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SOMANETICS CORP  
Form 10-K  
February 22, 2005

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, 2004 OR

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

For the transition period from \_\_\_\_TO \_\_\_\_\_ Commission File No. 0-19095

SOMANETICS CORPORATION  
(Exact name of Registrant as specified in its charter)

MICHIGAN  
(State or other jurisdiction of incorporation or organization) 38-2394784  
(I.R.S. Employer Identification No.)  
48083-4208  
1653 EAST MAPLE ROAD, TROY, MICHIGAN (Zip Code)  
(Address of principal executive offices)

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 28, 2004 (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 \$141,700,000.

The number of the Registrant's common shares outstanding as of February

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22, 2005 was 10,145,382

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the 2005 Annual Meeting of Shareholders, scheduled to be held April 21, 2005, are incorporated by reference in Part III, if the Proxy Statement is filed no later than March 30, 2005.

## SOMANETICS CORPORATION

### ANNUAL REPORT ON FORM 10-K

FOR THE FISCAL YEAR ENDED NOVEMBER 30, 2004

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#### PART I

ITEM 1. BUSINESS

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### THE COMPANY

We were incorporated 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. We also develop and market the CorRestore(R) 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.

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 target the sale of the INVOS Cerebral Oximeter for use in surgical procedures with a high risk of brain oxygen imbalances, initially adult and pediatric cardiac surgeries, carotid artery surgeries, and other major surgeries involving elderly patients, such as orthopedic surgeries, abdominal surgeries and head and neck surgeries.

Surgeons, anesthesiologists, perfusionists and other medical professionals use the Cerebral Oximeter to identify brain oxygen imbalances and take corrective action. Clinical research with the INVOS Cerebral Oximeter suggests its use improves patient outcomes and reduces the cost of care.

The Cerebral Oximeter is a relatively inexpensive, portable and easy-to-use neurological monitoring system. It is predominately used in hospital critical care areas, especially operating rooms and intensive care units. It is comprised of

- a portable monitor,
- dual single-use, disposable sensors, called SomaSensors(R),
- proprietary software, and
- a preamplifier cable.

SomaSensors are placed on both sides of a patient's forehead to offer bi-lateral monitoring and are connected to the monitor through the preamplifier cable. The monitor 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 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.

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We develop and market the CorRestore System, which includes a cardiac implant, the CorRestore Patch, designed by CorRestore LLC, for use in cardiac repair and reconstruction, including heart surgeries called surgical ventricular restoration, or SVR. During SVR, the surgeon restores an enlarged, poorly functioning left ventricle to more normal size and function by inserting an implant, in most instances, or closing the defect directly.

We entered into a License Agreement as of June 2, 2000 giving us exclusive, worldwide, royalty-bearing licenses to specified rights relating to the CorRestore System, subject to the terms and conditions of the license agreement.

Our objective is to have the CorRestore System used in SVR surgeries. Our initial target market is SVR surgeries on patients with dilated ischemic cardiomyopathy due to a previous myocardial infarction involving the anterior wall of the ventricle. Ischemic cardiomyopathy is a damaged heart muscle caused by the obstruction of the inflow of blood from the arteries, resulting in an enlarged ventricle. Myocardial infarction is the death of an area of the middle muscle layer in the heart wall.

In November 2001 we received clearance from the FDA to market the CorRestore Patch in the United States and 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. In September 2004, the European Economic Community changed its regulations, limiting approval authority for animal tissue implant products sold in Europe to some independent registration agencies that do not include our registrar. We are currently evaluating new registrars to obtain approval to allow us to use the CE Mark and resume sales of the CorRestore System in Europe.

THE INVOS CEREBRAL OXIMETER

### MARKET OVERVIEW

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

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strategies must be developed to lessen these injuries.

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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 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 arterial blood oxygen saturation, which is the percentage of oxygenated hemoglobin contained in a given amount of blood which carries oxygen in the arteries to the tissues of the body, 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. 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.

In the United States in 2003, industry sources estimate 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 adult and pediatric cardiac surgeries, carotid endarterectomies and other major general surgeries involving elderly patients. The INVOS Cerebral Oximeter is a practical, non-invasive, reliable and relatively inexpensive neurological monitoring system used to monitor changes in regional brain blood oxygen saturation in patients undergoing these surgical procedures.

Currently, several different methods are used to detect one or more of the factors affecting brain oxygen levels or the effects of brain oxygen imbalances. These methods include invasive jugular bulb catheter monitoring, transcranial Doppler, electroencephalograms, or EEGs, intracranial pressure monitoring, and neurological examination. These methods have not been widely adopted to monitor brain oxygen levels in critical care situations for a variety of reasons. The use of these methods is limited because they are either expensive, difficult or impractical to use, invasive, not reliable under some circumstances, not organ specific, not able to measure more than one factor affecting oxygen imbalances in the brain, or not able to provide continuous information.

### MARKET TRENDS

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

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

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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

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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.

**Aging Population.** According to the Administration on Aging, United States Department of Health and Human Services, approximately 36 million persons in the United States were age 65 or older in 2003, representing more than 12% of the population. The number of Americans age 65 or older increased by approximately 3.3 million, or more than 10%, between 1992 and 2002. The Administration on Aging predicts that the number of Americans age 65 or older will nearly double to approximately 71.5 million by the year 2030. Because most older persons have at least one chronic condition, and many have multiple conditions, 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.

**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.

### 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, and some of our target markets are adult and pediatric cardiac surgeries, carotid artery surgeries, other major surgeries involving elderly patients and some intensive care unit applications. 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.

**Promote Expanded Acceptance of the Cerebral Oximeter.** We continue to 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 sponsor peer-to-peer educational opportunities, and promote use of the Cerebral Oximeter in regional centers of influence that we believe will influence the adoption by others.

**Invest in Marketing and Sales Activities.** We continue to increase our

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investment in our distribution network consisting of our direct sales employees, independent sales representative firms and distributors. We have also entered into a co-promotion relationship with Fresenius' North American Extracorporeal Alliance. We are supporting this distribution network with the needed marketing programs and materials. We participate in trade shows and medical conferences, ongoing peer-to-peer educational programs and targeted public relations opportunities. Outside the United States, the Cerebral Oximeter is marketed primarily by Tyco Healthcare in Europe, the Middle East, South Africa and Canada, and Edwards Lifesciences Ltd. in Japan.

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Interface and Integrate Our Technology into Other Manufacturers' Multi-Function Monitors. We have interfaced the Cerebral Oximeter with the Philips VueLink System to provide data, alarm events and status messages from the INVOS System on any monitor that accepts the VueLink module. This enables cerebral oximetry data to be displayed on the VueLink screen, and to be integrated with other vital patient information. We plan to support the interface and integration of our Cerebral Oximeter technology with other medical device manufacturers to expand the installed base of Cerebral Oximeters and increase the demand for SomaSensors as the opportunities arise. Such arrangements provide another distribution channel for our Cerebral Oximeter.

Develop Additional Applications of the Cerebral Oximeter. We are developing product-line extensions of the Cerebral Oximeter for use with newborns, for monitoring non-brain tissues and other advances to the design and performance features of the Cerebral Oximeter and disposable SomaSensor. We believe that these natural extensions of our technology will increase our market potential without the more significant risks and development costs associated with developing entirely new products.

### PRODUCTS AND TECHNOLOGY

#### INVOS Technology

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

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.

#### The INVOS Cerebral Oximeter

The Cerebral Oximeter, based on our INVOS technology, is used to analyze and measure changes in regional oxygen saturation of the blood in 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

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information about portions of the body that previously could not be analyzed using traditional optical spectroscopy.

The INVOS Cerebral Oximeter measurement is made by transmitting low-intensity visible and near-infrared light through a portion of the body, with sensors, called SomaSensors, and detecting the manner in which the molecules of the exposed substance interact with light at specific wavelengths.

Each SomaSensor contains a light source and two light detectors. 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. While both detectors receive similar information about the tissue outside

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the brain, the detector further from the light source detects light that has penetrated deeper into the brain, and, therefore, receives more information specific to the brain than does the detector closer to the light source. By subtracting the two measurements, INVOS technology is able to suppress the influence of the tissues outside the brain to provide a measurement of changes in brain oxygen saturation.

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 saturation level in the brain. It is a portable and easy-to-use monitoring system that is predominantly used in hospital critical care areas, especially operating rooms and ICUs.

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.

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.

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, store data for up to 30 surgical procedures, and retrieve data by disk or computer. 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 purchase disposable SomaSensors on a regular



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basis because of their single-use nature. The SomaSensor may only be used once because after one use it may become contaminated and we do not warrant its effectiveness after one use. We provide a one-year warranty on the Cerebral Oximeter, which we will satisfy by repairing or exchanging those units in need of repair, and we offer service for the Cerebral Oximeter for a fee after the warranty expires.

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

| FEATURES<br>-----                           | BENEFITS<br>-----  |
|---|--|
| <p>FDA-cleared<br/>Non-invasive</p>         | <ul style="list-style-type: none"> <li>- Access to United States and certain foreign markets</li> <li>- Consistent with market trend toward less invasive m procedures</li> <li>- No risk to patients and medical professionals</li> <li>- No added patient recovery costs</li> </ul>  |
| <p>Continuous Information</p>               | <ul style="list-style-type: none"> <li>- Immediate information regarding brain oxygen imbalanc</li> <li>- Real-time guide to therapeutic interventions</li> </ul>  |
| <p>Organ-Specific Information</p>           | <ul style="list-style-type: none"> <li>- Provides information about oxygen imbalances in bot of the brain</li> </ul>   |
| <p>Relatively Inexpensive</p>               | <ul style="list-style-type: none"> <li>- Low cost relative to other brain monitors and medic</li> <li>- Small portion of the cost of the procedures in whic</li> <li>- New information can potentially improve patient out reduce the cost of care</li> </ul>  |
| <p>Easy to Use</p>                          | <ul style="list-style-type: none"> <li>- Does not require a trained technician to operate or</li> <li>- Automatic SomaSensor calibration</li> <li>- Simple user interface and controls</li> <li>- Audible alarm limits</li> </ul>  |
| <p>Effective in Difficult Circumstances</p> | <ul style="list-style-type: none"> <li>- Provides information when the patient is unconsciou strong peripheral pulse or has suppressed neural ac specifically during cardiac arrest, hypothermia, hy hypotension and hypovolemia</li> <li>- Indicates oxygen imbalances in the brain, not just flow, oxygenation of the arteries or the effects of imbalances</li> </ul> |
| <p>Portable</p>                             | <ul style="list-style-type: none"> <li>- Placed at patient's bedside</li> </ul>  |

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### RESEARCH AND DEVELOPMENT

We are developing product-line extensions of the Cerebral Oximeter for use with newborns, for monitoring non-brain tissues and other advances to the design and performance features of the Cerebral Oximeter and disposable SomaSensor. We are also working to interface our Cerebral Oximeter with multi-functional monitors provided by other manufacturers.

We spent \$369,106 during fiscal 2004 on research, development and engineering, \$412,953 during fiscal 2003, and \$571,126 during fiscal 2002.

### MARKETING, SALES AND DISTRIBUTION

#### MARKETING

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 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

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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 2004, the results of the first prospective, randomized, blinded intervention trial were presented. The study showed that when the INVOS Cerebral Oximeter was used to monitor and help manage the regional brain blood oxygen saturation of cardiac surgery patients the occurrence of adverse clinical outcomes was reduced from 12.5 percent to 2 percent, including stroke and other severe adverse outcomes that can significantly add to hospital costs.

Also during 2004, the results of a large retrospective review showed a 50 percent reduction in the incidence of permanent stroke, from two percent to less than one percent, reduced time to extubation, reduced incidence of prolonged ventilation, and reduced length of hospital stay when the Cerebral Oximeter was used with cardiac surgery patients.

We attend trade shows and medical conferences to promote the Cerebral Oximeter and to meet medical professionals with an interest in performing research and reporting their results in peer-reviewed medical journals and at major international meetings. We also sponsor peer-to-peer educational opportunities, promote use of the Cerebral Oximeter in regional centers of influence that we believe will influence the adoption by others, and participate in targeted public relations opportunities.

#### SALES AND DISTRIBUTION

In the United States, we sell the Cerebral Oximeter through our 17 direct salespersons, which approximately doubled from a year ago, and 13 independent sales representative firms. We have also entered into a co-promotion relationship with Fresenius' North American Extracorporeal Alliance. We expect

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to increase our direct sales headcount in fiscal 2005. We believe the selling cycle for the Cerebral Oximeter averages approximately six to nine months.

Outside the United States, 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, the Middle East, South Africa and Canada, and Edwards Lifesciences Ltd., formerly Baxter Limited, in Japan. We also have one international sales consultant.

We offer 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 SomaSensors. It has been our experience that 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, 2005 or as of January 10, 2004. We generally do not have a backlog of firm orders because we generally ship product upon receipt of customer order.

For a description of sales to major customers, see Note 9 of Notes to Financial Statements included in Item 8 of this Report. Edwards Lifesciences was our largest customer in fiscal 2004, and Tyco Healthcare was our largest customer in fiscal 2003 and 2002. We are dependent on our sales to Edwards Lifesciences and Tyco Healthcare, and the loss of either of them as a customer would have an adverse effect on our business, financial condition and results of operations in the near-term, until such time as they could be replaced as our distributor in the respective market.

Our export sales were approximately \$2,092,000 for the fiscal year ended November 30, 2004, \$1,945,000 for the fiscal year ended November 30, 2003, and \$1,348,000 for the fiscal year ended

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November 30, 2002. See Note 9 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 unit enclosure, the printed circuit boards and other mechanical components are the primary components that must be manufactured according to specifications provided by us. We are currently dependent on one manufacturer of the SomaSensor, and we believe that it would require approximately four to five months to change SomaSensor suppliers. We do not currently intend to manufacture on a commercial scale the disposable SomaSensor or the components of the Cerebral Oximeter.

On June 11, 1998, we received ISO 9001 certification and met the requirements under the European Medical Device Directive to use the CE Mark, thereby allowing us to continue to market our Cerebral Oximeter and SomaSensor in the European Economic Community. Our most recent ISO 9001 compliance surveillance audit occurred in August 2004.

### COMPETITION

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In the United States, we believe there is currently no direct commercial competition for the Cerebral Oximeter, although we are aware that several companies and individuals are engaged in the research and development of cerebral oximeters. Outside the United States, Japanese manufacturers offer competitive products for sale in that country and primarily for research in other parts of the world.

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.

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

### PROPRIETARY RIGHTS INFORMATION

We have twelve United States patents and three patents in various foreign countries. These patents expire on various dates from February 2006 to October 2019. We currently do not have any

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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.

In September 2003, we were issued a new patent by the United States 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. This patent is pending in other markets outside the United States. We believe the design concepts covered in this patent are important to providing a clinically viable cerebral oximeter.

Our other patents cover methods and apparatus for introducing light into a body part and receiving, measuring and analyzing the resulting light and its interaction with tissue. These methods also involve receiving, measuring and analyzing the light transmissivity of various body parts of a single subject, as well as of body parts of different subjects, which provides a standard against which a single subject can be compared. Eleven of the issued patents expressly refer to examination of the brain or developments involving the Cerebral

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Oximeter.

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," "INVOS," "SOMASENSOR" and "WINDOW TO THE BRAIN." We have also obtained registrations of our basic mark, "SOMANETICS," in eleven foreign countries.

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

### GOVERNMENT REGULATION

The testing, manufacture and sale of our products are subject to regulation by numerous governmental authorities, principally the FDA and corresponding state and foreign agencies. Pursuant to the Federal Food, Drug, and Cosmetic Act, and the related regulations, the FDA regulates the preclinical and clinical testing, manufacture, labeling, distribution and promotion of medical devices. If we do not comply with applicable requirements, we can be subject to, among other things, fines, civil penalties, injunctions, recall or seizure of products, withdrawal of marketing clearances or approvals, failure of the government to grant premarket clearance or premarket approval for devices, total or partial suspension of production, or 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. Our INVOS Cerebral Oximeter and CorRestore System have been categorized as Class II devices and were granted authorization under "510(k) clearance." 510(k) clearance generally is granted when submitted information establishes that a proposed device is

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"substantially equivalent" in intended use and other factors, such as technological characteristics, to a Class I or II device already legally on the market, which requires clinical 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. When we modify or enhance our products, we must determine whether the modifications or enhancements could significantly affect safety or effectiveness or constitute a major change in the intended use of the device and require new 510(k) submissions. The FDA could disagree with our determination not to submit a new 510(k) notice. If the FDA requires us to submit a new 510(k) notice for our Cerebral Oximeter or SomaSensor or for any device modification or enhancement, we might be prohibited from marketing the modified or enhanced devices until the 510(k) notice is cleared by the FDA. We believe that the product line extensions of the Cerebral Oximeter for monitoring non-brain tissues will require 510(k) clearance before we can market and sell these products in the United States. We believe that it now usually takes from three

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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. We do not currently have any 510(k) applications pending.

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

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

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 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

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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 June 2004. 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 under certain conditions.

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. We do not currently have any 510(k) applications pending. If we file any 510(k) applications during fiscal 2005, our fees would be approximately \$3,000 for each 510(k) review.

### SEASONALITY

Our business is seasonal. Our fourth quarter has typically been our strongest quarter due to a larger number of patients undergoing procedures using the Cerebral Oximeter and SomaSensors and higher Cerebral Oximeter monitor revenues associated with hospital budgeting cycles.

### THE CORRESTORE SYSTEM

#### Market Overview

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

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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

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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.

Before the availability of the CorRestore Patch, the surgeon formed the implant by hand from bovine pericardium tissue or medical grade fabrics. These 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. We believe it will be possible to demonstrate the clinical benefits of SVR and 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.

### Business Strategy

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

Promote the Benefits of SVR with the CorRestore System. Our initial target market is SVR surgeries on Class III and IV congestive heart failure patients with dilated ischemic cardiomyopathy due to a previous myocardial infarction in the anterior wall of the left ventricle. Dilated ischemic cardiomyopathy is a damaged heart muscle caused by the obstruction of the inflow of blood from the arteries and resulting in an enlarged ventricle. Myocardial infarction is death of an area of the middle muscle layer in the heart wall. We promote SVR by sponsoring education programs teaching the concepts of ventricular geometry, the benefits of SVR and the operative technique of SVR with the CorRestore System to cardiac surgeons and cardiologists.

We 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 educate their referring cardiologists about SVR and to use the CorRestore System during their SVR operations. We believe that randomized, prospective clinical data, such as that expected to be developed by the NIH-funded STICH trial, is required to gain broad acceptance of the SVR surgical option by cardiologists. Currently, we demonstrate the clinical benefits of SVR with data

developed by the RESTORE Group, an international group of cardiac surgeons and cardiologists, which shows five-year survival of 69% and a five-year hospital



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readmission rate of 22% for SVR patients. In comparison, the annual hospital admission rate for severe, Class III and IV, heart failure patients is more than 40 percent, while 24% are admitted two or more times each year and nearly 40% of severe heart failure patients die within 12 months following their initial hospital admission for heart failure.

**Invest in Marketing and Sales Activities.** We sell the CorRestore System in the United States through our direct sales force and independent sales representative firms. We are currently evaluating new registrars to obtain approval to allow us to use the CE Mark and resume sales of the CorRestore System in Europe. Internationally, 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 develop and market 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. Before the availability of the CorRestore System, SVR was generally performed using a patch formed by the surgeon during the surgery out of medical grade fabrics or bovine pericardium tissue. These hand-formed patches take time for the surgeon to make, 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, to standardize the operation 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, three 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. Two of those issued patents also expire in May 2018, and one expires July 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-reviewed clinical data is a key element to a product's success in the medical equipment industry. In October 2004, the results of a 13-center, 1,198-patient study evaluating the safety and effectiveness of SVR reported a dramatic improvement in ejection fraction and ventricular volume. In addition, there was low (5 percent) operative mortality and an overall five-year survival rate of 69 percent. In addition, there was very low re-hospitalization rate in a high-risk population, as 78 percent of the patients were not readmitted to the hospital for congestive heart failure during the five 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. Pre-operatively, 67 percent 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, 85 percent were functionally Class I or Class II.

The study was published in the October 2004 issue of the Journal of the American College of Cardiology.

#### Sales and Distribution

We sell the CorRestore System through our 17 direct salespersons and 11 independent sales representative firms in the United States. In September 2004, the European Economic Community changed its regulations, limiting approval authority for animal tissue implant products sold in Europe to some independent registration agencies that do not include our registrar. We are currently evaluating new registrars to obtain approval to allow us to use the CE Mark and resume sales of the CorRestore System in Europe. Internationally, we have distribution agreements with two independent distributors covering two countries for the CorRestore System.

#### License Agreement

We entered into a license agreement as of June 2, 2000 with the inventors and their company, CorRestore LLC. The license grants us exclusive, worldwide, royalty-bearing licenses to specified rights relating to the CorRestore 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

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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;

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- 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 specified breaches by us, for the remaining term of the warrants. In April 2004, CorRestore LLC exercised its warrant to purchase 380,000 of our newly-issued common shares, at \$3.00 per share, for proceeds of \$1,140,000.
- 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:

| 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                                  |

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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 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 was added as a Class I director. Mr. Wolfe will not continue as a director after the end of his term on April 21, 2005. 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

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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, if Bruce J. Barrett ceases to be our chief executive officer or ceases to be responsible for our activities relating to the licenses, but only if (1) one of these events happens before June 2, 2005, and (2) CorRestore LLC or either of the inventors exercises the right to terminate within 120 days after the event occurs.
- In their sole discretion, if we materially breach specified covenants in the license agreement and fail to cure the breach within 90 days (30 days for payment obligations) after CorRestore LLC notifies us of the breach, but only if CorRestore LLC exercises its right to terminate within 120 days after the 90-day cure period expires.
- In their sole discretion, if our common shares are delisted from The Nasdaq Stock Market and are not re-listed within 90 days, but only if CorRestore LLC exercises its right to terminate within 120 days after the 90-day period expires.
- In their sole discretion, if we make an assignment for the benefit of our creditors or voluntarily commence any bankruptcy, receivership, insolvency or liquidation proceedings and the action is not reversed or terminated within 90 days, but only if CorRestore LLC exercises its right to terminate within 120 days after the 90-day period expires.

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

- CorRestore LLC may exclude specified countries from the geographic scope of the license if we have not begun marketing the CorRestore System products or begun the process of obtaining necessary regulatory approval to sell CorRestore System products in that country within one year after the date we file a 510(k) clearance application or PMA approval application with the FDA with respect to the CorRestore Patch. We filed a 510(k) clearance application with

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the FDA with respect to the CorRestore Patch 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 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.

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### Competition

The CorRestore System competes against existing patches, which are formed by the surgeon during SVR surgeries out of medical grade fabrics or bovine pericardium tissue. These 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 hand-formed patches, including its ease of use and better seal against leaks at the edge, hand-formed 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 medical grade fabric patches indicates that they are effective. SVR is in the early stages of its development and, if it develops, the market for patches used in SVR might become highly competitive. There are many larger companies in this industry that have significantly larger research and development budgets than ours. Competitors may be able to develop additional or better treatments for congestive heart failure.

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

### INSURANCE

Because the Cerebral Oximeter and the CorRestore System are intended to be used in hospital critical care units with patients who may be seriously ill or may be undergoing dangerous procedures, we might be exposed to serious potential products liability claims. We have obtained products liability insurance with a liability limit of \$5,000,000. We also maintain coverage for property damage or

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loss, general liability, business interruption, travel-accident, directors' and officers' liability and workers' compensation. We do not maintain key-man life insurance.

### EMPLOYEES

As of February 18, 2005, we employed 35 full-time individuals, including 19 in sales and marketing, four in research and development, five in general and administration and seven in manufacturing, quality and service. We also employed two part-time individuals, one in general and administration and one in manufacturing, quality and service. In addition, we use one contract manufacturing employee, 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, sales, marketing and technical personnel. We expect to add additional sales and marketing employees in fiscal 2005. Our employees are not represented by a union or subject to a collective bargaining agreement. We believe that our relations with our current employees are good.

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

We are located in Troy, Michigan and have no other locations. Our export sales were approximately \$2,092,000 for the fiscal year ended November 30, 2004, \$1,945,000 for the fiscal year ended November 30, 2003 and \$1,348,000 for the fiscal year ended November 30, 2002, including approximately \$944,000 in fiscal 2004, \$1,166,000 in fiscal 2003 and \$820,000 in fiscal 2002 to Tyco Healthcare, our distributor in Europe and Canada, and approximately \$970,000 in fiscal 2004, \$616,000 in fiscal 2003, and \$352,000 in fiscal 2002 to Edwards Lifesciences Ltd., our distributor in Japan. See Note 9 of Notes to Financial Statements included in Item 8 of this Report.

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### 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 April 2004, with the extension commencing August 1, 2004 and expiring December 31, 2009. The minimum monthly lease payment was

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approximately \$15,100 for fiscal 2004, \$16,800 for fiscal 2003, and \$16,500 for fiscal 2002. The minimum monthly lease payment will be approximately \$11,700 for fiscal 2005 and fiscal 2006, \$11,900 for fiscal 2007, \$12,200 for fiscal 2008, and \$12,400 for fiscal 2009, 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, 2004.

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### SUPPLEMENTAL ITEM. EXECUTIVE OFFICERS OF THE REGISTRANT

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

| Name                 | Executive<br>Officer<br>Since | Age | Position   |
|----------------------|-------------------------------|-----|--|
| ----                 | -----                         | --- | -----  |
| Bruce J. Barrett     | 6/94                          | 45  | President and Chief Executive Officer                  |
| William M. Iacona    | 12/00                         | 34  | Vice President, Finance, Controller, and Treasurer     |
| Richard S. Scheuing  | 1/98                          | 49  | Vice President, Research and Development               |
| Dominic J. Spadafore | 8/02                          | 45  | Vice President, Sales and Marketing                    |
| Mary Ann Victor      | 1/98                          | 47  | Vice President, Communications and Administration, and |
| Ronald A. Widman     | 1/98                          | 54  | Vice President, Medical Affairs                        |
| Pamela A. Winters    | 1/98                          | 46  | 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. Earlier in his career, Mr. Barrett served as the Director, Hospital Products Division for Abbott Laboratories, Ltd., a health care equipment manufacturer and distributor, and 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. Prior to joining Abbott Laboratories, 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

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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), and was on the audit staff of Deloitte & Touche LLP, independent auditors. 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 and prior to that was our Director of Research and Development and 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. was a Development Engineer with the Sarns division of Minnesota Mining and Manufacturing Company, or 3M. He received a B.S. degree in mechanical engineering from the University of Michigan.

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

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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 prior to that held field sales representative and regional manager positions with progressive responsibilities with Datascope Corporation. Earlier in his career Mr. Spadafore was a sales representative with the Upjohn Company, a pharmaceutical manufacturer, and 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 and prior to that was our Director, Communications and Administration. Her prior experience includes various investor relations and public relations positions with publicly-held companies. She also is an attorney and practiced with the law firm Varnum Riddering Schmidt & Howlett. 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 and prior to that was our Director of Medical Affairs and Marketing Manager. Prior to joining us in 1991, he was employed by Mennen Medical, Inc., a manufacturer and marketer of medical monitoring and diagnostic devices, where he held various positions in domestic and international medical product marketing. 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 and since joining Somanetics in 1991 has served as Director of Operations and Manager of Quality Assurance. 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, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

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 sales prices as reported by Nasdaq.

|                                     | HIGH<br>----- | LOW<br>----- |
|-------------------------------------|---------------|--------------|
| Fiscal Year Ended November 30, 2003 |               |              |
| First Quarter.....                  | \$ 2.18       | \$ 1.48      |
| Second Quarter.....                 | 3.50          | 1.54         |
| Third Quarter.....                  | 5.80          | 3.06         |
| Fourth Quarter.....                 | 9.43          | 5.30         |
| Fiscal Year Ended November 30, 2004 |               |              |
| First Quarter.....                  | \$ 9.69       | \$ 6.00      |
| Second Quarter .....                | 15.86         | 8.77         |
| Third Quarter .....                 | 16.70         | 9.23         |
| Fourth Quarter .....                | 14.98         | 10.65        |

As of February 17, 2005, we had 644 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, 2004, 2003, 2002, 2001 and 2000, and for each of the years in the five-year period ended November 30, 2004 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 2005. 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 NOVEMBER 30,

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|  | 2004      | 2003     | 2002     | 2001     |
|--|-----------|----------|----------|----------|
| (in thousands, except per share data)                                    |           |          |          |          |
| STATEMENT OF OPERATIONS DATA:  |           |          |          |          |
| Net revenues (1) .....   | \$ 12,609 | \$ 9,361 | \$ 6,706 | \$ 5,656 |
| Cost of sales .....  | 2,050     | 2,140    | 2,049    | 2,094    |
| Gross margin .....   | 10,558    | 7,221    | 4,657    | 3,561    |
| Research, development and engineering expenses .....                     | 369       | 413      | 571      | 778      |
| Selling, general, and administrative expenses .....                      | 8,237     | 6,759    | 5,344    | 5,133    |
| Net income (loss) (2) .....  | 8,707     | 73       | (1,207)  | (2,331)  |
| Net income (loss) per common share - basic (3) .....                     | .89       | .01      | (.13)    | (.31)    |
| Net income (loss) per common share - diluted (3) .....                   | .77       | .01      | (.13)    | (.31)    |
| Weighted average number of common shares outstanding - basic (3) .....   | 9,780     | 9,114    | 8,951    | 7,606    |
| Weighted average number of common shares outstanding - diluted (3) ..... | 11,323    | 9,467    | 8,951    | 7,606    |

|                                     | AT NOVEMBER 30, |          |          |          |
|-------------------------------------|-----------------|----------|----------|----------|
|                                     | 2004            | 2003     | 2002     | 2001     |
| (in thousands)                      |                 |          |          |          |
| BALANCE SHEET DATA:                 |                 |          |          |          |
| Cash and marketable securities..... | \$ 7,070        | \$ 2,239 | \$ 2,382 | \$ 168   |
| Working capital.....                | 9,311           | 4,480    | 4,047    | 1,724    |
| Total assets.....                   | 18,785          | 7,156    | 6,164    | 3,587    |
| Total liabilities.....              | 1,232           | 991      | 664      | 575      |
| Accumulated deficit.....            | (44,882)        | (53,589) | (53,661) | (52,455) |
| Shareholders' equity (4).....       | 17,553          | 6,165    | 5,501    | 3,013    |

- (1) Net revenues recorded in fiscal years 2001 and 2000 relate primarily to the sale of Cerebral Oximeters and SomaSensors for commercial use. Fiscal years 2004, 2003, and 2002 net revenues include sales of CorRestore Systems.
- (2) See Note 5 of Notes to Financial Statements included in Item 8 of this Report for information with respect to the reversal of a portion of our income tax valuation allowance as of November 30, 2004.
- (3) See Note 3 of Notes to Financial Statements included in Item 8 of this Report for information with respect to the calculation of per share data.
- (4) 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, 2001 through November 30, 2004.

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### 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 economic conditions in general and in the healthcare market, the demand for and market for our products in domestic and international markets, our history of losses, our current dependence on the Cerebral Oximeter and SomaSensor, the challenges associated with developing new products and of obtaining regulatory approvals if necessary, research and development activities, the uncertainty of acceptance of our products by the medical community, the lengthy sales cycle for our products, third party reimbursement, competition in our markets, including the potential introduction of competitive products by others, our dependence on our distributors, physician training, enforceability and the costs of enforcement of our patents, potential infringement of our patents and the other factors discussed under the caption "Risk Factors" and elsewhere in our Registration Statement on Form S-1 (file no. 333-74788) effective January 11, 2002 and elsewhere in this report, all 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. In September 2004, the European Economic Community changed its regulations, limiting approval authority for animal tissue implant products sold in Europe to some independent registration agencies that do not include our registrar. We are currently evaluating new registrars to obtain approval to allow us to use the CE Mark and resume sales of the CorRestore System in Europe.

During fiscal 2004, 2003 and 2002, our primary activities consisted of sales and marketing of the Cerebral Oximeter, the related disposable SomaSensor, and the CorRestore System.

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

As described in more detail below, we achieved net income before income taxes for fiscal 2004 of approximately \$2,007,000. Our net income before income taxes for the year ended November 30, 2004 was primarily a result of our 35% increase in net revenues and a seven percentage point increase in gross margin percentage. Our increase in net revenues was primarily a result of increased unit sales and increased average selling prices for our disposable SomaSensor in the United States. Our increase in gross margin percentage was also primarily attributable to the increase in average selling prices for our disposable SomaSensors, as well as the reduction in the cost of our disposable SomaSensor by approximately 40%, effective May 2004, as a result of changes in our manufacturing process. Our operating expenses increased approximately 20% for the fiscal year ended November 30, 2004 primarily due to increased commissions paid to our independent sales representative firms and direct sales employees as a result of increased sales, and increased salaries as a result of our hiring additional direct sales personnel in fiscal 2004. As of November 30, 2004, we adjusted our deferred tax asset valuation allowance resulting in the recognition of a deferred tax asset of approximately \$6,700,000 due to expected future tax benefits related to our net operating loss carryforwards. Recognition of this deferred tax asset resulted in a non-cash tax benefit on our statement of operations for fiscal 2004, and increased our net income for fiscal 2004 to approximately \$8,707,000, or \$.77 per diluted common share. We had approximately \$2,233,000 of cash provided by operations in fiscal 2004, and a net increase in cash and cash equivalents of approximately \$4,830,000, primarily as a result of the exercise of stock options and warrants, in addition to our net income before taxes.

For 2005, we project an increase in net revenues of approximately 40% to 45%, and an increase in our gross margin percentage to approximately 87%. In addition, we project an increase in net income before income taxes of approximately 70% to 80%, to approximately \$3.4 million to \$3.6 million. We expect our operating expenses to increase in fiscal 2005, primarily as a result of our hiring additional direct sales personnel and increasing our expenses associated with the sales and marketing of our products. We project our year-end fiscal 2005 cash balance will be approximately \$10,000,000. While we do not expect to pay income taxes for fiscal 2005, beginning in the first quarter of 2005, we will be recognizing income tax expense at the statutory rate of 34% on our statement of operations. As 2005 progresses and we assess our plans for future years, we will review the appropriateness of adjusting our deferred tax asset valuation allowance and recognizing additional deferred tax assets.

Fiscal Year Ended November 30, 2004 Compared to Fiscal Year Ended November 30, 2003

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Our net revenues increased \$3,247,722, or 35%, from \$9,360,893 in the fiscal year ended November 30, 2003 to \$12,608,615 in the fiscal year ended November 30, 2004. The increase in net revenues is primarily attributable to

- an increase in United States sales of approximately \$3,101,000, or 42%, from approximately \$7,416,000 in fiscal 2003 to approximately \$10,517,000 in fiscal 2004. The increase in United States sales was primarily due to an increase in sales of the disposable

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SomaSensor of approximately \$2,967,000, or 49%, as a result of a 22% increase in SomaSensor unit sales and a 22% increase in SomaSensor average selling prices. In addition, sales of the Cerebral Oximeter in the United States increased approximately \$333,000, or 49%, as a result of increased purchases by pediatric hospitals. These increases were partially offset by a decrease in CorRestore System revenues of approximately \$199,000, or 29%, and

- an increase in international sales of approximately \$147,000, or 8%, from approximately \$1,945,000 in fiscal 2003 to approximately \$2,092,000 in fiscal 2004, primarily due to increased purchases of the Cerebral Oximeter and disposable SomaSensor by Edwards Lifesciences in Japan, partially offset by decreased purchases by Tyco Healthcare in Europe.

As described above, during fiscal 2004 we achieved a 22% increase in the average selling price of SomaSensors in the United States. This increase in our average selling prices is attributable to

- the addition of new customers at our higher suggested retail prices, which were effective September 1, 2003,
- increased sales of our small adult SomaSensor that was launched in the third quarter of fiscal 2003 and sells for a premium price compared to the adult SomaSensor,
- increased sales of our pediatric SomaSensor which also sells for a higher price than the adult SomaSensor, and
- the upgrade of certain customers to our most recent model Cerebral Oximeter in exchange for the customer agreeing to pay a higher price for the disposable SomaSensor.

In addition, as described above, we had a 22% increase in SomaSensor unit sales in the United States to 111,406 units. We expect that the average selling price of SomaSensors in the United States will increase by approximately 10% in fiscal 2005, as a result of the factors described above.

We placed 197 Cerebral Oximeters in the United States and 133 internationally in fiscal 2004, and our installed base of Cerebral Oximeters in the United States is approximately 770, in 380 hospitals, as of November 30, 2004.

Approximately 17% of our net revenues in fiscal 2004 were export sales, compared to approximately 21% of our net revenues in fiscal 2003. One international distributor accounted for approximately 12% of net revenues in fiscal 2003. For fiscal 2005, we expect international net revenues will continue to represent approximately 15% to 20% of our total net revenues.

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

| PRODUCT<br>-----        | PERCENT OF NET REVENUE            |                              |
|-------------------------|-----------------------------------|------------------------------|
|                         | FISCAL YEAR ENDED<br>2004<br>---- | NOVEMBER 30,<br>2003<br>---- |
| SomaSensors.....        | 78%                               | 71%                          |
| Cerebral Oximeters..... | 18%                               | 21%                          |
| CorRestore Systems..... | 4%                                | 8%                           |
|                         | ----                              | ----                         |
| Total.....              | 100%                              | 100%                         |
|                         | ====                              | ====                         |

For fiscal 2005, we expect sales of SomaSensors to account for 75% to 80% of net revenues, sales of Cerebral Oximeters 15% to 20%, and sales of CorRestore Systems less than 5%.

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Gross margin as a percentage of net revenues was approximately 84% for the fiscal year ended November 30, 2004 and approximately 77% for the fiscal year ended November 30, 2003. The increase in gross margin as a percentage of net revenues is primarily attributable to

- a change in the sales mix with increased sales of the disposable SomaSensor, which has a higher gross margin than the Cerebral Oximeter or CorRestore System,
- the increase in the average selling price of SomaSensors described above,
- a reduction in the cost of our SomaSensor by approximately 40%, in May 2004, as a result of changes in our manufacturing process, and
- the change in sales mix with increased sales in the United States, which have higher gross margins than our international sales to distributors.

We expect our gross margin percentage in fiscal 2005 to increase to approximately 87%, primarily due to our expected increase in the average selling price of the disposable SomaSensor in the United States described above, and sales of our new cost reduced SomaSensor for all of fiscal 2005, compared with approximately half of fiscal 2004.

Our research, development and engineering expenses decreased approximately \$44,000, or 11%, from \$412,953 in fiscal 2003 to \$369,106 in fiscal 2004. The decrease is primarily attributable to approximately \$47,000 in decreased costs associated with the development of the CorRestore System and approximately \$25,000 in decreased costs associated with the development of the Cerebral Oximeter, partially offset by increased costs associated with the development of the disposable SomaSensor and increased engineering salaries.

Selling, general and administrative expenses increased approximately \$1,479,000, or 22%, from \$6,758,637 for the fiscal year ended November 30, 2003

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to \$8,237,401 for the fiscal year ended November 30, 2004. The increase in selling, general and administrative expense is primarily attributable to

- a \$399,000 increase in salaries, wages and related expenses, primarily as a result of an increase in the number of employees, principally sales and marketing (from an average of 28 employees for the fiscal year ended November 30, 2003 to an average of 32 employees for the fiscal year ended November 30, 2004),
- a \$393,000 increase in employee sales commissions as a result of increased sales and increased sales headcount during fiscal 2004,
- a \$353,000 increase in commissions paid to our independent sales representative firms as a result of increased sales,
- a \$227,000 increase in accrued incentive compensation expense due to our fiscal 2004 financial performance, primarily increased sales and net income, in accordance with the 2004 Incentive Compensation Plan,
- a \$117,000 increase in travel and selling-related expenses as a result of our increased sales headcount and increased sales and marketing activities,
- \$97,000 in costs associated with a 401(k) matching contribution program that we implemented in fiscal 2004, and
- \$96,000 in costs associated with the termination of some of our independent sales representative firms in the second quarter of fiscal 2004.

These increases were partially offset by a \$170,000 decrease in customer education expenses for the CorRestore System.

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We expect our selling, general and administrative expenses to increase in fiscal 2005, primarily as a result of our hiring additional direct sales personnel in fiscal 2004 and 2005, increased sales commissions payable to our independent sales representative firms and increased sales and marketing expenses.

As of November 30, 2004, we adjusted our deferred tax asset valuation allowance resulting in the recognition of a deferred tax asset of approximately \$6,700,000 as a result of expected future tax benefits related to our net operating loss carryforwards. Recognition of this deferred tax asset resulted in a non-cash tax benefit on our statement of operations for fiscal 2004, and increased our net income for fiscal 2004 to approximately \$8,700,000, or \$.77 per diluted common share.

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

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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 United States 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                 | PERCENT OF NET REVENUE         |      |
|-------------------------|--------------------------------|------|
|                         | FISCAL YEAR ENDED NOVEMBER 30, |      |
|                         | 2003                           | 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 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.

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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,



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- 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.

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 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.

### 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 provided by operations during fiscal 2004 was approximately \$2,233,000. Cash was provided primarily by

- our net income before income taxes of approximately \$2,007,000, and depreciation and amortization expense of approximately \$283,000, and
- a \$354,000 increase in accrued liabilities, primarily as a result of the increased accrued incentive compensation and accrued 401(k) matching contribution described above.

Cash provided by operations was partially offset by

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- a \$159,000 increase in inventories, primarily due to the acquisition of SomaSensors and components associated with our Cerebral Oximeter due to anticipated sales; inventories on our balance sheet declined because we capitalized Cerebral Oximeters to property and equipment that are being used as demonstration units and no-cap sales equipment, as described below,
- a \$135,000 increase in prepaid expenses, primarily due to the timing of the renewal of our products liability insurance, and
- a \$112,000 decrease in accounts payable, primarily as a result of more timely payments made to vendors.

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

We capitalized approximately \$566,000 of costs from inventory for Cerebral Oximeters being used as demonstration units and no-cap sales equipment at customers during fiscal 2004, compared to approximately \$371,000 in fiscal 2003. As of November 30, 2004, we have capitalized approximately \$1,628,000 in costs for Cerebral Oximeters being used as demonstration and no-cap sales equipment, and these assets have a net book value of approximately \$901,000. We depreciate these assets over five years.

In addition, we had capital expenditures in fiscal 2004 of approximately \$84,000. These expenditures were primarily for computer equipment and tooling for our SomaSensor.

Our principal sources of operating funds have been the proceeds of equity investments from sales of our common shares and, in 2004, cash provided by operating activities. 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, which was subsequently terminated on April 10, 2001. 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 exercise price of the warrants was 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. In March 2004, Kingsbridge Capital Limited purchased 40,000 common shares under its warrants by a cashless exercise. As a result of this cashless exercise, we issued 24,097 common shares to Kingsbridge, retaining 15,903 common shares in payment of the exercise price. In May 2004, Kingsbridge Capital Limited purchased the remaining 65,097 common shares under its warrants by a cashless exercise. As a result of this cashless exercise, we issued 47,475 common shares to Kingsbridge, retaining 17,622 common shares in payment of the exercise price. Kingsbridge now has no warrants remaining to purchase common shares.

On April 9, 2001, we completed a private placement of newly-issued common shares for which Brean Murray & Co., Inc., as our exclusive placement agent, received warrants to purchase 25,000 common shares at \$2.10 per share. 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,

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retaining 6,168 common shares in payment of the exercise price, and no more common shares remain subject to these warrants.

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On January 16, 2002, we completed a public offering of newly-issued common shares for which Brean Murray & Co., Inc., as our exclusive placement agent, received warrants to purchase 100,000 common shares at \$5.10 per share. In June 2004, Brean Murray & Co., Inc. purchased 100,000 common shares under its warrants by a cashless exercise. As a result of this cashless exercise, we issued 66,265 common shares to Brean Murray & Co., Inc., retaining 33,735 common shares in payment of the exercise price. Brean Murray & Co., Inc. now has no warrants remaining to purchase common shares.

In April 2004, CorRestore LLC exercised its warrant to purchase 380,000 of our newly-issued common shares, at \$3.00 per share, for proceeds of \$1,140,000.

During fiscal 2004, we issued 321,276 common shares as a result of stock option exercises by employees, directors and former employees, for proceeds of approximately \$1,541,000. 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, 2004, we had working capital of \$9,310,683, cash and cash equivalents of \$7,069,542, total current liabilities of \$1,232,206 and shareholders' equity of \$17,552,666. We had an accumulated deficit of \$44,882,147 through November 30, 2004.

We expect that our primary needs for liquidity in fiscal 2005 will be

- to fund our operations, including funding for
  - marketing costs for the Cerebral Oximeter and the CorRestore System, and
  - research and development efforts for the Cerebral Oximeter related to newborns, for monitoring non-brain tissues and other advances to the design and performance features of the Cerebral Oximeter and disposable SomaSensor, and
- for working capital, primarily accounts receivable and inventory, as our sales increase.

In addition, we have budgeted approximately \$1,000,000 during fiscal 2005 for capitalizing Cerebral Oximeters and capital expenditures, primarily for new demonstration and no-cap sales equipment at customers, and tooling for the Cerebral Oximeter and disposable SomaSensor.

We believe that the cash and cash equivalents on hand at November 30, 2004 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.

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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 5 of Notes to Financial Statements included in Item 8 of this Report.

### NEW ACCOUNTING PRONOUNCEMENTS

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 123 (revised), Share Based Payment. This Statement, which is effective for interim or annual reporting periods that begin after June 15, 2005, revises Statement No. 123, "Accounting for Stock-Based Compensation," and requires that compensation costs related to share-based

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payment transactions, including stock options, be recognized in the financial statements. This Statement will be effective for our fiscal quarter ending November 30, 2005. We expect the equity compensation to be recognized in our statement of operations for fiscal 2005, related to unvested stock options as of our required adoption date, will be the equivalent of \$.01 per diluted common share, and we expect the impact for fiscal 2006 will be approximately \$.03 per diluted common share. The future approval of any additional equity incentive plans would have an additional 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 rights relating to the CorRestore System and related products and accessories, our accounting treatment of stock options issued to employees, our accounting treatment for income taxes, and our revenue recognition associated with our no-cap sales program.

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 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 would have been 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.

We have adopted Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets." This statement establishes accounting

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and reporting standards for 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 2004, 2003 or 2002. 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. Indefinite lived intangible assets are reviewed annually for impairment at the end of our fiscal year, and whenever events or changes in circumstances indicate that the carrying value of the asset may not be recovered. We evaluate impairment by comparing the fair value of the intangible asset, determined using a cash flow method, with its carrying value.

In October 1995, Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation," was issued. In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 123 (revised), Share Based Payment. This Statement, which is effective for interim or annual reporting periods that begin after June 15, 2005, revises Statement

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No. 123, "Accounting for Stock-Based Compensation," and requires that compensation costs related to share-based payment transactions, including stock options, stock appreciation rights and restricted stock be recognized in the financial statements. This Statement will be effective for our fiscal quarter ending November 30, 2005.

We currently 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. 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. 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, and \$5,597 of compensation expense in fiscal 2002. We recorded no such expense in fiscal 2004. During fiscal 2004, we granted 53,500 stock options to our employees and directors, in fiscal 2003 we granted 471,000 stock options to our employees and directors, and in fiscal 2002 we granted 509,500 stock options to our employees and directors.

Had we recognized compensation expense for our stock options granted to employees and directors in fiscal 2004, using the fair value method of accounting based on the fair value of the options on the grant date using the Black-Scholes valuation model, we would have recorded approximately \$796,000 in compensation expense and realized pro forma net income of approximately \$7,911,000, or \$.70 per diluted common share. For fiscal 2003, had we recognized compensation expense for stock options granted to employees and directors, using the fair value method of accounting based on the fair value of the options on

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the grant date using the Black-Scholes valuation model, we would have recorded approximately \$962,000 in compensation expense and incurred a pro forma net loss of approximately \$889,000, or \$.09 per diluted common share. For fiscal 2002, had we recognized compensation expense for stock options granted to employees and directors, using the fair value method of accounting based on the fair value of the options on the grant date using the Black-Scholes valuation model, we would have recorded approximately \$760,000 in compensation expense and increased our pro forma net loss to \$1,967,000, or \$.08 per diluted common share.

We have adjusted our deferred tax asset valuation allowance resulting in the recognition of a deferred tax asset of \$6,700,000 related to the expected future benefits of our net operating loss carryforwards, in accordance with Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes." We have performed the required assessment of positive and negative evidence regarding realization of our deferred tax assets in accordance with SFAS No. 109, including our past operating results, the existence of cumulative losses over our history up to the most recent two fiscal years, and our forecast for future net income. Our assessment of our deferred tax assets, and the reversal of part of our valuation allowance, included evaluating our financial plans and our future projected earnings, making allowance for the uncertainties surrounding, among other things, our future rate of growth in net revenues, the rate of adoption of our products in the marketplace, and the potential for competition to enter the marketplace. In reversing a portion of our valuation allowance, we have concluded that it is more likely than not that such assets will be realized.

The effect of recognizing this asset on our balance sheet, and associated tax benefit on our statement of operations, is to increase our net income for fiscal 2004 to approximately \$8,707,000, or \$.77 per diluted common share. Given the assumptions inherent in our financial plans, it is possible to calculate a

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different value for our deferred tax asset by changing one or more of the variables in our assessment. However, we believe that our evaluation of our financial plans was reasonable, and that the judgments and assumptions that we made at the time of developing the plan were appropriate.

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 SomaSensors. We recognize SomaSensor revenue when we receive purchase orders and ship the product to the customer. We do not recognize any revenue upon the initial shipment of the Cerebral Oximeter to the customer at no charge. At the time of shipment, we capitalize the Cerebral Oximeter as an asset and depreciate this asset over five years. We believe this is consistent with our stated revenue recognition policy, which is compliant with Staff Accounting Bulletin No. 104 and Emerging Issues Task Force No. 00-21, "Revenue Arrangements with Multiple Deliverables."

### CONTRACTUAL OBLIGATIONS

The following information is provided as of November 30, 2004 with respect to our known contractual obligations specified in the following table, aggregated by type of contractual obligation:

| Payments due by period |      |
|------------------------|------|
| -----                  |      |
| Less                   | More |

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| Contractual Obligations      | Total     | than 1<br>year | 1-3<br>years | 3-5<br>years | than 5<br>years |
|------------------------------|-----------|----------------|--------------|--------------|-----------------|
| Long-term debt obligations.. | \$ 0      | \$ 0           | \$ 0         | \$ 0         | \$ 0            |
| Capital lease obligations... | \$ 0      | \$ 0           | \$ 0         | \$ 0         | \$ 0            |
| Operating lease obligations. | \$730,600 | \$140,400      | \$283,300    | \$294,500    | \$12,400        |
| Purchase obligations .....   | \$818,600 | \$818,600      | \$ 0         | \$ 0         | \$ 0            |
| Other long-term liabilities. | \$ 0      | \$ 0           | \$ 0         | \$ 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

#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheets of Somanetics Corporation (the "Company") as of November 30, 2004 and 2003, and the related statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended November 30, 2004. 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 the standards of the Public Company Accounting Oversight Board (United States). 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 consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, 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 Somanetics Corporation at November 30, 2004

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and 2003, and the results of its operations and its cash flows for each of the three years in the period ended November 30, 2004, in conformity with accounting principles generally accepted in the United States of America.

/s/ DELOITTE & TOUCHE LLP

-----  
 Detroit, Michigan

February 11, 2005

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### SOMANETICS CORPORATION

#### BALANCE SHEETS

|  | Nove                          |
|--|-------------------------------|
|  | -----<br>2004<br>-----        |
| <b>ASSETS</b>  |                               |
| <b>CURRENT ASSETS:</b>                                     |                               |
| Cash and cash equivalents (Note 2) .....                   | \$ 7,069,542                  |
| Accounts receivable.....                                   | 2,022,544                     |
| Inventory (Note 2).....                                    | 682,910                       |
| Prepaid expenses.....                                      | 257,893                       |
| Deferred tax asset - current (Note 5).....                 | 510,000                       |
| Total current assets.....                                  | -----<br>10,542,889<br>-----  |
| <b>PROPERTY AND EQUIPMENT: (Note 2)</b>                    |                               |
| Demonstration and no-cap sales equipment at customers..... | 1,628,431                     |
| Machinery and equipment.....                               | 704,581                       |
| Furniture and fixtures.....                                | 255,044                       |
| Leasehold improvements.....                                | 171,882                       |
| Total.....   | -----<br>2,759,938<br>-----   |
| Less accumulated depreciation and amortization.....        | (1,675,881)                   |
| Net property and equipment.....                            | -----<br>1,084,057<br>-----   |
| <b>OTHER ASSETS:</b>                                       |                               |
| Deferred tax asset - non-current (Note 5).....             | 6,190,000                     |
| Intangible assets, net (Note 2).....                       | 952,926                       |
| Other.....   | 15,000                        |
| Total other assets.....                                    | -----<br>7,157,926<br>-----   |
| <b>TOTAL ASSETS.....</b>                                   | <b>\$ 18,784,872</b><br>===== |
| <b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>                |                               |
| <b>CURRENT LIABILITIES:</b>                                |                               |
| Accounts payable.....                                      | \$ 529,097                    |
| Accrued liabilities (Notes 4 and 6).....                   | 703,109                       |
| Total current liabilities.....                             | -----<br>1,232,206<br>-----   |



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|   |  |               |
|---|--|---------------|
| COMMITMENTS AND CONTINGENCIES (Note 6).....   |  |               |
| SHAREHOLDERS' EQUITY: (Note 3)  |  |               |
| Preferred shares; authorized, 1,000,000 shares of \$.01 par value; no shares issued or outstanding.....   |  | ---           |
| Common shares; authorized, 20,000,000 shares of \$.01 par value; issued and outstanding, 10,137,782 shares at November 30, 2004, and 9,298,669 shares at November 30, 2003..... |  | 101,378       |
| Additional paid-in capital.....   |  | 62,333,435    |
| Accumulated deficit.....  |  | (44,882,147)  |
| Total shareholders' equity.....   |  | 17,552,666    |
| TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY.....   |  | \$ 18,784,872 |

See notes to financial statements

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### SOMANETICS CORPORATION

#### STATEMENTS OF OPERATIONS

|  | For the Years Ended November 30, |             |                |
|--|----------------------------------|-------------|----------------|
|  | 2004                             | 2003        | 2002           |
|  | -----                            | -----       | -----          |
| NET REVENUES (Notes 2 and 9) .....                   | \$12,608,615                     | \$9,360,893 | \$ 6,705,647   |
| COST OF SALES .....                                  | 2,050,253                        | 2,139,827   | 2,048,758      |
|  | -----                            | -----       | -----          |
| Gross margin .....                                   | 10,558,362                       | 7,221,066   | 4,656,889      |
|  | -----                            | -----       | -----          |
| OPERATING EXPENSES:                                  |                                  |             |                |
| Research, development and engineering (Note 2) ..... | 369,106                          | 412,953     | 571,126        |
| Selling, general and administrative .                | 8,237,401                        | 6,758,637   | 5,343,513      |
|  | -----                            | -----       | -----          |
| Total operating expenses .....                       | 8,606,507                        | 7,171,590   | 5,914,639      |
|  | -----                            | -----       | -----          |
| OPERATING INCOME (LOSS) .....                        | 1,951,855                        | 49,476      | (1,257,750)    |
|  | -----                            | -----       | -----          |
| OTHER INCOME (EXPENSE):                              |                                  |             |                |
| Interest income .....                                | 54,721                           | 23,110      | 51,892         |
| Interest expense and other .....                     | --                               | --          | (794)          |
|  | -----                            | -----       | -----          |
| Total other income (expense) ....                    | 54,721                           | 23,110      | 51,098         |
|  | -----                            | -----       | -----          |
| INCOME (LOSS) BEFORE INCOME TAXES .....              | \$ 2,006,576                     | \$ 72,586   | \$ (1,206,652) |
| INCOME TAX BENEFIT .....                             | 6,700,000                        | --          | --             |
|  | -----                            | -----       | -----          |
| NET INCOME (LOSS) .....                              | \$ 8,706,576                     | \$ 72,586   | \$ (1,206,652) |
|  | =====                            | =====       | =====          |
| NET INCOME (LOSS) PER COMMON                         |                                  |             |                |

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|  |            |           |           |
|--|------------|-----------|-----------|
| SHARE - BASIC (Note 2) .....             | \$ .89     | \$ .01    | \$ (.13)  |
|  | =====      | =====     | =====     |
| NET INCOME (LOSS) PER COMMON             |            |           |           |
| SHARE - DILUTED (Note 2) .....           | \$ .77     | \$ .01    | \$ (.13)  |
|  | =====      | =====     | =====     |
| WEIGHTED AVERAGE NUMBER OF COMMON SHARES |            |           |           |
| OUTSTANDING -- BASIC (Note 2) .....      | 9,780,104  | 9,113,854 | 8,951,266 |
|  | =====      | =====     | =====     |
| WEIGHTED AVERAGE NUMBER OF COMMON SHARES |            |           |           |
| OUTSTANDING -- DILUTED (Note 2) .....    | 11,323,272 | 9,466,838 | 8,951,266 |
|  | =====      | =====     | =====     |

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 | TOT<br>SHAREH<br>EQU |
|--|----------------|----------------------------------|------------------------|----------------------|
|  | -----          | -----                            | -----                  | -----                |
| Balance at December 1, 2001.....                   | \$ 80,751      | \$ 55,386,453                    | \$ (52,454,657)        | \$ 3,                |
| For cash, less issuance costs of<br>\$570,418..... | 10,000         | 3,669,582                        |                        | 3,                   |
| 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)            | (1,                  |
|  | -----          | -----                            | -----                  | -----                |
| Balance at November 30, 2002.....                  | \$ 90,779      | \$ 59,071,122                    | \$ (53,661,309)        | \$ 5,                |
| 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)        | \$ 6,                |
| For cash, exercise of stock options.....           | 3,213          | 1,537,809                        |                        | 1,                   |
| For cash, exercise of warrants.....                | 3,800          | 1,136,200                        |                        | 1,                   |
| Cashless exercise of warrants.....                 | 1,378          | (1,378)                          |                        |                      |
| Net income and comprehensive income.....           |                |                                  | 8,706,576              | 8,                   |
|  | -----          | -----                            | -----                  | -----                |
| Balance at November 30, 2004.....                  | \$ 101,378     | \$ 62,333,435                    | \$ (44,882,147)        | \$ 17,               |
|  | =====          | =====                            | =====                  | =====                |

See notes to financial statements

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## SOMANETICS CORPORATION

### STATEMENTS OF CASH FLOWS

|   | For the Years Ended No |                     |
|---|------------------------|---------------------|
|   | 2004                   | 2003                |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>  |                        |                     |
| Net income (loss).....  | \$ 8,706,576           | \$ 72,586           |
| Adjustments to reconcile net income (loss) to net cash used in operations:                  |                        |                     |
| Income tax benefit.....   | (6,700,000)            | --                  |
| Depreciation and amortization.....  | 282,558                | 235,537             |
| Compensation expense for non-employee stock options.....                                    | --                     | 8,471               |
| Changes in assets and liabilities:  |                        |                     |
| Accounts receivable (increase) decrease.....  | (3,929)                | (790,830)           |
| Inventory (increase).....   | (158,611)              | (456,579)           |
| Prepaid expenses (increase).....  | (134,690)              | (26,895)            |
| Other assets decrease.....  | --                     | --                  |
| Accounts payable increase (decrease).....   | (112,135)              | 170,352             |
| Accrued liabilities increase.....   | 353,562                | 156,781             |
|   | 2,233,331              | (630,577)           |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>  |                        |                     |
| Acquisition of property and equipment (net).....  | (84,003)               | (50,665)            |
|   | (84,003)               | (50,665)            |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>  |                        |                     |
| Proceeds from issuance of Common Shares.....  | 2,681,022              | 538,626             |
|   | 2,681,022              | 538,626             |
| <b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS.....</b>                            | <b>4,830,350</b>       | <b>(142,616)</b>    |
| <b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD.....</b>                                  | <b>2,239,192</b>       | <b>2,381,808</b>    |
|   | <b>7,069,542</b>       | <b>2,239,192</b>    |
| <b>CASH AND CASH EQUIVALENTS, END OF PERIOD.....</b>  | <b>\$ 7,069,542</b>    | <b>\$ 2,239,192</b> |
|   | <b>7,069,542</b>       | <b>2,239,192</b>    |
| <b>Supplemental Disclosure of Non cash investing activities:</b>                            |                        |                     |
| Demonstration and no-cap sales equipment capitalized from inventory (Note 2).....           | \$ 565,962             | \$ 370,623          |
| Issuance of warrants and stock options in connection with license acquisition (Note 2)..... | \$ --                  | \$ 44,793           |

See notes to financial statements

SOMANETICS CORPORATION

NOTES TO FINANCIAL STATEMENTS

1. ORGANIZATION AND OPERATIONS

We are a Michigan corporation that was formed in 1982. We develop, manufacture and market the INVOS(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, based on our In Vivo Optical Spectroscopy, or INVOS, technology, is used to analyze and measure changes in regional blood oxygen saturation in the brain. The INVOS Cerebral Oximeter measurement is made by transmitting low-intensity visible and near-infrared light through a portion of the body with sensors, called SomaSensors, and detecting the manner in which the exposed substance interacts with light at specific wavelengths.

In June 1996 we received clearance from the FDA to market our model 3100A Cerebral Oximeter in the United States, and in October 1997 we received clearance from the FDA to market enhancements to our Cerebral Oximeter in the United States. In September 2000 we received FDA clearance to market our latest model Cerebral Oximeter in the United States, which has the added capability of being able to monitor pediatric patients.

We also develop and market the CorRestore(R) System, including the CorRestore Patch, 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 2).

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. In September 2004, the European Economic Community changed its regulations, limiting approval authority for animal tissue implant products sold in Europe to some independent registration agencies that do not include our registrar. We are currently evaluating new registrars to obtain approval to allow us to use the CE Mark and resume sales of the CorRestore System in Europe.

2. 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:

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### NOTES TO FINANCIAL STATEMENTS - (CONTINUED)

|                           | NOVEMBER 30, |              |
|---------------------------|--------------|--------------|
|                           | 2004         | 2003         |
| Finished goods.....       | \$ 358,815   | \$ 354,024   |
| Purchased components..... | 323,053      | 563,044      |
| Work in process.....      | 1,042        | 173,193      |
|                           | -----        | -----        |
| Total.....                | \$ 682,910   | \$ 1,090,261 |
|                           | =====        | =====        |

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 SomaSensors. The Cerebral Oximeters that are shipped to our customers are classified as no-cap sales equipment and are depreciated over five years. As of November 30, 2004, we have capitalized approximately \$1,628,000 in costs for Cerebral Oximeters being used as demonstration and no-cap sales equipment, and these assets had a net book value of approximately \$901,000. As of November 30, 2003, we have capitalized approximately \$1,309,000 in costs for Cerebral Oximeters being used as demonstration and no-cap sales equipment, and these assets had a net book value of approximately \$530,000. 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, |            |
|-------------------------------------|--------------|------------|
|                                     | 2004         | 2003       |
| Patents and trademarks.....         | \$ 111,733   | \$ 111,733 |
| Less: accumulated amortization..... | (87,900)     | (80,988)   |
|                                     | -----        | -----      |
| Total.....                          | \$ 23,833    | \$ 30,745  |
|                                     | =====        | =====      |

Amortization expense was \$6,912 for the fiscal years ended November 30, 2004, November 30, 2003, and November 30, 2002. Amortization expense for each of the next three 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, worldwide, royalty-bearing licenses to specified rights relating to the CorRestore 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

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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.

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### SOMANETICS CORPORATION

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

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. In April 2004, CorRestore LLC exercised its warrant to purchase 380,000 of our newly-issued common shares, at \$3.00 per share, for proceeds of \$1,140,000.

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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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:

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### SOMANETICS CORPORATION

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

|                                     | NOVEMBER 30, |              |
|-------------------------------------|--------------|--------------|
|                                     | 2004         | 2003         |
|                                     | -----        | -----        |
| License acquisition costs.....      | \$ 1,258,163 | \$ 1,258,163 |
| Less: accumulated amortization..... | (329,070)    | (329,070)    |
|                                     | -----        | -----        |
| Total.....                          | \$ 929,093   | \$ 929,093   |
|                                     | =====        | =====        |

Indefinite lived intangible assets are reviewed annually for impairment at the end of our fiscal year, 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 years ended November 30, 2004 and November 30, 2003, include the potential dilution that could occur for common stock issuable under stock options or warrants. As of November 30, 2004 and 2003, the difference between weighted average shares - diluted and weighted average shares - basic is calculated as follows:

|                                 | 2004      | 2003      |
|---------------------------------|-----------|-----------|
|                                 | -----     | -----     |
| Weighted average shares - basic | 9,780,104 | 9,113,854 |
| Add: effect of dilutive common  |           |           |

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|                                   |            |           |
|-----------------------------------|------------|-----------|
| shares and warrants               | 1,543,168  | 352,984   |
|                                   | -----      | -----     |
| Weighted average shares - diluted | 11,323,272 | 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 year ended November 30, 2002 because such inclusion would be antidilutive. At November 30, 2004, there were approximately 500 stock options outstanding that were excluded from the computation of net income per common share - diluted, and 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. In addition, there were approximately 2,100,000 warrants outstanding that were excluded from the computation, as the warrants are contingent on achieving specified future sales targets. As of November 30, 2004, we had outstanding 4,436,315 warrants and options to purchase common shares, as of November 30, 2003, we had outstanding 5,308,819 warrants and options to purchase common shares, and as of November 30, 2002, we had outstanding 5,162,850 warrants and options to purchase common shares.

Accounting Pronouncements In December 2002, the Financial Accounting Standards Board

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### SOMANETICS CORPORATION

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

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 (Note 7).

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 123 (revised), Share Based Payment. This Statement, which is effective for interim or annual reporting periods that begin after June 15, 2005, revises Statement No. 123, "Accounting for Stock-Based Compensation," and requires that compensation costs related to share-based payment transactions, including stock options, be recognized in the financial statements. This Statement will be effective for our fiscal quarter ending November 30, 2005. We expect the equity compensation to be recognized in our statement of operations for fiscal 2005, related to unvested stock options as of our required adoption date, will be the equivalent of \$.01 per diluted common share, and we expect the impact for fiscal 2006 will be approximately \$.03 per diluted common share. The future approval of any additional equity incentive plans would have an additional 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



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assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities, and the reported amounts of revenues and expenses for each fiscal period. Actual results could differ from those estimated.

Reclassifications Certain reclassifications have been made to the financial statements for 2003 and 2002 to conform to 2004 presentation.

### 3. STOCK OFFERINGS AND COMMON SHARES

On March 6, 2000, we entered into the Private Equity Line Agreement with Kingsbridge Capital Limited, a private institutional investor, which was subsequently terminated on April 10, 2001. 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 exercise price of the warrants was 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. In March 2004, Kingsbridge Capital Limited purchased 40,000 common shares under its warrants by a cashless exercise. As a result of this cashless exercise, we issued 24,097 common shares to Kingsbridge, retaining 15,903 common shares in payment of the exercise price. In May 2004, Kingsbridge Capital Limited purchased the remaining 65,097 common shares under its warrants by a cashless exercise. As a result of this cashless exercise, we issued 47,475 common shares to Kingsbridge, retaining 17,622 common shares in payment of the exercise price. Kingsbridge now has no warrants remaining to purchase common shares.

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## SOMANETICS CORPORATION

### NOTES TO FINANCIAL STATEMENTS - (CONTINUED)

On April 9, 2001, we completed the private placement of newly-issued common shares for which Brean Murray & Co., Inc., as our exclusive placement agent, received warrants to purchase 25,000 common shares at \$2.10 per share. 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 \$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. In June 2004, Brean Murray & Co., Inc. purchased 100,000 common shares under its warrants by a cashless exercise. As a result of this cashless exercise, we issued 66,265 common shares to Brean Murray & Co., Inc., retaining 33,735 common

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shares in payment of the exercise price. Brean Murray & Co., Inc. now has no warrants remaining to purchase common shares.

Pursuant to the CorRestore License Agreement, CorRestore, LLC and its agent, Joe B. Wolfe, received warrants to purchase 400,000 common shares exercisable at \$3.00 per share until June 2, 2005, and received warrants to purchase an additional 2,100,000 common shares exercisable at \$3.00 per share until November 21, 2006, dependent upon our cumulative net sales of CorRestore products. In April 2004, CorRestore LLC exercised its warrant to purchase 380,000 of our newly-issued common shares, at \$3.00 per share, for proceeds of \$1,140,000. As of November 30, 2004, Mr. Wolfe's 20,000 warrants remain outstanding and, additionally, the 2,100,000 warrants remain outstanding, but the sales requirements for exercise of those warrants have not been met.

During fiscal 2004, we issued 321,276 common shares as a result of stock option exercises by employees, directors and former employees, for proceeds of approximately \$1,541,000. 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.

Common shares reserved for future issuance upon exercise of stock options and warrants as discussed above at November 30, 2004, are as follows:

|  |           |
|--|-----------|
| 1991 Incentive Stock Option Plan.....            | 26,618    |
| 1993 Director Stock Option Plan.....             | 500       |
| 1997 Stock Option Plan.....                      | 2,186,452 |
| Options Granted Independent of Option Plans..... | 169,786   |
| License Acquisition Warrants.....                | 2,120,000 |
|  | -----     |
| Total shares reserved for future issuance.....   | 4,503,356 |
|  | =====     |

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### SOMANETICS CORPORATION

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

#### 4. ACCRUED LIABILITIES

Accrued liabilities consist of the following:

|                             | NOVEMBER 30, |            |
|-----------------------------|--------------|------------|
|                             | 2004         | 2003       |
|                             | -----        | -----      |
| Incentive Compensation..... | \$ 390,978   | \$ 166,360 |
| Sales Commissions.....      | 153,180      | 123,356    |
| 401(k) Match.....           | 97,071       | --         |
| Professional Fees.....      | 42,000       | 10,500     |
| Warranty.....               | 10,750       | 5,850      |
| Royalty.....                | 9,130        | 13,645     |
| Insurance.....              | --           | 29,836     |
|                             | -----        | -----      |

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|            |            |            |
|------------|------------|------------|
| Total..... | \$ 703,109 | \$ 349,547 |
|            | =====      | =====      |

5. INCOME TAX

Deferred income taxes reflect the estimated future tax effect of (1) temporary differences between the amount of assets and liabilities for financial reporting purposes and such amounts as measured by tax laws and regulations and (2) net operating loss and tax credit carryforwards. Our deferred tax assets primarily represent the tax benefit of net operating loss carryforwards and research and general business tax credit carryforwards. We had deferred tax assets of approximately \$16,657,000 as of November 30, 2004, partially offset by valuation allowances of approximately \$9,957,000, due to the uncertainty of utilizing such assets against future earnings, prior to their expiration. As of November 30, 2003, we had deferred tax assets of \$17,061,000 which were entirely offset by valuation allowances, due to the uncertainty of utilizing such assets against future earnings, prior to their expiration. We have used a statutory income tax rate of 34% when calculating our deferred tax assets. We have paid no income taxes for fiscal 2004 or fiscal 2003.

The components of deferred income tax assets as of November 30, 2004 and 2003 were as follows:

|  | NOVEMBER 30,   |           |
|--|----------------|-----------|
|  | 2004           | 2003      |
|  | (IN THOUSANDS) |           |
| Net operating loss carryforwards.....                          | \$ 16,216      | \$ 16,549 |
| Other.....   | 90             | 88        |
| Basis difference of fixed assets and intangibles...            | (92)           | (19)      |
| Research and general business tax credit<br>carryforwards..... | 443            | 443       |
| Subtotal.....  | 16,657         | 17,061    |
| Valuation allowance.....                                       | (9,957)        | (17,061)  |
| Deferred tax asset.....  | \$ 6,700       | \$ --     |
|  | =====          | =====     |

SOMANETICS CORPORATION

NOTES TO FINANCIAL STATEMENTS-(CONTINUED)

The items accounting for the difference between income taxes computed at the federal statutory rate and the provision for income taxes are as follows:

|   | FOR THE FISCAL YEAR ENDED NOVEMBER 30, |           |              |
|---|--|-----------|--------------|
|   | 2004                                   | 2003      | 2002         |
|   | -----                                  | -----     | -----        |
| Taxes at U.S. statutory rate - 34%..... | \$ 682,236                             | \$ 24,679 | \$ (410,262) |

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|  |                |             |            |
|--|----------------|-------------|------------|
| Nondeductible meals and entertainment.....                   | \$ 15,109      | \$ 9,531    | \$ 7,592   |
| Change in valuation allowance.....                           | \$ (7,397,345) | \$ (34,210) | \$ 402,670 |
|  | -----          | -----       | -----      |
| Income tax expense (benefit) from continuing operations..... | \$ (6,700,000) | \$ -        | \$ -       |
|  | =====          | =====       | =====      |
| Effective tax rate.....                                      | (333.9)%       | 0%          | 0%         |
|  | =====          | =====       | =====      |

For the fiscal year ended November 30, 2004, our income tax benefit of \$6,700,000 consisted entirely of deferred tax benefits. We had no current or deferred income tax expense or benefit for the fiscal years ended November 30, 2003 or 2002.

We have performed the required assessment of positive and negative evidence regarding realization of our deferred tax assets in accordance with SFAS No. 109, "Accounting for Income Taxes," including our past operating results, the existence of cumulative losses over our history up to the most recent two fiscal years, and our forecast for future net income. Our assessment of our deferred tax assets, and the reversal of part of our valuation allowance, included evaluating our financial plans and our future projected earnings, making allowance for the uncertainties surrounding, among other things, our future rate of growth in net revenues, the rate of adoption of our products in the marketplace, and the potential for competition to enter the marketplace. In reversing a portion of our valuation allowance, we have concluded that it is more likely than not that our net deferred tax assets will be realized.

As of November 30, 2004, net operating loss carryforwards of approximately \$47.7 million were available for Federal income tax purposes for future years. 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 2004 through 2024.

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.

6. 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, 2009.

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SOMANETICS CORPORATION

NOTES TO FINANCIAL STATEMENTS-(CONTINUED)

Operating lease expense for the years ended November 30, 2004, 2003 and 2002 was approximately \$204,000, \$216,000, and \$205,000, respectively. Approximate future minimum lease commitments are as follows:

YEAR ENDED NOVEMBER 30,  
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|            |    |         |
|------------|----|---------|
| 2005.....  | \$ | 140,400 |
| 2006.....  | \$ | 140,400 |
| 2007.....  | \$ | 142,900 |
| 2008.....  | \$ | 145,800 |
| 2009.....  | \$ | 148,700 |
| 2010.....  | \$ | 12,400  |
|            |    | -----   |
| Total..... | \$ | 730,600 |
|            |    | =====   |

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 25% of their compensation. In November 2004, our Board of Directors approved a discretionary contribution to the 401(k) Plan, as soon as practicable after December 31, 2004, equal to \$2 for every \$1 contributed by Company employees to the 401(k) Plan during calendar 2004, up to a Company contribution of 4% of the employee's compensation, and also approved matching contributions to the 401(k) Plan equal to \$2 for every \$1 contributed by Company employees to the 401(k) Plan at each payroll date on or after January 1, 2005, up to a Company contribution of 4% of the employee's compensation, and continuing until terminated by further action of the Board of Directors. In addition, at the discretion of the Board of Directors, we may make other annual discretionary contributions to the plan. The discretionary contribution made in February 2005, for calendar 2004, was approximately \$113,000. We did not make any matching or discretionary contributions to the plan for the years ended November 30, 2003 or 2002.

As of November 30, 2004, 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, 2004, 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.

7. 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-

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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, 2004, 2003 and 2002 are listed below.

At November 30, 2004, no additional options may be granted under the 1991 plan, and 67,041 common shares were available for options to be granted under the 1997 plan.

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

In October 1995, SFAS No. 123, "Accounting for Stock-Based Compensation," was issued. In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 123 (revised), Share Based Payment. This Statement, which is effective for interim or annual reporting periods that begin after June 15, 2005, revises Statement No. 123, "Accounting for Stock-Based Compensation," and requires that compensation costs related to share-based payment transactions, including stock options, be recognized in the financial statements. This Statement will be effective for our fiscal quarter ending November 30, 2005.

We currently 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, and \$5,597 of compensation expense in fiscal 2002. We recorded no such expense in fiscal 2004.

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 NOVEMBER 30, |           |                |
|------------------------|--|-----------|----------------|
|                        | 2004                                   | 2003      | 2002           |
| Net income (loss)..... | \$ 8,706,576                           | \$ 72,586 | \$ (1,206,652) |

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|   |    |           |    |           |    |             |
|---|----|-----------|----|-----------|----|-------------|
| Add: Stock-based employee compensation included in actual net income (loss).....                | \$ | 0         | \$ | 8,471     | \$ | 5,597       |
| Deduct: Pro-forma stock-based employee compensation, had fair value method been applied.....    | \$ | (796,000) | \$ | (962,000) | \$ | (760,000)   |
| Pro-forma net income (loss).....  | \$ | 7,911,576 | \$ | (880,943) | \$ | (1,961,055) |
| Net income (loss) per common share - diluted.....   | \$ | .77       | \$ | .01       | \$ | (.13)       |
| Pro-forma net income (loss) per common share - diluted, had fair value method been applied..... | \$ | .70       | \$ | (.09)     | \$ | (.22)       |

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 2004, 2003 and 2002: expected volatility (the measure by which the stock price has fluctuated or is expected to fluctuate during the period) 61.00% for 2004 (64.32% for 2003 and 89.45% for 2002), risk-free interest rate of 4.0% for 2004 (4.0% for 2003 and 2002), expected lives of 7 years for fiscal 2004 (7 years for 2003 and 4 years for 2002) and dividend yield of 0%.

A summary of our stock option activity and related information for the years ended November 30, 2004, 2003 and 2002 is as follows:

|                        | 2004          |                                 | 2003          |                                 |               |
|------------------------|---------------|---------------------------------|---------------|---------------------------------|---------------|
|                        | COMMON SHARES | WEIGHTED AVERAGE EXERCISE PRICE | COMMON SHARES | WEIGHTED AVERAGE EXERCISE PRICE | COMMON SHARES |
| Options outstanding    |               |                                 |               |                                 |               |
| December 1,.....       | 2,603,722     | \$ 3.89                         | 2,332,753     | \$ 4.04                         | 1,846,1       |
| Options granted.....   | 53,500        | 10.23                           | 471,000       | 3.75                            | 509,5         |
| Options exercised..... | (321,276)     | 4.79                            | (148,371)     | 3.63                            | (2,8          |
| Options canceled.....  | (19,631)      | 13.94                           | (51,660)      | 10.08                           | (20,0         |
| Options outstanding    |               |                                 |               |                                 |               |
| November 30,.....      | 2,316,315     | 3.83                            | 2,603,722     | 3.89                            | 2,332,7       |
| Options exercisable    |               |                                 |               |                                 |               |
| November 30,.....      | 1,827,008     | \$ 3.91                         | 1,784,482     | \$ 4.27                         | 1,606,7       |

SOMANETICS CORPORATION

NOTES TO FINANCIAL STATEMENTS-(CONTINUED)

A summary of the price ranges of our stock options outstanding and exercisable as of November 30, 2004 is as follows:

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| RANGE OF EXERCISE PRICES | Options outstanding    |  |  | Options exercisable    |  |
|--------------------------|------------------------|--|--|------------------------|--|
|                          | OPTIONS<br>OUTSTANDING | WEIGHTED<br>AVERAGE<br>EXERCISE<br>PRICE | WEIGHTED<br>AVERAGE<br>REMAINING<br>LIFE (YEARS) | OPTIONS<br>EXERCISABLE | WEIGHTED<br>AVERAGE<br>EXERCISE<br>PRICE |
| \$1.70 - \$5.00.....     | 1,837,904              | \$ 3.18                                  | 6.47   | 1,385,097              | \$ 3.09                                  |
| \$5.01 - \$10.00.....    | 422,811                | 5.95                                     | 3.46   | 402,811                | 5.86                                     |
| \$10.01 - \$26.30.....   | 55,600                 | 12.43                                    | 5.67   | 39,100                 | 12.79                                    |
| Total.....               | 2,316,315              | \$ 3.91                                  | 5.90   | 1,827,008              | \$ 3.91                                  |

8. RELATED PARTY TRANSACTIONS

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 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 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. In June 2004, Brean Murray & Co., Inc. purchased 100,000 common shares under its warrants by a cashless exercise. As a result of this cashless exercise, we issued 66,265 common shares to Brean Murray & Co., Inc., retaining 33,735 common shares in payment of the exercise price. Brean Murray & Co., Inc. now has no warrants remaining to purchase common shares.

9. MAJOR CUSTOMERS AND FOREIGN SALES

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

Additionally, foreign net revenues for the fiscal year ended November 30, 2004 were approximately \$2,092,000, for the fiscal year ended November 30, 2003 were approximately \$1,945,000, and for the fiscal year ended November 30, 2002 were approximately \$1,348,000.



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### 10. 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 96% of our net revenues in fiscal 2004 were derived from our INVOS Cerebral Oximeter product line, compared to 92% of our net revenues in fiscal 2003 and 96% of our net revenues in fiscal 2002.

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### QUARTERLY INFORMATION (UNAUDITED)

The following is a summary of our quarterly operating results for the fiscal years ended November 30, 2004 and 2003:

|   | QUARTER                               |             |             |             |
|---|---------------------------------------|-------------|-------------|-------------|
|   | FIRST                                 | SECOND      | THIRD       | FOURTH      |
|   | (IN THOUSANDS, EXCEPT PER SHARE DATA) |             |             |             |
| YEAR ENDED NOVEMBER 30, 2004                  |                                       |             |             |             |
| Net revenues.....                             | \$2,670,265                           | \$3,032,976 | \$3,076,373 | \$3,829,001 |
| Gross margin.....                             | 2,149,872                             | 2,513,660   | 2,632,536   | 3,262,294   |
| Net income.....                               | 292,744                               | 409,730     | 539,722     | 7,464,380*  |
| Net income per common<br>share - basic.....   | \$ 0.03                               | \$ 0.04     | \$ 0.05     | \$ 0.74     |
| Net income per common<br>share - diluted..... | \$ 0.03                               | \$ 0.04     | \$ 0.05     | \$ 0.64     |

-----  
\*Includes the effects of a reversal of \$6,700,000 of our valuation allowance, as described in Note 5 of Notes to Financial Statements.

#### YEAR ENDED NOVEMBER 30, 2003

|   |             |             |             |             |
|---|-------------|-------------|-------------|-------------|
| Net revenues.....                                       | \$1,950,946 | \$2,203,442 | \$2,303,880 | \$2,902,625 |
| Gross margin.....                                       | 1,500,749   | 1,642,246   | 1,784,335   | 2,293,736   |
| Net income (loss).....                                  | (195,450)   | (129,373)   | 75,454      | 321,955     |
| Net income (loss) per<br>common share -<br>basic.....   | \$ (0.02)   | \$ (0.01)   | \$ 0.01     | \$ 0.04     |
| Net income (loss) per<br>common share -<br>diluted..... | \$ (0.02)   | \$ (0.01)   | \$ 0.01     | \$ 0.03     |

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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, 2004, 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, 2004. 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, 2004 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.

### ITEM 9B. OTHER INFORMATION

None.

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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 2005 Annual Meeting of Shareholders scheduled to be held April 21, 2005, 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 2005 Annual Meeting of Shareholders scheduled to be held April 21, 2005, 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 Business Conduct and Ethics" in our Proxy Statement in connection with the 2005 Annual Meeting of Shareholders scheduled to be held April 21, 2005, and is incorporated in this Item 10 by reference.

### ITEM 11. EXECUTIVE COMPENSATION

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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 2005 Annual Meeting of Shareholders scheduled to be held April 21, 2005, 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 2005 Annual Meeting of Shareholders scheduled to be held April 21, 2005, 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 2005 Annual Meeting of Shareholders scheduled to be held April 21, 2005, 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 2005 Annual Meeting of Shareholders scheduled to be held April 21, 2005, 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 2005 Annual Meeting of Shareholders scheduled to be held April 21, 2005, and is incorporated in this Item 14 by reference.

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## PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

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

Report of Independent Registered Public Accounting Firm  
Balance Sheets - November 30, 2004 and 2003  
Statements of Operations - For Each of the Three Years in the Period  
Ended November 30, 2004  
Statements of Shareholders' Equity - For Each of the Three Years in  
the Period Ended November 30, 2004  
Statements of Cash Flows - For Each of the Three Years in the Period  
Ended November 30, 2004  
Notes to Financial Statements

#### (2) Financial Statement Schedules

None.

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### (3) Exhibits

The Exhibits to this Report are as set forth in the "Index to Exhibits" on pages 61 to 63 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.

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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.

Somanetics Corporation

Date: February 18, 2005

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>-----   | Date<br>----      |
|--|--|-------------------|
| /s/ Bruce J. Barrett<br>-----<br>Bruce J. Barrett            | President and Chief Executive Officer<br>and a Director (Principal Executive<br>Officer)                                   | February 18, 2005 |
| /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) | February 22, 2005 |
| /s/ Daniel S. Follis<br>-----<br>Daniel S. Follis            | Director   | February 18, 2005 |
| /s/ James I. Ausman<br>-----<br>James I. Ausman, M.D., Ph.D. | Director   | February 19, 2005 |
| /s/ Robert R. Henry<br>-----<br>Robert R. Henry              | Director   | February 18, 2005 |
| /s/ Joe B. Wolfe<br>-----<br>Joe B. Wolfe                    | Director   | February 18, 2005 |

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## EXHIBIT INDEX

| EXHIBIT | DESCRIPTION  |
|---------|--|
| 3(i)    | Restated Articles of Incorporation of Somanetics Corporation, incorporated by reference to Exhibit 3(i) to the Company's Quarterly Report on Form 10-Q for the quarter ended February 28, 1998.  |
| 3(ii)   | Amended and Restated Bylaws of Somanetics Corporation, incorporated by reference to Exhibit 3(ii) to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 2003.   |
| 10.1    | Lease Agreement, dated September 10, 1991, between Somanetics Corporation and WS Development Company, incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended August 31, 1991.  |
| 10.2    | Extension of Lease, between Somanetics Corporation and WS Development Company, dated July 22, 1994, incorporated by reference to Exhibit 10.11 to the Company's Quarterly Report on Form 10-Q for the quarter ended August 31, 1994.   |
| 10.3    | Change in ownership of Lease Agreement for 1653 E. Maple Road, Troy, MI 48083, dated September 12, 1994, between Somanetics Corporation and First Industrial, L.P., incorporated by reference to Exhibit 10.12 to the Company's Quarterly Report on Form 10-Q for the quarter ended August 31, 1994. |
| 10.4    | Second Addendum, between Somanetics Corporation and First Industrial Mortgage Partnership, L.P., dated April 14, 1997, incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended May 31, 1997.  |
| 10.5    | Third Amendment, between Somanetics Corporation and First Industrial Mortgage Partnership, L.P., dated April 23, 1999, incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended May 31, 1999.  |
| 10.6    | Fourth Amendment, between Somanetics Corporation and First Industrial Mortgage Partnership, L.P., dated April 13, 2000, incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended May 31, 2000.   |
| 10.7    | 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    | Sixth Amendment, between Somanetics Corporation and  |

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First Industrial Mortgage Partnership, L.P., dated April 21, 2004, incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended May 31, 2004.

- \*10.9 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.
- \*10.10 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.
- \*10.11 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.
- \*10.12 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.
- \*10.13 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.
- \*10.14 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.
- \*10.15 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.

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### EXHIBIT INDEX

| EXHIBIT | DESCRIPTION  |
|---------|--|
| *10.16  | 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.  |
| *10.17  | 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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- \*10.18 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.
- \*10.19 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.
- \*10.20 Somanetics Corporation 2004 Incentive Compensation Plan, dated as of December 12, 2003, incorporated by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 2003.
- \*10.21 Somanetics Corporation 2005 Incentive Compensation Plan, dated as of November 9, 2004, incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, dated November 9, 2004 and filed November 12, 2004.
- \*10.22 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.
- \*10.23 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.
- \*10.24 Amendment to Employment Agreement, dated as of April 24, 1997, between Somanetics Corporation and Bruce J. Barrett, incorporated by reference to Exhibit 10.21 to Amendment No. 1 to the Registration Statement on Form S-1 (file no. 333-25275), filed with the Securities and Exchange Commission on May 30, 1997.
- \*10.25 Amendment to Employment Agreement, dated as of April 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.
- \*10.26 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.
- \*10.27 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.
- \*10.28 Employment Agreement, dated August 1, 2002, between Somanetics Corporation and Dominic J. Spadafore, incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended August 31, 2002.

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- \*10.29 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.
- \*10.30 Form of Director Stock Option Agreement.
- \*10.31 Form of Officer Non-Qualified Stock Option Agreement.
- \*10.32 Form of Employee Non-Qualified Stock Option Agreement.
- \*10.33 Form of Incentive Stock Option Agreement.

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### EXHIBIT INDEX

| EXHIBIT | DESCRIPTION   |
|---------|---|
| *10.34  | Form of Stock Option Agreement, dated December 22, 1995, between Somanetics Corporation and various employees, incorporated by reference to Exhibit 10.29 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1995.  |
| *10.35  | Form of Stock Option Agreement, dated December 22, 1995, between Somanetics Corporation and various officers, incorporated by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1995.   |
| *10.36  | Form of new Stock Option agreement, dated December 22, 1995, between Somanetics Corporation and various employees, incorporated by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1995.  |
| *10.37  | Form of Stock Option Agreement, dated January 5, 1996, between Somanetics Corporation and two officers, incorporated by reference to Exhibit 10.32 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1995.   |
| *10.38  | Form of Stock Option Agreement, dated as of April 24, 1997, between Somanetics Corporation and twenty-three employees, incorporated by reference to Exhibit 10.32 to Amendment No. 1 to the Registration Statement on Form S-1 (file no. 333-25275), filed with the Securities and Exchange Commission on May 30, 1997. |
| *10.39  | 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.  |



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- \*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 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.
- 10.44 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.
- 10.45 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, incorporated by reference to Exhibit 14.1 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 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.

