-infrared light transmitted into portions of the body.

We also develop and market the CorRestore(TM) System for use in cardiac repair and reconstruction, including heart surgeries called surgical ventricular restoration, or SVR. We entered into a License Agreement as of June 2, 2000 with the inventors and their company, CorRestore LLC. The license grants us exclusive, worldwide, royalty-bearing licenses to specified rights relating to the CorRestore System and related products and accessories for SVR, subject to the terms and conditions of the license agreement (Note 3). In November 2001 we received clearance from the FDA to market the CorRestore patch in the United States. In April 2003, we met the requirements to use the CE Mark for the CorRestore patch, which allows us to market the CorRestore System in the European Economic Community.

#### 2. FINANCIAL STATEMENT PRESENTATION

We have incurred an accumulated deficit of \$53,588,723 through November 30, 2003. We had working capital of \$4,480,492, cash and cash equivalents of \$2,239,192, total current liabilities of \$990,779 and shareholders' equity of

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\$6,165,068, as of November 30, 2003.

On June 6, 1996, we received clearance from the FDA to market our model 3100A Cerebral Oximeter in the United States, and on October 13, 1997, we received clearance from the FDA to market enhancements to our Cerebral Oximeter in the United States. On September 15, 2000, we received FDA clearance to market our model 5100 Cerebral Oximeter in the United States. The model 5100 has the added capability of being able to monitor pediatric patients. In November 2001, we received clearance from the FDA to market the CorRestore patch in the United States, and in April 2003, we met the requirements to use the CE Mark for the CorRestore patch, which allows us to market the CorRestore System in the European Economic Community. 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.

We have three international distributors for the Cerebral Oximeter, two international distributors for the CorRestore System, seven direct sales personnel, two clinical specialists, one international sales consultant, and 12 independent sales representative firms. During fiscal 2003, we devoted most of our marketing to continuing to introduce cerebral oximetry patient monitoring and the CorRestore System into the operating rooms of hospitals. There can be no assurance that we will be successful in marketing the Cerebral Oximeter, the related SomaSensor, and the CorRestore System.

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

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### SOMANETICS CORPORATION

#### NOTES TO FINANCIAL STATEMENTS

We believe that the cash and cash equivalents on hand at November 30, 2003 will be adequate to satisfy our operating and capital requirements for more than the next twelve months.

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

#### 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

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

NOVEMBER 30,

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|                            | -----<br>2003<br>---- | 2002<br>----- |
|----------------------------|-----------------------|---------------|
| Finished goods .....       | \$ 354,024            | \$ 410,133    |
| Work in process .....      | 173,193               | 154,816       |
| Purchased components ..... | 563,044               | 439,356       |
|                            | -----                 | -----         |
| Total .....                | \$1,090,261           | \$1,004,305   |
|                            | =====                 | =====         |

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. We offer to our United States customers a no-cap sales program whereby we ship the 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. The Cerebral Oximeters that are shipped to our customers are classified as property and equipment and are depreciated over five years. As of November 30, 2003, we have capitalized approximately \$1,309,000 in costs for Cerebral Oximeters being used as demonstration and no-cap units, and these assets had a net book value of approximately \$530,000. As of November 30, 2002, we have capitalized approximately \$948,000 in costs for Cerebral Oximeters being used as demonstration and no-cap units, and these assets had a net book value of approximately \$296,000. Property and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the net book value of the asset may not be recovered.

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. The carrying amount and accumulated amortization of these patents and trademarks is as follows:

|                                      | NOVEMBER 30,          |               |
|--------------------------------------|-----------------------|---------------|
|                                      | -----<br>2003<br>---- | 2002<br>----- |
| Patents and trademarks .....         | \$ 111,733            | \$ 111,733    |
| Less: accumulated amortization ..... | (80,988)              | (74,076)      |
|                                      | -----                 | -----         |
| Total .....                          | \$ 30,745             | \$ 37,657     |
|                                      | =====                 | =====         |

SOMANETICS CORPORATION

NOTES TO FINANCIAL STATEMENTS - (Continued)

Amortization expense was \$6,912 for the fiscal years ended November 30, 2003, November 30, 2002, and November 30, 2001. Amortization expense for each of the next four fiscal years is expected to be approximately \$6,900 per year, and approximately \$3,100 in fiscal 2008.

License acquisition costs are related to our acquisition of exclusive,



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

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

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

We estimated the value of the stock options to purchase 50,000 common shares using the Black-Scholes valuation model with the following assumptions: expected volatility (the measure by which the stock price has fluctuated or is expected to fluctuate during the period) 111.16%, risk-free interest rate of 7.5%, expected life of 4 years and dividend yield of 0%. We estimated the value of the warrants to purchase 300,000 common shares that vested immediately in this transaction using the Black-Scholes valuation model with the following assumptions: expected volatility (the measure by which the stock price has fluctuated or is expected to fluctuate during the period) 111.16%, risk-free interest rate of 7.5%, expected life of 5 years and dividend yield of 0%. We estimated the value of the warrants to purchase 50,000 common shares that vested upon receipt of FDA clearance in November 2001 using the Black-Scholes valuation model with the following assumptions: expected volatility (the measure by which the stock price has fluctuated or is expected to fluctuate during the period) 100.68%, risk-free interest rate of 4.0%, expected life of 42 months and dividend yield of 0%. We estimated the value of the warrants to purchase 50,000 common shares that vested upon receipt of CE Mark certification in April 2003 using the Black-Scholes valuation model with the following assumptions: expected volatility (the measure by which the stock price has fluctuated or is expected to fluctuate during the period) 64.70%, risk-free interest rate of 2.0%, expected life of 25 months and dividend yield of 0%.

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## NOTES TO FINANCIAL STATEMENTS - (Continued)

In June 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets." This statement establishes accounting and reporting standards for goodwill and other intangible assets. We adopted this statement in the first quarter of fiscal 2002. The effect of adopting this statement has been to discontinue amortizing our license acquisition costs related to our acquisition of exclusive, worldwide, royalty-bearing licenses to specified rights relating to the CorRestore System and related products and accessories described above because we believe these licenses have an indefinite life. The carrying amount and accumulated amortization of these license acquisition costs is as follows:

|                                      | NOVEMBER 30, |              |
|--------------------------------------|--------------|--------------|
|                                      | 2003         | 2002         |
| License acquisition costs .....      | \$ 1,258,163 | \$ 1,213,370 |
| Less: accumulated amortization ..... | (329,070)    | (329,070)    |
|                                      | -----        | -----        |
| Total .....                          | \$ 929,093   | \$ 884,300   |

Amortization expense was \$219,378 for the fiscal year ended November 30, 2001. Net loss for fiscal 2001, excluding the effect of amortizing our license acquisition costs, would have been approximately \$2,112,000, or \$(.28) per common share.

Indefinite lived intangible assets are reviewed annually for impairment and whenever events or changes in circumstances indicate that the carrying value of the asset may not be recovered. The company evaluates impairment by comparing the fair value of the intangible asset, determined using a cash flow method, with its carrying value.

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

Research, Development and Engineering costs are expensed as incurred.

Net Income (Loss) Per Common Share - basic and diluted is computed using the weighted average number of common shares outstanding during each period. Weighted average shares outstanding - diluted, for the year ended November 30, 2003, includes the potential dilution that could occur for common stock issuable under stock options or warrants. As of November 30, 2003, the difference between weighted average shares - diluted and weighted average shares - basic is calculated as follows:

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|  |           |
|--|-----------|
| Weighted average shares - basic                    | 9,113,854 |
| Add: effect of dilutive common shares and warrants | 352,984   |
|  | -----     |
| Weighted average shares - diluted                  | 9,466,838 |

Common shares issuable under stock options and warrants have not been included in the computation of net loss per common share - diluted for the fiscal years ended November 30, 2002 or November 30, 2001, because such inclusion would be antidilutive. At November 30, 2003, there were approximately 99,000 stock options outstanding that were excluded from the computation of net income per common share - diluted, as the exercise price of these options exceeded the average price per share of our common stock, and there were approximately 1,633,000 warrants outstanding that were excluded from the computation, as the warrants are contingent on achieving specified future sales targets. As of November 30, 2003, we had outstanding 5,308,819 warrants and options to purchase common shares, as of November 30, 2002, we had outstanding 5,162,850 warrants and options to purchase common shares, and as of November 30, 2001, we had outstanding 4,774,228 warrants and options to purchase common shares.

Accounting Pronouncements In December 2002, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure." This Statement, which is effective for fiscal years ending after December 15, 2002, amends Statement No. 123, "Accounting for Stock-Based Compensation," and provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based compensation. In addition, Statement No. 148 amends the disclosure requirements of Statement No. 123 regardless of the accounting method used to account for stock-based compensation. We have chosen to continue to account for stock-based compensation of employees using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. However, we adopted the enhanced disclosure provisions as defined by Statement No. 148 beginning with our fiscal quarter ended February 28, 2003.

During the first quarter of fiscal 2003, we adopted Financial Accounting Standards Board Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." The adoption of this interpretation had no impact on our financial statements.

During the fourth quarter of fiscal 2003, we adopted Emerging Issues Task Force Issue 00-21, "Revenue Arrangements with Multiple Deliverables." The adoption of EITF 00-21 had no 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.

#### 4. STOCK OFFERINGS AND COMMON SHARES

Kingsbridge Capital Limited has warrants to purchase 105,097 common shares exercisable at \$4.25 per share until September 3, 2005 pursuant to the Private Equity Line Agreement described below. In addition, CorRestore, LLC and its agent, Joe B. Wolfe, received warrants to purchase 400,000 common shares

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exercisable at \$3.00 per share until June 2, 2005 pursuant to the CorRestore license agreement, and received warrants to purchase an additional 2,100,000 common shares exercisable at \$3.00 per share until November 21, 2006 pursuant to the CorRestore license agreement. Also, as described below, the

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### SOMANETICS CORPORATION

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

placement agent in the January 16, 2002 public offering received warrants to purchase 100,000 common shares exercisable at \$5.10 per share until January 11, 2007.

On March 6, 2000, we entered into the Private Equity Line Agreement with Kingsbridge Capital Limited, a private institutional investor. In consideration for Kingsbridge's commitment under the Private Equity Line Agreement, we issued warrants to Kingsbridge on March 6, 2000. The warrants entitled the holder to purchase 205,097 common shares, after adjustment for the April 2001 private placement and the January 2002 public offering, at a purchase price of \$4.25 per share. The warrants are exercisable at any time until September 3, 2005. The warrants contain standard provisions that protect the holder against dilution by adjustment of the exercise price and the number of shares issuable pursuant to the warrants if various events occur. The exercise price of the warrants is payable either in cash or by a cashless exercise. In November 2003, Kingsbridge purchased 100,000 common shares under the warrants by a cashless exercise. As a result of this cashless exercise, we issued 53,603 common shares to Kingsbridge, retaining 46,397 common shares in payment of the exercise price, and Kingsbridge's warrants now entitle it to purchase 105,097 more common shares.

Pursuant to the Private Equity Line Agreement, we completed the sales of 714,484 common shares, for gross proceeds of \$2,000,000, through December 4, 2000. Our net proceeds, after deducting the commissions and the estimated expenses of the offerings, were approximately \$1,793,000. On April 10, 2001, we mutually agreed with Kingsbridge to terminate the Private Equity Line Agreement, the related Registration Rights Agreement, and Kingsbridge's right to the discount on any unsold shares, in exchange for our payment of \$200,000 to Kingsbridge.

On April 9, 2001, we completed the private placement of 1,325,000 newly-issued common shares at a price of \$1.75 per share, for gross proceeds of \$2,318,750. Our net proceeds, after deducting the placement agent's commission and the expenses of the offering, were approximately \$2,152,000. Brean Murray & Co., Inc. was our exclusive placement agent for the offering and received for its services (1) \$104,363 as a placement agent fee, and (2) warrants to purchase 25,000 common shares at \$2.10 per share exercisable during the four-year period beginning April 9, 2002. In addition, the Brean Murray & Co., Inc. Profit Sharing Plan purchased 32,285 common shares in the offering, and Robert R. Henry, one of our directors, purchased 100,000 common shares in the offering. In October 2003, Brean Murray & Co., Inc. transferred the 25,000 warrants to persons who are or were employees of Brean Murray & Co., Inc., and in November 2003, those persons exercised the warrants to purchase all 25,000 common shares under the warrants by a cashless exercise. As a result of this cashless exercise, we issued 18,832 restricted common shares to those individuals, retaining 6,168 common shares in payment of the exercise price, and no more common shares remain subject to these warrants.

On January 16, 2002, we completed a public offering of 1,000,000 newly-issued common shares at a price of \$4.25 per share, for gross proceeds of

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\$4,250,000. Our estimated net proceeds, after deducting the placement agent's commission and the estimated expenses of the offering, were approximately \$3,680,000. Brean Murray & Co., Inc. was our exclusive placement agent for the offering and received for its services (1) \$340,000 as a placement agent fee, and (2) warrants to purchase 100,000 common shares at \$5.10 per share exercisable during the four-year period beginning January 11, 2003.

During fiscal 2003, we issued 148,371 common shares as a result of stock option exercises by employees, directors and former employees, for proceeds of approximately \$539,000.

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### SOMANETICS CORPORATION

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

Common shares reserved for future issuance upon exercise of stock options and warrants as discussed above at November 30, 2003, are as follows:

|  |           |
|--|-----------|
| 1991 Incentive Stock Option Plan.....            | 55,656    |
| 1993 Director Stock Option Plan.....             | 500       |
| 1997 Stock Option Plan.....                      | 2,428,796 |
| Options Granted Independent of Option Plans..... | 236,311   |
| Kingsbridge Capital Limited Warrants.....        | 105,097   |
| Placement Agent Warrants.....                    | 100,000   |
| License Acquisition Warrants.....                | 2,500,000 |
|  | -----     |
| Total reserved for future issuance.....          | 5,426,360 |
|  | =====     |

#### 5. ACCRUED LIABILITIES

Accrued liabilities consist of the following:

|                        | NOVEMBER 30, |            |
|------------------------|--------------|------------|
|                        | 2003         | 2002       |
| Incentive.....         | \$ 166,360   | \$ 8,000   |
| Sales Commissions..... | 123,356      | 55,381     |
| Insurance.....         | 29,836       | 34,464     |
| Royalty.....           | 13,645       | 12,071     |
| Professional Fees..... | 10,500       | 15,000     |
| Warranty.....          | 5,850        | 6,400      |
| Training.....          | --           | 40,000     |
| Clinical Research..... | --           | 21,450     |
|                        | -----        | -----      |
| Total.....             | \$ 349,547   | \$ 192,766 |
|                        | =====        | =====      |

#### 6. INCOME TAX

Deferred income taxes reflect the estimated future tax effect of (1)

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temporary differences between the amount of assets and liabilities for financial reporting purposes and such amounts as measured by tax laws and regulations and (2) net operating loss and tax credit carryforwards. Our deferred tax assets primarily represent the tax benefit of net operating loss carryforwards and research and general business tax credit carryforwards. We had deferred tax assets of approximately \$17,061,000 and \$17,210,000 for the years ended November 30, 2003 and 2002, 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, 2003 and 2002 were as follows:

|  | NOVEMBER 30,   |           |
|--|----------------|-----------|
|  | 2003           | 2002      |
|  | (IN THOUSANDS) |           |
| Net operating loss carryforwards.....                    | \$ 16,549      | \$ 16,638 |
| Other.....   | 88             | 115       |
| Basis difference of fixed assets and intangibles         | (19)           | 14        |
| Research and general business tax credit carryforwards.. | 443            | 443       |
|  | -----          | -----     |
| Subtotal.....  | 17,061         | 17,210    |
| Valuation allowance.....                                 | (17,061)       | (17,210)  |
|  | -----          | -----     |
| Deferred tax asset.....                                  | \$ --          | \$ --     |
|  | =====          | =====     |

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### SOMANETICS CORPORATION

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

As of November 30, 2003, net operating loss carryforwards of approximately \$48.5 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 approximately \$443,000 are also available to offset future taxes. These losses and credits expire, if unused, at various dates from 2003 through 2023.

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

#### 7. COMMITMENTS AND CONTINGENCIES

We have a lease agreement for a 23,392 square foot, stand-alone office, assembly and warehouse facility. The current lease, as amended, expires December 31, 2004.

Operating lease expense for the years ended November 30, 2003, 2002 and 2001 was approximately \$216,000, \$205,000, and \$196,000, respectively. Approximate future minimum lease commitments are as follows:

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YEAR ENDED NOVEMBER 30,  
-----

|            |    |         |
|------------|----|---------|
| 2004.....  | \$ | 201,700 |
| 2005.....  |    | 16,800  |
|            |    | -----   |
| Total..... | \$ | 218,500 |
|            |    | =====   |

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, 2003, 2002 or 2001.

As of November 30, 2003, 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, 2006 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.

As of November 30, 2003, we had an employment agreement with Dominic J. Spadafore, our Vice President of Sales and Marketing. Mr. Spadafore's employment agreement terminates as provided in the agreement. Mr. Spadafore is entitled to receive an annual base salary, plus potential bonuses. Mr. Spadafore 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. We might not be able to maintain such insurance or such insurance might not be sufficient to protect us against products liability.

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### SOMANETICS CORPORATION

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

#### 8. STOCK OPTION PLANS

In February 1991 and January 1997, we adopted stock option plans for our key employees, directors, consultants and advisors. The plans provide for our issuance of options to purchase a maximum of 115,000 common shares under the 1991 plan and 2,560,000 common shares under the 1997 plan. In addition, we granted options to employees independent of the plans. Options granted generally have a 10-year life, and vest over a three-year period. Awards and expirations under the 1991 plan, 1997 plan, and independent of the plans during the years ended November 30, 2003, 2002 and 2001 are listed below.

At November 30, 2003, no additional options may be granted under the 1991 plan, and 117,541 common shares were available for options to be granted under the 1997 plan.

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

In October 1995, SFAS No. 123, "Accounting for Stock-Based Compensation," was issued. We have chosen to continue to account for stock-based compensation of employees using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. Accordingly, compensation costs for stock options granted to employees are measured as the excess, if any, of the market price of our stock at the date of the grant over the amount an employee must pay to acquire the stock. No compensation expense has been charged against income for stock option grants to employees. Stock-based compensation of consultants and advisors is determined based on the fair value of the options or warrants on the grant date pursuant to the methodology of SFAS No. 123, estimated using the Black-Scholes model with the assumptions described in the next paragraph. The resulting amount is recognized as compensation expense and an increase in additional paid-in capital over the vesting period of the options or warrants. As a result, we recorded \$8,471 of compensation expense, and an equal increase in additional paid in capital, for stock options issued to non-employees in fiscal 2003, \$5,597 of compensation expense in fiscal 2002, and \$4,984 of compensation expense in fiscal 2001.

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

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### SOMANETICS CORPORATION

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

|   | FOR THE FISCAL YEAR ENDED<br>2003 | 2002           | NOVEMBER 30,<br>2001 |
|---|-----------------------------------|----------------|----------------------|
|   | -----                             | -----          | -----                |
| Net income (loss) .....   | \$ 72,586                         | \$ (1,206,652) | \$ (2,330,911)       |
| Pro-forma net loss, had fair value method<br>been applied .....                               | \$ (889,000)                      | \$ (1,967,000) | \$ (2,937,000)       |
| Net income (loss) per common share -<br>diluted .....   | .01                               | (.13)          | (.31)                |
| Pro-forma net loss per common share -<br>diluted, had fair value method been<br>applied ..... | (.09)                             | (.22)          | (.39)                |
| Stock-based employee compensation<br>included in actual net loss .....                        | \$ 8,471                          | \$ 5,597       | \$ 4,984             |
| Pro-forma stock-based employee compensation,<br>had fair value method been applied .....      | \$ 962,000                        | \$ 760,000     | \$ 606,000           |

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 2003, 2002 and 2001: expected volatility (the measure by which the stock price has fluctuated or is expected to fluctuate during the



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period) 64.32% for 2003 (89.45% for 2002 and 100.68% for 2001), risk-free interest rate of 4.0% for 2003 (4.0% for 2002 and 2001), expected lives of 7 years for fiscal 2003 (4 years for 2002 and 2001) and dividend yield of 0%.

A summary of our stock option activity and related information for the years ended November 30, 2003, 2002 and 2001 is as follows:

|                        | 2003             |  | 2002             |  | COMMON<br>SHARES |
|------------------------|------------------|--|------------------|--|------------------|
|                        | COMMON<br>SHARES | WEIGHTED<br>AVERAGE<br>EXERCISE<br>PRICE | COMMON<br>SHARES | WEIGHTED<br>AVERAGE<br>EXERCISE<br>PRICE |                  |
| Options outstanding    |                  |  |                  |  |                  |
| December 1, .....      | 2,332,753        | \$ 4.04                                  | 1,846,120        | \$ 4.52                                  | 1,394,5          |
| Options granted.....   | 471,000          | 3.75                                     | 509,500          | 2.82                                     | 529,8            |
| Options exercised..... | (148,371)        | 3.63                                     | (2,833)          | 3.36                                     |                  |
| Options canceled.....  | (51,660)         | 10.08                                    | (20,034)         | 17.17                                    | (78,2            |
|                        |                  |  |                  |  |                  |
| Options outstanding    |                  |  |                  |  |                  |
| November 30, .....     | 2,603,722        | 3.89                                     | 2,332,753        | 4.04                                     | 1,846,1          |
|                        |                  |  |                  |  |                  |
| Options exercisable    |                  |  |                  |  |                  |
| November 30, .....     | 1,784,482        | \$ 4.27                                  | 1,606,767        | \$ 4.80                                  | 1,267,8          |
|                        |                  |  |                  |  |                  |

A summary of the price ranges of our stock options outstanding and exercisable as of November 30, 2003 is as follows:

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### SOMANETICS CORPORATION

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

| RANGE OF EXERCISE<br>PRICES | Options outstanding    |  |  | Options exerci         |
|-----------------------------|------------------------|--|--|------------------------|
|                             | OPTIONS<br>OUTSTANDING | WEIGHTED<br>AVERAGE<br>EXERCISE<br>PRICE | WEIGHTED<br>AVERAGE<br>REMAINING<br>LIFE (YEARS) | OPTIONS<br>EXERCISABLE |
| \$1.44 - \$5.00.....        | 2,077,091              | \$ 3.19                                  | 7.32   | 1,257,851              |
| \$5.01 - \$10.00.....       | 462,072                | 6.13                                     | 3.92   | 462,072                |
| \$10.01 - \$26.30.....      | 64,559                 | 13.31                                    | 1.08   | 64,559                 |
|                             |                        |  |  |                        |
| Total.....                  | 2,603,722              | \$ 3.89                                  | 6.56   | 1,784,482              |
|                             |                        |  |  |                        |

#### 9. RELATED PARTY TRANSACTIONS

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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 2001, we paid Brean Murray & Co., Inc. \$7,000 in commissions pursuant to this engagement letter.

In connection with our April 2001 private placement of common shares, Brean Murray & Co., Inc. was our exclusive placement agent and received for its services (1) \$104,363 as a placement agent fee, and (2) warrants to purchase 25,000 common shares at \$2.10 per share exercisable during the four-year period beginning April 9, 2002. At the time, A. Brean Murray, one of our then current directors, and his wife controlled Brean Murray & Co., Inc. In addition, the Brean Murray & Co., Inc. Profit Sharing Plan purchased 32,285 common shares in the offering, and Robert R. Henry, one of our directors, purchased 100,000 common shares in the offering. In October 2003, Brean Murray & Co., Inc. transferred the 25,000 warrants to persons who are or were employees of Brean Murray & Co., Inc., and in November 2003, those persons exercised the warrants to purchase all 25,000 common shares under the warrants by a cashless exercise. As a result of this cashless exercise, we issued 18,832 restricted common shares to those individuals, retaining 6,168 common shares in payment of the exercise price, and no common shares remain subject to these warrants.

In connection with our CorRestore license, effective November 21, 2001, we granted Joe B. Wolfe five-year warrants to purchase 180,000 common shares, exercisable at \$3.00 a share. Mr. Joe B. Wolfe is one of our directors.

In connection with our January 2002 public offering of common shares, Brean Murray & Co., Inc. was our exclusive placement agent and received for its services (1) \$340,000 as a placement agent fee, and (2) warrants to purchase 100,000 common shares at \$5.10 per share exercisable during the four-year period beginning January 11, 2003.

### 10. MAJOR CUSTOMERS AND FOREIGN SALES

One international distributor (Europe) accounted for approximately 12% of net revenues for the fiscal year ended November 30, 2003, approximately 12% of net revenues for the fiscal year ended November 30, 2002, and approximately 17% for the fiscal year ended November 30, 2001.

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## SOMANETICS CORPORATION

### NOTES TO FINANCIAL STATEMENTS - (CONTINUED)

Additionally, foreign net revenues for the fiscal year ended November 30, 2003 were approximately \$1,945,000, for the fiscal year ended November 30, 2002 were approximately \$1,348,000, and for the fiscal year ended November 30, 2001 were approximately \$1,595,000.

### 11. NOTES PAYABLE - BANK LINE OF CREDIT

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

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The principal amount outstanding bears interest, payable monthly, at the prime rate (4.00% at November 30, 2003) plus 2% plus a 2.4% service fee, and we paid a \$45,000 commitment fee for the loan. As of November 30, 2003, \$750,000 was available for borrowing, at Crestmark's discretion, under the facility. We have agreed to use the proceeds of the loans solely as working capital. The line of credit requires us to maintain minimum tangible net worth of \$500,000 and a ratio of total liabilities to tangible net worth not to exceed 3:1. The line of credit terminates upon Crestmark's demand.

As of April 24, 2003, we amended our Loan and Security Agreement with Crestmark Bank. Pursuant to the amendment, we paid a \$5,000 renewal commitment fee to continue our lending relationship for the remainder of 2003. We must negotiate a new lending relationship if we would like to continue the lending relationship into 2004. Pursuant to the amendment, we also agreed to give the bank at least 30 days advance notice of any intended draw on our line of credit.

Effective December 31, 2003, our Loan and Security Agreement with Crestmark Bank expired. We do not intend to renew this lending agreement.

### 12. SEGMENT INFORMATION

We operate our business in one reportable segment, the development, manufacture and marketing of medical devices. Each of our two product lines have similar characteristics, customers, distribution and marketing strategies, and are subject to similar regulatory requirements. In addition, in making operating and strategic decisions, our management evaluates net revenues based on the worldwide net revenues of each major product line, and profitability on an enterprise-wide basis due to shared costs. Approximately 92% of our net revenues in fiscal 2003 were derived from our INVOS Cerebral Oximeter product line, compared to 96% of our net revenues in fiscal 2002 and 100% of our net revenues in fiscal 2001.

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### QUARTERLY INFORMATION (UNAUDITED)

The following is a summary of our quarterly operating results for the fiscal years ended November 30, 2003 and 2002:

|   | QUARTER                               |             |             |
|---|---------------------------------------|-------------|-------------|
|   | FIRST                                 | SECOND      | THIRD       |
|   | (IN THOUSANDS, EXCEPT PER SHARE DATA) |             |             |
| YEAR ENDED NOVEMBER 30, 2003            |                                       |             |             |
| Net revenues.....                       | \$1,950,946                           | \$2,203,442 | \$2,303,880 |
| Gross margin.....                       | 1,500,749                             | 1,642,246   | 1,784,335   |
| Net income (loss).....                  | (195,450)                             | (129,373)   | 75,454      |
| Net income (loss) per<br>common share - |                                       |             |             |
| basic.....                              | \$ (0.02)                             | \$ (0.01)   | \$ 0.01     |
| Net income (loss) per<br>common share - |                                       |             |             |
| diluted.....                            | \$ (0.02)                             | \$ (0.01)   | \$ 0.01     |
| YEAR ENDED NOVEMBER 30, 2002            |                                       |             |             |

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|  |             |             |             |
|--|-------------|-------------|-------------|
| Net revenues.....  | \$1,591,820 | \$1,659,606 | \$1,432,826 |
| Gross margin.....  | 1,098,430   | 1,116,990   | 1,023,750   |
| Net (loss).....  | (354,508)   | (389,253)   | (377,042)   |
| Net (loss) per<br>common share - basic<br>and diluted..... | \$ (0.04)   | \$ (0.04)   | \$ (0.04)   |

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

NONE

ITEM 9A. CONTROLS AND PROCEDURES

Our management has evaluated, with the participation of our principal executive and principal financial officers, the effectiveness of our disclosure controls and procedures as of November 30, 2003, and, based on their evaluation, our principal executive and principal financial officers have concluded that these controls and procedures are effective as of November 30, 2003. There was no change in our internal control over financial reporting identified in connection with such evaluation that occurred during our fourth fiscal quarter ended November 30, 2003 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Disclosure controls and procedures are our controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

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### PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required by this Item 10 regarding our executive officers is included in the Supplemental Item in Part I of this Report, and is incorporated in this Item 10 by reference. The information required by this Item 10 regarding our directors will be set forth under the caption "Election of Director" in our Proxy Statement in connection with the 2004 Annual Meeting of Shareholders scheduled to be held March 31, 2004, 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 2004 Annual Meeting of Shareholders scheduled to be held March 31, 2004, and is incorporated in this Item 10 by reference.

The information required by this Item 10 concerning our Code of Business Conduct and Ethics will be set forth under the caption "Code of

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Business Conduct and Ethics" in our Proxy Statement in connection with the 2004 Annual Meeting of Shareholders scheduled to be held March 31, 2004, 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 2004 Annual Meeting of Shareholders scheduled to be held March 31, 2004, and is incorporated in this Item 11 by reference.

### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

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 Director" in our Proxy Statement in connection with the 2004 Annual Meeting of Shareholders scheduled to be held March 31, 2004, and is incorporated in this Item 12 by reference. The equity compensation plan information required by this Item 12 will be set forth under the caption "Equity Compensation Plan Information" in our Proxy Statement in connection with the 2004 Annual Meeting of Shareholders scheduled to be held March 31, 2004, 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 2004 Annual Meeting of Shareholders scheduled to be held March 31, 2004, and is incorporated in this Item 13 by reference.

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item 14 concerning principal accountant fees and services will be set forth under the caption "Independent Accountants" in our Proxy Statement in connection with the 2004 Annual Meeting of Shareholders scheduled to be held March 31, 2004, and is incorporated in this Item 14 by reference.

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## PART IV

### ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

#### (a) (1) Financial Statements

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

Independent Auditors' Report  
Balance Sheets - November 30, 2003 and 2002  
Statements of Operations - For Each of the Three Years in the Period Ended November 30, 2003  
Statements of Shareholders' Equity - For Each of the Three Years in the Period Ended November 30, 2003

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Statements of Cash Flows - For Each of the Three Years in the  
 Period Ended November 30, 2003  
 Notes to Financial Statements

(2) Financial Statement Schedules

None.

(3) Exhibits

The Exhibits to this Report are as set forth in the "Index to Exhibits" on pages 61 to 64 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, 2003. We furnished a Current Report on Form 8-K on September 16, 2003, reporting under Item 12 that on September 15, 2003, we announced our financial results for our third quarter of fiscal 2003 and certain other information. No financial statements were filed, although we furnished the financial information included in the press release furnished with the Form 8-K.

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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 30, 2004

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<br>-----                                  | Title<br>-----   | Da<br>----- |
|---|--|-------------|
| /s/ Bruce J. Barrett<br>-----<br>Bruce J. Barrett   | President and Chief Executive Officer<br>and a Director (Principal Executive<br>Officer)                                   | January     |
| /s/ William M. Iacona<br>-----<br>William M. Iacona | Vice President, Finance, Controller,<br>and Treasurer (Principal Financial<br>Officer and Principal Accounting<br>Officer) | January     |
| /s/ Daniel S. Follis<br>-----<br>Daniel S. Follis   | Director   | January     |

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|  |          |         |
|--|----------|---------|
| /s/ James I. Ausman<br>-----<br>James I. Ausman, M.D., Ph.D. | Director | January |
| /s/ Robert R. Henry<br>-----<br>Robert R. Henry              | Director | January |
| /s/ Joe B. Wolfe<br>-----<br>Joe B. Wolfe                    | Director | January |

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EXHIBIT INDEX

| EXHIBIT<br>----- | DESCRIPTION<br>-----   |
|------------------|--|
| 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.   |
| 10.1             | Lease Agreement, dated September 10, 1991, between Somanetics Corporation and WS Development Company, incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended August 31, 1991.  |
| 10.2             | Extension of Lease, between Somanetics Corporation and WS Development Company, dated July 22, 1994, incorporated by reference to Exhibit 10.11 to the Company's Quarterly Report on Form 10-Q for the quarter ended August 31, 1994.   |
| 10.3             | Change in ownership of Lease Agreement for 1653 E. Maple Road, Troy, MI 48083, dated September 12, 1994, between Somanetics Corporation and First Industrial, L.P., incorporated by reference to Exhibit 10.12 to the Company's Quarterly Report on Form 10-Q for the quarter ended August 31, 1994. |
| 10.4             | Second Addendum, between Somanetics Corporation and First Industrial Mortgage Partnership, L.P., dated April 14, 1997, incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended May 31, 1997.  |
| 10.5             | Third Amendment, between Somanetics Corporation and First Industrial Mortgage Partnership, L.P., dated April 23, 1999, incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended May 31, 1999.  |
| 10.6             | Fourth Amendment, between Somanetics Corporation and First Industrial Mortgage Partnership, L.P., dated April  |

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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 Fifth Amendment, between Somanetics Corporation and First Industrial Mortgage Partnership, L.P., dated January 22, 2003, incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 2002.
- \*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 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, incorporated by reference to Exhibit 10.16 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 2000.



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| EXHIBIT<br>----- | DESCRIPTION<br>-----   |
|------------------|--|
| *10.17           | Fifth Amendment to Somanetics Corporation 1997 Stock Option Plan, incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended February 28, 2002.  |
| *10.18           | Sixth Amendment to Somanetics Corporation 1997 Stock Option Plan, incorporated by reference to Exhibit 10.18 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 2002.  |
| *10.19           | Somanetics Corporation 2003 Incentive Compensation Plan, dated as of October 24, 2002, incorporated by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 2002.   |
| *10.20           | Somanetics Corporation 2004 Incentive Compensation Plan, dated as of December 12, 2003   |
| *10.21           | 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.  |
| *10.22           | 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 April 24, 1997, between Somanetics Corporation and Bruce J. Barrett, incorporated by reference to Exhibit 10.21 to Amendment No. 1 to the Registration Statement on Form S-1 (file no. 333-25275), filed with the Securities and Exchange Commission on May 30, 1997. |
| *10.24           | 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.   |
| *10.25           | Amendment to Employment Agreement, dated as of March 5, 2001, between Somanetics Corporation and Bruce J. Barrett, incorporated by reference to Exhibit 10.2 to the Company's Quarterly report on Form 10-Q for the quarter ended February 28, 2001.   |
| *10.26           | Amendment to Employment Agreement, dated as of January 24, 2003, between Somanetics Corporation and Bruce J. Barrett, incorporated by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 2002.  |
| *10.27           | Employment Agreement, dated August 1, 2002, between Somanetics Corporation and Dominic J. Spadafore, incorporated by reference to Exhibit 10.2 to the  |

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Company's Quarterly Report on Form 10-Q for the quarter ended August 31, 2002.

- \*10.28 Change in Control, Invention, Confidentiality, Non-Compete and Non-Solicitation Agreement, dated January 11, 2002, between Somanetics Corporation and Richard S. Scheuing, incorporated by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 2001.
- \*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.

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### EXHIBIT INDEX

| EXHIBIT<br>----- | DESCRIPTION<br>-----   |
|------------------|--|
| *10.33           | Form of Stock Option Agreement, dated December 22, 1995, between Somanetics Corporation and various employees, incorporated by reference to Exhibit 10.29 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1995.     |
| *10.34           | 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.      |
| *10.35           | Form of new Stock Option agreement, dated December 22, 1995, between Somanetics Corporation and various employees, incorporated by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1995. |

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- \*10.36 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.
- \*10.37 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.
- \*10.38 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.
- \*10.39 Stock Option Agreement, dated as of August 1, 2002, between Somanetics Corporation and Dominic J. Spadafore, incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended August 31, 2002.
- \*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), filed January 7, 1991.
- 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), filed January 7, 1991.

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10.45 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.

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### EXHIBIT INDEX

| EXHIBIT<br>----- | DESCRIPTION<br>-----  |
|------------------|---|
| 10.46            | Registration Rights Agreement, dated as of April 9, 2001, among Somanetics Corporation and the selling shareholders, incorporated by reference to Exhibit 4.3 to the Somanetics Corporation Registration Statement on Form S-3 (file no. 333-59376) filed April 23, 2001 and effective May 3, 2001.   |
| 10.47            | Form of Warrant Agreement and Warrant, dated January 16, 2002, between Brean Murray & Co., Inc. and Somanetics Corporation, incorporated by reference to Exhibit 1.3 to the Somanetics Corporation Registration Statement on Form S-1 (file no. 333-74788) filed December 7, 2001 and effective January 11, 2002.   |
| 10.48            | 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 Joe B. Wolfe, incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended May 31, 2000. |
| 10.49            | Amendment No. 1 to License Agreement, dated as of August 1, 2002, among Somanetics Corporation, CorRestore LLC, Constantine L. Athanasuleas, M.D., and Gerald D. Buckberg, M.D., incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended August 31, 2002.  |
| 14.1             | Somanetics Corporation Code of Business Conduct and Ethics, adopted December 12, 2003.  |
| 23.1             | Consent of Deloitte & Touche LLP.   |
| 31.1             | Certifications of Chief Executive Officer Pursuant to Rule 13a-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.   |
| 31.2             | Certifications of Chief Financial Officer Pursuant to Rule 13a-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.   |
| 32.1             | Certifications of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act  |

of 2002.