

SOMANETICS CORP  
Form 10-K  
February 08, 2007

**Table of Contents**

**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, 2006 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 number 0-19095  
SOMANETICS CORPORATION**

(Exact name of registrant as specified in its charter)

**MICHIGAN**

(State or other jurisdiction of  
incorporation or organization)

**38-2394784**

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

**1653 East Maple Road, Troy, Michigan**

(Address of principal executive offices)

**48083-4208**

(Zip Code)

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

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

Title of each class	Name of each exchange on which registered
<b>Common Shares, par value \$.01 per share</b>	<b>The Nasdaq Stock Market</b>

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No .

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No .

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 a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer" and "large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Edgar Filing: SOMANETICS CORP - Form 10-K

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No .

The aggregate market value of the common shares held by non-affiliates of the registrant as of May 31, 2006 (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 \$198,880,000.

The number of the registrant's common shares outstanding as of February 8, 2007 was 13,165,127.

**Documents Incorporated by Reference**

Portions of the Proxy Statement for the 2007 Annual Meeting of Shareholders, scheduled to be held April 19, 2007, are incorporated by reference in Part III, if the Proxy Statement is filed no later than March 30, 2007.

---

**SOMANETICS CORPORATION  
ANNUAL REPORT ON FORM 10-K  
FOR THE FISCAL YEAR ENDED NOVEMBER 30, 2006  
TABLE OF CONTENTS**

	PAGE
<u>PART I</u>	2
<u>ITEM 1. BUSINESS</u>	2
<u>ITEM 1A. RISK FACTORS</u>	20
<u>ITEM 1B. UNRESOLVED STAFF COMMENTS</u>	32
<u>ITEM 2. PROPERTIES</u>	32
<u>ITEM 3. LEGAL PROCEEDINGS</u>	32
<u>ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</u>	32
<u>SUPPLEMENTAL ITEM. EXECUTIVE OFFICERS OF THE REGISTRANT</u>	33
 <u>PART II</u>	 34
<u>ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	34
<u>ITEM 6. SELECTED FINANCIAL DATA</u>	36
<u>ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	37
<u>ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	48
<u>ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	49
<u>ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	68
<u>ITEM 9A. CONTROLS AND PROCEDURES</u>	68
<u>ITEM 9B. OTHER INFORMATION</u>	69
 <u>PART III</u>	 70
<u>ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	70
<u>ITEM 11. EXECUTIVE COMPENSATION</u>	70
<u>ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	70
<u>ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>	70
<u>ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	71
 <u>PART IV</u>	 72
<u>ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES</u>	72
<u>Code of Business Conduct and Ethics</u>	
<u>Consent of Deloitte &amp; Touche LLP</u>	
<u>Certification of Chief Executive Officer Pursuant to Section 302</u>	
<u>Certification of Chief Financial Officer Pursuant to Section 302</u>	
<u>Certifications of Chief Executive Officer &amp; Chief Financial Officer Pursuant to Section 906</u>	



**Table of Contents**

**PART I**

**ITEM 1. BUSINESS**

**Overview**

We develop, manufacture and market the INVOS System, a non-invasive patient monitoring system that continuously measures changes in the blood oxygen levels in the brain and elsewhere in the body in somatic, or skeletal muscle, tissue in patients with or at risk for restricted blood flow. The brain is the organ least tolerant of oxygen deprivation. Without sufficient oxygen, brain damage may occur within minutes, which can result in paralysis, other 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. The INVOS System consists of a portable monitoring system, including proprietary software, which is used with multiple single-use disposable sensors, called SomaSensors. During our fiscal year ended November 30, 2006, net revenues from SomaSensors comprised approximately 75 percent of our net revenues. As of November 30, 2006, we had an installed base of 1,497 INVOS System monitors in the United States in 584 hospitals, and during fiscal 2006 we sold approximately 289,000 SomaSensors worldwide.

Clinical studies have shown that using the INVOS System to monitor and provide information to help manage the regional brain blood oxygen saturation of patients is associated with significantly fewer incidences of major organ dysfunction, which can significantly improve patient outcomes and reduce hospital costs. During fiscal 2004, the results of the first prospective, randomized, blinded intervention trial were presented, and the results were published in the January 2007 issue of a peer-reviewed anesthesia journal. The study showed that when the INVOS System was used to monitor and provide information to help manage the regional brain blood oxygen saturation of coronary artery bypass surgery patients, the occurrence of major organ morbidity or mortality was reduced from 11 percent to three percent and patients with major organ morbidity or mortality have significantly longer length of stay in the intensive care unit than those without. Additionally, in 2004, the results of a large retrospective review showed a statistically significant greater than 50 percent reduction (2.01 percent versus 0.97 percent) in the incidence of permanent stroke when information from the INVOS System was used to help manage brain blood oxygen saturation of cardiac surgery patients. The results also showed a reduced length of hospital stay and reduced incidence of prolonged ventilation when the INVOS System was used.

Our INVOS System has U.S. Food and Drug Administration, or FDA, clearance in the United States for use on adults, children and infants. We target the sale of the INVOS System for use in surgical procedures and other critical care situations with a high risk of oxygen imbalances. We initially focused our marketing efforts primarily on adult and pediatric cardiac surgeries and carotid artery surgeries. In the first quarter of fiscal 2005, we initiated selling and marketing efforts for the INVOS System in the pediatric ICU. We plan to launch the product into the neonatal ICU in 2007, after completing development of a smaller SomaSensor. Some of our potential future markets may include major surgeries involving diabetic and elderly patients. While our initial focus has been commercializing the INVOS System to measure blood oxygen saturation changes in the brain, we believe that there are opportunities to use the INVOS System in regions of the body other than the brain. In November 2005, we received 510(k) clearance from the FDA to market our INVOS System to monitor changes in blood oxygen saturation elsewhere in the body in somatic, or skeletal muscle, tissue in patients with or at risk for restricted blood flow. Our next generation INVOS System monitor, which we launched in the second quarter of 2006, can display information from four SomaSensors, which allows for the simultaneous monitoring of changes in blood oxygen saturation in the brain and, in patients with or at risk for restricted blood flow, in somatic tissue.

We are currently sponsoring a prospective, randomized, blinded clinical trial involving diabetic patients over age 50 who are undergoing major general surgery. The study group will consist of patients whose surgeries are managed based on information provided by the INVOS System, and the control group will consist of similarly situated patients whose surgeries are not managed based on information provided by the INVOS System. The two groups will be compared across measures of patient outcomes and hospital costs, including length of hospital stay. Diabetics are at particular risk of oxygen imbalances because of a higher incidence of vascular disease. If results of this trial are positive, we intend to target more actively the sale of the INVOS System for use in diabetic patients undergoing major general surgeries, consistent with FDA requirements. We expect to begin this marketing in 2009.

We are also evaluating sponsorship of other clinical trials which may allow us to more actively target the sale of the

2

---

**Table of Contents**

INVOS System for use in other patient populations. There are also numerous other independent clinical studies evaluating the use of the INVOS System.

We sell the INVOS System through a direct sales team in the United States, consisting of salespersons and clinical specialists, the size of which has increased from 26 persons at the end of fiscal 2005 to 44 persons at the end of fiscal 2006, and six independent sales representative firms. Outside the United States, we market the INVOS System through independent distributors, including Tyco Healthcare in Europe, Canada, the Middle East and Africa, and Edwards Lifesciences Ltd. in Japan. We expect to increase the size of our U.S. direct sales team in fiscal 2007 and are evaluating placing direct salespersons and clinical specialists in Europe to support Tyco Healthcare. Our net revenues have increased from \$12.6 million in the fiscal year ended November 2004 to \$28.7 million in fiscal 2006, representing a compounded annual growth rate of 50.9 percent. As a percentage of net revenues, our gross margin improved from 84 percent in fiscal 2004 to 88 percent in fiscal 2006.

**Our Corporate Information**

We were incorporated under the laws of the State of Michigan in 1982. Our principal executive offices are located at 1653 East Maple Road, Troy, Michigan 48083-4208, and our telephone number is (248) 689-3050. Our website address is [www.somanetics.com](http://www.somanetics.com). The information on, or that can be accessed through, our website is not a part of this report. Unless the context indicates otherwise, as used in this report, the terms Somanetics, Somanetics Corporation, the Company, we, us and our refer to Somanetics Corporation, a Michigan corporation.

Somanetics®, INVOS®, SomaSensor®, Window to the Brain® and CorRestore® are our registered trademarks. Each of the other trademarks, trade names or service marks appearing in this report belongs to its respective holder.

**Industry**

***Market Opportunity***

We believe that in the United States in 2007 there will be approximately five million surgeries involving elderly patients who, due to the type of surgery, age of the patient or other factors, have a higher risk of developing post-operative complications. Such surgeries include cardiac surgeries, carotid surgeries and other major general surgeries involving elderly patients. In addition, we believe that there are other patient populations, such as non-elderly adult, pediatric and neonatal patients, undergoing major surgeries and patients undergoing ICU treatment or in other critical care situations that face a high risk of brain oxygen imbalances.

Hospitals in the United States have economic incentives to control health care costs. They often receive a fixed fee from Medicare, managed care organizations and private insurers based on the disease diagnosed, rather than on the services actually performed. Therefore, hospitals are increasingly focused on avoiding unexpected costs, such as those associated with increased hospital stays of patients with brain or other organ damage or other adverse outcomes following surgery or ICU treatment. The costs to the health care system associated with adverse surgical and ICU outcomes and lengthened hospital stays can be significant. In addition, lack of immediate knowledge about blood oxygen levels in areas such as the brain or somatic tissue can result in unnecessary medical treatments and associated costs. With the increasing focus by hospitals on avoiding unexpected costs, especially in the operating room, ICU and other critical care areas, we believe that there are significant incentives to evaluate and adopt new monitoring technologies which could provide information to improve patient care and reduce costs.

***Brain Oxygen Imbalances and Its Effects***

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.

The brain is the human organ least tolerant of oxygen deprivation. Without sufficient oxygen, brain damage may occur within minutes, which can result in paralysis, severe and complex disabilities, or death.



**Table of Contents**

Undetected brain hypoxia, which is a condition in which there is a decrease of oxygen supply to the brain even though there is adequate blood flow, and ischemia, a condition in which blood flow, and thus oxygen, is restricted to a part of the body, are common causes of brain damage and death during and after many surgical procedures and in other critical care situations.

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. Once alerted to these imbalances, medical professionals can use this and other information to take corrective action through the introduction of medications, anesthetic agents or mechanical intervention, potentially improving patient outcomes 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 in an attempt to ensure adequate brain oxygen levels and may have an adverse impact on patient safety and increase hospital costs.

***Limitations of Traditional Monitoring Technologies***

We believe that it is uncommon for patients undergoing surgery to receive any sort of direct neuromonitoring of brain blood oxygen saturation, in part due to some of the shortcomings of the traditional technologies. When patients are monitored directly, 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.

**Our Solution**

Our INVOS System is a non-invasive patient monitoring system that provides continuous information about changes in blood oxygen saturation levels. We believe that our INVOS System addresses the market's need for a solution that is non-invasive, continuous, immediate, effective and easy to use. The INVOS System, which is predominantly used in hospital critical care areas such as operating rooms and ICUs, consists of a portable monitoring system, including proprietary software, which is used with multiple single-use disposable SomaSensors. For multi-channel cerebral monitoring, SomaSensors are placed on both sides of a patient's forehead and are connected to the monitor. The INVOS System uses our proprietary software to analyze information received from the SomaSensors and provides a continuous digital and trend display of an index of the blood oxygen saturation in the area of the body under the SomaSensors. Our next generation INVOS System monitor, which we launched in the second quarter of 2006, can display information from four SomaSensors, which allows for the simultaneous monitoring of changes in blood oxygen saturation in the brain and, in patients with or at risk for restricted blood flow, in somatic tissue.

Surgeons, anesthesiologists and other medical professionals can use the information provided by the INVOS System, in conjunction with other available information, to identify brain oxygen imbalances and take necessary corrective action, potentially improving patient outcomes and reducing the costs of care. Once the cause of a cerebral oxygen imbalance is identified and therapy is initiated, the INVOS System 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.

**Table of Contents**

Unlike some existing monitoring methods, the INVOS System functions even when the patient is unconscious, lacks a strong peripheral pulse or has suppressed neural activity. The measurement made by the INVOS System is dominated by information from the blood in the veins, where the balance of oxygen supply and demand can be more effectively assessed. 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 INVOS System responds to global changes in brain oxygen levels and to events that affect brain oxygen levels in the region beneath the SomaSensor.

The following table summarizes some of the principal features and related benefits of the INVOS System :

<b>Features</b>	<b>Benefits</b>
Non-invasive	<ul style="list-style-type: none"> <li>Reduced risk to patients and medical professionals</li> <li>Consistent with market trend toward less invasive medical procedures</li> </ul>
Continuous Information	<ul style="list-style-type: none"> <li>Immediate information regarding brain oxygen imbalances to help guide therapeutic interventions</li> <li>Trend information, rather than at a single point in time</li> </ul>
4-Channel Monitoring	<ul style="list-style-type: none"> <li>Simultaneous cerebral and somatic tissue monitoring</li> <li>Provides more data points to help manage patient care</li> </ul>
Cost-Effective	<ul style="list-style-type: none"> <li>Low cost relative to traditional brain monitoring methods</li> <li>Small portion of the total cost of the procedures in which it is used</li> <li>Information can potentially improve patient outcomes and reduce the overall cost of care</li> </ul>
Easy to Use	<ul style="list-style-type: none"> <li>Does not require a dedicated technician to operate or interpret</li> <li>Automatic SomaSensor calibration</li> <li>Simple user interface and controls</li> </ul>
Effective in Difficult Circumstances	<ul style="list-style-type: none"> <li>Provides information when the patient is unconscious, lacks a strong peripheral pulse or has suppressed neural activity, specifically during cardiac arrest, hypothermia, hypertension, hypotension and hypovolemia</li> </ul>
Portable/Compatible	<ul style="list-style-type: none"> <li>Placed at patient's bedside</li> <li>Lightweight</li> <li>Can be integrated or interfaced with existing multi-modality systems</li> </ul>

**The CorRestore System**

In addition to the INVOS System, we also develop and market the CorRestore System, which includes a cardiac implant, which we call the CorRestore Patch, 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. Sales of CorRestore Systems represented one percent of our fiscal 2006 net revenues.

**Business Strategy**

Our objective is to establish the INVOS System as a standard of care in surgical procedures requiring general anesthesia and in other critical care situations. Key elements of our strategy include to:

*Target Surgical Procedures and Other Critical Care Situations with a High Risk of Oxygen Imbalances.* We target surgical procedures and other critical care situations with a high risk of oxygen imbalances. Some of our current and potential future markets include cardiac surgeries, carotid artery surgeries, pediatric and neonatal ICU applications and other major surgeries involving diabetic or elderly patients. We believe that the medical professionals involved in these surgeries and ICU treatments are most aware of

**Table of Contents**

the risks of brain and other damage resulting from oxygen imbalances. Therefore, we believe that it will be easier to demonstrate the clinical importance of the information provided by the INVOS System to these professionals and potentially gain market acceptance for our products in connection with these surgeries and ICU treatments.

***Sponsor Clinical Studies to Promote Expanded Acceptance of the INVOS System.*** We believe that our INVOS System has been evaluated in over 400 presentations, study abstracts and published papers. During the second quarter of fiscal 2004, results of both the first prospective, randomized clinical trial and a larger retrospective review evaluating the INVOS System were presented, which we believe have contributed to the INVOS System gaining further market penetration. In addition, in January 2007 the results of the first prospective, randomized clinical trial mentioned above were published in a peer-reviewed anesthesia journal. We plan to sponsor clinical studies using the INVOS System to demonstrate its benefits. We are currently sponsoring a prospective, randomized, blinded clinical trial involving diabetic patients over age 50 who are undergoing major general surgery. The study group will consist of patients whose surgeries are managed based on information provided by the INVOS System, and the control group will consist of similarly situated patients whose surgeries are not managed based on information provided by the INVOS System. The two groups will be compared across measures of patient outcomes and hospital costs, including length of hospital stay. Diabetics are at particular risk of oxygen imbalances because of a higher incidence of vascular disease. If results of this trial are positive, we intend to target more actively the sale of the INVOS System for use in diabetic patients undergoing major general surgeries, consistent with FDA requirements. We expect to begin this marketing in 2009. We are also evaluating sponsorship of other clinical trials which may allow us to more actively target the sale of the INVOS System for use in other patient populations. We use the results of clinical studies to help convince the medical community of the clinical importance of the information provided by the INVOS System. We also sponsor peer-to-peer educational opportunities and promote use of the INVOS System in regional centers of influence that we believe will influence its adoption by others.

***Invest in Sales and Marketing Activities.*** We continue to increase our investment in our distribution network consisting of our direct sales employees, independent sales representative firms and distributors. We sell the INVOS System through a direct sales team in the United States, the size of which has increased from 26 persons at the end of fiscal 2005 to 44 persons at the end of fiscal 2006, and six independent sales representative firms. We expect to increase the size of our U.S. direct sales team in fiscal 2007 and are evaluating placing direct salespersons and clinical specialists in Europe to support Tyco Healthcare. We also have a co-promotion relationship with Fresenius Medical Care Cardiovascular Resources, Inc.'s North American Extracorporeal Alliance. We participate in trade shows and medical conferences, ongoing peer-to-peer educational programs and targeted public relations opportunities.

***Interface and Integrate Our Technology into Other Manufacturers' Multi-Modality Systems.*** There are many existing monitoring systems in the operating room and the ICU. We would like to interface with these monitors. We have interfaced the INVOS System with the Philips Medical Systems' VueLink System to provide data, alarm events and status messages from the INVOS System on any monitor that accepts the VueLink module, a multi-parameter monitor. This enables oximetry data from our INVOS System to be displayed on the VueLink screen and integrated with other vital patient information. We plan to support the interface and integration of our INVOS System technology with other medical device manufacturers to expand the installed base of INVOS System monitors and increase the demand for SomaSensors. We expect that such arrangements will provide another distribution channel for our INVOS System.

***Develop Additional Applications and Markets for the INVOS System.*** We are developing a smaller SomaSensor for use with newborns, and making other advances to the design and performance features of the INVOS System, including the SomaSensor. We are also evaluating additional potential market segments for our INVOS System, such as use in other major surgeries, in the adult ICU, and for other somatic applications

of the technology. We are also exploring several novel near-infrared spectroscopy and imaging technologies and products under a Contract Development and Exclusive Licensing Agreement with NeuroPhysics Corporation. See NeuroPhysics Corporation below. Pursuit of some of these potential market segments may require additional FDA clearance. We believe that these natural extensions

**Table of Contents**

of our technology will increase our market potential without the more significant risks and costs associated with developing entirely new products.

**The INVOS System**

***Components of the INVOS System***

The INVOS System consists of a portable monitoring system, including proprietary software, which is used with multiple single-use disposable SomaSensors.

***Monitor and Software.*** Our oximeter is a portable monitor that uses our proprietary software to analyze information received from the SomaSensors. It provides a continuous digital and trend display of an index of the oxygen saturation in the region of the body under the SomaSensors. The monitor includes menus for users to set high and low audible alarms, customize the display and retrieve data. Single-function keys allow users to silence alarms, mark important events, store data for up to 28 surgical procedures, and retrieve data by disk or through a USB link to a computer. Our next generation INVOS System monitor, which we launched in the second quarter of 2006, measures approximately 11 inches wide, 9 inches high, and 7 inches deep and weighs approximately 11 pounds. We provide a one-year warranty on the monitor, and we offer service for the monitor for a fee after the warranty expires. As of November 30, 2006, we had an installed base of 1,497 INVOS System monitors in the United States in 584 hospitals.

***SomaSensors.*** Each single-use SomaSensor contains a light source and two light detectors. For multi-channel cerebral monitoring, SomaSensors are placed on both sides of a patient's forehead and are connected to the monitor, which allows for monitoring both sides of the brain. Our next generation INVOS System monitor, which we launched in the second quarter of 2006, can display information from four SomaSensors, which allows for the simultaneous monitoring of changes in blood oxygen saturation in the brain and, in patients with or at risk for restricted blood flow, in somatic tissue. The number of sensors used depends on the application. The INVOS System is being used to monitor simultaneously the brain and somatic tissue initially for patients in the pediatric and neonatal ICU, and we expect that it will later also be used on adults and for monitoring somatic tissue alone. The SomaSensors contain information that is processed by the INVOS System allowing it to automatically calibrate each sensor. During our fiscal year ended November 30, 2006, net revenues from SomaSensors comprised approximately 75 percent of our net revenues. During fiscal 2006 we sold approximately 289,000 SomaSensors worldwide.

***Overview of 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, scattered by 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 of each, 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, traditional 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.

We have developed a method of reducing extraneous spectroscopic data caused by surrounding bone, muscle and other tissue. This method, which is embedded in our INVOS System, allows us to gather information about portions of the body that previously could not be analyzed using traditional optical spectroscopy. The INVOS System measurement is made by our SomaSensors transmitting low-intensity visible and near-infrared light through

## **Table of Contents**

a portion of the body and detecting the manner in which the molecules of the exposed substance interact with light at specific wavelengths.

Each single-use 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 bone in a separate process. While both detectors receive similar information about the tissue between the sensor and the area under examination, the detector further from the light source detects light that has penetrated deeper into the body, and, therefore, receives more information specific to the brain or skeletal muscle tissue under examination than does the detector closer to the light source. By comparing the two measurements, our INVOS technology is able to suppress the influence of the tissues between the sensor and the brain or somatic tissue under examination to provide a measurement of changes in brain or skeletal muscle tissue blood oxygen saturation.

### ***Applications and Market Segments***

We target the sale of the INVOS System for use in surgical procedures and other critical care situations with a high risk of oxygen imbalances. We believe that our INVOS System has applications for cerebral and somatic monitoring in the following key market segments:

***Cardiac and Carotid Artery Surgery.*** Until the first quarter of fiscal 2005, we focused our marketing efforts primarily on cardiac and carotid artery surgeries. We believed it would be easier to demonstrate clinical importance of the information provided by the INVOS System and potentially gain market acceptance for our products in connection with these surgeries. Moreover, much of the earliest clinical data regarding the use of the INVOS System involved these surgeries. In September 2000, we received 510(k) clearance from the FDA to market the model 5100 INVOS System in the United States. Unlike earlier models, the model 5100 INVOS System has the added capability of being able to monitor pediatric patients. After receiving this clearance, we expanded our marketing efforts to include pediatric cardiac surgeries.

***Pediatric and Neonatal ICU.*** In the first quarter of fiscal 2005, we initiated selling and marketing efforts for the INVOS System in the pediatric ICU. We plan to launch the product into the neonatal ICU in 2007, after completing development of a smaller SomaSensor. Our next generation INVOS System monitor, which we launched in the second quarter of 2006, can display information from four SomaSensors, which will allow for the simultaneous monitoring of changes in blood oxygen saturation in the brain and, in patients with or at risk for restricted blood flow, in somatic tissue. We expect that the INVOS System will be used to monitor simultaneously the brain and somatic tissue initially for patients in the pediatric and neonatal ICU.

***Diabetic Patient Major Surgeries.*** We are currently sponsoring a prospective, randomized, blinded clinical trial involving diabetic patients over age 50 who are undergoing major general surgery. The study group will consist of patients whose surgeries are managed based on information provided by the INVOS System, and the control group will consist of similarly situated patients whose surgeries are not managed based on information provided by the INVOS System. The two groups will be compared across measures of patient outcomes and hospital costs, including length of hospital stay. Diabetics are at particular risk of oxygen imbalances because of a higher incidence of vascular disease. If results of this trial are positive, we intend to target more actively the sale of the INVOS System for use in diabetic patients undergoing major general surgeries, consistent with FDA requirements. We expect to begin this marketing in 2009.

***Other Applications.*** We are also evaluating sponsorship of other clinical trials which may allow us to more actively target the sale of the INVOS System for use in other patient populations. If the results of these trials are positive, following completion of these trials and publication of the results, we intend to target the sale of the INVOS System for use on elderly patients undergoing major surgeries. We are also evaluating additional potential market segments for our INVOS System, such as use in other major surgeries, in the adult ICU, and for other somatic applications of the technology. We are also exploring several novel near-infrared spectroscopy and imaging technologies and products under a Contract Development and Exclusive





**Table of Contents**

Licensing Agreement with NeuroPhysics Corporation. See NeuroPhysics Corporation below. Pursuit of some of these potential market segments may require additional FDA clearance.

**Clinical Development**

We believe that favorable peer-reviewed publication is a key element to the INVOS System's success. Accordingly, we support clinical research programs with third-party clinicians and researchers intended to demonstrate the need for the INVOS System and the clinical importance of the information it provides with the specific objective of publishing the results in peer-reviewed journals. The research includes studies comparing patients managed based on information provided by the INVOS System with other patients, based on measures of patient outcome and hospital costs, including patient length of stay, length of time on the ventilator, cognitive dysfunction and incidence of stroke. In addition to the studies described below, we believe that our INVOS System has been evaluated in over 400 presentations, study abstracts and published papers. During the second quarter of fiscal 2004, results of the studies described below were presented, which we believe have contributed to the INVOS System gaining further market penetration. In addition, in January 2007 the results of the first prospective, randomized clinical trial mentioned below were published in a peer-reviewed anesthesia journal.

***Murkin Study***

In the second quarter of 2004, the results of the first prospective, randomized, blinded intervention study using the INVOS System were presented. The study showed a statistically significant reduction in incidences of major organ dysfunction when the INVOS System was used to provide information to help manage regional brain blood oxygen saturation in coronary artery bypass surgery patients. The 200-patient study was conducted by John Murkin, M.D., professor of anesthesiology at the University of Western Ontario, and was presented at Outcomes 2004: Neurobehavioral Assessment, Physiological Monitoring and Cerebral Protective Strategies held in Key West, Florida. The data and results of the intervention study reported on by Dr. Murkin at Outcomes 2004 were published as John M. Murkin, M.D., et al., *Monitoring Brain Oxygen Saturation During Coronary Bypass Surgery: A Randomized, Prospective Study*, in *Anesthesia and Analgesia*. (January 2007).

Patients undergoing coronary artery bypass surgery were randomly assigned to the control or intervention group. Patients in both groups were monitored with the INVOS System during their operations, but the monitor display in the control group (100 patients) was covered and patients' treatments were managed routinely. In the intervention group (100 patients) the patients' treatments were managed using information from the INVOS System, and the patients received a pre-determined series of interventions to maintain the INVOS System's index of regional cerebral blood oxygen saturation within 75 percent of baseline values taken at the beginning of the operation.

Independent observers assessed all of the patients for predefined clinical outcomes. The complication criteria were those reported by cardiac surgeons to the Society of Thoracic Surgeons National Database. These complications consist of common adverse outcomes following cardiac surgery, such as stroke, respiratory failure, renal failure and other major morbidities.

Dr. Murkin found that regional brain oxygen desaturations were quite common and are related to major organ dysfunction. The intervention group experienced statistically significantly fewer incidents of major organ dysfunction than the control group: three patients in the intervention group experienced incidents of major organ morbidity or mortality, compared to 11 patients in the control group. With respect to stroke specifically, one patient in the intervention group experienced a stroke, compared to four patients in the control group. The difference was not statistically significant.

A financial analysis of Dr. Murkin's data was conducted by Leaden Hickman, Ph.D., assistant professor, health sciences and administration at the University of Michigan, and Dr. Murkin. This analysis was presented at Outcomes 2005: Neurobehavioral Assessment, Physiological Monitoring and Cerebral Protective Strategies held in Key West, Florida in May 2005. The analysis showed measurable cost differences between the intervention and control groups. Total cost per patient was lower in the intervention group than in the control group (\$14,921 vs. \$15,619). This difference was not statistically significant. The potential complication avoidance results in a total savings of \$231,540, or a savings of \$1,158 per patient averaged over the entire study group. The data and results of

**Table of Contents**

the financial analysis conducted by Leaden Hickman, Ph.D., and presented at Outcomes 2005, have not been published in a peer-reviewed publication.

**Goldman Study**

In the second quarter of 2004, the results of a retrospective, blinded intervention study using the INVOS System were presented. The study showed a statistically significant reduction in permanent stroke when information from the INVOS System was used to help manage regional brain blood oxygen saturation in cardiac surgery patients. The principal investigator in the 2,279-patient study was Scott Goldman, M.D., chairman of the department of surgery at Pennsylvania-based Main Line Health Center, Lankenau Hospital. Findings from the study were presented at the Cardiothoracic Techniques and Technologies Annual Meeting in March 2004 and were published as Scott Goldman, M.D., et al., *Optimizing Intraoperative Cerebral Oxygen Delivery Using Noninvasive Cerebral Oximetry Decreases the Incidence of Stroke for Cardiac Surgical Patients*, in *The Heart Surgery Forum* #2004-1062 (September 2004).

The study included all patients who underwent cardiac surgery for any reason at the Lankenau Hospital and Institute for Medical Research from July 1, 2000 to June 30, 2003. The control group consisted of 1,245 patients who underwent surgery in the 18 months before cerebral oximetry monitoring with the INVOS System was introduced at the hospital on January 1, 2002. The study group consisted of 1,034 patients who underwent surgery during the following 18 months and were monitored with the INVOS System. Operative techniques were modified in the study group to maintain cerebral oximetry values at or near the pre-operative baseline throughout the surgery. The study group included a significantly sicker population of patients than the control group, as determined by pre-operative New York Heart Association, or NYHA, classification and co-morbidities.

The incidence of permanent stroke in the study group (0.97 percent) was statistically significantly less than in the control group (2.01 percent), despite a sicker population according to the higher NYHA class of the study group. Although the incidence of permanent stroke was lower in the study group, the incidence of all neurologic dysfunction, including stroke and transient ischemic attack, was similar in the two groups. The proportion of patients requiring prolonged ventilation also was statistically significantly smaller in the study group, 6.8 percent, compared to 10.6 percent in the control group. Total ventilator time was statistically significantly shorter in the study group (four hours) than the control group (five hours). The length of hospital stay was similar overall in the two groups, but was statistically significantly shorter in the study group when examined by pre-operative NYHA classifications of patients.

Dr. Goldman's later analysis of these data concluded that the difference in incidence of cerebrovascular accidents, or CVA, between the two groups translated into a potential avoidance of 12 CVAs in the study group and approximately \$254,214 in direct costs and more than \$425,000 in total costs.

**Diabetic Patients Studies**

In the second quarter of 2005, Dr. Murkin presented the results of a 56-patient sub-study of his prospective, randomized, blinded intervention study using the INVOS System described above under Murkin Study. The sub-study showed that avoidance of cerebral oxygen desaturations in actively managed diabetic coronary artery bypass graft patients was associated with improved clinical outcomes. The sub-study was presented at the Society of Cardiovascular Anesthesiologists 27<sup>th</sup> Annual Meeting in Baltimore. The data and results of the intervention study presented by Dr. Murkin in Baltimore have not been published in a peer-reviewed publication.

Diabetic patients have impaired cerebral autoregulation and oxygenation during cardiopulmonary bypass surgery. This sub-study analyzed outcomes of two coronary artery bypass graft patient groups: an intervention group of diabetic and non-diabetic patients who were monitored with the INVOS System and received a pre-determined series of interventions to maintain the INVOS System's index of regional cerebral blood oxygen saturation within 75 percent of baseline values taken at the beginning of the operation and a control group of diabetic and non-diabetic patients who were monitored with the INVOS System, but the display was covered and the patients were managed routinely. Diabetic patients in the intervention group required shorter ventilation (nine hours versus 30 hours), shorter stays in the ICU (30 hours versus 69 hours) and shorter hospital stays (5.5 days versus 8.4 days) than diabetic patients in the control group. All of these differences were statistically significant. There were

**Table of Contents**

no statistically significant differences between the regional cerebral oxygen saturation levels of the diabetic patients in the intervention group and the levels of the non-diabetic patients in the intervention group.

We are currently sponsoring a prospective, randomized, blinded clinical trial involving diabetic patients over age 50 who are undergoing major general surgery. The study group will consist of patients whose surgeries are managed based on information provided by the INVOS System, and the control group will consist of similarly situated patients whose surgeries are not managed based on information provided by the INVOS System. The two groups will be compared across measures of patient outcomes and hospital costs, including length of hospital stay. The initial phase of this trial is being conducted at Duke University Medical Center and the neighboring Veteran's Administration Hospital. In the initial phase, which began in 2006, the investigators will determine the number of patients to study in each of the intervention and control groups so that the results are expected to be statistically significant. If results of this trial are positive, we intend to target more actively the sale of the INVOS System for use in diabetic patients undergoing major general surgeries, consistent with FDA requirements. We expect to begin this marketing in 2009.

***Other Future Studies***

We are evaluating sponsoring other clinical trials which may allow us to more actively target the sale of the INVOS System for use in other patient populations.

**The CorRestore System**

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 from 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, two heart surgeons and their company developed and patented the CorRestore System with the intent 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 CorRestore System consists of a non-circular bovine pericardium, or cow heart-sac, tissue patch with an integrated pericardial suture ring, as well as accessories for aiding the implantation of the patch.

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.

In October 2004, the results of a multi-center, 1,198-patient study evaluating the safety and effectiveness of the SVR surgical technique, not using the CorRestore Patch, were reported. SVR was performed on all patients. Surgeries performed concurrently included coronary artery bypass grafting (95 percent), mitral valve repair (22 percent) and mitral valve replacement (one percent). Patients experienced a statistically significant improvement in ejection fraction and ventricular volume. Thirty-day mortality after SVR was 5.3 percent, and the overall five-year survival rate was 68.3 percent. In addition, the re-hospitalization rate in this high-risk population was low, as 78 percent of the patients were not readmitted to the hospital for congestive heart failure during the five years after their SVR surgery. Pre-operatively, 67 percent of the patients in the study had severe New York Hospital Association functional Class III and Class IV symptoms. For those patients whose New York Hospital Association Class was reported at last follow-up, 85 percent were functionally Class I or Class II, with lower or no symptoms of congestive heart failure than Class III or Class IV. Findings from the study were published as Constantine L. Athanasuleas, M.D. and Gerald D. Buckberg, M.D., et al., *Surgical Ventricular Restoration in the Treatment of Congestive Heart Failure Due to Post-Infarction Ventricular Dilation*, in the *Journal of the American College of Cardiology*, Volume 44, No. 7 (2004).

## **Table of Contents**

The retail price of the CorRestore System is approximately \$4,000. Sales of CorRestore Systems represented one percent of our fiscal 2006 net revenues. We expect that as sales of our INVOS System increase, the CorRestore System will become an even less significant component of our business. In November 2005, we wrote off the remaining CorRestore license acquisition cost intangible asset and recorded an impairment expense of \$929,093. We wrote this off based on the cash flow impairment analysis that was performed, the declining sales of CorRestore products and the uncertainty regarding future prospective, randomized clinical data.

### ***License Agreement***

In 2000, we entered into a license agreement with the inventors of the CorRestore System and their company, CorRestore LLC, granting us exclusive, worldwide, royalty-bearing licenses to specified rights relating to the CorRestore System and related products and accessories for SVR. Transfer and sublicensing of our licenses are restricted by the license agreement.

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 percent in the aggregate of our net sales of products subject to the licenses, for the term of the patent relating to the CorRestore System, (2) five-year warrants to purchase an aggregate of 400,000 common shares at \$3.00 per share, which were exercised in full in 2004 and 2005, (3) five-year warrants to purchase an aggregate of 2,100,000 common shares at \$3.00 per share, which expired unexercised in November 2006 because cumulative net sales of the CorRestore System products did not meet the requirements for exercise of these warrants, and (4) a consulting fee of \$25,000 a year to each of the two inventors until we sell 1,000 CorRestore Patches.

CorRestore LLC and the inventors may terminate the licenses (1) if we materially breach specified covenants in the license agreement, (2) if our common shares are delisted from the Nasdaq Stock Market, and (3) in connection with specified bankruptcy and insolvency events. CorRestore LLC and the inventors may exclude specified countries from the geographic scope of the license to the extent we did not begin marketing the CorRestore System products or begin the process of obtaining necessary regulatory approval to sell CorRestore System products in that country by May 15, 2002. 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.

We may terminate the licenses (1) in our sole discretion, within 120 days after we sign a definitive agreement for specified types of business combination transactions with another entity, if we pay a total of \$1,000,000 to CorRestore LLC and the inventors, or (2) if CorRestore LLC or either of the inventors materially breaches specified covenants in the license agreement.

## **Marketing, Sales and Distribution**

### ***Marketing***

We market the INVOS System primarily to cardiac and vascular surgeons, anesthesiologists and other medical professionals. We believe that these specialists are the medical professionals most aware of the risks of brain and other damage resulting from oxygen imbalances.

We believe that favorable peer-reviewed publication is a key element to the INVOS System's success. Accordingly, we support clinical research programs with third-party clinicians and researchers intended to demonstrate the need for the INVOS System and the clinical importance of the information it provides with the specific objective of publishing the results in peer-reviewed journals. The research includes studies comparing patients managed based on information provided by the INVOS System with similarly situated patients not managed based on information provided by the INVOS System, based on measures of patient outcomes and hospital costs, including patient length of stay, length of time on the ventilator, cognitive dysfunction and incidence of stroke.

We attend trade shows and medical conferences to promote the INVOS System and to meet medical professionals with an interest in performing research and reporting their results in peer-reviewed medical journals and at major international medical conferences. We also sponsor peer-to-peer educational opportunities, promote

**Table of Contents**

use of the INVOS System in regional centers of influence that we believe will influence its adoption by others, and participate in targeted public relations opportunities.

***Sales and Distribution***

We sell the INVOS System through a direct sales team in the United States, the size of which has increased from 26 persons at the end of fiscal 2005 to 44 persons at the end of fiscal 2006, and six independent sales representative firms. We expect to increase the size of our U.S. direct sales team in fiscal 2007. We believe the selling cycle for the INVOS System is approximately six to nine months.

We also have a co-promotion relationship with Fresenius Medical Care Cardiovascular Resources, Inc.'s North American Extracorporeal Alliance where Fresenius provides INVOS Systems to its cardiovascular perfusion customers. Fresenius provides extracorporeal therapies and provides contract perfusion services, which are services to operate the heart-lung machine in cardiac procedures. In exchange for profits on SomaSensor sales, Fresenius assists us in placing our INVOS Systems in hospitals for which it provides contract perfusion services and facilitates the use of INVOS technology during cardiac surgery by supplying hospitals with SomaSensors.

Outside the United States, we have distribution agreements with independent distributors covering 56 countries for the INVOS System. Our distributors for the INVOS System include Tyco Healthcare, part of Tyco International Ltd., in Europe, the Middle East, Africa and Canada, and Edwards Lifesciences Ltd., formerly Baxter Limited, in Japan. We are evaluating placing direct salespersons and clinical specialists in Europe to support Tyco Healthcare. We also have one international sales consultant. For fiscal 2006, 19 percent of our net revenues were represented by international sales.

We offer a no capital cost sales program in the United States whereby we ship the INVOS System monitor to the customer at no charge. It has been our experience that hospitals in the United States prefer to use this method to acquire INVOS System monitors.

We did not have any backlog of firm orders as of January 10, 2007 or as of January 10, 2006. We generally do not have a backlog of firm orders because we generally ship product upon receipt of a 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. Tyco Healthcare was our largest customer in fiscal 2006 and 2005, and Edwards Lifesciences was our largest customer in fiscal 2004. We are dependent on our sales to Tyco Healthcare and Edwards Lifesciences, 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 international sales were \$5,424,536 for the fiscal year ended November 30, 2006, \$3,303,692 for the fiscal year ended November 30, 2005 and \$2,091,602 for the fiscal year ended November 30, 2004, including approximately \$4,211,000 in fiscal 2006, \$2,202,000 in fiscal 2005 and \$944,000 in fiscal 2004 to Tyco Healthcare, our distributor in Europe, the Middle East, Africa and Canada, and approximately \$910,000 in fiscal 2006, \$707,000 in fiscal 2005 and \$970,000 in fiscal 2004 to Edwards Lifesciences Ltd., our distributor in Japan. See Note 9 of Notes to Financial Statements. For a description of the breakdown of sales between INVOS System monitors, SomaSensors and CorRestore Systems, see Management's Discussion and Analysis of Financial Condition and Results of Operations Results of Operations in Item 7 of this report.

We sell the CorRestore System through our 49 direct salespersons and five independent sales representative firms in the United States as of February 5, 2007. 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.

**Table of Contents****Research and Development**

Our research and development activities are conducted internally by a staff consisting of five employees. We are developing a smaller SomaSensor for use with newborns and making other advances to the design and performance features of the INVOS System, including the SomaSensor. We are also working to interface our INVOS System with multi-functional monitors provided by other manufacturers. Our research, development and engineering expenditures were \$1,582,521 during fiscal 2006, \$525,679 during fiscal 2005, and \$369,106 during fiscal 2004. We expect our research, development and engineering expenses to increase in fiscal 2007 from the level in fiscal 2006, excluding the \$1,000,000 expense under our Contract Development and Exclusive Licensing Agreement, described below. We expect this increase primarily as a result of development costs associated with our smaller SomaSensor, development costs associated with advances to the design and performance features of the INVOS System, including the disposable SomaSensor, and the hiring of additional research and development personnel.

***NeuroPhysics Corporation***

We entered into a Contract Development and Exclusive Licensing Agreement with NeuroPhysics Corporation as of September 18, 2006. The agreement provides us with feasibility research, contract development and consulting services and certain ownership and licensing rights, subject to the rights of the United States Federal government, to intellectual property and technical knowledge associated with several novel near-infrared spectroscopy, or NIRS, and imaging technologies and products under development at NeuroPhysics. We paid an initial license fee of \$1,000,000 and have agreed to pay monthly license fees of up to \$30,000 a month (depending on which projects are continuing under development at NeuroPhysics at the time) for products continuing under development at NeuroPhysics beginning April 1, 2008 and a royalty on future sales of the new products.

NeuroPhysics is in the early stage of feasibility research and development of several NIRS-based technologies and products, including a novel approach to depth resolved NIRS measurements. In addition to this NIRS-based, depth-resolved technology, products under development at NeuroPhysics include (1) a fetal cerebral oximetry system, (2) a monitor for measuring oxygen saturation in deep tissues for assessing hemorrhagic shock, (3) devices to assess tumors or swelling containing blood, including in the brain of head trauma victims and neonates with intra-ventricular hemorrhage, (4) a continuous and non-invasive blood gas monitor, and (5) a new imaging concept intended to improve resolution and expand the applicability of endoscopes. We may terminate any or all of the projects under this agreement at any time. We might not be able to develop these technologies or products into commercially viable products, and competitors might develop and market similar products before we do.

**Manufacturing**

We assemble the INVOS System in our facilities in Troy, Michigan, from components purchased from outside suppliers. We assemble the INVOS System to control its quality and costs and to permit us to make changes to the INVOS System faster than we could if third parties assembled it. Although we believe that most components are generally available from several potential suppliers, we depend on one supplier for one of our components. We are not aware of any validated alternative supplier for this component, although we are currently in the process of validating in accordance with FDA requirements a second source of supply and are carrying approximately a six-month supply of this component. Moreover, we typically use one supplier for custom-designed components, including the unit enclosure, the printed circuit boards, other mechanical components and the SomaSensor. We are currently dependent on one manufacturer of the SomaSensor and another component of the INVOS System, 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 INVOS System.

We received ISO 13485 certification and met the requirements under the European Medical Device Directive to use the CE Mark, thereby allowing us to continue to market our INVOS System and SomaSensor in the European Economic Community. Our most recent ISO 13485 compliance surveillance audit occurred in June 2006.

## **Table of Contents**

### **Competition**

We believe that the markets for cerebral and somatic oximetry products may become highly competitive. In the United States, we believe there is currently only one other company with FDA clearance to sell a cerebral oximeter. In December 2005, one U.S. competitor announced that it received 510(k) clearance to market a cerebral oximeter, and they have shown their product at an industry trade show for the first time in late 2006. Outside the United States, several Japanese manufacturers offer competitive products for sale in that country and primarily for research in other parts of the world, but, to our knowledge, none has pursued FDA clearance to market its product in the United States. We are aware that several companies and individuals are engaged in the research and development of non-invasive cerebral oximeters, and we believe that there are several other potential entrants into the market. Other companies have FDA clearance to market somatic oximeters in the United States. Competition might cause our sales cycle to lengthen to the extent that customers take longer to make purchasing decisions. Competition might also reduce our gross margins and market share and prevent us from achieving further market penetration. Competitors might be more successful than we are in obtaining FDA clearance with broader claims in their labeling or more successful than we are in manufacturing and marketing their products and may be able to take advantage of the significant time and effort we have invested to gain medical acceptance of cerebral oximetry.

We also compete with numerous medical equipment companies for the portions of hospital budgets allocated to capital equipment and for the limited amount of space on a patient's forehead for sensors. The medical products industry is characterized by extensive research and development and intense competition in an increasingly cost-conscious environment. Some of these potential competitors have well-established reputations, customer relationships and marketing, distribution and service networks. Some of them have substantially longer histories in the medical products industry, larger product lines and greater financial, technical, manufacturing, research and development and management resources than we do. Many of these potential competitors have long-term product supply relationships with our potential customers. These potential competitors might be able to use their resources, reputations and ability to leverage existing customer relationships to give them a competitive advantage over us, including in securing forehead sensor space for their products and dollars from hospital capital equipment budgets to purchase their products. They might also succeed in developing products that are at least as reliable and effective as our products, that make additional measurements, that are less costly than our products or that provide alternatives to our products. Competitors might be more successful than we are in manufacturing and marketing their products and may be able to take advantage of the significant time and effort we have invested to gain medical acceptance of cerebral oximetry.

The CorRestore System competes against existing patches. Although we believe the CorRestore System has important advantages over hand-formed patches, hand-formed patches are significantly less expensive. At least one study using medical grade fabric patches indicates that they are effective. We also compete against alternative methods of treating congestive heart failure. SVR is in the early stages of its development and will likely require significant clinical studies before it is widely accepted. 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 and may be able to take advantage of the significant time and effort we have invested to gain medical acceptance of SVR surgeries.

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

### **Proprietary Rights Information**

We have 11 United States patents and two patents in various foreign countries. These patents expire on various dates from March 2009 to October 2019. We currently have two patent applications pending in the United States, including one reissuance application, and 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 covering the application of non-invasive, near-infrared spectroscopy to measure continuously and substantially





## **Table of Contents**

concurrently a blood metabolite (such as oxygen saturation) in at least two separate internal regions of the brain. This patent is now the subject of a reissue proceeding in the United States Patent and Trademark Office. We requested the reissuance of this patent because we believe that we are entitled to broader claims than those that were originally issued. However, the outcome of the reissue proceeding cannot be predicted, and the claims which ultimately issue may be broader in scope than the original claims, they may be narrower in scope than the original claims, they may be the same in scope as the original claims or they may be rejected. The corresponding Australian patent for

Multi-Channel, Noninvasive, Tissue Oximeter issued in December 2003, will expire 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 apparatuses for introducing light into a body part and receiving, measuring and analyzing the transmitted 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.

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 INVOS System. We are not aware of any infringement of the claims of any issued patents by our products or by their methods of use, and no charge of patent infringement has 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. A United States service mark application for Enlightening Medicine, and United States Trademark applications for Reflecting the Color of Life and NIRSensor are pending. 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 our other legal rights will necessarily prevent third parties from developing or using a similar or a 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.

The inventors of the CorRestore System and their company 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 six other United States patents and two international patents have been issued to the inventors, also relating primarily to the product design of a soft suture ring integrated with a patch. Six of those issued patents also expire in May 2018, one expires in July 2018, and one expires in November 2018. In addition, other United States and foreign patent applications are pending. We have also obtained United States Trademark registration for the trademark CorRestore.

### **Government Regulation**

Our products are medical devices subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, under the Federal Food, Drug, and Cosmetic Act, or FDCA. FDA regulations govern, among other things, the following activities that we will perform:

product development;

product testing;

product manufacturing;

product labeling;

product storage;

premarket clearance or approval;

advertising and promotion; and  
product sales and distribution.

**Table of Contents**

Medical devices to be commercially distributed in the U.S. must receive either 510(k) clearance or PMA approval prior to marketing from the FDA pursuant to the FDCA. Devices deemed to pose relatively less risk are placed in either class I or II, which requires the manufacturer to submit a premarket notification requesting permission for commercial distribution; this is known as 510(k) clearance. Some low risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously 510(k) cleared device or a preamendment class III device for which PMA applications have not been called, are placed in class III requiring PMA approval.

**510(k) Clearance Pathway.** To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent in intended use and in safety and effectiveness to a previously 510(k) cleared device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not called for submission of PMA applications. The FDA's 510(k) clearance pathway usually takes from three to six months, but it can last longer.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a PMA approval. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance or PMA approval. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained, to redesign the device or to submit new data or information to the FDA.

**PMA Approval Pathway.** A product not eligible for 510(k) clearance must follow the PMA approval pathway, which requires proof of the safety and effectiveness of the device to the FDA's satisfaction. The PMA approval pathway is much more costly, lengthy and uncertain. It generally takes from one to three years or even longer. A PMA application must provide extensive preclinical and clinical trial data and also information about the device and its components regarding, among other things, device design, manufacturing and labeling. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with Quality System Regulation, or QSR, requirements, which impose elaborate testing, control, documentation and other quality assurance procedures. The PMA can include postapproval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval. Even after approval of a PMA, a new PMA or PMA supplement is required in the event of a modification to the device, its labeling or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA.

**Clinical Trials.** A clinical trial is almost always required to support a PMA application and is sometimes required for a premarket notification. All clinical studies of investigational devices must be conducted in compliance with FDA's requirements. If an investigational device could pose a significant risk to patients (as defined in the regulations), the FDA must approve an Investigational Device Exemption, or IDE, application prior to initiation of investigational use. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. FDA typically grants IDE approval for a specified number of patients to be treated at specified study centers. A nonsignificant risk device does not require FDA approval of an IDE. Both significant risk and nonsignificant risk investigational devices require approval from institutional review boards, or IRBs, at the study centers where the device will be used or from private IRBs.

During the study, the sponsor must comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting, and record keeping. The investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with all reporting and record keeping requirements. The IDE requirements apply to all investigational devices, whether considered significant or nonsignificant risk. Prior to granting PMA approval, the FDA typically inspects



**Table of Contents**

the records relating to the conduct of the study and the clinical data supporting the PMA application for compliance with IDE requirements.

**Postmarket.** After a device is placed on the market, numerous regulatory requirements apply. These include: the QSR, labeling regulations, the FDA's general prohibition against promoting products for unapproved or off-label uses, the Medical Device Reporting regulation (which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur), and the Reports of Corrections and Removals regulation (which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA).

FDA enforces these requirements by inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as: fines, injunctions, consent decrees and civil penalties;

repair, replacement, refunds, recall or seizure of products;

limitations on exports;

operating restrictions or partial suspension or total shutdown of production;

refusing or delaying our requests for 510(k) clearance or PMA approval of new products or new intended uses;

withdrawing 510(k) clearance or PMA approvals already granted; and

criminal prosecution.

In October 1997, we obtained FDA clearance for an earlier generation INVOS System incorporating advances in our INVOS technology. In September 2000, we received 510(k) clearance from the FDA to market the model 5100 INVOS System in the United States. Unlike earlier models, the model 5100 INVOS System has the added capability of being able to monitor pediatric patients. In November 2005, we received 510(k) clearance from the FDA to market our INVOS System to monitor changes in somatic tissue blood oxygen saturation in regions of the body other than the brain in patients with or at risk for restricted blood flow. In November 2001, we received clearance from the FDA to market the CorRestore Patch in the United States. Our most recent FDA QSR inspection occurred in June 2004.

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) submissions pending.

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.

**Table of Contents**

**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 INVOS System, including SomaSensors, and higher INVOS System monitor revenues associated with hospital budgeting cycles.

**Employees**

As of February 5, 2007, we had 84 full-time employees, including 53 in sales and marketing, five in research and development, eight in general and administration and 18 in manufacturing, quality and service. We also employed two part-time individuals in general and administration. In addition, we use two contract employees, and we use one consultant. 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 and research and development employees in fiscal 2007. Our employees are not represented by a union or subject to a collective bargaining agreement. We believe that our relations with our employees are good.

**Insurance**

Because the INVOS System 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 product liability claims. We have obtained product liability insurance with a liability limit of \$5,000,000. We also maintain coverage for property damage or loss, general liability, business interruption, travel-accident, directors and officers liability and workers compensation. We do not maintain key-man life insurance.

**Where You Can Get Information We File With The SEC**

We file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission. You can read and copy any materials we file with the Securities and Exchange Commission at the Securities and Exchange Commission's Public Reference Room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the Securities and Exchange Commission at 1-800-SEC-0330. The Securities and Exchange Commission 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 Securities and Exchange Commission. The address of the Securities and Exchange Commission's website is <http://www.sec.gov>.

We also maintain a website at <http://www.somanetics.com>. We make available free of charge on or through our website, 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 Securities and Exchange Commission. We will voluntarily provide electronic or paper copies of our filings free of charge upon request.

This report includes statistical data that were obtained from industry publications. These industry publications generally indicate that the authors of these publications have obtained information from sources believed to be reliable but do not guarantee the accuracy and completeness of their information. While we believe these industry publications to be reliable, we have not independently verified their data.

**Table of Contents****ITEM 1A. RISK FACTORS**

*An investment in our common shares involves a high degree of risk. You should carefully consider the specific factors described below, together with the cautionary statement under the caption *Forward Looking Statements* below and in Item 7 of this report and the other information included in this report, before purchasing our common shares. The risks described below are not the only ones that we face. Additional risks that are not yet known to us or that we currently think are immaterial could also impair our business, financial condition or results of operations. If any of the following risks actually occurs, our business, financial condition or results of operations could be adversely affected. In such case, the trading price of our common shares could decline, and you may lose all or part of your investment.*

**Risks Relating to Our Business**

***Our future growth depends on increased market acceptance of our INVOS System in existing market segments and market acceptance in new market segments.***

Since sales of the INVOS System, including SomaSensors, currently account for substantially all of our revenues, our future growth will depend on the degree to which our INVOS System is accepted by hospitals and clinicians in our existing market segments and in new market segments, such as the neonatal ICU, major surgeries involving diabetic and elderly patients and other applications. There are numerous factors that could adversely impact market acceptance of our INVOS System.

Part of our marketing strategy is to encourage and support clinical research programs. We depend on favorable peer-reviewed publication and successful clinical use of our products for our success. The INVOS System has not had extensive clinical use in the new market segments. We cannot assure you that additional research papers will be published or that any such papers will conclude that the INVOS System provides information that is clinically important. In addition, researchers might publish results that do not support the clinical importance of the information provided by the INVOS System or that conclude that another product provides better or more important information. Performance problems or adverse research results could prevent acceptance of the product in existing and new market segments, adversely affect our reputation in the medical community, result in unexpected expense and adversely affect future sales.

In addition, we compete with numerous medical equipment companies for the portions of hospital budgets allocated to capital equipment and for the limited amount of space on a patient's forehead for sensors. Sales of our INVOS System might be limited or delayed because of resistance to major capital equipment expenditures by hospital purchasing committees. Even if we are successful in convincing physicians, other medical professionals and hospital purchasing committees that the INVOS System provides valuable benefits, they might be unwilling or unable to commit funds to the purchase of the INVOS System due to budgetary constraints. Moreover, even if one or two units are sold to a hospital, we believe that it will take additional time and experience with the INVOS System before additional medical professionals in the hospital might be interested in using the INVOS System in other procedures or other areas of the hospital.

Sales of all of our products might be limited because hospitals might fear that the cost of a new device or product will lower their profits because medical insurers generally fix reimbursement amounts for the procedures in which our products might be used. Moreover, medical professionals may be reluctant to use our INVOS System in some new market segments, particularly those involving diagnostic applications, unless they receive reimbursement from medical insurers for using the system. Our INVOS System is not currently cleared by the FDA for use in the diagnosis of disease states. Additionally, the INVOS System is not currently approved for separate reimbursement, and we might not be able to obtain reimbursement for these uses of our INVOS System.

If the INVOS System fails to achieve market acceptance in existing or new market segments or if these market segments fail to develop as rapidly as expected, our business, financial condition and results of operations could be adversely affected and our plan to increase our investments in our direct sales team, additional clinical trials and our research and development team might not produce favorable results.

**Table of Contents**

***We are dependent on our distributors and our independent sales representative firms for a substantial portion of our sales, and their failure to sell our products adequately would adversely affect our business.***

We are dependent on our distributors to generate all of our international sales, and on our independent sales representative firms for a substantial portion of our sales in the United States. Independent distributors or independent sales representative firms might fail to commit the necessary resources to market and sell our products to the level of our expectations, especially as significant customer education and long lead times are typically required to market and sell our products successfully. If our distributors or independent sales representative firms fail to market, promote and sell our products adequately, our business, financial condition and results of operations would be adversely affected. We might not be able to engage additional distributors on a timely basis, enter into other third-party marketing arrangements or retain or replace our existing distributors, when required. If we are unable to engage, replace or retain distributors, our ability to market and sell our products internationally could be adversely affected. In addition, if any of our distributor or independent sales representative firm arrangements are terminated or discontinued, we will likely be faced with increased costs as we attempt to replace these arrangements, and the terminated distributors or firms might begin to sell a competitor's product. Even if we are able to engage new distributors or retain existing ones, they might incur conflicting obligations to sell other companies' products or they might distribute other products that provide greater revenues to them than are provided by our products.

Tyco Healthcare, part of Tyco International Ltd., our international distributor in Europe, the Middle East, Africa and Canada for our INVOS System, accounted for 15 percent and 11 percent of our net revenues for fiscal 2006 and for fiscal 2005, respectively. Edwards Lifesciences Ltd., formerly Baxter Limited, our international distributor in Japan for our INVOS System, was our largest customer for fiscal 2004, although it accounted for less than 10 percent of our net revenues for fiscal 2004. The loss of either of these distributors could have an adverse effect on our business, financial condition and results of operations.

***We currently depend on single-source suppliers for key components of the INVOS System, and the loss of any of these suppliers could harm our ability to manufacture and sell our products, increase the cost of our components or delay our clinical trials.***

We are dependent on various suppliers for manufacturing the components for our INVOS System. Although we believe that most components are generally available from several potential suppliers, we depend on one supplier for one of our components. We are not aware of any validated alternative supplier for this component, although we are currently in the process of validating in accordance with FDA requirements a second source of supply. Moreover, we typically use one supplier for custom-designed components, including the unit enclosure, the printed circuit boards, other mechanical components and the SomaSensor. SomaSensors represented approximately 75 percent of our net revenues in fiscal 2006. Engaging additional or replacing existing suppliers of custom-designed components is costly and time consuming. We estimate that it would require approximately four to five months to change SomaSensor suppliers. We do not intend to maintain significant inventories of components, other than an approximate six-month supply of the one component for which we currently have no alternative supplier. If we fail to obtain custom-designed components from our sole suppliers, if we lose any of our present suppliers and cannot replace them on a timely basis when necessary, if there is an interruption of production at one or more of our suppliers, or if any supplier is otherwise unable or unwilling to meet our requirements at current prices or at all, our ability to manufacture and sell our products would be impaired or we might have to pay higher prices for our components or our clinical trials could be delayed. In addition, because we do not have long-term agreements with our suppliers, we might be subject to unexpected price increases which might adversely affect our profit margins.

In addition, we do not have direct control over the activities of our suppliers and are dependent on them for quality control, capacity, processing technologies and, in required cases, compliance with FDA Quality System Regulation requirements. If we are unsuccessful in managing our suppliers, our business could be adversely affected.

***We may become subject to competition which may adversely affect us.***

We believe that the markets for cerebral and somatic oximetry products may become highly competitive. In the United States, we believe there is currently only one other company with FDA clearance to sell a cerebral oximeter. In December 2005, one U.S. competitor announced that it received 510(k) clearance to market a cerebral





**Table of Contents**

oximeter, and they have shown their product at an industry trade show for the first time in late 2006. Outside the United States, several Japanese manufacturers offer competitive products for sale in that country and primarily for research in other parts of the world, but, to our knowledge, as of yet, none has pursued FDA clearance to market its product in the United States. We are aware that several companies and individuals are engaged in the research and development of non-invasive cerebral oximeters, and we believe that there are several other potential entrants into the market. Other companies have FDA clearance to market somatic oximeters in the United States. Competition might cause our sales cycle to lengthen to the extent that customers take longer to make purchasing decisions. Competition might also reduce our gross margins and market share and prevent us from achieving further market penetration. Competitors might be more successful than we are in obtaining FDA clearance with broader claims in their labeling or more successful than we are in manufacturing and marketing their products and may be able to take advantage of the significant time and effort we have invested to gain medical acceptance of cerebral oximetry.

***We also compete with companies that have longer operating histories, more established products and greater resources than we do for, among other things, forehead monitoring space, limited hospital capital budgets and alternative products.***

The medical products industry is characterized by extensive research and development and intense competition in an increasingly cost-conscious environment. Some of these potential competitors have well-established reputations, customer relationships and marketing, distribution and service networks. Some of them have substantially longer histories in the medical products industry, larger product lines and greater financial, technical, manufacturing, research and development and management resources than we do. Many of these potential competitors have long-term product supply relationships with our potential customers. These potential competitors might be able to use their resources, reputations and ability to leverage existing customer relationships to give them a competitive advantage over us, including in securing forehead sensor space for their products and dollars from hospital capital equipment budgets to purchase their products. They might also succeed in developing products that are at least as reliable and effective as our products, that make additional measurements, that are less costly than our products or that provide alternatives to our products.

***If we fail to manage our growth effectively, our business and operating results could be harmed.***

If we experience growth in our business, our growth could place a significant strain on our management, customer service, operations, sales and administrative personnel and other resources. To serve the needs of our existing and future customers, we will be required to train, motivate and manage qualified employees. We have incurred and will continue to incur significant costs to retain qualified management, sales and marketing, engineering, production, manufacturing and administrative personnel, as well as expenses for marketing and promotional activities. Our ability to manage our planned growth depends upon our success in expanding our operating, management and information and financial systems, which might significantly increase our operating expenses.

We have invested substantial resources to develop the INVOS System. We expect to continue to invest resources to develop a smaller SomaSensor for use with newborns and other advances to the design and performance features of the INVOS System, including the disposable SomaSensor. New products require extensive testing and regulatory clearance before they can be marketed, and substantial customer education concerning the product's use, advantages and effectiveness. We might not be able to develop commercially viable products. We might not be able to manage effectively our future growth, and if we fail to do so, our business, financial condition and results of operations would be adversely affected.

***Patients might assert product liability claims against us.***

Because we test, market and sell a patient monitoring device and a heart patch, patients might assert product liability claims against us. The INVOS System is used in operating rooms and other critical care hospital units with patients who might be seriously ill or might be undergoing dangerous procedures. The CorRestore Patch is used on seriously ill patients undergoing a dangerous procedure. On occasion, patients on whom the INVOS System is being used, or in whom a CorRestore Patch is implanted, may be injured or die as a result of their medical treatment or condition. We might be sued because of such injury or death, and regardless of whether we are ultimately determined to be liable or our products are determined to be defective and a contributing factor in such



**Table of Contents**

injury or death, we might incur significant legal expenses not covered by insurance. In addition, product liability litigation could damage our reputation and impair our ability to market our products, regardless of the outcome. Litigation could also impair our ability to retain product liability insurance or make our insurance more expensive. We have product liability insurance with a liability limit of \$5,000,000. This insurance is costly and even though it has been obtained, we might not be able to retain it. Even if we are able to retain this insurance, it might not be sufficient to protect us in the event of a major defect in the INVOS System or the CorRestore Patch. If we are subject to an uninsured or inadequately insured product liability claim based on the performance of the INVOS System or the CorRestore Patch, our business, financial condition and results of operations could be adversely affected.

***If we fail to obtain and maintain necessary U.S. Food and Drug Administration clearances for our products and indications or if clearances for future products and indications are delayed or not issued, our business would be harmed.***

Our products are classified as medical devices and are subject to extensive regulation in the United States by the FDA and other federal, state and local authorities. These regulations relate to manufacturing, labeling, sale, promotion, distribution, importing and exporting and shipping of our products. In the United States, before we can market a new medical device, or a new use of, or claim for, an existing product such as the INVOS System, we must first receive either 510(k) clearance or premarket approval from the FDA, unless an exemption applies. Both of these processes can be expensive and lengthy. The FDA's 510(k) clearance process usually takes from three to six months, but it can last longer. The process of obtaining premarket approval is much more costly and uncertain than the 510(k) clearance process. It generally takes from one to three years, or even longer, from the time the premarket approval application is submitted to the FDA until an approval is obtained.

In order to obtain premarket approval and, in some cases, a 510(k) clearance, a product sponsor must conduct well-controlled clinical trials designed to test the safety and effectiveness of the product. Conducting clinical trials generally entails a long, expensive and uncertain process that is subject to delays and failure at any stage. The data obtained from clinical trials may be inadequate to support approval or clearance of a submission. In addition, the occurrence of unexpected findings in connection with clinical trials may prevent or delay obtaining approval or clearance. If we conduct clinical trials, they may be delayed or halted, or be inadequate to support approval or clearance.

Medical devices may be marketed only for the indications for which they are approved or cleared. The FDA may fail to approve or clear indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or premarket approval of new products, or new intended uses or modifications to existing products. Our clearances can be revoked if safety or effectiveness problems develop. ***The FDA might require us to obtain a new clearance to label or promote the INVOS System for specific patient subgroups, such as diabetics; if we fail to obtain such clearances, our sales and revenues may be adversely affected.***

Our INVOS System 510(k) clearance states that the prospective clinical value of the INVOS System has not been demonstrated in patients with specific disease states. If we wish to label or promote more actively the INVOS System for specific types of patients, such as diabetics, the FDA may require us to obtain a new 510(k) clearance and would likely carefully scrutinize the data support for any such claim. We cannot assure you that the FDA would grant additional 510(k) clearances in a timely fashion, or at all, or that the FDA would not require us to undertake the more burdensome premarket approval process as a prerequisite for marketing the INVOS System with this type of specific claim. Any of the above could delay our ability to market and sell new products or to promote the INVOS System for specific patient subgroups such as diabetics and would thereby have an adverse effect on our business, financial condition and results of operations.

**Table of Contents**

***After clearance or approval of our products, we are subject to continuing regulation by the FDA, and if we fail to comply with FDA regulations, our business could suffer.***

Even after clearance or approval of a product, we are subject to continuing regulation by the FDA, including the requirements that our facility be registered and our devices listed with the agency. We are subject to Medical Device Reporting regulations, which require us to report to the FDA if our products may have caused or contributed to a death or serious injury or malfunction in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. We must report corrections and removals to the FDA where the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the Federal Food, Drug, and Cosmetic Act caused by the device that may present a risk to health, and maintain records of other corrections or removals. The FDA closely regulates promotion and advertising, and our promotional and advertising activities could come under scrutiny. If the FDA objects to our promotional and advertising activities or finds that we failed to submit reports under the Medical Device Reporting regulations, for example, the FDA may allege our activities resulted in violations of law.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;

repair, replacement, refunds, recall or seizure of our products;

limitations on exports;

operating restrictions or partial suspension or total shutdown of production;

refusing or delaying our requests for 510(k) clearance or premarket approval of new products or new intended uses;

withdrawing 510(k) clearance or premarket approvals that have already been granted; and

criminal prosecution.

If any of these events were to occur, they could harm our business.

***We have modified some of our products without FDA clearance. The FDA could retroactively determine that the modifications were improper and require us to stop marketing and recall the modified products.***

Any modifications to one of our FDA-cleared devices that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or a premarket approval. We may be required to submit extensive pre-clinical and clinical data depending on the nature of the changes. We may not be able to obtain additional 510(k) clearances or premarket approvals for modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and operating results. We have made modifications to our devices in the past, such as changes to the SomaSensor, and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. We believe that these changes do not require the submission of a new 510(k) notice. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices, to redesign our products or submit new data or information to the FDA. This could harm our operating results.

***If we fail to comply with the FDA's Quality System Regulation, our manufacturing operations could be halted, and our business would suffer.***

We are currently required to demonstrate and maintain compliance with the FDA's Quality System Regulation, or QSR. The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing,

control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. The FDA enforces the QSR through periodic unannounced inspections. We have been, and anticipate in the future being, subject to such inspections. Our failure to comply with the QSR or to take satisfactory corrective action in response to an adverse QSR inspection could result in enforcement actions, including a public warning letter, a

**Table of Contents**

shutdown of or restrictions on our manufacturing operations, delays in approving or clearing a product, refusal to permit the import or export of our products, a recall or seizure of our products, fines, injunctions, civil or criminal penalties, or other sanctions, any of which could cause our business and operating results to suffer.

***Failure to obtain or maintain regulatory approval in foreign jurisdictions would prevent us from marketing our products abroad.***

We market our products through distributors in foreign markets. In order to market our products in the European Community and many other foreign jurisdictions, we must obtain separate regulatory approvals. We depend on our distributors to obtain and maintain certain of these regulatory approvals. The approval procedure varies among countries and can involve additional requirements and testing, and the time required to obtain approval may differ from that required to obtain FDA clearance. The foreign regulatory approval process may include all of the risks associated with obtaining FDA clearance in addition to other risks. Our distributors might not be able to obtain or maintain foreign approvals on a timely basis or at all. Clearance by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or approval or clearance by the FDA. Failure to obtain or maintain regulatory approval in foreign jurisdictions would prevent us from marketing our products abroad.

***Federal regulatory reforms may adversely affect our ability to sell our products profitably.***

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing clearance or approval, manufacture and marketing of a device. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. We cannot predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

***Changes in our actual or estimated future taxable income could change the value of our deferred tax asset, potentially resulting in a decrease in net income, which could adversely affect the price of our common shares.***

We have recognized deferred tax assets relating to the expected future benefits of our net operating loss carryforwards. Our assessment of our deferred tax assets, and the reversal of part of our valuation allowance relating to those assets in fiscal 2006, 2005, and 2004, included assuming that our net revenues and pre-tax income will grow in future years consistent with the growth guidance given for fiscal 2007 and making allowance for the uncertainties surrounding, among 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. Given the assumptions inherent in our financial plans, it is possible to calculate a different value for our deferred tax assets by changing one or more of the variables in our assessment. In addition, changes in our actual or estimated future taxable income could change the value of our deferred tax asset, potentially resulting in a decrease in net income, which could adversely affect the price of our common shares.

***New stock option accounting rules will increase our reported expenses, which could adversely affect the price of our common shares.***

Effective December 1, 2005, we became subject to new stock option accounting rules that require that compensation costs related to share-based payment transactions, including stock options, stock appreciation rights and restricted stock, be recognized in our financial statements. Previously, we accounted for stock-based compensation of employees using the intrinsic value method, which resulted in no compensation expense charged against income for stock option grants to employees for fiscal 2005 and 2004. In addition, in November 2005, we accelerated the vesting of all unvested stock options to eliminate compensation expense that we would otherwise have recognized in our results of operations after the adoption of the new stock option accounting rules when those options would have otherwise vested. During fiscal 2006, we recorded approximately \$304,000 in stock compensation expense in our financial statements in accordance with the new stock option accounting rules. Options and restricted stock granted in fiscal 2006 and future grants of options and restricted stock will also require us to recognize compensation expense in our income statement, increasing our reported expenses for the same activities, which could adversely affect the price of our common shares.

**Table of Contents**

***The lengthy sales cycle for the INVOS System could cause variability in our operating results.***

The decision-making process for our INVOS System customers is often complex and time-consuming. We believe the period between initial discussions with a potential customer and a sale of even one unit is approximately six to nine months. The process can be delayed as a result of hospital capital budgeting procedures. These delays could have an adverse effect on our business, financial condition and results of operations and cause variability in our operating results from quarter to quarter, which could cause fluctuations in the trading price of our common shares.

***Sales employee turnover could have an adverse effect on our business and cause variability in our operating results.***

As we expand the number of our sales employees and alter our sales territories, we increase the chance of sales employee turnover. We have incurred and expect to continue to incur significant costs to hire and train new qualified sales employees. In addition, the process of replacing sales employees can lengthen our sales cycle. These delays could have an adverse effect on our business, financial condition and results of operations and could cause variability in our operating results from quarter to quarter, which could adversely affect the price of our common shares.

***If we are unable to obtain or maintain intellectual property rights relating to our technology and products, the commercial value of our technology and products will likely be adversely affected and our competitive position could be harmed.***

Our success and ability to compete depends in part upon our ability to obtain protection in the United States and other countries for our products by establishing and maintaining intellectual property rights relating to or incorporated into our technology and products. We own or license a variety of patents and patent applications in the United States and corresponding patents and patent applications in certain foreign jurisdictions. Pending and future patent applications owned or licensed by us may not issue as patents or, if issued, may not issue in a form that will be commercially advantageous to us. Even if issued, patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of remaining patent protection we may have for our products. In addition, already issued patents owned or licensed by us may not be valid or enforceable. Further, even if valid and enforceable, these already issued patents may not be sufficiently broad to prevent others from marketing competitive products, despite our patent rights. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

For example, one of our significant patents is the subject of a reissue proceeding in the U.S. Patent and Trademark Office. Our reissue application was filed for the sole purpose of seeking to broaden certain claims. We cannot predict the outcome of this proceeding, which may result in some or all of the claims being maintained, broadened, narrowed or rejected. Another of our patents may be expired for ultimately claiming priority to a patent that was filed more than 20 years ago. We believe that this patent does not have a claim of priority that extends back for more than 20 years, and that the patent is still extant and will expire on March 29, 2009. However, there is a risk that a court might find that the earliest effective filing date for this patent is more than 20 years ago, and rule that this patent is expired and unenforceable.

The validity of our patents depends, in part, on whether prior art references disclosed or rendered obvious our inventions as of the filing date of our patent applications. It is possible that all relevant prior art may not have been identified, such as U.S. and foreign patents or published applications or published scientific literature, that could adversely affect the validity of our issued patents or the patentability of our pending patent applications. For example, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside the United States are also not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries.



**Table of Contents**

We may initiate litigation to enforce our patent rights, which may prompt our adversaries in such litigation to challenge the validity, scope or enforceability of our patents. If a court decides that one or more of our patents are not valid, not enforceable or of a limited scope, our rights to stop others from using our inventions may be compromised.

The outcome of litigation to enforce our patent rights is subject to substantial uncertainties, especially in medical device-related patent cases that may, for example, turn on the interpretation of patent claim language by the court which may not be to our advantage, and also the testimony of experts as to technical facts upon which experts may reasonably disagree. Our involvement in such intellectual property litigation could result in significant expense.

We also cannot be certain that we were the first to invent the cerebral oximeter technologies upon which our patents are based or that we were the first to file patent applications based upon those technologies, in those foreign jurisdictions where patent rights are granted to the first to file as opposed to the first to invent. In the event that a third party has also filed a U.S. patent application covering our cerebral oximeter devices, the sensors used with these devices, or a similar invention, we may have to participate in an adversarial proceeding known as an interference, which is declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. It is possible that we may be unsuccessful in the interference, resulting in a loss of some or all of our U.S. patent claims. We may also face similar proceedings outside the United States, including oppositions, to determine priority of invention or patentability. Even if we are successful in these proceedings, we may incur substantial costs, and the time and attention of our management and scientific personnel will be diverted in pursuit of these proceedings. Moreover, the laws or enforcement procedures of some foreign jurisdictions may not protect intellectual property rights to the same extent as in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties or if we are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, we may incur substantial costs and our business prospects could be substantially harmed.

We rely on trade secret and copyright protection to protect our interests in proprietary information and know-how, and for processes for which patents are undesirable to obtain or are difficult to obtain or enforce. We may not be able to protect our trade secrets or copyrights adequately. For example, none of our copyrights have been registered with the U.S. Copyright Office, which limits our ability to sue for and collect damages from third party infringers. In addition, we rely on non-disclosure and confidentiality agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology. These agreements may be breached, and we may not have adequate remedies for any breach. Moreover, others may independently develop equivalent proprietary information, and third parties may otherwise gain access to our trade secrets and proprietary knowledge. Any disclosure of confidential data into the public domain or to third parties could allow our competitors to learn our trade secrets and use the information in competition against us.

***If we are found to infringe or are alleged to infringe any third party intellectual property rights, then our business may be adversely affected.***

There are numerous U.S. and foreign issued patents and pending patent applications owned by third parties with patent claims in the field of tissue or organic matter oximetry, including cerebral oximetry and areas that are the focus of our product development efforts. We are aware of patents owned by third parties, to which we do not have licenses, that relate to, among other things, optical spectroscopy and the interaction of light with tissue and optical spectroscopy in the area of brain metabolism. For example, possible competitors own patents that are directed to the non-invasive determination of blood oxygen saturation levels with a near infra-red spectrophotometric sensor and to an apparatus for measuring oxygen saturation in blood using two different wavelengths of light. There may be other patents in addition to those of which we are aware that relate to aspects of our technology and that may materially and adversely affect our business. Moreover, because patent applications can take many years to issue as patents, there may be currently pending but unpublished patent applications, unknown to us, which may later result in issued patents that pose a material risk to us.

We may pose a threat to companies that own or control patents relating to cerebral oximetry systems or their components, or to the manufacture and use of such systems, and one or more third parties may file a lawsuit asserting a patent infringement claim against the manufacture, use or sale of the INVOS System based on one or



**Table of Contents**

more of these patents. We are not aware of any infringement of the claims of any issued patents by our products, and no charge of patent infringement has been asserted against us. However, potential competitors would have more incentive to assert infringement claims or challenge our patents if a more significant market for the INVOS System develops.

Whether the manufacture, sale or use of the INVOS System, or whether any products under development would, upon commercialization, infringe any patent claim will not be known with certainty unless and until a court interprets the patent claim in the context of litigation. If an infringement allegation is made against us, we may seek to invalidate the asserted patent claim and/or to allege non-infringement of the asserted patent claim. In order for us to invalidate a U.S. patent claim, we would need to rebut the presumption of validity afforded to issued patents in the United States with clear and convincing evidence of invalidity, which is a high burden of proof.

The outcome of infringement litigation is subject to substantial uncertainties, especially in medical device-related patent cases that may, for example, turn on the interpretation of patent claim language by the court which may not be to our advantage, and also the testimony of experts as to technical facts upon which experts may reasonably disagree. Our defense of an infringement litigation lawsuit could result in significant expense. Regardless of the outcome, infringement litigation could significantly disrupt our marketing, development and commercialization efforts, divert our management's attention and quickly consume our financial resources.

In the event that we are found to infringe any valid claim in a patent held by a third party, we may, among other things, be required to:

pay damages, including up to treble damages and the other party's attorneys' fees, which may be substantial;

cease the development, manufacture, importation, use and sale of products that infringe the patent rights of others, including our INVOS System, through a court-imposed sanction called an injunction;

expend significant resources to redesign our technology so that it does not infringe others' patent rights, or to develop or acquire non-infringing intellectual property, which may not be possible;

discontinue manufacturing or other processes incorporating infringing technology; and/or

obtain licenses to the infringed intellectual property, which may not be available to us on acceptable terms, or which may not be available at all.

Any development or acquisition of non-infringing products or technology or licenses could require the expenditure of substantial time and other resources and could have a materially adverse effect on our business and financial results. If we are required to, but cannot, obtain a license to valid patent rights held by a third party, we would likely be prevented from commercializing the relevant product, or from further manufacture, sale or use of the relevant product. If we need to redesign products or need to develop new methods to avoid third-party patents, we may suffer significant regulatory delays associated with conducting additional studies or submitting technical, manufacturing or other information related to the redesigned product and, ultimately, in obtaining approval.

While our products are in clinical trials, and prior to commercialization, we believe our activities in the United States related to the submission of data to the FDA fall within the scope of the exemptions that cover activities related to developing information for submission to the FDA and fall under general investigational use or similar laws in other countries. However, the U.S. exemptions would not cover the manufacturing, sale or use of products which are no longer in clinical trials, or other activities in the United States that support overseas clinical trials if those activities are not also reasonably related to developing information for submission to the FDA. In any event, the fact that no third party has asserted a patent infringement claim against us to date should not be taken as an indication, or as a level of comfort, that a patent infringement claim will not be asserted against us prior to or upon commercialization.

Some of our agreements, including our distribution and sales representative agreements require us to indemnify the other party in certain circumstances where our products have been found to infringe a patent or other proprietary rights of others. An indemnification claim against us may require us to pay substantial sums to the indemnified party, including its attorneys' fees.



**Table of Contents**

***Our success depends on our ability to attract and retain key personnel.***

Our future performance depends in significant part on the continued service of our senior management, including Bruce J. Barrett, our President and Chief Executive Officer, and various scientific, technical and manufacturing personnel. Our loss of any of these key personnel could have an adverse effect on us. We do not maintain key-man life insurance on any of our key personnel, and our employment agreement with Mr. Barrett currently expires April 30, 2009. In addition, competition for qualified employees is intense, and if we are unable to attract, retain and motivate additional, highly-skilled employees required for the expansion of our operations, our business, financial condition and results of operations could be adversely affected. We cannot assure you that we will be able to retain our existing personnel or attract additional, qualified persons when required and on acceptable terms.

***Any acquisitions that we make could disrupt our business and harm our financial condition.***

From time to time, we evaluate potential strategic acquisitions of complementary businesses, products or technologies, as well as consider joint ventures and other collaborative projects. We may not be able to identify appropriate acquisition candidates or strategic partners, or successfully negotiate, finance or integrate any businesses, products or technologies that we acquire. We do not have any experience with acquiring companies or products, other than the CorRestore System. Any acquisition we pursue could diminish our cash otherwise available to us for other uses or be dilutive to our shareholders, and could divert management's time and resources from our core operations.

***We have had limited success in marketing the CorRestore System, which could result in claims against us.***

Since we acquired rights in the CorRestore System in 2000, we have had limited success in marketing the system. The CorRestore System competes against existing patches also used for cardiac reconstruction and repair that are significantly less expensive and at least one study indicates are effective. We also compete against alternative methods of treating congestive heart failure. Surgical Ventricular Restoration, or SVR, is in the early stages of its development and will likely require significant clinical studies before it is widely accepted. 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 and may be able to take advantage of the significant time and effort we have invested to gain medical acceptance of SVR surgeries.

We are dependent on a third party to manufacture the CorRestore System. Our license agreement limits the parties that we may engage. The ultimate success of our CorRestore business is dependent on our ability to manage the manufacturer of the CorRestore System. If we are unsuccessful in managing the manufacturer of the CorRestore System, our business could be adversely affected.

We entered into a license agreement with respect to the CorRestore System in 2002. Although we believe we have complied with our obligations under the license agreement, our limited success in marketing the CorRestore System could result in claims against us. As part of the compensation for the acquisition of our CorRestore licenses, we issued five-year warrants to purchase an aggregate of 2,100,000 common shares at \$3.00 per share, exercisable based on our cumulative net sales of the CorRestore System products. These warrants expired unexercised in November 2006 because cumulative net sales of the CorRestore System products did not meet the requirements for exercise of these warrants. The expiration of these warrants could cause the holders of these warrants to make claims against us under the license agreement. If we are required to pay any significant amounts to defend or as a result of any such claims, our results of operations would be adversely affected.

***We have broad discretion to determine how to allocate our cash, cash equivalents, marketable securities and investments and may not use them effectively.***

As of November 30, 2006, we have approximately \$71,571,000 of cash, cash equivalents, marketable securities and long-term investments on hand, which provides us with flexibility in implementing our business plans and responding to future business conditions and opportunities. We have broad discretion to determine how to allocate our cash, cash equivalents, marketable securities and investments.. If we fail to apply these funds

## **Table of Contents**

effectively, the failure could result in financial losses that could have a material adverse effect on our business and cause the price of our common shares to decline. We intend to keep sufficient cash, cash equivalents, marketable securities and investments in cash and bank accounts to avoid becoming an inadvertent investment company subject to regulation under the Investment Company Act of 1940. The remaining cash, cash equivalents, marketable securities and investments are expected to be invested in short-term, U.S. government or other investment grade, interest-bearing investments. These restrictions on our investments might limit the income otherwise available from investing these funds, lowering our income and potentially decreasing our earnings and the price of our common shares.

### **Risks Relating to Our Common Shares**

#### ***Provisions of our corporate charter documents and Michigan law may delay or prevent attempts by our shareholders to change our management and hinder efforts to acquire a controlling interest in us.***

Our board of directors has the authority, without further approval of our shareholders, to issue preferred shares having such rights, preferences and privileges as the board may determine. Any such issuance of preferred shares could, under some circumstances, have the effect of delaying or preventing a change in control of us and might adversely affect the rights of holders of common shares. In addition, we are subject to Michigan statutes regulating business combinations, takeovers and control share acquisitions, which might also hinder or delay a change in control of our company. Anti-takeover provisions that could be included in the preferred shares when issued and the Michigan statutes regulating business combinations, takeovers and control share acquisitions can depress the market price of our securities and can limit the shareholders' ability to receive a premium on their shares by discouraging takeover and tender offer bids, even if such events could be viewed as beneficial by our shareholders.

Our directors serve staggered three-year terms, and directors may be removed only for cause by a vote of the holders of a majority of the shares entitled to vote at an election of directors. Our Restated Articles of Incorporation also set the minimum number of directors constituting the entire board at three and the maximum at fifteen, and they require approval of holders of 90 percent of our voting shares to amend these provisions. Our bylaws contain procedures, including notice requirements, for nominating persons for election to our board of directors. These provisions could have an anti-takeover effect by making it more difficult to acquire our company by means of a tender offer, a proxy contest or otherwise or by removing incumbent officers and directors. These provisions could delay, deter or prevent a tender offer or takeover attempt that a shareholder might consider in his or her best interests, including those attempts that might result in a premium over the market price for the common shares held by our shareholders.

#### ***The market price of our common shares has been volatile and may continue to remain so.***

The market price of our common shares has been highly volatile. The following could cause the market price of the common shares to continue to fluctuate substantially:

changes in our quarterly financial condition or operating results;

changes in general conditions in the economy;

changes in the financial markets;

changes in the medical equipment industry;

changes in financial estimates by securities analysts or differences between those estimates and our actual results;

the liquidity of the market for the common shares;

developments with respect to patents and proprietary rights;

publication of clinical research results regarding our products;

changes in health care policies in the United States or foreign countries;

grants or exercises of stock options or warrants;

news announcements;

litigation involving us;

actions by governmental agencies, including the FDA, or changes in regulations; and

30

---

## **Table of Contents**

other developments affecting us or our competitors.

In particular, the stock market might experience significant price and volume fluctuations that might affect the market price of the common shares for reasons that are unrelated to our operating performance and that are beyond our control.

*We have never paid cash dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.*

We have never paid cash dividends on our common shares and do not expect to pay 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. As a result, capital appreciation, if any, of our common shares will be your sole source of gain for the foreseeable future.

*The market price of the common shares might be lower because of shares eligible for future sale and shares reserved for future issuance upon the exercise of options and warrants we have granted.*

Future sales of substantial amounts of common shares in the public market or the perception that such sales could occur could adversely affect the market price of the common shares. Any substantial sale of common shares or even the possibility of such sales occurring may have an adverse effect on the market price of the common shares. We have outstanding options and warrants to purchase an aggregate of 2,070,490 common shares. We have also reserved up to an additional 193,284 common shares for issuance upon exercises of options or awards of restricted stock or restricted stock units which have not yet been granted or awarded under our stock incentive plans. We have effective registration statements for the shares underlying these options and stock awards. Therefore, except for volume limitations imposed by Securities and Exchange Commission Rule 144, these shares are freely tradable. The market price of our common shares could fall if the holders of these shares sell them or are perceived by the market as intending to sell them.

### **Forward-Looking Statements**

Some of the statements in this report are forward-looking statements. These forward-looking statements include statements relating to our performance in the sections entitled Risk Factors, Management's Discussion and Analysis of Financial Condition and Results of Operations and Business and elsewhere in this report. Forward-looking statements include statements regarding the intent, belief or current expectations of us or our management, including statements preceded by, followed by or including forward-looking terminology such as may, will, should, believe, expect, anticipate, plan, intend, propose, estimate, continue, predict or similar expressions, with respect to various

These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by the forward-looking statements. We discuss many of these risks, uncertainties and other factors in this report in greater detail in this Item 1A above under the heading Risk Factors. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this report. You should read this report and the documents that we have filed as exhibits and incorporated by reference into this report completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify all of our forward-looking statements by these cautionary 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.



**Table of Contents**

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

Our headquarters, manufacturing facility and warehouse space are located in a single building in Troy, Michigan. We lease approximately 23,000 square feet, including approximately 12,000 square feet is office space for sales and marketing, engineering, accounting and other administrative activities. Our lease expires on December 31, 2009. The minimum monthly lease payment will be approximately \$11,900 for fiscal 2007, \$12,200 for fiscal 2008 and \$12,400 for fiscal 2009, excluding other occupancy costs. We believe that this facility is suitable and adequate for our needs now and for the foreseeable future and will allow for substantial expansion of our business and number of employees, except that we are exploring opportunities for additional office space because of the growth of our business.

**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, 2006.

**Table of Contents****SUPPLEMENTAL ITEM. EXECUTIVE OFFICERS OF THE REGISTRANT**

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

Name	Executive Officer Since	Age	Position
Bruce J. Barrett	6/94	47	President and Chief Executive Officer
William M. Iacona	12/00	36	Vice President and Chief Financial Officer, Controller, and Treasurer
Dominic J. Spadafore	8/02	47	Vice President, Sales and Marketing
Mary Ann Victor	1/98	49	Vice President and Chief Administrative Officer and Secretary

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 holds.

Mr. William M. Iacona has served as our Vice President and Chief Financial Officer since January 2006, as our Treasurer since February 2000 and as our Controller since April 1997. From December 2000 until January 2006, he served as our Vice President, Finance. 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. Dominic J. Spadafore has served as our Vice President, Sales and Marketing, since August 2002. Mr. Spadafore previously served, from July 2000 until July 2002, as National Sales and Clinical Director of the Cardiac Assist Division of Datascope Corporation, a medical device company that manufactures and markets healthcare products including medical devices used in high-risk cardiac patients. In this position, Mr. Spadafore supervised approximately 50 sales and clinical personnel and approximately \$80 million in domestic revenues. From July 1997 until July 2000, he served as Western Area Manager of the Patient Monitoring Division of Datascope Corporation, and prior to that he 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 and Chief Administrative Officer since January 2006 and as our Secretary since January 1998. From January 1998 until January 2006, she served as our Vice President, Communications and Administration. Prior to that she 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.

**Table of Contents****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 Global Market (until February 7, 2006 on The Nasdaq Capital Market) under the trading symbol SMTS. The following table sets forth, for the periods indicated, the range of high and low sales prices of our common shares as reported by Nasdaq.

	<b>High</b>	<b>Low</b>
Fiscal Year Ended November 30, 2005		
First Quarter	\$16.00	\$13.00
Second Quarter	18.85	12.50
Third Quarter	25.74	17.66
Fourth Quarter	36.95	21.51
Fiscal Year Ended November 30, 2006		
First Quarter	\$36.64	\$21.53
Second Quarter	27.02	15.28
Third Quarter	19.97	14.51
Fourth Quarter	24.75	16.55

As of February 5, 2007, we had 509 shareholders of record of our common shares.

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 any financing agreements, business conditions and other factors deemed relevant by the board.

**Performance Graph**

The following line graph compares for the fiscal years ended November 30, 2002, 2003, 2004, 2005 and 2006 (1) the yearly percentage change in our cumulative total shareholder return (*i.e.*, the change in share price divided by the initial share price, expressed as the resulting value of a \$100 investment; we have not paid cash dividends) on our common shares, with (2) the cumulative total return of The Russell 2000 Index and with (3) the cumulative total return on the Nasdaq Medical Devices Index.

**Table of Contents**

**COMPARISON OF CUMULATIVE TOTAL RETURN\*  
AMONG SOMANETICS CORPORATION,  
THE RUSSELL 2000 INDEX, AND  
NASDAQ MEDICAL DEVICES INDEX\*\***

	2001	2002	2003	2004	2005	2006
Somanetics Corporation	100.00	52.47	203.12	360.52	802.86	503.90
The Russell 2000 Index	100.00	89.40	121.85	142.88	154.51	181.45
Nasdaq Medical Devices Index	100.00	88.04	127.30	147.14	166.60	163.08

Assumes \$100 invested on November 30, 2001 in Somanetics Corporation common shares, The Russell 2000 Index and the Nasdaq Medical Devices Index.

\* Total return  
assumes  
reinvestment of  
dividends.

\*\* Fiscal Year  
ending  
November 30.

**Table of Contents****ITEM 6. SELECTED FINANCIAL DATA**

You should read the following selected financial data together with our financial statements and related notes 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. We have derived the statement of operations data for the years ended November 30, 2006, 2005 and 2004 and the balance sheet data as of November 30, 2006 and 2005 from our audited financial statements, which are included in Item 8 of this report. We have derived the statement of operations data for the years ended November 30, 2003 and 2002 and the balance sheet data as of November 30, 2004, 2003 and 2002 from our audited financial statements, which are not included in this report. Our historical results for any prior period are not necessarily indicative of results to be expected for any future period.

	<b>2006</b>	<b>Year Ended November 30,</b>			<b>2002</b>
		<b>2005</b>	<b>2004</b>	<b>2003</b>	
		<b>(in thousands, except per share data)</b>			
<b>Statement of Operations Data:</b>					
Net revenues	\$ 28,701	\$ 20,509	\$ 12,609	\$ 9,361	\$ 6,706
Cost of sales	3,566	2,601	2,050	2,140	2,049
Gross margin	25,135	17,908	10,558	7,221	4,657
Operating expenses:					
Research, development and engineering (1)	1,582	526	369	413	571
Selling, general and administrative (2)	16,485	13,241	8,237	6,759	5,344
Total operating expenses	18,067	13,767	8,606	7,172	5,915
Operating income (loss)	7,068	4,141	1,952	49	(1,258)
Other income:					
Interest income	2,582	310	55	23	52
Interest expense and other					(1)
Total other income	2,582	310	55	23	51
Income (loss) before income taxes	\$ 9,650	\$ 4,451	\$ 2,007	72	(1,207)
Income tax benefit (3)	750	3,300	6,700		
Net income (loss)	\$ 10,400	\$ 7,751	\$ 8,707	\$ 72	\$ (1,207)
Net income (loss) per common share basic	\$ 0.83	\$ 0.75	\$ 0.89	\$ 0.01	\$ (0.13)
Net income (loss) per common share diluted	\$ 0.75	\$ 0.66	\$ 0.77	\$ 0.01	\$ (0.13)
Weighted average number of common shares outstanding basic	12,463	10,322	9,780	9,114	8,951
Weighted average number of common shares outstanding diluted	13,824	11,798	11,323	9,467	8,951

	2006	2005	As of November 30, 2004 (in thousands)	2003	2002
<b>Balance Sheet Data:</b>					
Cash, cash equivalents, securities and investments	\$ 71,571	\$ 13,148	\$ 7,070	\$ 2,239	\$ 2,382
Working capital	57,968	18,044	9,311	4,480	4,047
Total assets	92,423	29,719	18,785	7,156	6,164
Total liabilities	2,205	1,878	1,232	991	664
Accumulated deficit	(26,731)	(37,131)	(44,882)	(53,589)	(53,661)
Total shareholders' equity	90,218	27,841	17,553	6,165	5,501

(1) Includes a \$1,000,000 expense in fiscal 2006 in connection with our Contract Development and Exclusive Licensing Agreement we entered into with NeuroPhysics Corporation.

(2) Includes an impairment expense of \$929,093 in fiscal 2005 in connection with the write-off of our intangible asset associated with the acquisition of the license for the CorRestore System.

(3) Represents income recognized in fiscal 2006, 2005 and 2004 as a result of a reversal of a portion of our

income tax  
valuation  
allowance.

36

---

**Table of Contents****ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS****Forward-Looking Statements**

*You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial data included elsewhere in this report. Some of the information contained in this discussion and analysis or set forth elsewhere in this report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the Risk Factors section of this report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. See also Forward-Looking Statements in Item 1A of this report.*

**Overview**

We develop, manufacture and market the INVOS System, a non-invasive patient monitoring system that continuously measures changes in the blood oxygen levels in the brain. We began commercializing our model 5100 INVOS System internationally in the third quarter of fiscal 1999 and in the United States in the fourth quarter of fiscal 2000. Unlike earlier models, the model 5100 has the added capability of being able to monitor pediatric patients. From product launch until the first quarter of fiscal 2005, we focused our marketing efforts primarily on adult and pediatric cardiac surgeries and carotid artery surgeries. During the second quarter of fiscal 2004, results of both the first prospective, randomized clinical trial and a larger retrospective review evaluating the INVOS System were presented, which we believe have contributed to the INVOS System gaining further market penetration.

In the first quarter of fiscal 2005, we initiated selling and marketing efforts for the INVOS System in the pediatric intensive care unit, or ICU. We plan to launch the product into the neonatal ICU in early 2007, after completing development of a smaller SomaSensor. We are currently sponsoring a clinical trial evaluating the use of the INVOS System on diabetic patients over age 50. If results of this trial are positive, we intend to target more actively the sale of the INVOS System for use in diabetic patients undergoing major general surgeries, consistent with FDA requirements. We expect to begin this marketing in 2009.

In November 2005, we received 510(k) clearance from the FDA to market our INVOS System to monitor changes in somatic tissue blood oxygen saturation in regions of the body other than the brain in patients with or at risk for restricted blood flow. Our next generation INVOS System monitor, which we launched in the second quarter of 2006, can display information from four SomaSensors, which allows for the simultaneous monitoring of changes in blood oxygen saturation in the brain and, in patients with or at risk for restricted blood flow, in somatic tissue.

We also develop and market the CorRestore System for use in cardiac repair and reconstruction. 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. However, 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. Sales of CorRestore Systems represented one percent of our fiscal 2006 net revenues. We expect that as sales of our INVOS System increase, the CorRestore System will become an even less significant component of our business.

**Net Revenues and Cost of Sales**

We derive our revenues from sales of INVOS Systems and CorRestore Systems to hospitals in the United States through our direct sales team and independent sales representative firms. Outside the United States, we have distribution agreements with independent distributors for the INVOS System, including Tyco Healthcare in Europe, Canada, the Middle East and Africa, and Edwards Lifesciences Ltd. in Japan. Our cost of sales represent the cost of



**Table of Contents**

producing monitors and disposable SomaSensors. Revenues from outside the United States contributed 19 percent to our fiscal 2006 net revenues. As a percentage of net revenues, the gross margins from our international sales are typically lower than gross margins from our U.S. sales, reflecting the difference between the prices we receive from distributors and from direct customers.

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 U.S. sales and net 60 days or longer for international sales.

Our INVOS System revenues are derived from the sale of monitors and our disposable SomaSensors. We intend that disposables will form the basis of a recurring revenue stream. We expect the percentage of revenue from disposables to increase over time as our installed base of monitors grows.

We offer to our customers in the United States a no capital cost sales program whereby we ship the INVOS System monitor to the customer at no charge. Under this program, we do not recognize any revenue upon the shipment of the monitor. We recognize SomaSensor revenue when we receive purchase orders and ship the product to the customer. At the time of shipment of the monitor, we capitalize the monitor as an asset and depreciate this asset over five years, and this depreciation is included in cost of goods sold.

***Operating Expenses***

Selling, general and administrative expenses generally consist of:  
salaries, wages and related expenses of our employees and consultants;

sales and marketing expenses, such as employee sales commissions, commissions to independent sales representatives, travel, entertainment, advertising, education and training expenses, depreciation of demonstration monitors and attendance at selected medical conferences;

clinical research expenses, such as costs of supporting clinical trials; and

general and administrative expenses, such as the cost of corporate operations, professional services, insurance, warranty and royalty expenses, investor relations, depreciation and amortization, facilities expenses and other general operating expenses.

We have increased the size of our direct sales team from 26 persons at the end of fiscal 2005 to 44 persons at the end of fiscal 2006. We expect to increase the size of our U.S. direct sales team in fiscal 2007 and are evaluating placing direct salespersons and clinical specialists in Europe to support Tyco Healthcare. We also expect our clinical research expenses to increase in fiscal 2007 as a result of sponsoring a clinical trial evaluating the use of the INVOS System on diabetic patients over age 50. As a result, we expect selling, general and administrative expenses to increase in fiscal 2007.

Research, development and engineering expenses consist of:  
salaries, wages and related expenses of our research and development personnel and consultants;

costs of various development projects; and

costs of preparing and processing applications for FDA clearance of new products.

For the fiscal year ended November 30, 2006, we recorded a research and development expense of \$1,000,000 in connection with our contract development and exclusive licensing agreement with NeuroPhysics Corporation.

***Deferred Tax Assets and Impairment Charges***

As of November 30, 2004, we adjusted our deferred tax asset valuation allowance resulting in the recognition of a deferred tax asset of \$6,700,000 as a result of expected future tax benefits related to our net

**Table of Contents**

operating loss carryforwards. Recognition of this deferred tax asset resulted in a non-cash tax benefit on our statement of operations for fiscal 2004 of \$6,700,000.

For the fiscal year ended November 30, 2005:

We recorded an impairment expense of \$929,093 associated with the write-down of our intangible asset associated with the acquisition of the license for the CorRestore System.

We further adjusted our deferred tax asset valuation allowance resulting in the recognition of additional deferred tax assets due to expected future tax benefits related to our net operating loss carryforwards.

Recognition of this additional deferred tax asset resulted in a non-cash tax benefit on our statement of operations for fiscal 2005 of \$3,300,000.

For the fiscal year ended November 30, 2006, we further adjusted our deferred tax asset valuation allowance resulting in the recognition of additional deferred tax assets due to expected future tax benefits related to our net operating loss carryforwards. Recognition of this additional deferred tax asset resulted in a non-cash tax benefit on our statement of operations for fiscal 2006 of \$750,000.

**Results of Operations*****Fiscal Year Ended November 30, 2006 Compared to Fiscal Year Ended November 30, 2005***

**Net Revenues.** Our net revenues increased \$8,191,348, or 40 percent, from \$20,509,252 in the fiscal year ended November 30, 2005 to \$28,700,600 in the fiscal year ended November 30, 2006. The increase in net revenues is primarily attributable to:

an increase in U.S. sales of \$6,070,504, or 35 percent, from \$17,205,560 in fiscal 2005 to \$23,276,064 in fiscal 2006. The increase in U.S. sales was primarily due to an increase in sales of the disposable SomaSensor of \$5,219,040, or 38 percent, primarily as a result of a 31 percent increase in SomaSensor unit sales. In addition, sales of the INVOS System monitor in the United States increased \$952,289, or 34 percent, primarily as a result of increased purchases by pediatric hospitals after the launch of our products into the pediatric ICU in the first quarter of fiscal 2005; and

an increase in international sales of \$2,120,844, or 64 percent, from \$3,303,692 in fiscal 2005 to \$5,424,536 in fiscal 2006. The increase in international sales was primarily due to increased purchases of the INVOS System monitor and disposable SomaSensor by Tyco Healthcare in Europe. In fiscal 2006, international sales represented 19 percent of our net revenues, compared to 16 percent of our net revenues in fiscal 2005.

Purchases by Tyco Healthcare accounted for 15 percent of net revenues in fiscal 2006, compared to 11 percent in fiscal 2005.

In the United States, we sold 199,907 SomaSensors in fiscal 2006, and internationally, we sold 89,080 SomaSensors in fiscal 2006. We placed 397 INVOS System monitors in the United States and 400 internationally in fiscal 2006, and our installed base of INVOS System monitors in the United States was 1,497, in 584 hospitals, as of November 30, 2006.

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

<b>Product</b>	<b>Fiscal Year Ended November 30,</b>	
	<b>2006</b>	<b>2005</b>
SomaSensors	75%	75%
INVOS System Monitors	24%	23%
Total INVOS System	99%	98%
CorRestore Systems	1%	2%
Total	100%	100%



**Table of Contents**

**Gross Margin.** Gross margin as a percentage of net revenues was 88 percent for the fiscal year ended November 30, 2006 and 87 percent for the fiscal year ended November 30, 2005. The increase in gross margin as a percentage of net revenues is primarily attributable to a five percent increase in the average selling price of SomaSensors in the United States and increased sales of the INVOS System monitors to pediatric hospitals in the United States. The increase in our average selling prices in the United States is attributable to increased sales of our pediatric SomaSensor, which sells for a higher price than the adult SomaSensor, and to the addition of new customers at our higher suggested retail prices. The increase in gross margin as a percentage of net revenues was partially offset by increased purchases of our next generation INVOS System monitor and disposable sensor by Tyco Healthcare, due to the lower margin we receive on sales to our distributors.

**Research, Development and Engineering Expenses.** Our research, development and engineering expenses increased \$1,056,842, or 201 percent, from \$525,679 in fiscal 2005 to \$1,582,521 in fiscal 2006. The increase is primarily attributable to a \$1,000,000 initial fee under our Contract Development and Exclusive Licensing Agreement entered into with NeuroPhysics Corporation in the fourth quarter of fiscal 2006. We expect our research, development and engineering expenses to increase in fiscal 2007 from the level in fiscal 2006, excluding the \$1,000,000 expense under our Contract Development and Exclusive Licensing Agreement. We expect this increase primarily as a result of development costs associated with our smaller SomaSensor, development costs associated with advances to the design and performance features of the INVOS System, including the disposable SomaSensor, and the hiring of additional research and development personnel.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses increased \$3,243,514, or 24 percent, from \$13,241,053 for the fiscal year ended November 30, 2005 to \$16,484,567 for the fiscal year ended November 30, 2006, primarily due to:

- a \$1,734,244 increase in salaries, wages and related expenses, primarily as a result of an increase in the number of employees, principally in sales and marketing (from an average of 42 employees for the fiscal year ended November 30, 2005 to an average of 64 employees for the fiscal year ended November 30, 2006) and an increase in salaries of existing employees;

- an \$897,099 increase in travel, marketing and selling-related expenses as a result of our increased sales personnel and increased sales and marketing activities, primarily sales training and trade shows;

- an \$527,765 increase in employee sales commissions as a result of increased sales and hiring additional sales employees in fiscal 2006;

- a \$403,352 increase in professional service fees, primarily due to increased legal and consulting fees;

- a \$293,026 increase in stock compensation expense due to stock compensation issued to directors, officers, employees and a consultant in fiscal 2006;

- a \$196,586 increase in office and facilities expenses primarily as a result of increased employees and increased insurance costs; and

- a \$101,405 increase in depreciation expense due to increased capitalized tooling for our next generation INVOS System.

During fiscal 2005 we incurred an impairment expense of \$929,093 as a result of the write-down of our intangible asset associated with the acquisition of the license for the CorRestore System.

We expect our selling, general and administrative expenses to increase in fiscal 2007, primarily as a result of our hiring additional direct sales personnel in fiscal 2006 and 2007, increased employee sales commissions payable as a result of increased sales, increased clinical research expense, increased stock compensation expenses, and increased sales and marketing expenses.

**Other Income.** During fiscal 2006, interest income increased to \$2,582,033, from \$310,055 in fiscal 2005, primarily due to our increased cash, cash equivalents, marketable securities and long-term investment balances as a result of the proceeds from our public offering of common shares that closed in the second quarter of fiscal 2006, and increased interest rates.

**Income Tax Benefit.** As of November 30, 2006, we further adjusted our deferred tax asset valuation allowance resulting in the recognition of additional deferred tax assets as a result of expected future tax benefits

**Table of Contents**

related to our net operating loss carryforwards. Recognition of this additional deferred tax asset resulted in a non-cash tax benefit on our statement of operations for fiscal 2006 of \$750,000, and increased our net income for fiscal 2006 to \$10,399,957, or \$0.75 per diluted common share. For fiscal 2006, the reversal of our valuation allowance was net of recorded taxes. The net income tax benefit of \$750,000 consisted of income tax expense recorded at an estimated effective tax rate of 34 percent in the amount of \$2,604,663 for the first three quarters of fiscal 2006, and a net deferred tax benefit of \$3,354,663 recorded in the fourth quarter of fiscal 2006.

***Fiscal Year Ended November 30, 2005 Compared to Fiscal Year Ended November 30, 2004***

**Net Revenues.** Our net revenues increased \$7,900,637, or 63 percent, from \$12,608,615 in the fiscal year ended November 30, 2004 to \$20,509,252 in the fiscal year ended November 30, 2005. The increase in net revenues is primarily attributable to:

an increase in U.S. sales of \$6,688,546, or 64 percent, from \$10,517,014 in fiscal 2004 to \$17,205,560 in fiscal 2005. The increase in U.S. sales was primarily due to an increase in sales of the disposable SomaSensor of \$4,900,660, or 54 percent, as a result of a 38 percent increase in SomaSensor unit sales and a 12 percent increase in SomaSensor average selling prices. This increase in our average selling prices is attributable to the addition of new customers at our higher suggested retail prices and increased sales of our pediatric SomaSensor which sells for a higher price than the adult SomaSensor. In addition, sales of the INVOS System monitor in the United States increased \$1,817,406, or 180 percent, primarily as a result of increased purchases by pediatric hospitals after the launch of our products into the pediatric ICU in the first quarter of fiscal 2005; and

an increase in international sales of \$1,212,090, or 58 percent, from \$2,091,602 in fiscal 2004 to \$3,303,692 in fiscal 2005. The increase in international sales was primarily due to increased purchases of the INVOS System monitor and disposable SomaSensor by Tyco Healthcare in Europe, which was partially offset by decreased purchases by Edwards Lifesciences in Japan. In fiscal 2005, international sales represented 16 percent of our net revenues, compared to 17 percent of our net revenues in fiscal 2004. Purchases by Tyco Healthcare accounted for 11 percent of net revenues in fiscal 2005.

In the United States, we sold 153,197 SomaSensors in fiscal 2005, and internationally, we sold 59,890 SomaSensors in fiscal 2005. We placed 306 INVOS System monitors in the United States and 215 internationally in fiscal 2005, and our installed base of INVOS System monitors in the United States was approximately 1,100, in 500 hospitals, as of November 30, 2005.

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

<b>Product</b>	<b>Fiscal Year Ended November 30,</b>	
	<b>2005</b>	<b>2004</b>
SomaSensors	75%	78%
INVOS System Monitors	23%	18%
Total INVOS System	98%	96%
CorRestore Systems	2%	4%
Total	100%	100%

Effective December 1, 2005, we increased the suggested list price of the adult SomaSensor and the pediatric SomaSensor in the United States to \$140.00 and \$155.00, respectively.

**Gross Margin.** Gross margin as a percentage of net revenues was 87 percent for the fiscal year ended November 30, 2005 and 84 percent for the fiscal year ended November 30, 2004. 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 and increased sales of the INVOS System monitors to pediatric hospitals in the United States.

**Research, Development and Engineering Expenses.** Our research, development and engineering expenses increased \$156,573, or 42 percent, from \$369,106 in fiscal 2004 to \$525,679 in fiscal 2005. The increase

41

---

## **Table of Contents**

is primarily attributable to development costs associated with our next generation INVOS System monitor, which was launched in the second quarter of 2006.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses increased \$5,003,652, or 61 percent, from \$8,237,401 for the fiscal year ended November 30, 2004 to \$13,241,053 for the fiscal year ended November 30, 2005, primarily due to a 62 percent increase in our sales and marketing expenses during fiscal 2005 because of our increased sales personnel and our increased sales and marketing efforts. The increase in selling, general and administrative expense is primarily attributable to:

a \$1,031,964 increase in salaries, wages and related expenses, primarily as a result of an increase in the number of employees, principally in sales and marketing (from an average of 32 employees for the fiscal year ended November 30, 2004 to an average of 42 employees for the fiscal year ended November 30, 2005);

an impairment expense of \$929,093 as a result of the write-down of our intangible asset associated with the acquisition of the license for the CorRestore System;

an \$832,012 increase in employee sales commissions as a result of increased sales and increased sales personnel during fiscal 2005;

an \$811,524 increase in commissions paid to our independent sales representative firms as a result of increased sales;

a \$661,785 increase in travel and selling-related expenses as a result of our increased sales personnel and increased sales and marketing activities;

a \$377,153 increase in audit-related expenses, primarily as a result of costs associated with our first internal control assessment under Section 404 of the Sarbanes-Oxley Act and related regulations;

a \$365,770 increase in accrued incentive compensation expense due to our fiscal 2005 financial performance, primarily increased sales and net income, in accordance with the 2005 Incentive Compensation Plan; and

a \$105,120 increase in employer 401(k) matching contributions as a result of increased personnel and increased salaries and wages as described above.

During fiscal 2004 we incurred \$95,998 of expenses as a result of the termination of some of our independent sales representative firms.

**Income Tax Benefit.** As of November 30, 2005, we further adjusted our deferred tax asset valuation allowance resulting in the recognition of additional deferred tax assets as a result of expected future tax benefits related to our net operating loss carryforwards. Recognition of this additional deferred tax asset resulted in a non-cash tax benefit on our statement of operations for fiscal 2005 of \$3,300,000, and increased our net income for fiscal 2005 to \$7,751,087, or \$0.66 per diluted common share. For fiscal 2005, the reversal of our valuation allowance was net of recorded taxes. The net income tax benefit of \$3,300,000 consisted of income tax expense recorded at an estimated effective tax rate of 34 percent in the amount of \$1,261,223 for the first three quarters of fiscal 2005, and a deferred tax benefit of \$4,561,223 recorded in the fourth quarter of fiscal 2005.

### ***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**

### ***General***

Our principal sources of operating funds have been the proceeds of equity investments from sales of our common shares and cash provided by operating activities. See Statements of Shareholders Equity of our financial statements included elsewhere in this report.





**Table of Contents**

As of November 30, 2006, we did not have any outstanding or available debt financing arrangements, we had working capital of \$58.0 million and our primary sources of liquidity were \$28.7 million of cash and cash equivalents, \$20.9 million of marketable securities and \$21.9 million of long-term investments. Marketable securities and long-term investments consist of Aaa-rated United States Government agency bonds, and cash and cash equivalents are currently invested in bank savings accounts and money market accounts, pending their ultimate use.

On March 6, 2006, we completed a public offering of 2,300,000 of our newly-issued common shares at a public offering price of \$24.00 per share. The net proceeds, after deducting the underwriting discount and the expense of the offering, were \$51,232,774. These amounts include the exercise in full by the underwriters of an option to purchase up to 300,000 shares to cover over-allotments. At completion of the offering, we had 13,015,885 shares outstanding. We are using, or intend to use, the net proceeds from the offering for the expansion of our direct sales team and other sales and marketing activities, to sponsor additional clinical trials, to expand research and development efforts, and for working capital and general corporate purposes, including potential acquisitions of complementary products, technologies or businesses.

We entered into a Contract Development and Exclusive Licensing Agreement with NeuroPhysics Corporation as of September 18, 2006. The agreement provides us with feasibility research, contract development and consulting services and certain ownership and licensing rights, subject to the rights of the United States Federal government, to intellectual property and technical knowledge associated with several novel near-infrared spectroscopy, or NIRS, and imaging technologies and products under development at NeuroPhysics. We paid an initial license fee of \$1,000,000 and have agreed to pay monthly license fees of up to \$30,000 a month (depending on which projects are continuing under development at NeuroPhysics at the time) for products continuing under development at NeuroPhysics beginning April 1, 2008 and a royalty on future sales of the new products.

We believe that cash, cash equivalents, marketable securities and long-term investments on hand at November 30, 2006 will be adequate to satisfy our operating and capital requirements for more than the next twelve months.

***Cash Flows From Operating Activities***

Net cash provided by operations during fiscal 2006, 2005 and 2004 was \$7,304,835, \$3,687,653 and \$2,233,331, respectively. In fiscal 2006, cash was provided primarily by:

\$10,000,600 of net income before income taxes and non-cash depreciation, amortization, stock compensation expense, accrued interest income, and accrued income tax expense;

a \$332,931 increase in accounts payable, primarily as a result of increased inventory and operating expenses, partially offset by more timely payments made to vendors; and

a \$128,481 decrease in prepaid expenses, primarily because we capitalized to machinery and equipment tooling that was completed in fiscal 2006 for our next generation INVOS System monitor, partially offset by increased prepaid insurance premiums as of November 30, 2006;

Cash provided by operations in fiscal 2006 was partially offset by:

a \$1,943,049 increase in inventories, primarily due to the acquisition of components associated with our SomaSensors and our INVOS System monitor due to anticipated sales; inventories on our balance sheet increased less because we capitalized INVOS System monitors to property and equipment that are being used as demonstration units and no capital cost sales equipment, as described below;

a \$1,208,303 increase in accounts receivable, primarily as a result of higher fourth quarter sales in fiscal 2006 than in the fourth quarter of fiscal 2005 and less timely collections;

a \$5,825 decrease in accrued liabilities, primarily as a result of the payment of year-end 2005 accrued incentive compensation and accrued sales commissions and lower amounts accrued for fiscal 2006, partially offset by increased accrued income taxes payable and accrued clinical research fees.

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



**Table of Contents**

The increase in inventories described above is greater than shown on our balance sheet because it includes INVOS System monitors that we capitalized because they are being used as demonstration units and no capital cost sales equipment. We capitalized \$828,692 of costs from inventory for INVOS System monitors being used as demonstration units and no capital cost sales equipment at customers during fiscal 2006, compared to \$484,121 in fiscal 2005. As of November 30, 2006, we have capitalized \$2,650,939 in costs for INVOS System monitors being used as demonstration and no capital cost sales equipment, and these assets have a net book value of \$1,529,946. We depreciate these assets over five years.

**Cash Flows From Investing Activities**

Net cash used in investing activities in fiscal 2006, 2005 and 2004 was \$43,390,890, \$134,637 and \$84,003, respectively. In fiscal 2006, these expenditures were primarily for investments in marketable securities and long-term investments with the proceeds from our public offering, described above, and also \$554,993 in capital expenditures, primarily tooling for the next generation INVOS System monitor.

**Cash Flows From Financing Activities**

Net cash provided by financing activities in fiscal 2006, 2005 and 2004 was \$51,672,687, \$2,525,679 and \$2,681,022, respectively. On March 6, 2006, we completed a public offering of 2,300,000 of our newly-issued common shares at a public offering price of \$24.00 per share. The net proceeds, after deducting the underwriting discount and the expense of the offering, were \$51,232,774. In addition, during fiscal 2006, we issued 79,742 common shares as a result of stock option exercises, for proceeds of \$439,913. During fiscal 2005, we issued 561,839 common shares as a result of stock option exercises by employees, directors and former employees, for proceeds of \$2,525,679. 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 \$1,541,022, and 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.

**Contractual Obligations**

The following information is provided as of November 30, 2006 with respect to our known contractual obligations specified in the following table, aggregated by type of contractual obligation:

Contractual Obligations	Total	Payments due by period			More than 5 years
		Less than 1 year	1 to 3 years	3 to 5 years	
Long-term debt obligations					
Capital lease obligations					
Operating lease obligations	\$ 449,800	\$ 142,900	\$ 294,500	\$ 12,400	
Purchase obligations	2,951,100	2,951,100			
Other long-term liabilities					

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

**Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements or financing activities.

**New Accounting Pronouncements**

In July 2006, the FASB adopted FASB Interpretation No. 48 Accounting for Uncertainty in Income Taxes (FIN 48). FIN 48 prescribes a recognition threshold and requires an assessment of the probability of the validity of tax positions taken or expected to be taken in income tax returns for recognition in financial statements.

**Table of Contents**

Only tax positions meeting a more-likely-than-not threshold of being sustained are recognized under FIN 48. FIN 48 also provides guidance on classification of interest and penalties and accounting and disclosures for annual and interim financial statements. FIN 48 is effective for our fiscal year beginning December 1, 2007. The cumulative effect of the changes arising from the initial application of FIN 48 is required to be reported as an adjustment to the opening balance of retained earnings in the period of adoption. We are currently evaluating the impact, if any, the adoption of FIN 48 will have on our financial statements.

In September 2006, the Securities and Exchange Commission released SAB No. 108 regarding the effects of prior year misstatements on assessing the materiality of current year misstatements. SAB 108 provides that if an error has occurred and was immaterial in a number of previous years, the cumulative effect should be considered in assessing the materiality of the error in the current year. If the cumulative effect of the error is material, then the current year financial statements should be restated. In the case of prior year statements, previously filed reports do not need to be amended if the error was considered immaterial to the prior year's financial statements. However the statements should be amended the next time they are filed. This guidance is applicable for our fiscal year ending November 30, 2007. Additional disclosure would be required regarding any cumulative adjustments made in the current year financial statements. We do not believe the adoption of this SAB will have a material impact on our financial statements.

**Critical Accounting Policies**

We believe our most significant accounting policies relate to our accounting treatment of stock compensation of employees, our accounting treatment for income taxes, and our revenue recognition associated with our no capital cost sales program.

***Stock Compensation***

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 123 (revised), Share Based Payment. This Statement 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 was effective for our fiscal quarter beginning December 1, 2005. We adopted this Statement for fiscal 2006 using a modified prospective application and, accordingly, prior period amounts have not been restated.

We previously accounted 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 was charged against income for fiscal 2005 and 2004 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 was 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 was 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 \$11,221 of compensation expense, and an equal increase in additional paid in capital, for stock options vesting in favor of non-employees in fiscal 2005.

In November 2005, we approved the acceleration of vesting of all unvested stock options as of November 30, 2005. The primary purpose of this accelerated vesting was to eliminate compensation expense we would recognize in our results of operations upon the adoption of SFAS 123R, which was effective for our fiscal quarter beginning December 1, 2005. After the effects of the accelerated vesting, the initial adoption of SFAS 123R was immaterial with respect to options granted before December 1, 2005. The issuance of additional stock compensation under the 2005 Stock Incentive Plan in fiscal 2006 had an impact on our financial statements.

During fiscal 2006, we granted 239,000 stock options to our officers, employees, directors and one of our consultants, and we issued 68,000 restricted common shares to our officers. These stock options and restricted shares were issued at the market price on the date of grant, and they vest and are expensed in the financial statements over five years. As a result of the stock options and restricted common shares that we granted during



**Table of Contents**

fiscal 2006, we have recorded \$304,248 in stock compensation expense in accordance with SFAS No. 123(R), which caused basic and diluted earning per share to decrease by \$.02 per share. The fair value of the stock option grants was estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions: expected volatility (the measure by which the stock price has fluctuated or is expected to fluctuate during the period) 54.00%, risk-free rate (approximate U.S. Treasury yield in effect at the time of grant) of 5%, expected lives of 6 years, and a dividend yield of 0%. The fair value of the restricted common shares was estimated based on the market value of the common shares on the date of issuance. During fiscal 2005 we granted 162,146 stock options to our employees and directors, and in fiscal 2004 we granted 53,500 stock options to our employees and directors.

Had we recognized compensation expense for our stock options that vested in fiscal 2005 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 \$1,804,000 in compensation expense and realized pro forma net income of \$5,958,308, or \$0.51 per diluted common share. For fiscal 2004, had we recognized compensation expense for our stock options that vested 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 \$796,000 in compensation expense and realized pro forma net income of \$7,911,576, or \$0.70 per diluted common share.

***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 four 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 assuming that our net revenues and pre-tax income will grow in future years consistent with the growth guidance given for fiscal 2007 and 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.

During fiscal 2004, we 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. During fiscal 2005, we further adjusted our deferred tax asset valuation allowance resulting in the recognition of an additional net deferred tax asset of \$3,300,000. During 2006, we further adjusted our deferred tax asset valuation allowance resulting in the recognition of an additional net deferred tax asset of \$750,000. For fiscal 2006 and 2005, the reversal of our valuation allowance was net of recorded taxes. For the fiscal year ended November 30, 2006, the recorded net income tax benefit of \$750,000 consisted of income tax expense recorded at an estimated effective tax rate of 34 percent in the amount of \$2,604,663 for the first three quarters of fiscal 2006, and a net deferred tax benefit of \$3,354,663 recorded in the fourth quarter of fiscal 2006. For the fiscal year ended November 30, 2005, the recorded net income tax benefit of \$3,300,000 consisted of income tax expense recorded at an estimated effective tax rate of 34 percent in the amount of \$1,261,223 for the first three quarters of fiscal 2005, and a deferred tax benefit of \$4,561,223 recorded in the fourth quarter of fiscal 2005.

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 2006 to \$10,399,957, or \$0.75 per diluted common share, and to increase our net income for fiscal 2005 to \$7,751,087, or \$0.66 per diluted common share. Given the assumptions inherent in our financial plans, it is possible to calculate a 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.

***No Capital Cost Sales Revenue Recognition***

We offer to our customers in the United States a no capital cost sales program whereby we ship the INVOS System monitor to the customer at no charge. Under this program, we do not recognize any revenue upon the

**Table of Contents**

shipment of the INVOS System monitor. We recognize SomaSensor revenue when we receive purchase orders and ship the product to the customer. At the time of shipment of the monitor, we capitalize the INVOS System monitor 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.



**Table of Contents****ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The table below provides information about our financial instruments that are sensitive to changes in interest rates, consisting of investments in United States government agency bonds. For these financial instruments, the table presents principal cash flows and related weighted average interest rates by expected maturity dates. Weighted average fixed rates are based on the contract rates. The actual cash flows of all instruments are denominated in U.S. dollars. We invest our cash on hand not needed in current operations in United States government agency bonds with varying maturity dates with the intention of holding them until maturity.

**November 30, 2006**

**Expected Maturity Dates By Fiscal Year**

	<b>2007</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>Thereafter</b>	<b>Total</b>	<b>Fair Value</b>
<b>Investments:</b>								
Marketable Securities and Long-term Investments:								
Fixed Rate (\$)	20,918,134	11,943,252	9,974,512				42,835,898	42,912,370
Average interest rate	5.17%	5.25%	5.33%	N/A	N/A	N/A	5.22%	

We invested in marketable securities and long-term investments with the proceeds from our public offering that was completed on March 6, 2006.

**Table of Contents**

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA  
MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING**

The management of Somanetics Corporation is responsible for establishing and maintaining adequate internal control over financial reporting. Somanetics Corporation's internal control system was designed to provide reasonable assurance to the company's management and board of directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Somanetics Corporation management assessed the effectiveness of the company's internal control over financial reporting as of November 30, 2006. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework. Based on our assessment, we believe that, as of November 30, 2006, the company's internal control over financial reporting is effective based on those criteria.

Somanetics Corporation's independent registered public accounting firm, that audited the financial statements prepared by the company included in Item 8 of this report, has issued an attestation report on management's assessment of the company's internal control over financial reporting. Their report on the financial statements appears on page 51, and their report on management's assessment of the company's internal control over financial reporting is included on the next page.

January 17, 2007

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

We have audited management's assessment, included in the accompanying *Management's Report on Internal Control Over Financial Reporting*, that Somanetics Corporation (the Company) maintained effective internal control over financial reporting as of November 30, 2006, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained, in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions. A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that the Company maintained effective internal control over financial reporting as of November 30, 2006, is fairly stated, in all material respects, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of November 30, 2006, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheet as of November 30, 2006, and the related statements of operations, shareholders' equity, and cash flows for the period ended November 30, 2006, and our report dated January 17, 2007, expressed an unqualified opinion on those financial statements.

/s/ Deloitte & Touche LLP  
Detroit, Michigan  
January 17, 2007



**Table of Contents**

**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, 2006 and 2005, and the related statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended November 30, 2006. 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 examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such financial statements present fairly, in all material respects, the financial position of Somanetics Corporation at November 30, 2006 and 2005, and the results of its operations and its cash flows for each of the three years in the period ended November 30, 2006, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of November 30, 2006, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission; and our report dated January 17, 2007, expressed an unqualified opinion on management's assessment of the effectiveness of the Company's internal control over financial reporting and an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ Deloitte & Touche LLP  
Detroit, Michigan  
January 17, 2007

**Table of Contents**

**SOMANETICS CORPORATION  
BALANCE SHEETS**

	November 30,	
	2006	2005
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents (Note 2)	\$ 28,734,869	\$ 13,148,237
Marketable securities	20,918,134	
Accounts receivable	4,740,043	3,531,740
Inventory (Note 2)	2,172,458	1,058,101
Prepaid expenses	494,822	623,303
Accrued interest receivable	351,666	
Deferred tax asset - current (Note 5)	2,761,217	1,561,322
<b>Total current assets</b>	<b>60,173,209</b>	<b>19,922,703</b>
<b>PROPERTY AND EQUIPMENT: (Note 2)</b>		
Demonstration and no capital cost sales equipment at customers	2,650,939	1,916,655
Machinery and equipment	1,263,015	768,992
Furniture and fixtures	300,037	289,397
Leasehold improvements	195,565	187,135
<b>Total</b>	<b>4,409,556</b>	<b>3,162,179</b>
Less accumulated depreciation and amortization	(2,285,279)	(1,836,438)
<b>Net property and equipment</b>	<b>2,124,277</b>	<b>1,325,741</b>
<b>OTHER ASSETS:</b>		
Long-term investments	21,917,764	
Deferred tax asset - non-current (Note 5)	8,182,783	8,438,678
Intangible assets, net (Note 2)	10,009	16,921
Other	15,000	15,000
<b>Total other assets</b>	<b>30,125,556</b>	<b>8,470,599</b>
<b>TOTAL ASSETS</b>	<b>\$ 92,423,042</b>	<b>\$ 29,719,043</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 1,045,727	\$ 712,796
Accrued liabilities (Notes 4 and 6)	1,159,770	1,165,594
<b>Total current liabilities</b>	<b>2,205,497</b>	<b>1,878,390</b>
<b>COMMITMENTS AND CONTINGENCIES (Note 6)</b>		
<b>SHAREHOLDERS' EQUITY: (Note 3)</b>		

Edgar Filing: SOMANETICS CORP - Form 10-K

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, 13,163,627 shares at November 30, 2006, and 10,715,885 shares at November 30, 2005	131,636	107,159
Additional paid-in capital	116,817,012	64,864,554
Accumulated deficit	(26,731,103)	(37,131,060)
Total shareholders' equity	90,217,545	27,840,653
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 92,423,042	\$ 29,719,043

See notes to financial statements

52

---

**Table of Contents**

**SOMANETICS CORPORATION**  
**STATEMENTS OF OPERATIONS**

	For the Years Ended November 30,		
	2006	2005	2004
NET REVENUES (Notes 2 and 9)	\$ 28,700,600	\$ 20,509,252	\$ 12,608,615
COST OF SALES	3,565,588	2,601,488	2,050,253
Gross margin	25,135,012	17,907,764	10,558,362
OPERATING EXPENSES:			
Research, development and engineering (Note 2)	1,582,521	525,679	369,106
Selling, general and administrative (Note 2)	16,484,567	13,241,053	8,237,401
Total operating expenses	18,067,088	13,766,732	8,606,507
OPERATING INCOME	7,067,924	4,141,032	1,951,855
OTHER INCOME:			
Interest income	2,582,033	310,055	54,721
Total other income	2,582,033	310,055	54,721
INCOME BEFORE INCOME TAXES	\$ 9,649,957	\$ 4,451,087	\$ 2,006,576
INCOME TAX BENEFIT	750,000	3,300,000	6,700,000
NET INCOME	\$ 10,399,957	\$ 7,751,087	\$ 8,706,576
NET INCOME PER COMMON SHARE BASIC (Note 2)	\$ .83	\$ .75	\$ .89
NET INCOME PER COMMON SHARE DILUTED (Note 2)	\$ .75	\$ .66	\$ .77
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING BASIC (Note 2)	12,463,075	10,322,226	9,780,104
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING DILUTED (Note 2)	13,824,467	11,797,799	11,323,272

See notes to financial statements



**Table of Contents**

**SOMANETICS CORPORATION**  
**STATEMENTS OF SHAREHOLDERS EQUITY**

	Common Shares	Share Value	Additional Paid-In Capital	Accumulated Deficit	Total Shareholders Equity	Comprehensive Income
Balance at December 1, 2003	9,298,669	\$ 92,987	\$ 59,660,804	\$ (53,588,723)	\$ 6,165,068	
For cash, exercise of stock options	321,276	3,213	1,537,809		1,541,022	
For cash, exercise of warrants	380,000	3,800	1,136,200		1,140,000	
Cashless exercise of warrants	137,837	1,378	(1,378)			
Net income and comprehensive income				8,706,576	8,706,576	\$ 8,706,576
Balance at November 30, 2004	10,137,782	\$ 101,378	\$ 62,333,435	\$ (44,882,147)	\$ 17,552,666	
For cash, exercise of stock options	561,839	5,618	2,520,061		2,525,679	
Cashless exercise of warrants	16,264	163	(163)			
Consultant stock option expense			11,221		11,221	
Net income and comprehensive income				7,751,087	7,751,087	\$ 7,751,087
Balance at November 30, 2005	10,715,885	\$ 107,159	\$ 64,864,554	\$ (37,131,060)	\$ 27,840,653	
For cash, less issuance costs of \$3,967,226	2,300,000	23,000	51,209,774		51,232,774	
For cash, exercise of stock options	79,742	797	439,116		439,913	
Stock compensation expense			304,248		304,248	
Restricted share grant	68,000	680	(680)			
Net income and comprehensive income				10,399,957	10,399,957	\$ 10,399,957

Edgar Filing: SOMANETICS CORP - Form 10-K

Balance at November 30, 2006	13,163,627	\$ 131,636	\$ 116,817,012	\$(26,731,103)	\$ 90,217,545
---------------------------------	------------	------------	----------------	----------------	---------------

See notes to financial statements

54

---

**Table of Contents**

**SOMANETICS CORPORATION  
STATEMENTS OF CASH FLOWS**

	<b>For the Years Ended November 30,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net income	\$ 10,399,957	\$ 7,751,087	\$ 8,706,576
Adjustments to reconcile net income to net cash provided by operations:			
Income tax benefit	(750,000)	(3,300,000)	(6,700,000)
Depreciation and amortization	592,061	383,986	282,558
Accrued interest income	(351,666)		
Stock compensation expense	304,248	11,221	
Accrued income tax expense	(194,000)		
Intangible asset impairment		929,093	
Changes in assets and liabilities:			
Accounts receivable (increase)	(1,208,303)	(1,509,196)	(3,929)
Inventory (increase)	(1,943,049)	(859,312)	(158,611)
Prepaid expenses (increase) decrease	128,481	(365,410)	(134,690)
Accounts payable increase (decrease)	332,931	183,699	(112,135)
Accrued liabilities increase (decrease)	(5,825)	462,485	353,562
Net cash provided by operating activities	7,304,835	3,687,653	2,233,331
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchases of marketable securities and long-term investments	(47,835,897)		
Proceeds from maturities of marketable securities and long-term investments	5,000,000		
Acquisition of property and equipment (net)	(554,993)	(134,637)	(84,003)
Net cash (used in) investing activities	(43,390,890)	(134,637)	(84,003)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of common shares	51,232,774		
Proceeds from issuance of common shares due to exercise of stock options	439,913	2,525,679	2,681,022
Net cash provided by financing activities	51,672,687	2,525,679	2,681,022
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>15,586,632</b>	<b>6,078,695</b>	<b>4,830,350</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>13,148,237</b>	<b>7,069,542</b>	<b>2,239,192</b>

Edgar Filing: SOMANETICS CORP - Form 10-K

CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 28,734,869	\$ 13,148,237	\$ 7,069,542
--	---------------	---------------	--------------

Supplemental Disclosure of Non cash investing activities:

Demonstration and no capital cost sales equipment capitalized from inventory (Note 2)	\$ 828,692	\$ 484,121	\$ 565,962
--	------------	------------	------------

See notes to financial statements

55

---

**Table of Contents**

**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® System, a non-invasive patient monitoring system that continuously measures changes in blood oxygen levels. The principal markets for our products are the United States, Europe, and Japan. The INVOS System, based on our In Vivo Optical Spectroscopy, or INVOS, technology, is used to measure changes in regional blood oxygen saturation in the brain and in somatic, or skeletal muscle, tissue in regions of the body other than the brain. The INVOS System 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 INVOS System in the United States, and in October 1997 we received clearance from the FDA to market enhancements to our INVOS System in the United States. In September 2000 we received FDA clearance to market our model 5100 INVOS System in the United States, which has the added capability of being able to monitor pediatric patients. In November 2005, we received FDA clearance to market the INVOS System to monitor changes in blood oxygen saturation in skeletal muscle tissue in regions of the body other than the brain in patients with or at risk for restricted blood flow.

We also develop and market the CorRestore® System, including the CorRestore Patch, for use in cardiac repair and reconstruction, including heart surgeries called surgical ventricular restoration, or SVR. In 2000, we entered into a license agreement with the inventors of the CorRestore System and their company, CorRestore LLC, granting us exclusive, worldwide, royalty-bearing licenses to specified rights relating to the CorRestore System and related products and accessories for SVR (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. However, 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. Refer to Note 2 for a discussion of the impairment of the CorRestore license acquisition cost intangible asset.

**2. Summary of Significant Accounting Policies**

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

*Marketable Securities and Long-Term Investments* consist of Aaa-rated United States government agency bonds, classified as held to maturity, maturing approximately eight months to three years from the date of acquisition, are stated at an amortized cost of \$42,835,898, and have a November 30, 2006 market value of \$42,912,370.

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

	<b>November 30,</b>	
	<b>2006</b>	<b>2005</b>
Purchased components	\$ 1,456,059	\$ 652,876
Finished goods	610,016	352,560
Work in process	106,383	52,665
Total	\$ 2,172,458	\$ 1,058,101

**Table of Contents**

**SOMANETICS CORPORATION**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

*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. Depreciation expense was \$585,149, \$377,074 and \$275,646 for the fiscal years ended November 30, 2006, November 30, 2005 and November 30, 2004, respectively. We offer to our United States customers a no capital cost sales program whereby we ship the INVOS System monitor to the customer at no charge. The INVOS System monitors that are shipped to our customers are classified as no capital cost sales equipment and are depreciated over five years to cost of goods sold. All other depreciation expense is recorded as a selling, general and administrative expense. As of November 30, 2006, we have capitalized \$2,650,939 in costs for INVOS System monitors being used as demonstration and no capital cost sales equipment, and these assets had a net book value of \$1,529,946. As of November 30, 2005, we have capitalized \$1,916,655 in costs for INVOS System monitors being used as demonstration and no capital cost sales equipment, and these assets had a net book value of \$1,096,730. 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. 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:

	<b>November 30,</b>	
	<b>2006</b>	<b>2005</b>
Patents and trademarks	\$ 111,733	\$ 111,733
Less: accumulated amortization	(101,724)	(94,812)
Total	\$ 10,009	\$ 16,921

Amortization expense was \$6,912 for the fiscal years ended November 30, 2006, November 30, 2005, and November 30, 2004. Amortization expense for fiscal 2007 is expected to be approximately \$6,900 and approximately \$3,100 in fiscal 2008.

In November 2005, we wrote off the remaining CorRestore license acquisition cost intangible asset, based on the cash flow impairment analysis that was performed, the declining sales of CorRestore products and the uncertainty regarding future prospective, randomized clinical data. Management does not expect net positive future cash flow from the CorRestore product. This impairment expense has been recognized in selling, general and administrative expenses in the financial statements.

*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 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, 2006, November 30, 2005 and November 30, 2004, include the potential dilution that could occur for common stock issuable under stock options or warrants. As of November 30, 2006, 2005 and 2004, the difference between weighted average shares diluted and weighted average shares basic is calculated as follows:

**Table of Contents**

**SOMANETICS CORPORATION**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

	2006	2005	2004
Weighted average shares basic	12,463,075	10,322,226	9,780,104
Add: effect of dilutive common shares and warrants	1,361,392	1,475,573	1,543,168
Weighted average shares diluted	13,824,467	11,797,799	11,323,272

At November 30, 2006 and November 30, 2005, there were no stock options outstanding that were excluded from the computation of net income per common share diluted, and at November 30, 2004 there were approximately 500 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, at November 30, 2005 and November 30, 2004, there were approximately 2,100,000 warrants outstanding that were excluded from the computation, as the warrants were contingent on achieving specified future sales targets that we did not expect to achieve. These warrants expired unexercised in November 2006. As of November 30, 2006, we had outstanding 2,071,990 warrants and options to purchase common shares, as of November 30, 2005, we had outstanding 4,014,232 warrants and options to purchase common shares, and as of November 30, 2004, we had outstanding 4,436,315 warrants and options to purchase common shares.

*Accounting Pronouncements* In July 2006, the FASB adopted FASB Interpretation No. 48 *Accounting for Uncertainty in Income Taxes* (FIN 48). FIN 48 prescribes a recognition threshold and requires an assessment of the probability of the validity of tax positions taken or expected to be taken in income tax returns for recognition in financial statements. Only tax positions meeting a more-likely-than-not threshold of being sustained are recognized under FIN 48. FIN 48 also provides guidance on classification of interest and penalties and accounting and disclosures for annual and interim financial statements. FIN 48 is effective for our fiscal year beginning December 1, 2007. The cumulative effect of the changes arising from the initial application of FIN 48 is required to be reported as an adjustment to the opening balance of retained earnings in the period of adoption. We are currently evaluating the impact, if any, the adoption of FIN 48 will have on our financial statements.

In September 2006, the Securities and Exchange Commission released SAB No. 108 regarding the effects of prior year misstatements on assessing the materiality of current year misstatements. SAB 108 provides that if an error has occurred and was immaterial in a number of previous years, the cumulative effect should be considered in assessing the materiality of the error in the current year. If the cumulative effect of the error is material, then the current year financial statements should be restated. In the case of prior year statements, previously filed reports do not need to be amended if the error was considered immaterial to the prior year's financial statements. However the statements should be amended the next time they are filed. This guidance is applicable for our fiscal year ending November 30, 2007. Additional disclosure would be required regarding any cumulative adjustments made in the current year financial statements. We do not believe the adoption of this SAB will have a material impact on our financial statements.

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

### **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.

Edgar Filing: SOMANETICS CORP - Form 10-K

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

58

---



**Table of Contents**

**SOMANETICS CORPORATION**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

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 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 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 these 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.

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. In May 2005, Joe B. Wolfe, agent for CorRestore LLC and one of our former directors, purchased 20,000 common shares under his warrants by a cashless exercise. As a result of this cashless exercise, we issued 16,264 common shares to Mr. Wolfe, retaining 3,736 common shares in payment of the exercise price. In November 2006, the 2,100,000 warrants expired unexercised because cumulative net sales of the CorRestore System products did not meet the requirements for exercise of these warrants.

On March 6, 2006, we completed a public offering of 2,300,000 of our newly-issued common shares at a public offering price of \$24.00 per share. The net proceeds, after deducting the underwriting discount and the expense of the offering, were \$51,232,774.

During fiscal 2006, we issued 79,742 common shares as a result of stock option exercises by employees and a former director, for proceeds of \$439,913. During fiscal 2005, we issued 561,839 common shares as a result of stock option exercises by employees, directors and former employees, for proceeds of \$2,525,679. 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 \$1,541,022.

Common shares reserved for future issuance upon exercise of stock options and warrants as discussed above at November 30, 2006, are as follows:

1991 Incentive Stock Option Plan	14,663
1997 Stock Option Plan	1,653,612
2005 Stock Incentive Plan	532,000
Options Granted Independent of Option Plans	71,500
<b>Total shares reserved for future issuance</b>	<b>2,271,775</b>

**Table of Contents**

**SOMANETICS CORPORATION**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**4. Accrued Liabilities**

Accrued liabilities consist of the following:

	<b>November 30,</b>	
	<b>2006</b>	<b>2005</b>
Incentive Compensation	\$ 495,014	\$ 701,658
Sales Commissions	277,521	352,459
Taxes	228,085	11,375
Clinical Research	60,005	21,675
401(k) Match	45,719	42,164
Professional Fees	22,053	5,625
Warranty	19,900	16,850
Royalty	11,473	13,788
Total	\$ 1,159,770	\$ 1,165,594

**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 \$15,734,000 as of November 30, 2006, which include approximately \$4,790,000 related to the exercise of stock options, which are subject to a full valuation allowance due to the uncertainty of using such assets against future earnings before they expire. If realized in the future, these tax benefits will be recognized in additional paid in capital. As of November 30, 2005, we had deferred tax assets of approximately \$18,321,000, partially offset by valuation allowances of approximately \$8,321,000, 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 percent when calculating our deferred tax assets. We have paid no income taxes for fiscal 2006, fiscal 2005 or fiscal 2004; however as of November 30, 2006 we have accrued approximately \$194,000 for alternative minimum tax due to be paid in the first quarter of fiscal 2007.

The components of deferred income tax assets as of November 30, 2006 and 2005 were as follows:

	<b>November 30,</b>	
	<b>2006</b>	<b>2005</b>
	<b>(in thousands)</b>	
Net operating loss carryforwards	\$ 14,834	\$ 17,620
Other	150	91
Basis difference of fixed assets and intangibles	113	167
Alternative minimum tax credit carryforward	194	
Research and general business tax credit carryforwards	443	443
Subtotal	15,734	18,321
Valuation allowance	(4,790)	(8,321)
Deferred tax asset	\$ 10,944	\$ 10,000

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

60

---

**Table of Contents**

**SOMANETICS CORPORATION**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

	<b>For the Fiscal Year Ended November 30,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Taxes at U.S. statutory rate 34 percent	\$ 3,280,985	\$ 1,513,370	\$ 682,236
Nondeductible meals and entertainment	\$ 37,628	\$ 24,050	\$ 15,109
Change in valuation allowance	\$ (4,068,613)	\$ (4,837,420)	\$ (7,397,345)
Income tax (benefit) from continuing operations	\$ (750,000)	\$ (3,300,000)	\$ (6,700,000)
Effective tax rate	(7.8)%	(74.1)%	(333.9)%

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 four 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 assuming that the net asset will be realized is that our net revenues and pre-tax income will grow in future years consistent with the growth guidance given for fiscal 2007 and 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.

For fiscal 2006 and 2005, the reversal of our valuation allowance was net of recorded taxes. For the fiscal year ended November 30, 2006, we recorded a net income tax benefit of \$750,000, which consisted of income tax expense recorded at an estimated effective tax rate of 34 percent in the amount of \$2,604,663 for the first three quarters of fiscal 2006 and a net deferred tax benefit of \$3,354,663 recorded in the fourth quarter of fiscal 2006. For the fiscal year ended November 30, 2005, we recorded a net income tax benefit of \$3,300,000, which consisted of income tax expense recorded at an estimated effective tax rate of 34 percent in the amount of \$1,261,223 for the first three quarters of fiscal 2005 and a deferred tax benefit of \$4,561,223 recorded in the fourth quarter of fiscal 2005. For the fiscal year ended November 30, 2004, our income tax benefit of \$6,700,000 consisted entirely of deferred tax benefits.

As of November 30, 2006, net operating loss carryforwards of approximately \$43.6 million were available for Federal income tax purposes for future years. Research and business general tax credits of approximately \$443,000 are also available to offset future taxes, and alternative minimum tax credits of approximately \$194,000 are also available to offset future taxes. These losses and credits expire, if unused, at various dates from 2008 through 2025.

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.

Operating lease expense for the years ended November 30, 2006, 2005 and 2004 was approximately \$163,300, \$162,800, and \$204,000, respectively. Approximate future minimum lease commitments are as follows:

**Year ending November 30,**

**Table of Contents**

**SOMANETICS CORPORATION**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

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 percent and 25 percent 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 percent 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 percent 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. Matching contributions made for fiscal 2006 and 2005 were approximately \$215,000 and \$202,000, respectively. The discretionary contribution made in February 2005, for calendar 2004, was approximately \$113,000.

As of November 30, 2006, we have employment agreements or change in control, invention, confidentiality, non-compete and non-solicitation agreements with all of our officers. The employment agreement with our Vice President, Sales and Marketing and the change in control agreements with five of our officers provide for severance benefits equal to one year's salary upon termination of employment without cause or for good reason 90 days before to one year after a change in control of the Company that occurs by June 13, 2008, June 29, 2008 for one officer. The change in control agreement with one of our officers provides for severance benefits equal to six month's salary upon termination of employment without cause or for good reason 90 days before to one year after a change in control of the Company that occurs by December 15, 2009. In addition, on April 19, 2006, we amended and restated the employment agreement with our President and Chief Executive Officer that was scheduled to expire on April 30, 2006. The amended and restated agreement provides for severance benefits consisting of fringe benefits for one year, a lump sum payment equal to one year's salary plus the target bonus for the year of termination (which must be at least 65% of his salary), plus a pro rata bonus through the date of termination, plus an amount equal to the cost of his automobile, cellular phone and Internet access for one year upon termination of his employment without cause or for good reason or if his employment terminates because his agreement expires. His amended and restated employment agreement expires April 30, 2009 unless earlier terminated as provided in the agreement. All officers have agreed not to compete with us and not to solicit our employees during specified periods following the termination of employment, and they have agreed to various confidentiality and assignment of invention obligations. The estimated financial exposure of these agreements, upon a change of control of the Company and termination of all of the officers without cause, is approximately \$1,375,000.

We entered into a Contract Development and Exclusive Licensing Agreement with NeuroPhysics Corporation as of September 18, 2006. The agreement provides us with feasibility research, contract development and consulting services and certain ownership and licensing rights, subject to the rights of the United States Federal government, to intellectual property and technical knowledge associated with several novel near-infrared spectroscopy, or NIRS, and imaging technologies and products under development at NeuroPhysics. We paid an initial license fee of \$1,000,000 and have agreed to pay monthly license fees of up to \$30,000 a month (depending on which projects are continuing under development at NeuroPhysics at the time) for products continuing under development at NeuroPhysics beginning April 1, 2008 and a royalty on future sales of the new products.

We may become subject to product liability claims by patients or physicians, and may become a defendant in product liability or malpractice litigation. We have obtained product 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 product liability.

**7. Stock Option Plans**

In February 1991 and January 1997, we adopted stock option plans, and in February 2005, we adopted a stock incentive plan, for our key employees, directors, consultants and advisors and, under the 2005 plan, independent contractors and agents. The stock option plans provided 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. The 2005 plan

permits us to grant stock options, including both nonqualified options and incentive options, restricted stock and restricted stock units, up to 600,000 common shares. In addition, we granted options to employees

**Table of Contents**

**SOMANETICS CORPORATION**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

independent of the plans. Options granted generally have a 10-year life, and vest over a three-year period, except the options granted in fiscal 2005 vested on November 30, 2005 and the options and restricted stock granted in fiscal 2006 vest over a five-year period. Awards and expirations under the 1991 plan, 1997 plan, 2005 plan and independent of the plans during the years ended November 30, 2006, 2005 and 2004 are listed below.

At November 30, 2006, no additional options may be granted under the 1991 plan, 6,501 common shares were available for options to be granted under the 1997 plan until January 15, 2007, and 193,284 common shares were available to be granted or awarded under the 2005 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 revises Statement No. 123, Accounting for Stock-Based Compensation, and requires that compensation costs related to share-based payment transactions, including stock options, restricted stock and restricted stock units be recognized in the financial statements. This Statement was effective for our fiscal quarter beginning December 1, 2005. We adopted this Statement for fiscal 2006 using a modified prospective application and, accordingly, prior period amounts have not been restated.

We previously accounted 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 were 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 for fiscal 2005 and 2004. Stock-based compensation of consultants and advisors was 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 below. The resulting amount was 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 \$11,221 of compensation expense, and an equal increase in additional paid in capital, for stock options issued to non-employees in fiscal 2005. We recorded no such expense in fiscal 2004.

In November 2005, we approved the acceleration of vesting of all unvested stock options as of November 30, 2005. The primary purpose of this accelerated vesting was to eliminate compensation expense we would recognize in our results of operations upon the adoption of SFAS 123R, which is effective for our fiscal quarter beginning December 1, 2005. After the effects of the accelerated vesting, the initial adoption of SFAS 123R was immaterial with respect to options granted before December 1, 2005. However, the issuance of additional stock compensation under the 2005 Stock Incentive Plan in fiscal 2006 had an additional impact on our financial statements.

On November 10, 2005, the Financial Accounting Standards Board (the FASB) issued FASB Staff Position ( FSP ) No. FAS 123(R)-3, Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards ( FSP 123R-3 ). FSP 123R-3 provides for an alternative transition method for establishing the beginning balance of the additional paid-in capital pool ( APIC pool ) related to the tax effects of employee share-based compensation, which is available to absorb tax deficiencies recognized subsequent to the adoption of SFAS No. 123R. We have elected to adopt this alternative transition method, otherwise known as the simplified method, in establishing our beginning APIC pool at November 30, 2006.

During fiscal 2006, we granted 239,000 stock options to our officers, employees, directors and one of our consultants, at the market price on the date of grant. We also issued 68,000 restricted common shares to our officers at the market price on the date of grant of \$18.06. These stock options and restricted shares vest and are expensed in the financial statements over five years. As a result of the stock options and restricted common shares that we





**Table of Contents**

**SOMANETICS CORPORATION**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

granted during fiscal 2006, we have recorded \$304,248 in stock compensation expense in accordance with SFAS No. 123(R), which caused basic and diluted earnings per share to decrease by \$.02 per share.

As of November 30, 2006, there was \$3,260,855 of total unrecognized compensation cost related to nonvested share-based compensation awards granted under the 2005 Plan. That cost is expected to be recognized over a weighted average period of 4.5 years.

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:

	<b>For the Fiscal Year Ended November 30,</b>	
	<b>2005</b>	<b>2004</b>
Net income	\$ 7,751,087	\$ 8,706,576
Add: Stock-based employee compensation included in actual net income	\$ 11,221	\$ 0
Deduct: Total stock-based employee compensation, had fair value method been applied	\$ (1,804,000)	\$ (796,000)
 Pro-forma net income	 \$ 5,958,308	 \$ 7,910,576
 Net income per common share basic	 \$ .75	 \$ .89
Net income per common share diluted	\$ .66	\$ .77
Pro-forma net income per common share basic, had fair value method been applied	\$ .58	\$ .81
Pro-forma net income per common share diluted, had fair value method been applied	\$ .51	\$ .70

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 2006, 2005 and 2004: expected volatility (the measure by which the stock price has fluctuated or is expected to fluctuate during the period) 54.00 percent for 2006 (57.00 percent for 2005 and 61.00 percent for 2004), risk-free interest rate (approximate U.S. Treasury yield in effect at the time of grant) 5.0 percent for 2006 (4.0 percent for 2005 and 2004), expected lives of 6 years for fiscal 2006 (7 years for 2005 and 2004) and dividend yield of 0 percent. The fair value of restricted common shares was estimated based on the market value of the common shares on the date of issuance.

A summary of our stock option activity and related information for the years ended November 30, 2006, 2005 and 2004 is as follows:

	<b>2006</b>		<b>2005</b>		<b>2004</b>	
	<b>Common Shares</b>	<b>Weighted Average Exercise Price</b>	<b>Common Shares</b>	<b>Weighted Average Exercise Price</b>	<b>Common Shares</b>	<b>Weighted Average Exercise Price</b>
Options outstanding December 1,	1,914,232	\$ 4.59	2,316,315	\$ 3.83	2,603,722	\$ 3.89
Options granted	239,000	17.30	168,257	13.79	53,500	10.23
Options exercised	(79,742)	5.52	(561,839)	4.50	(321,276)	4.79
Options canceled	(1,500)	17.56	(8,501)	8.29	(19,631)	13.94
	2,071,990	6.01	1,914,232	4.59	2,316,315	3.83

Options outstanding  
November 30,

Options exercisable  
November 30,

1,832,990	\$	4.53	1,914,232	\$	4.59	1,827,008	\$	3.91
-----------	----	------	-----------	----	------	-----------	----	------

**Table of Contents**

**SOMANETICS CORPORATION**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

As of November 30, 2006, the aggregate intrinsic value of stock options outstanding was \$27,743,946, and the aggregate intrinsic value of stock options exercisable was \$27,256,561. The total intrinsic value of options exercised during fiscal 2006, 2005 and 2004 was \$1,188,554, \$10,245,571, and \$2,192,325, respectively.

A summary of the price ranges of our stock options outstanding and exercisable as of November 30, 2006 is as follows:

Range of Exercise Prices	Options Outstanding	Options outstanding		Options exercisable		
		Weighted Average Exercise Price	Weighted Average Remaining Life (years)	Options Exercisable	Weighted Average Exercise Price	Weighted Average Remaining Life (years)
\$1.70 - \$5.00	1,371,597	\$ 3.03	5.13	1,371,597	\$ 3.03	5.13
\$5.01 - \$10.00	272,132	5.88	1.40	272,132	5.88	1.40
\$10.01 - \$18.06	428,261	15.63	9.09	189,261	13.52	8.46
Total	2,071,990	\$ 6.01	5.46	1,832,990	\$ 4.53	4.92

The weighted-average grant-date fair value of options granted during fiscal 2006, 2005 and 2004 was \$9.78, \$8.41, and \$6.50, respectively. The total fair value of shares vested during fiscal 2006, 2005, and 2004 was \$0, \$2,596,945, and \$905,182, respectively. No modifications were made to any share awards that required an accounting charge, and no cash was paid for share-based liabilities during fiscal 2006, 2005 and 2004.

Also, see Note 11 for approval of an amendment to the 2005 plan.

### 8. Related Party Transactions

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 per share. Mr. Joe B. Wolfe was one of our then current directors. In May 2005, Joe B. Wolfe, agent for CorRestore LLC and one of our former directors, purchased 20,000 common shares under his warrants by a cashless exercise. As a result of this cashless exercise, we issued 16,264 common shares to Mr. Wolfe, retaining 3,736 common shares in payment of the exercise price. Mr. Wolfe has no vested warrants remaining to purchase common shares.

In connection with our January 2002 public offering of common shares, Brean Murray & Co., Inc. was our 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 these 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

Tyco Healthcare, part of Tyco International Ltd., our international distributor in Europe, the Middle East, Africa and Canada for our INVOS System, accounted for 15 percent of net revenues for the fiscal year ended November 30, 2006, and 11 percent of net revenues for the fiscal year ended November 30, 2005.

Additionally, foreign net revenues for the fiscal year ended November 30, 2006 were \$5,424,536, for the fiscal year ended November 30, 2005 were \$3,303,692, and for the fiscal year ended November 30, 2004 were \$2,091,602.

**Table of Contents**

**SOMANETICS CORPORATION  
NOTES TO FINANCIAL STATEMENTS (Continued)**

**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 99 percent of our net revenues in fiscal 2006 were derived from our INVOS System product line, compared to 98 percent of our net revenues in fiscal 2005 and 96 percent of our net revenues in fiscal 2004.

**11. Subsequent Events**

On January 17, 2007, our board of directors approved an amendment to the Somanetics Corporation 2005 Stock Incentive Plan to increase the number of common shares reserved for issuance under the 2005 plan by 600,000 shares, from 600,000 to 1,200,000 shares, subject to shareholder approval at the 2007 Annual Meeting of Shareholders.

**Table of Contents****QUARTERLY INFORMATION (unaudited)**

The following is a summary of our quarterly operating results for the fiscal years ended November 30, 2006 and 2005:

	Quarter			
	First	Second (in thousands, except per share data)	Third	Fourth
<b>Year Ended November 30, 2006</b>				
Net revenues	\$5,753,715	\$7,394,857	\$7,867,739	\$7,684,289
Gross margin	5,043,216	6,470,360	6,785,849	6,835,587
Net income	988,287	2,174,452	1,893,371	5,343,847*
Net income per common share basic	\$ 0.09	\$ 0.17	\$ 0.14	\$ 0.41
Net income per common share diluted	\$ 0.08	\$ 0.15	\$ 0.13	\$ 0.37

\* Includes the effects of a net reversal of \$3,354,663 of our valuation allowance, as described in Note 5 of Notes to Financial Statements. Also includes a research and development expense of \$1,000,000 in connection with the Contract Development and Exclusive Licensing Agreement we entered into with NeuroPhysics Corporation, as described in Note 6 of Notes to Financial Statements.

**Year Ended November 30, 2005**

Net revenues	\$4,032,617	\$5,082,746	\$5,242,848	\$6,151,041
Gross margin	3,482,468	4,437,906	4,581,652	5,405,738
Net income	563,926	890,183	994,147	5,302,831**

Edgar Filing: SOMANETICS CORP - Form 10-K

Net income per common share	basic	\$	0.06	\$	0.09	\$	0.10	\$	0.50
Net income per common share	diluted	\$	0.05	\$	0.08	\$	0.08	\$	0.43

\*\* Includes the effects of a net reversal of \$4,561,223 of our valuation allowance, as described in Note 5 of Notes to Financial Statements. Also includes an impairment expense of \$929,093 in connection with the write-off of our intangible asset associated with the acquisition of the license for the CorRestore System, as described in Note 2 of Notes to Financial Statements.

**Table of Contents**

**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 and of our internal control over financial reporting, both as of November 30, 2006. Based on their evaluation, our principal executive and principal financial officers have concluded that these controls and procedures are effective as of November 30, 2006. See Item 8 of this report for Management's Report on Internal Control Over Financial Reporting and our Independent Registered Public Accounting Firm's Attestation Report, which are incorporated in this Item 9A by reference. 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, 2006 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.

Internal control over financial reporting is a process designed by, or under the supervision of, our principal executive and principal financial officers, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that: (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect our transactions and dispositions of assets, (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors, and (3) and provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

**Table of Contents**

**ITEM 9B. OTHER INFORMATION**

None.

69

---



**Table of Contents****PART III****ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

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 2007 Annual Meeting of Shareholders scheduled to be held April 19, 2007, 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 2007 Annual Meeting of Shareholders scheduled to be held April 19, 2007, 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 2007 Annual Meeting of Shareholders scheduled to be held April 19, 2007, and is incorporated in this Item 10 by reference. The information required by this Item 10 concerning the procedures by which security holders may recommend nominees to our board of directors will be set forth under the caption Corporate Governance Nominating Committee in our Proxy Statement in connection with the 2007 Annual Meeting of Shareholders scheduled to be held April 19, 2007, and is incorporated in this Item 10 by reference. The information required by this Item 10 concerning our Audit Committee and our Audit Committee financial experts will be set forth under the caption Corporate Governance Audit Committee and Corporate Governance Audit Committee Financial Expert in our Proxy Statement in connection with the 2007 Annual Meeting of Shareholders scheduled to be held April 19, 2007, and is incorporated in this Item 10 by reference.

**ITEM 11. EXECUTIVE COMPENSATION**

The information required by this Item 11 concerning executive compensation will be set forth under the caption Executive Compensation in our Proxy Statement in connection with the 2007 Annual Meeting of Shareholders scheduled to be held April 19, 2007, and is incorporated in this Item 11 by reference. The information required by this Item 11 concerning Compensation Committee Interlocks and Insider Participation will be set forth under the caption Corporate Governance Compensation Committee Interlocks and Insider Participation in our Proxy Statement in connection with the 2007 Annual Meeting of Shareholders scheduled to be held April 19, 2007, and is incorporated in this Item 11 by reference. The information required by this Item 11 concerning the Compensation Committee Report will be set forth under the caption Corporate Governance Compensation Committee Report in our Proxy Statement in connection with the 2007 Annual Meeting of Shareholders scheduled to be held April 19, 2007, 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 2007 Annual Meeting of Shareholders scheduled to be held April 19, 2007, 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 2007 Annual Meeting of Shareholders scheduled to be held April 19, 2007, and is incorporated in this Item 12 by reference.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required by this Item 13 concerning transactions with related persons, if any, will be set forth under the caption Certain Transactions or Compensation Committee Interlocks and Insider Participation and under the caption Review, Approval or Ratification of Transactions with Related Persons in our Proxy Statement in connection with the 2007 Annual Meeting of Shareholders scheduled to be held April 19, 2007, and is incorporated in this Item 13 by reference. The information required by this Item 13 concerning director independence will be set forth under the caption Corporate Governance Independence in our Proxy Statement in



**Table of Contents**

connection with the 2007 Annual Meeting of Shareholders scheduled to be held April 19, 2007, 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 2007 Annual Meeting of Shareholders scheduled to be held April 19, 2007, and is incorporated in this Item 14 by reference.

**Table of Contents**

**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, 2006 and 2005

Statements of Operations For Each of the Three Years in the Period Ended November 30, 2006

Statements of Shareholders Equity For Each of the Three Years in the Period Ended November 30, 2006

Statements of Cash Flows For Each of the Three Years in the Period Ended November 30, 2006

Notes to Financial Statements

(2) Financial Statement Schedules

None.

(3) Exhibits

The Exhibits to this report are as set forth in the Exhibit Index on pages 74 to 77 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.

**Table of Contents****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 8, 2007

By: /s/ Bruce J. Barrett  
 Bruce J. Barrett  
 President & Chief Executive Officer

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

Signature	Title	Date
/s/ BRUCE J. BARRETT  <b>Bruce J. Barrett</b>	President and Chief Executive Officer and a Director (Principal Executive Officer)	February 8, 2007
/s/ WILLIAM M. IACONA  <b>William M. Iacona</b>	Vice President and Chief Financial Officer, Controller, and Treasurer (Principal Financial Officer and Principal Accounting Officer)	February 8, 2007
/s/ JAMES I. AUSMAN  <b>James I. Ausman, M.D., Ph.D.</b>	Director	February 8, 2007
/s/ DANIEL S. FOLLIS  <b>Daniel S. Follis</b>	Director	February 7, 2007
/s/ ROBERT R. HENRY  <b>Robert R. Henry</b>	Director	February 7, 2007
/s/ RICHARD R. SORENSEN  <b>Richard R. Sorensen</b>	Director	February 7, 2007

**Table of Contents****EXHIBIT INDEX**

<b>Exhibit</b>	<b>Description</b>
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 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.

Edgar Filing: SOMANETICS CORP - Form 10-K

- \*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 1997 Stock Option Plan, incorporated by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1996.
- \*10.13 First Amendment to Somanetics Corporation 1997 Stock Option Plan, incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1997.
- \*10.14 Second Amendment to Somanetics Corporation 1997 Stock Option Plan, incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1998.

**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit</b>	<b>Description</b>
*10.15	Third Amendment to Somanetics Corporation 1997 Stock Option Plan, incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1999.
*10.16	Fourth Amendment to Somanetics Corporation 1997 Stock Option Plan, incorporated by reference to Exhibit 10.16 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 2000.
*10.17	Fifth Amendment to Somanetics Corporation 1997 Stock Option Plan, incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended February 28, 2002.
*10.18	Sixth Amendment to Somanetics Corporation 1997 Stock Option Plan, incorporated by reference to Exhibit 10.18 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 2002.
*10.19	Somanetics Corporation 2005 Stock Incentive Plan, incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, dated February 24, 2005
*10.20	First Amendment to Somanetics Corporation 2005 Stock Incentive Plan, incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, dated January 17, 2007 and filed January 23, 2007.
*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	Somanetics Corporation 2006 Incentive Compensation Plan, incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, dated March 24, 2006 and filed March 30, 2006.
*10.23	Summary of Dominic Spadafore Fiscal 2006 Commission Arrangement, incorporated by reference to the last two paragraphs of Item 1.01 of the Company's Current Report on Form 8-K, dated March 24, 2006 and filed March 30, 2006.
*10.24	Somanetics Corporation 2007 Executive Officer Incentive Compensation Plan, incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, dated January 17, 2007 and filed January 23, 2007.
*10.25	Summary of Dominic Spadafore Fiscal 2007 Commission Arrangement, incorporated by reference to the two paragraphs under the heading "2007 Sales Commission Arrangement for Dominic Spadafore" in Item 5.02 of the Company's Current Report on Form 8-K, dated January 17, 2007 and filed January 23, 2007.
*10.26	



## Edgar Filing: SOMANETICS CORP - Form 10-K

Amended and Restated Employment Agreement between Somanetics Corporation and Bruce J. Barrett, incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K, dated April 19, 2006 and filed April 24, 2006.

- \*10.27 Amended and Restated Employment Agreement between Somanetics Corporation and Dominic J. Spadafore, incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K, dated June 13, 2005 and filed June 14, 2005.
- \*10.28 Form of Change in Control, Invention, Confidentiality, Non-Compete and Non-Solicitation Agreement, between Somanetics Corporation and five officers, dated as of June 13, 2005, incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K, dated June 13, 2005 and filed June 14, 2005.
- \*10.29 Form of Director Stock Option Agreement, incorporated by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 2004.
- \*10.30 Form of Officer Non-Qualified Stock Option Agreement, incorporated by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 2004.
- \*10.31 Form of Employee Non-Qualified Stock Option Agreement, incorporated by reference to Exhibit 10.32 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 2004.
- \*10.32 Form of Incentive Stock Option Agreement, incorporated by reference to Exhibit 10.33 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 2004.

**Table of Contents****EXHIBIT INDEX**

<b>Exhibit</b>	<b>Description</b>
*10.33	Form of 2005 Stock Incentive Plan Incentive Stock Option Agreement, incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended May 31, 2005.
*10.34	Form of 2005 Stock Incentive Plan Officer Non-Qualified Stock Option Agreement, incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended May 31, 2005.
*10.35	Form of 2005 Stock Incentive Plan Non-Officer Non-Qualified Stock Option Agreement, incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended May 31, 2005.
*10.36	Form of 2005 Stock Incentive Plan Director Stock Option Agreement, incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended May 31, 2005.
*10.37	Form of Restricted Stock Agreement, incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, dated June 29, 2006 and filed July 5, 2006.
*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.
*10.40	Summary of Outside Director Compensation, incorporated by reference to Item 1.01 to the Company's Current Report on Form 8-K dated June 29, 2006 and filed July 5, 2006.
*10.41	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.
10.42	Contract Development and Exclusive Licensing Agreement, dated as of September 18, 2006, among Somanetics Corporation, NeuroPhysics Corporation, Hugh F. Stoddart, and Hugh A. Stoddart, incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K, dated September 18, 2006 and filed September 20, 2006.
10.43	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.
10.44	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

## Edgar Filing: SOMANETICS CORP - Form 10-K

Report on Form 10-Q for the quarter ended August 31, 1992.

- 10.45 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.
- 10.46 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.
- 10.47 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, as re-adopted November 16, 2006.
- 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

**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit</b>	<b>Description</b>
	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.