

SOMANETICS CORP  
Form 10-K  
February 03, 2010

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, 2009

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.)

**2600 Troy Center Drive, Troy, Michigan**

(Address of principal executive offices)

**48084-4771**

(Zip Code)

Registrant's telephone number, including area code: **(248) 244-1400**

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

Title of each class  
**Common Shares, par value \$.01 per share**

Name of each exchange on which registered  
**The NASDAQ Stock Market**

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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

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. ☒

Edgar Filing: SOMANETICS CORP - Form 10-K

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐ Smaller reporting company ☐  
(Do not check if a smaller reporting company)

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 29, 2009 (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 \$199,500,000.

The number of the registrant's common shares outstanding as of February 2, 2010 was 11,946,102.

**Documents Incorporated by Reference**

Portions of the Proxy Statement for the 2010 Annual Meeting of Shareholders, scheduled to be held April 21, 2010, are incorporated by reference in Part III, if the Proxy Statement is filed no later than March 29, 2010.

---

**SOMANETICS CORPORATION  
ANNUAL REPORT ON FORM 10-K  
FOR THE FISCAL YEAR ENDED NOVEMBER 30, 2009  
TABLE OF CONTENTS**

	PAGE
<u>PART I</u>	2
<u>ITEM 1. BUSINESS</u>	2
<u>ITEM 1A. RISK FACTORS</u>	21
<u>ITEM 1B. UNRESOLVED STAFF COMMENTS</u>	34
<u>ITEM 2. PROPERTIES</u>	34
<u>ITEM 3. LEGAL PROCEEDINGS</u>	34
<u>ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</u>	34
<u>SUPPLEMENTAL ITEM. EXECUTIVE OFFICERS OF THE REGISTRANT</u>	35
<u>PART II</u>	37
<u>ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	37
<u>ITEM 6. SELECTED FINANCIAL DATA</u>	40
<u>ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	41
<u>ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	53
<u>ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	54
<u>ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	73
<u>ITEM 9A. CONTROLS AND PROCEDURES</u>	73
<u>ITEM 9B. OTHER INFORMATION</u>	73
<u>PART III</u>	74
<u>ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	74
<u>ITEM 11. EXECUTIVE COMPENSATION</u>	74
<u>ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	74
<u>ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>	74
<u>ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	75
<u>PART IV</u>	76
<u>ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES</u>	76
<u>EX-14.1</u>	
<u>EX-21.1</u>	
<u>EX-23.1</u>	
<u>EX-31.1</u>	
<u>EX-31.2</u>	
<u>EX-32.1</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 provides accurate, real-time blood oxygen measurements in the brain and elsewhere in the body in tissues beneath the sensor in patients greater than 2.5 kilograms, and continuously measures changes in blood oxygen levels for individuals of any weight. The INVOS System is the only commercially-available cerebral/somatic oximeter proven to improve outcomes.

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 technology, which is used with multiple single-use disposable sensors, called SomaSensors or OxyAlert sensors. During our fiscal year ended November 30, 2009, net revenues from disposable sensors comprised approximately 81% of our net revenues. As of November 30, 2009, we had an installed base of 2,927 INVOS System monitors in the United States in 782 hospitals, and during fiscal 2009 we sold 502,026 sensors 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% to 3% and patients with major organ morbidity or mortality have significantly longer length of stay in the intensive care unit, or ICU, than those without. Additionally, in 2004, the results of a large retrospective review showed a statistically significant greater than 50% reduction (2.01% versus 0.97%) 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, infants and neonates. 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 fiscal 2005, we initiated selling and marketing efforts for the INVOS System in the pediatric ICU, and in fiscal 2008 we expanded the use of our INVOS System in the pediatric and neonatal ICUs with the launch of our smaller sensor. Some of our potential future markets may include other major surgeries involving high risk patients. While our initial focus has been commercializing the INVOS System to measure blood oxygen saturation changes in the brain, many clinicians in the pediatric and neonatal ICU use the INVOS System to assess changes in oxygen saturation in regions of the body other than the brain in addition to cerebral oxygen saturation.

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 May 2008, we received 510(k) clearance from the FDA to market our INVOS System to monitor changes in blood oxygen saturation in any tissues beneath the sensor, not limited to brain and somatic tissue, in any individual. In April 2009, we received 510(k) clearance from the FDA to expand the indications for use to reflect the INVOS System's ability to provide accurate, immediate blood oxygen saturation measurements in patients greater than 2.5 kilograms at risk for restricted or no blood flow, in addition to our previous FDA clearance to measure changes in blood oxygen saturation in any individual. In addition, this most recent 510(k) clearance expanded the labeling for our INVOS System to include the following new labeling claims:



## **Table of Contents**

The measurement of regional cerebral oxygen saturation (rSO<sub>2</sub>) is an indication of whether oxygen delivery to the brain is adequate. Prolonged declines in rSO<sub>2</sub> are indicative of, or may result in, potential brain injury.

When used as an indication of compromised cerebral oxygenation, interventions to return the patient's rSO<sub>2</sub> to baseline using the INVOS System have been shown to improve outcomes after surgery.

In neonates, infants and children, cerebral and somatic rSO<sub>2</sub> provide noninvasive indications of oxygen changes in the cerebral and peripheral circulatory systems and may provide an early indication of oxygen deficits associated with impending shock states and anaerobiosis.

Our four-channel cerebral and somatic INVOS System monitor, which we launched in the second quarter of 2006, can display information from four disposable sensors. This feature allows for the simultaneous monitoring of blood oxygen saturation in tissues beneath the sensor in four different places in the body in patients greater than 2.5 kilograms at risk for restricted or no blood flow, and also allows for the simultaneous monitoring of changes in blood oxygen saturation in four different places in the body in all individuals.

We are sponsoring and evaluating sponsorship of clinical trials which may allow us to more actively target the sale of the INVOS System for use in high risk patient populations and other patient populations. There are also numerous other independent clinical studies currently evaluating the use of the INVOS System.

In November 2008, we acquired substantially all of the assets of ICU Data Systems, Inc. ICU Data Systems developed a patented technology that integrates data from a broad array of hospital bedside devices, such as physiological monitors, ventilators and infusion devices, into a single bedside display for comparison, data management and storage. The data integration technology allows customized presentation of data from various bedside devices for comparison on the same display and on the same timeline. The device can also calculate and display derived parameters, or calculated parameters based on the combination of two or more discrete parameters. In addition, the device can produce user-defined, automated event marks and alerts. All resulting information can be stored for inclusion in the patient record and clinical research. We launched our newly-acquired data integration technology, as a stand-alone device that we call Vital Sync, in the third quarter of fiscal 2009. The INVOS System is one of many devices whose data can be integrated into the stand-alone device. To support the addition of the derived parameter features to the system, we have filed a new FDA 510(k) premarket notification in the fourth quarter of fiscal 2009. In addition, we expect to invest to combine the ICU Data Systems and INVOS System technologies in a single product in fiscal 2010. Upon completion of development of a single product combining the Vital Sync System with our INVOS System technology, we also plan to pursue a new FDA 510(k) clearance for this integrated device for a launch currently expected in mid-2011.

We sell the INVOS System and Vital Sync System through a direct sales team in the United States, consisting of salespersons and clinical specialists, the size of which has increased from 53 persons at the end of fiscal 2007 to 63 persons at the end of fiscal 2009, and an independent sales representative firm. Outside the United States, we have distribution agreements with independent distributors for the INVOS System, including Covidien in Europe, Canada, the Middle East and South Africa, and Edwards Lifesciences Ltd. in Japan. During fiscal 2009, we extended our distribution agreement with Covidien for three years beginning in February 2010 and in December 2009, we extended our distribution agreement with Edwards through fiscal 2014. We expect to increase the size of our U.S. direct sales team in fiscal 2010 and have hired and may hire additional direct salespersons and clinical specialists in Europe to support Covidien. Our net revenues have increased from \$38.6 million in the fiscal year ended November 2007 to \$50.0 million in fiscal 2009, representing a compounded annual growth rate of 13.8%. As a percentage of net revenues, our gross margin decreased from 88% in fiscal 2007 to 87% in fiscal 2009.

### **Our Corporate Information**

We were incorporated under the laws of the State of Michigan in 1982. Our principal executive offices are located at 2600 Troy Center Drive, Troy, Michigan 48064-4771, and our telephone number is (248) 244-1400. 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,



## **Table of Contents**

Somanetics Corporation, the Company, we, us and our refer to Somanetics Corporation, a Michigan corporation. Somanetics®, INVOS®, SomaSensor®, Window to the Brain®, Reflecting the Color of Life®, Enlightening Medicine®, OxyAlert®, OxyAlert NIRSensor®, and iCuro® are our United States registered trademarks. Each of the other trademarks, trade names or service marks appearing in this report is either pending registration or belongs to its respective holder.

### **Industry**

#### ***Market Opportunity***

We believe that in the United States in 2008 there were 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, orthopedic 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 tissue 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 other tissues 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. 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

**Table of Contents**

attempt to ensure adequate brain oxygen levels and may have an adverse impact on patient safety and increase hospital costs.

**Our Solution**

Our INVOS System is a non-invasive patient monitoring system that provides accurate, real-time blood oxygen measurements in the brain and elsewhere in the body in tissues beneath the sensor in patients greater than 2.5 kilograms, and continuously measures changes in blood oxygen levels for individuals of any weight. 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 is the only commercially-available cerebral/somatic oximeter proven to improve outcomes. 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 technology, which is used with multiple single-use disposable sensors. For multi-channel cerebral monitoring, disposable sensors are placed on both sides of a patient's forehead and are connected to the monitor. The INVOS System uses our proprietary technology to analyze information received from the disposable sensors and provides a continuous digital and trend display of the blood oxygen saturation in the area of the body under the sensors. Our four-channel cerebral and somatic INVOS System monitor, which we launched in the fiscal 2006, can display information from four disposable sensors. This feature allows for the simultaneous monitoring of blood oxygen saturation in tissues beneath the sensor in four different places in the body in patients with or at risk for restricted blood flow.

Surgeons, anesthesiologists, pediatric and neonatal ICU physicians, and other medical professionals can use the information provided by the INVOS System, in conjunction with other available information, to identify brain and other tissue oxygen imbalances and take necessary corrective action, potentially improving patient outcomes and reducing the costs of care. Once the cause of a cerebral or other tissue 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.

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 oxygen supply and demand, including changes in arterial oxygen saturation, blood flow, hemoglobin concentration and oxygen consumption. The INVOS System responds to global changes in brain or other tissue oxygen levels and to events that affect oxygen levels in the region beneath the sensor.

**Table of Contents**

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

<b>Features</b>	<b>Benefits</b>
Non-invasive	Reduced risk to patients and medical professionals  Consistent with market trend toward less invasive medical procedures
Continuous Information	Immediate information regarding oxygen imbalances to help guide therapeutic interventions  Trend information, rather than at a single point in time
4-Channel Monitoring	Simultaneous cerebral and other tissue monitoring  Provides more data points to help manage patient care
Cost-Effective	Low cost relative to traditional brain monitoring methods  Small portion of the total cost of the procedures in which it is used  Information can potentially improve patient outcomes and reduce the overall cost of care
Easy to Use	Does not require a dedicated technician to operate or interpret  Automatic sensor calibration  Simple user interface and controls
Effective in Difficult Circumstances	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
Portable/Compatible	Placed at patient's bedside  Lightweight  Can be integrated or interfaced with existing multi-modality systems

**ICU Data Systems, Inc.**

In November 2008, we acquired substantially all of the assets of ICU Data Systems, Inc. ICU Data Systems developed a patented technology that integrates data from a broad array of hospital bedside devices, such as physiological monitors, ventilators and infusion devices, into a single bedside display for comparison, data management and storage. The data integration technology allows customized presentation of data from various bedside devices for comparison on the same display and on the same timeline. The device can also calculate and display derived parameters, or calculated parameters based on the combination of two or more discrete parameters. In addition, the device can produce user-defined, automated event marks and alerts. All resulting information can be stored for inclusion in the patient record and clinical research.

We launched our newly-acquired data integration technology, as a stand-alone device that we call Vital Sync<sup>®</sup>, in the third quarter of fiscal 2009. The INVOS System is one of many devices whose data can be integrated into the

stand-alone device. To support the addition of the derived parameter features to the system, we have filed a new FDA 510(k) premarket notification in the fourth quarter of fiscal 2009. In addition, we expect to invest to combine the ICU Data Systems and INVOS System technologies in a single product in fiscal 2010. Upon completion of development of a single product combining the Vital Sync System with our INVOS System technology, we also plan to pursue a new FDA 510(k) clearance for this integrated device for a launch currently expected in mid-2011.

**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:

## Table of Contents

***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, orthopedic surgeries and other major surgeries involving high risk patients. We believe that the medical professionals involved in these surgeries and ICU treatments are most aware of 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 700 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 also sponsoring and evaluating sponsorship of other clinical trials which may allow us to more actively target the sale of the INVOS System for use in other high risk patient populations and 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. In early 2008, The Society of Thoracic Surgeons began collecting cerebral oximetry information as part of its STS Adult Cardiac Surgery Database, which is used to develop practice standards intended to improve quality and safety.

***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 firm and distributors. We sell the INVOS System and Vital Sync System through a direct sales team in the United States, the size of which has increased from 53 persons at the end of fiscal 2007 to 63 persons at the end of fiscal 2009, and an independent sales representative firm. We expect to increase the size of our U.S. direct sales team in fiscal 2010 and have hired and may hire additional direct salespersons and clinical specialists in Europe to support Covidien and to sell our Vital Sync System. 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 our sensors. We expect that such arrangements will provide another distribution channel for our INVOS System. We launched our newly-acquired data integration technology, as a stand-alone device that we call Vital Sync, in the third quarter of fiscal 2009. The INVOS System is one of many devices whose data can be integrated into the stand-alone device. To support the addition of the derived parameter features to the system, or calculated parameters based on the combination of two or more discrete parameters, we have filed a new FDA 510(k) premarket notification in the fourth quarter of fiscal 2009. In addition, we expect to invest to combine the ICU Data Systems and INVOS System technologies in a single product in fiscal 2010. Upon completion of development

of a single product combining the Vital Sync System with our INVOS System technology, we also plan to pursue a new FDA 510(k) clearance for this integrated device for a launch currently expected in mid-2011.

## **Table of Contents**

***Develop Additional Applications and Markets for the INVOS System.*** We have developed a smaller sensor for use with infants and neonates, and are making other advances to the design and performance features of the INVOS System, including the disposable sensor. We are also evaluating additional potential market segments for our INVOS System, such as use in orthopedic surgeries and other major surgeries, in the adult ICU, in assessing individuals with sleep disorders, and for applications of the technology to monitor other tissues. We are also exploring several novel near-infrared spectroscopy and imaging technologies and products under a Contract Development Agreement with Shirley Research Corporation, an Exclusive Sublicense Agreement with Raba Equity Partners II, LLC ( Raba coreFoundry ), and a Development and Exclusive License Agreement with an inventor and his company. See NeuroPhysics Corporation and Shirley Research Corporation , Raba Equity Partners II, LLC and Compartment Syndrome below. Pursuit of some of these potential market segments may require additional FDA clearance. We believe that these natural extensions 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 technology, which is used with multiple single-use disposable sensors.

***Monitor.*** Our oximeter is a portable monitor that uses our proprietary technology to analyze information received from the disposable sensors. It provides a continuous digital and trend display of the blood oxygen saturation in the region of the body under the sensors. 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 USB storage device or through a direct link to a computer. Our four-channel cerebral and somatic INVOS System monitor, which we launched in fiscal 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. As of November 30, 2009, we had an installed base of 2,927 INVOS System monitors in the United States in 782 hospitals.

***Disposable sensors.*** Each single-use disposable sensor contains a light source and two light detectors. For multi-channel cerebral monitoring, disposable sensors 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 four-channel cerebral and somatic INVOS System monitor, which we launched in fiscal 2006, can display information from four sensors. This feature allows for the simultaneous monitoring of blood oxygen saturation in tissues beneath the sensors in four different places in the body in patients with or at risk for restricted blood flow. The number of sensors used depends on the application. The INVOS System is being used to monitor simultaneously the brain and other tissue initially for patients in the pediatric and neonatal ICU and for monitoring other, non-brain tissue alone, and we expect that it will later also be used on adults for other, non-brain tissue. The disposable sensors contain information that is processed by the INVOS System allowing it to automatically calibrate each sensor. During our fiscal year ended November 30, 2009, net revenues from our disposable sensors comprised approximately 81% of our net revenues. During fiscal 2009 we sold 502,026 sensors 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



## **Table of Contents**

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 disposable sensors transmitting low-intensity visible and near-infrared light through a portion of the body and detecting the manner in which the molecules of the exposed substance interact with light at specific wavelengths.

Each single-use disposable sensor contains a light source and two light detectors. The dual detector design of the sensor 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 other 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 other tissue under examination to provide a measurement of brain or other 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 other tissue monitoring in the following key market segments:

***Cardiac and Carotid Artery Surgery.*** Until 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 fiscal 2005, we initiated selling and marketing efforts for the INVOS System in the pediatric ICU. In the first half of fiscal 2008, we expanded the use of our INVOS System in the pediatric and neonatal ICUs with the launch of our smaller sensor. Our four-channel cerebral and somatic INVOS System monitor, which we launched in fiscal 2006, can display information from four disposable sensors. This feature allows for the simultaneous monitoring of blood oxygen saturation in tissues beneath the sensor in four different places in the body in patients with or at risk for restricted blood flow. The INVOS System is being used to monitor simultaneously the brain and other tissue initially for patients in the pediatric and neonatal ICU.

***Other Applications.*** We are also sponsoring and evaluating sponsorship of other clinical trials which may allow us to more actively target the sale of the INVOS System for use in other high risk patient populations and other patient populations. In addition, we are evaluating other potential market segments for our INVOS System, such as use in orthopedic surgeries and other major surgeries, in the adult ICU, in assessing individuals with sleep disorders, and for applications of the technology in other tissues in the body.

## **Table of Contents**

In November 2008, we acquired substantially all of the assets of ICU Data Systems, Inc., a technology development company. See ICU Data Systems, Inc. above. ICU Data Systems, Inc. developed a patented technology that integrates data from a broad array of hospital bedside devices, such as physiological monitors, ventilators and infusion devices, into a single bedside display for comparison, data management and storage. We launched our newly-acquired data integration technology, as a stand-alone device that we call Vital Sync, in the third quarter of fiscal 2009. The product is expected to be used primarily on patients undergoing surgeries or who in the ICU and who are being monitored by multiple monitors. The INVOS System is one of many devices whose data can be integrated into the stand-alone device. To support the addition of the derived parameter features to the system, or calculated parameters based on the combination of two or more discrete parameters, we have filed a new FDA 510(k) premarket notification in the fourth quarter of fiscal 2009. In addition, we expect to invest to combine the ICU Data Systems and INVOS System technologies in a single product in fiscal 2010. Upon completion of development of a single product combining the Vital Sync System with our INVOS System technology, we also plan to pursue a new FDA 510(k) clearance for this integrated device for a launch currently expected in mid-2011.

We are also exploring several novel near-infrared spectroscopy and imaging technologies and products under a Contract Development Agreement with Shirley Research Corporation, an Exclusive Sublicense Agreement with Raba Equity Partners II, LLC (Raba coreFoundry), and a Development and Exclusive License Agreement with an inventor and his company. See NeuroPhysics Corporation and Shirley Research Corporation, Raba Equity Partners II, LLC and Compartment Syndrome below. Pursuit of some of these potential market segments may require additional FDA clearance. We believe that these natural extensions of our technology will increase our market potential without the more significant risks and costs associated with developing entirely new products.

## **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 using 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 700 presentations, study abstracts and published papers. During 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% of baseline values taken at the beginning of the operation.

## **Table of Contents**

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 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%) was statistically significantly less than in the control group (2.01%), 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%, compared to 10.6% 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.

**Table of Contents**

***Other Future Studies***

We are sponsoring and evaluating sponsoring other clinical trials which may allow us to more actively target the sale of the INVOS System for use in other high risk patient populations and other patient populations. In addition, in early 2008, The Society of Thoracic Surgeons began collecting cerebral oximetry information as part of its STS Adult Cardiac Surgery Database, which is used to develop practice standards intended to improve quality and safety.

**Marketing, Sales and Distribution**

***Marketing***

We market the INVOS System primarily to cardiac and vascular surgeons, anesthesiologists, pediatric and neonatal ICU physicians, 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 intend to market our Vital Sync System to the same specialists and medical professionals as our INVOS System.

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 Vital Sync 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 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 and Vital Sync System through a direct sales team in the United States, consisting of salespersons and clinical specialists, the size of which has increased from 53 persons at the end of fiscal 2007 to 63 persons at the end of fiscal 2009, and an independent sales representative firm. We expect to increase the size of our U.S. direct sales team in fiscal 2010. We believe the selling cycle for the INVOS System is approximately six to nine months, although given the current economic downturn in the United States and abroad, we believe that the sales cycle has been and may continue to be lengthened significantly.

Outside the United States, we have distribution agreements with independent distributors covering 69 countries for the INVOS System. Our distributors for the INVOS System include Covidien, in Europe, the Middle East, South Africa and Canada, and Edwards Lifesciences Ltd. in Japan. During fiscal 2009, we extended our distribution agreement with Covidien for three years beginning in February 2010 and in December 2009, we extended our distribution agreement with Edwards through fiscal 2014. We have hired and may hire additional direct salespersons and clinical specialists in Europe to support Covidien and to sell our Vital Sync System. We also have an international sales consultant. For fiscal 2009, 20% 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 many 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, 2010 or as of January 10, 2009. We generally do not have a backlog of firm orders because we generally ship product upon receipt of a customer order.

## **Table of Contents**

For a description of sales to major customers, see Note 9 of Notes to Financial Statements included in Item 8 of this report. Covidien was our largest customer in fiscal 2009, 2008 and 2007. We are dependent on our sales to Covidien 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 \$9,854,238 for the fiscal year ended November 30, 2009, \$9,420,472 for the fiscal year ended November 30, 2008 and \$7,024,902 for the fiscal year ended November 30, 2007, including approximately \$6,650,000 in fiscal 2009, \$6,698,000 in fiscal 2008 and \$5,043,000 in fiscal 2007 to Covidien, our distributor in Europe, the Middle East, South Africa and Canada, and approximately \$2,305,000 in fiscal 2009, \$2,118,000 in fiscal 2008 and \$1,431,000 in fiscal 2007 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 and sensors, see Management's Discussion and Analysis of Financial Condition and Results of Operations - Results of Operations in Item 7 of this report.

## **Research and Development**

Our research and development activities are conducted internally by a staff consisting of 16 employees. We have developed a smaller sensor for use with infants and neonates, and are making other advances to the design and performance features of the INVOS System, including the disposable sensor. We are also working to interface our INVOS System with multi-functional monitors provided by other manufacturers. We launched our newly-acquired data integration technology, as a stand-alone device that we call Vital Sync, in the third quarter of fiscal 2009. The INVOS System is one of many devices whose data can be integrated into the stand-alone device. To support the addition of the derived parameter features to the Vital Sync System, or calculated parameters based on the combination of two or more discrete parameters, we have filed a new FDA 510(k) premarket notification in the fourth quarter of fiscal 2009. In addition, we expect to invest to combine the ICU Data Systems and INVOS System technologies in a single product in fiscal 2010. Upon completion of development of a single product combining the Vital Sync System with our INVOS System technology, we also plan to pursue a new FDA 510(k) clearance for this integrated device for a launch currently expected in mid-2011.

Our research, development and engineering expenditures were \$3,947,509 during fiscal 2009, \$1,259,227 during fiscal 2008 and \$668,815 during fiscal 2007. We expect our research, development and engineering expenses to increase in fiscal 2010 from the level in 2009, excluding the \$2,000,000 expense under our Exclusive Sublicense Agreement and our Development and Exclusive License Agreement, described below. We expect this increase primarily as a result of the hiring of additional research and development personnel, development costs associated with the integration of the INVOS System and Vital Sync System, development costs associated with our Exclusive Sublicense Agreement with Raba Equity Partners II, LLC (Raba coreFoundry), development costs associated with our Contract Development Agreement with Shirley Research Corporation, and development costs associated with advances to the design and performance features of the INVOS System, including the disposable sensor.

### ***NeuroPhysics Corporation and Shirley Research Corporation***

We entered into a Contract Development and Exclusive Licensing Agreement with NeuroPhysics Corporation as of September 18, 2006. The agreement provided 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. We terminated this agreement in February 2009, except for various provisions regarding our ownership of the technology related to the potential new products. In February 2009, we entered into a similar agreement with Shirley Research Corporation and Hugh F. Stoddart and Hugh A. Stoddart, formerly of NeuroPhysics Corporation, and have agreed to pay monthly development and consulting fees of \$15,000 a month during the term of the agreement and a royalty on future sales of the new products.

Shirley Research Corporation 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



## **Table of Contents**

this NIRS-based, depth-resolved technology, products that may be developed under the agreement 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.

### ***Raba Equity Partners II, LLC ( Raba coreFoundry )***

We entered into an Exclusive Sublicense Agreement with Raba Equity Partners II, LLC ( Raba coreFoundry ) in October 2009. Under terms of the agreement, we have obtained exclusive rights, subject to specified rights of the U.S. Government and rights retained by The Johns Hopkins University, to make, use and sell products using new cerebral autoregulation technology developed at The Johns Hopkins University. Integration of this technology into our INVOS® Cerebral/Somatic Oximeter would yield the first noninvasive monitor providing cerebral autoregulation data for routine clinical use. The cerebral autoregulation technology is associated with two pending patents. We paid Raba coreFoundry up-front, non-refundable payments of \$1.8 million and will pay a royalty on future revenue associated with products using the licensed technology. The up-front payments were accounted for as research and development expenses in the fourth quarter of fiscal 2009.

Cerebral autoregulation refers to the body's ability to maintain constant blood flow to the brain despite changes in blood pressure. In many critical care situations, the brain's autoregulation can become impaired, making it vulnerable to changes in blood pressure and to potential brain injury due to loss of this critical protective mechanism. For example, blood pressure below the patient's autoregulation threshold can result in cerebral ischemia, while blood pressure above the patient's upper limit of autoregulation can result in cerebral bleeding. Patients at highest risk of impaired cerebral autoregulation include those undergoing certain surgical procedures, such as cardiovascular, neurological and major orthopedic procedures, and liver transplants. Others at risk include patients with traumatic brain injury, those who have suffered a stroke, infants on ventilators and premature babies.

We plan to use this patent-pending method of combining blood pressure measurements and signals from the INVOS System to continuously monitor and display cerebral autoregulatory function information. We plan to file a new 510(k) premarket notification with the FDA for the new module and pursue a product launch in the first half of 2011.

### ***Compartment Syndrome***

We entered into a Development and Exclusive Agreement with an inventor and his company in November 2009 to develop and market a product that uses INVOS technology and methods and means described in the inventor's patent to monitor, detect and assess acute compartment syndrome in parts of the human body. Under terms of the agreement, we have obtained exclusive rights to the rights of the inventor under a pending patent regarding methods and means for using near infrared spectroscopy to monitor, detect and assess acute compartment syndrome in parts of the human body, such as the legs, but only in the field of monitoring, detecting and assessing compartment syndrome. We paid the inventor's company an up-front, non-refundable payment of \$200,000 and will pay an additional \$300,000 upon obtaining 510(k) clearance for the product and a royalty on future revenue associated with products using the licensed technology. The up-front payment was accounted for as research and development expenses in the fourth quarter of fiscal 2009.

The U.S. Department of Defense has provided a grant for the research and development of a monitor and sensors to monitor, detect and assess compartment syndrome. As part of the agreement, over a three-year period, we expect to receive approximately \$2.1 million for product and prototype sales and research and development fees, derived from the grant, for its work to develop the compartment syndrome product.

Compartment syndrome is a limb and life-threatening condition that occurs with the compression of nerves, blood vessels and muscle inside a closed space (compartment) within the body. This leads to tissue death due to the lack of oxygenation as the blood vessels are compressed by the raised pressure within the compartment.

## **Table of Contents**

### **Manufacturing**

We assemble the INVOS System and Vital Sync System in our facilities in Troy, Michigan, from components purchased from outside suppliers. We assemble the INVOS System and Vital Sync System to control their quality and costs and to permit us to make changes to them faster than we could if third parties assembled them. Although we believe that most components are generally available from several potential suppliers, we depend on one supplier for one of our components for the INVOS System. We are not aware of any validated alternative supplier for this component, although we are currently in the process of evaluating 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 disposable sensor. We are currently dependent on one manufacturer of the sensor and another component of the INVOS System, and we believe that it would require approximately four to five months to change sensor suppliers. We do not currently intend to manufacture on a commercial scale the disposable sensor 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 disposable sensor in the European Economic Community. Our most recent ISO 13485 compliance surveillance audit occurred in July 2009.

### **Competition**

There are numerous and varied forms of patient monitoring products that constitute our competition. Other cerebral and somatic oximeters are just one form of these competing products. In the United States, we believe there are currently three other companies with FDA clearance to sell a cerebral oximeter. In December 2005, CAS Medical Systems, Inc. announced that it received 510(k) clearance for a cerebral oximeter, and it began sales of its product during 2007. In August 2009, we filed a patent infringement action against CAS Medical Systems, Inc. See Item 3

Legal Proceedings in this report. During 2009, one other U.S. company announced that it received 510(k) clearance for a cerebral oximeter, and it began sales of its product late in 2009. Outside the United States, several Japanese manufacturers offer a cerebral oximeter for sale in that country and primarily for research in other parts of the world, but, to our knowledge, none has pursued FDA clearance for 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 others who may begin development of a cerebral oximeter. Other companies have FDA clearance for 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 compete with numerous medical equipment companies and medical device integration 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 competitors and potential competitors have long-term product supply relationships with our potential customers. These competitors and 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.





## **Table of Contents**

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 10 United States patents and two patents in various foreign countries. These patents expire on various dates from June 2010 to October 2019. We currently have 15 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.

In September 2003, we were issued a new patent by the United States Patent and Trademark Office covering, among other things, the application of non-invasive, near-infrared spectroscopy to measure continuously and substantially 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. CAS Medical Systems, Inc. has requested re-examination of this patent, and the reissuance and re-examination proceedings have been combined. The outcome of the reissue and re-examination 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 inventions covered in this patent are important to providing a high quality cerebral oximeter in the clinical setting.

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, WINDOW TO THE BRAIN, REFLECTING THE COLOR OF LIFE, ENLIGHTENING MEDICINE, OXYALERT, OXYALERT NIRSENSOR, ICURO, SCR, and SCR and design. We also have trademark applications pending for AUC, AREA UNDER THE CURVE, SOMANETICS ALLIANCE, SOMANETICS ALLIANCE and design, the ALLIANCE logo, Vital Sync, and PUTTING PATIENT DATA TO WORK FOR YOU. We have also obtained registrations for our SOMANETICS mark in more than 30 foreign jurisdictions, with additional foreign applications for this mark pending, and we have the marks INVOS, SOMASENSOR, BRAINSENSOR SOMASENSOR, OXYALERT, SCR, SCR and design, and VITAL SYNC registered or pending in other 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.

In addition, ICU Data Systems developed a patented technology that integrates data from a broad array of hospital bedside devices into a single bedside display for comparison, data management and storage. The patent

## **Table of Contents**

underlying the technology is licensed by us from the University of Florida College of Medicine and Engineering and expires in 2023.

In addition, Raba Equity Partners II, LLC and The Johns Hopkins University developed a patent-pending method of combining blood pressure measurements and signals from the INVOS System to continuously monitor and display cerebral autoregulatory function information. The patent-pending underlying the technology is licensed by us from Raba Equity Partners II, LLC and, if issued, the patents would expire in 2027 and 2028.

### **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 perform:

product development;

product testing;

product manufacturing;

product labeling;

product storage;

premarket clearance or approval;

advertising and promotion;

product sales and distribution; and

product event reports and complaint handling.

Medical devices to be commercially distributed in the U.S. must receive either 510(k) clearance or a Premarket Approval, or PMA, from the FDA pursuant to the FDCA, prior to marketing. Devices deemed to pose relatively less risk are placed in either class I or II, which generally requires the manufacturer to submit a premarket notification requesting permission for commercial distribution; this is known as 510(k) clearance. Most lower risk, or class I, 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.

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 May 2008, we received 510(k) clearance from the FDA to market our INVOS System to monitor changes in blood oxygen saturation in any tissues beneath the sensor, not limited to brain and somatic tissue, in any individual. In April 2009, we received 510(k)

## **Table of Contents**

clearance from the FDA to expand the indications for use to reflect the INVOS System's ability to provide accurate, immediate blood oxygen saturation measurements in patients greater than 2.5 kilograms at risk for restricted or no blood flow, in addition to our previous FDA clearance to measure changes in blood oxygen saturation in any individual. In addition, this most recent 510(k) clearance expanded the labeling for our INVOS System to include the following new marketing claims:

The measurement of regional cerebral oxygen saturation (rSO<sub>2</sub>) is an indication of whether oxygen delivery to the brain is adequate. Prolonged declines in rSO<sub>2</sub> are indicative of, or may result in, potential brain injury.

When used as an indication of compromised cerebral oxygenation, interventions to return the patient's rSO<sub>2</sub> to baseline using the INVOS System have been shown to improve outcomes after surgery.

In neonates, infants and children, cerebral and somatic rSO<sub>2</sub> provide noninvasive indications of oxygen changes in the cerebral and peripheral circulatory systems and may provide an early indication of oxygen deficits associated with impending shock states and anaerobiosis.

**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, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, 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.

Upon approval, 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. In addition, modifications made to the device that affect its safety or effectiveness, including, for example, certain modifications to the indications for use, manufacturing process, labeling or design, require the submission and approval of a PMA Supplement. 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.

None of our marketed products have required the submission or approval of a 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. Most IDE requirements apply to all investigational devices,

## **Table of Contents**

whether considered significant or nonsignificant risk. Prior to granting PMA approval and at times 510(k) clearance, the FDA typically inspects the records relating to the conduct of the study and the clinical data supporting the 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, field and other remedial actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device that may present a risk to health, and maintain records of other corrections or removals).

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.

Our most recent FDA QSR inspection occurred in July 2009.

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.

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.

### **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 sensors, and higher INVOS System monitor revenues associated with hospital budgeting cycles.

### **Employees**

As of February 1, 2010, we had 133 full-time employees, including 73 in sales and marketing, 16 in research and development, 15 in general and administration and 29 in manufacturing, quality and service. We also employed one part-time individual in general and administration. In addition, we use one contract employee 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, technical and manufacturing personnel. We expect to add additional sales and marketing and research and development employees in fiscal 2010. 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.



**Table of Contents**

**Insurance**

Because the INVOS System and the Vital Sync 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., 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 disposable sensors, 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 high risk 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 and medical device integration 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 and Vital Sync System might be limited or delayed because of resistance to major capital equipment expenditures by hospital purchasing committees, especially during the current economic conditions. Even if we are successful in convincing physicians, other medical professionals and hospital purchasing committees that the INVOS System or Vital Sync System provides valuable benefits, they might be unwilling or unable to commit funds to the purchase of the INVOS System or Vital Sync 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 or Vital Sync System before additional medical professionals in the hospital might be interested in using the INVOS System or Vital Sync 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 are generally used. Moreover, medical professionals may be reluctant to use our INVOS System or Vital Sync 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 or Vital Sync System is not currently approved for separate reimbursement, and we might not be able to obtain reimbursement for these uses of our INVOS System or Vital Sync 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

## **Table of Contents**

could be adversely affected and our plan to increase our investments in our direct sales team and our research and development team might not produce favorable results.

***We are dependent on our international distributors 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. These independent distributors might fail to commit the necessary resources to market and sell our products at the level we expect, especially as significant customer education and long lead times are typically required to market and sell our products successfully. If our distributors 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 arrangements are terminated or discontinued, we will likely be faced with increased costs as we attempt to replace these arrangements, and the terminated distributors 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.

Covidien, our international distributor in Europe, the Middle East, South Africa and Canada for our INVOS System, accounted for 13%, 14% and 13% of our net revenues for fiscal years 2009, 2008 and 2007, respectively. Edwards Lifesciences Ltd. is our international distributor in Japan for our INVOS System. The loss of either of these distributors could have an adverse effect on our business, financial condition and results of operations.

***The global economic crisis has had and may continue to have a negative effect on our business and operations.***

The global economic crisis has caused, among other things, lower business spending, which has had and may continue to have a negative effect on our business and results of operations, including an increase in the sales cycle for our products. Many of our customers and suppliers have been affected by the current economic turmoil. Current or potential customers and suppliers may no longer be in business, may be unable to fund purchases or determine to reduce purchases, all of which have led and could continue to lead to delays in purchases of our products and customer payment delays. Further, suppliers may not be able to supply us with needed components on a timely basis, may increase prices or go out of business, which could result in our inability to meet customer demand or affect our gross margins. The timing and nature of any recovery in the economy remains uncertain, and there can be no assurance that market conditions will improve in the near future or that our results will not be materially and adversely affected. Such conditions make it very difficult to forecast operating results, make business decisions and identify and address material business risks.

***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 and Vital Sync 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 evaluating 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 disposable sensor. Sensors represented approximately 81% of our net revenues in fiscal 2009. 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 sensor 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



## Table of Contents

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.***

There are numerous and varied forms of patient monitoring products that constitute our competition. Other cerebral and somatic oximeters are just one form of these competing products. In the United States, we believe there are currently three other companies with FDA clearance to sell a cerebral oximeter. In December 2005, CAS Medical Systems, Inc. announced that it received 510(k) clearance for a cerebral oximeter, and it began sales of its product during 2007. In August 2009, we filed a patent infringement action against CAS Medical Systems, Inc. See Item 3

Legal Proceedings in this report. During 2009, one other U.S. company announced that it received 510(k) clearance for a cerebral oximeter, and it began sales of its product late in 2009. Outside the United States, several Japanese manufacturers offer a cerebral oximeter 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 for 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 others who may begin development of a cerebral oximeter. Other companies have FDA clearance for 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 compete with numerous medical equipment companies and medical device integration 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. 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 competitors and potential competitors have long-term product supply relationships with our potential customers.

***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 competitors and 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 competitors and potential competitors have long-term product supply relationships with our potential customers. These competitors and 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.

## **Table of Contents**

### ***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 advances to the design and performance features of the INVOS System, including the disposable sensor, to interface our INVOS System with multi-functional monitors provided by other manufacturers, to further develop our Vital Sync System, and to combine the Vital Sync System and INVOS System technologies in a single product. In addition, we expect to invest resources in development costs associated with our Exclusive Sublicense Agreement with Raba Equity Partners II, LLC, our Contract Development Agreement with Shirley Research Corporation and our Development and Exclusive License Agreement with an inventor and his company. 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 patient monitoring devices, patients might assert product liability claims against us. The INVOS System and the Vital Sync System are used in operating rooms and other critical care hospital units with patients who might be seriously ill or might be undergoing dangerous procedures. On occasion, patients on whom the INVOS System or Vital Sync System is being used 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 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 Vital Sync System. If we are subject to an uninsured or inadequately insured product liability claim based on the performance of the INVOS System or Vital Sync System, 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 or our Vital Sync 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



## **Table of Contents**

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; 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, 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 and would thereby have an adverse effect on our business, financial condition and results of operations.

***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 FDCA 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.

25

---



## **Table of Contents**

***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 disposable sensor, 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 governs 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 inspections, which may be unannounced. 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 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.

***Our products may in the future be subject to product recalls that could harm our reputation, business and financial results.***

The FDA and similar foreign governmental authorities have the authority to require the recall of commercial products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action against us if we fail to properly report field actions to the FDA.

***If our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.***

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report these events to the FDA within the required timeframes, or at all, FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action,



## **Table of Contents**

such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

***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.

***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. In addition, the process has been and may continue to be delayed significantly as a result of the current economic downturn in the United States and abroad. 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 and clinical specialist 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 clinical specialist 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

## **Table of Contents**

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 and re-examination proceeding in the U.S. Patent and Trademark Office. Our reissue application was filed for the sole purpose of seeking to broaden certain claims. CAS Medical Systems, Inc. has requested re-examination of this patent, and the reissuance and re-examination proceedings have been combined. We cannot predict the outcome of this proceeding, which may result in some or all of the claims being maintained, broadened, narrowed or rejected.

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.

We may initiate litigation to enforce some of 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. For example, during 2009, we filed a patent infringement action against CAS Medical Systems, Inc., one of our competitors. The defendant in the litigation has answered the complaint denying that it infringes any asserted patent and asserting defenses and counterclaims, including those for patent invalidity and/or unenforceability, and antitrust violations. The defendant was also the party that requested re-examination of one of our patents.

The outcome of this litigation and any other 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. We expect our involvement in such intellectual property litigation to 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.



## Table of Contents

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 fields of cerebral and somatic oximetry, and other 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 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;

**Table of Contents**

cease the development, manufacture, importation, use and sale of products that infringe the patent rights of others, including our INVOS System and Vital Sync 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.

***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 June 17, 2011. In addition, 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. For example, in November 2008, we acquired substantially all of the assets of ICU Data Systems, Inc., a technology development company, for approximately \$2,000,000 in cash plus the assumption of specified liabilities. In October 2009, we entered into an Exclusive Sublicense Agreement with Raba Equity Partners II, LLC and paid up-front, non-refundable payments of \$1.8 million to Raba Equity Partners II, LLC. In November 2009, we entered into a Development and Exclusive Agreement with an inventor and his company and paid an up-front, non-refundable payment of \$200,000 and will pay an additional \$300,000 upon obtaining 510(k) clearance for the product. 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. Any acquisition we pursue could diminish our cash otherwise



## **Table of Contents**

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 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, 2009, we have approximately \$79,733,000 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 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 and takeovers, 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 and takeovers 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% 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 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;

**Table of Contents**

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

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 currently do not expect to pay any cash dividends in the foreseeable future.***

We have never paid cash dividends on our common shares and currently do not expect to pay such dividends in the foreseeable future. We currently intend to retain any future earnings for use in our business or in our share repurchase program. 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. As of February 1, 2010, we have outstanding options and warrants to purchase an aggregate of 1,814,637 common shares. We have also reserved up to an additional 305,593 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 on affiliates, 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

**Table of Contents**

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 new headquarters, office, assembly and storage facility is located in an approximately 48,000 square foot, stand-alone building in Troy, Michigan. We lease approximately 48,000 square feet, approximately 36,000 square feet of which is office space for sales and marketing, engineering, accounting and other administrative activities. We lease this space for a lease term that began December 15, 2009 and expires March 31, 2017, with two consecutive options to renew the lease for a term of five years each. The minimum monthly lease payment through March 31, 2011 is approximately \$36,900 (except that rent is abated for the first three months of the term), excluding other occupancy costs, and it will increase to approximately \$42,800 during the term of the lease, excluding other occupancy costs. Rent expense will be recorded on a straight-line basis over the lease term, including consideration of lease incentives. Somanetics also pays other occupancy costs relating to the premises, including utilities, taxes and insurance.

The new premises replace our existing headquarters, manufacturing facility and warehouse space in Troy, Michigan, which we currently lease under a lease that expires March 31, 2010. We believe that this new facility is suitable and adequate for our present needs and for the foreseeable future and will allow for substantial expansion of our business and number of employees.

**ITEM 3. LEGAL PROCEEDINGS**

On August 7, 2009, we filed a patent infringement action against CAS Medical Systems, Inc. in the United States District Court for the Eastern District of Michigan. The complaint asserts that CAS Medical's FORE-SIGHT® Cerebral Oximeter willfully infringes upon one or more of Somanetics' patents. The complaint also asserts that CAS Medical has engaged in unfair competition and false advertising, by making false or misleading statements in connection with its advertising and promotion of FORE-SIGHT, and false or misleading statements related to Somanetics' products. The complaint seeks, among other things, compensation for damages and an injunction against CAS Medical from infringing upon Somanetics' patents. CAS Medical Systems, Inc. has answered the complaint denying that it infringes any asserted patent and asserting defenses and counterclaims, including those for patent invalidity and/or unenforceability, and antitrust violations.

**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, 2009.

**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	50	President and Chief Executive Officer
Arik A. Anderson	01/09	43	Senior Vice President, R&D and Operations
William M. Iacona	12/00	39	Vice President, Chief Financial Officer, Controller and Treasurer
Dominic J. Spadafore	8/02	50	Senior Vice President, U.S. Sales and Marketing
Mary Ann Victor	1/98	52	Vice President, Chief Administrative Officer, General Counsel 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. Arik A. Anderson has served as our Senior Vice President, R&D and Operations since January 2009. From October 2007 until January 2009, he served as our Senior Vice President, Research and Development. From July 2005 until joining Somanetics, Mr. Anderson served as Director of Product Development for Delphi Medical Systems, a provider of technology and products to the infusion, respiratory care, vital signs monitoring and power mobility medical device markets. He was in charge of a team of 45 engineers in the United States, Mexico and India who supported existing products and developed next generation products. From April 2004 until July 2005, Mr. Anderson was the President and Chief Executive Officer of Tasso Solutions, a product development and manufacturing consulting firm specializing in helping companies outsource design and manufacturing work. From December 2002 until April 2004, Mr. Anderson was the Vice President of Engineering Services for TriVirix International, a design and manufacturing services company focused specifically on the medical device industry, serving customers such as Johnson & Johnson and Medtronic. In this capacity, Mr. Anderson was in charge of 50 engineers for TriVirix in the U.S. and Europe. Mr. Anderson received a Bachelor of Science degree in Electrical and Computer Engineering from the University of Wisconsin - Madison.

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 AT&T), 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 Senior Vice President, U.S. Sales and Marketing, since December 2007. From August 2002 until December 2007, he served as our Vice President, U.S. Sales and Marketing. 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.



**Table of Contents**

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 General Counsel since September 2009, as our Vice President, 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 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, 2008		
First Quarter	\$29.53	\$19.45
Second Quarter	28.00	10.01
Third Quarter	26.17	16.76
Fourth Quarter	25.21	14.11
Fiscal Year Ended November 30, 2009		
First Quarter	\$18.25	\$12.09
Second Quarter	17.25	10.18
Third Quarter	18.48	12.94
Fourth Quarter	17.23	12.90

As of February 1, 2010, we had 494 shareholders of record of our common shares.

We have never paid cash dividends on our common shares and currently do not expect to pay such dividends in the foreseeable future. We currently intend to retain any future earnings for use in our business or in our share repurchase program. 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, 2005, 2006, 2007, 2008 and 2009 (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\*\*  
Comparison of Cumulative Five Year Total Return**

	2004	2005	2006	2007	2008	2009
Somanetics Corporation	100.00	222.69	139.77	144.16	126.37	103.24
The Russell 2000 Index	100.00	108.14	127.00	125.50	78.49	97.75
NASDAQ Medical Devices Index	100.00	113.23	117.33	148.09	78.74	111.89

Assumes \$100 invested on November 30, 2004 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****Unregistered Sales of Equity Securities and Use of Proceeds**

The following table provides information with respect to any purchase made by or on behalf of us or any affiliated purchaser of our common shares for each month during the fourth quarter ended November 30, 2009:

<b>Period</b>	<b>Total Number of Shares Purchased</b>	<b>Average Price Paid Per Share</b>	<b>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs</b>	<b>Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs</b>
September 1-30, 2009				13,550,580
October 1-31, 2009				13,550,580
November 1-30, 2009				13,550,580
<b>Total</b>	<b>0</b>	<b>N/A</b>	<b>0</b>	

On April 3, 2008, we publicly announced that our Board of Directors authorized the repurchase of up to \$15 million of our common shares. Purchases may be made from time to time in the open market or in privately negotiated transactions. The prices, timing and amount of, and purposes for, any purchases will be determined by management. On May 9, 2008, we publicly announced that our Board of Directors approved an increase in the limit on the share repurchase program and authorized the repurchase of up to an additional \$15 million of our common shares, and on July 1, 2008, we publicly announced that our Board of Directors approved an increase in the limit on the share repurchase program and authorized the repurchase of up to an additional \$15 million of our common shares, for a total of \$45 million of our common shares under the repurchase program. During the fiscal year 2008, we repurchased 1,805,129 common shares at an average price of \$17.42 per share and an aggregate cost of \$31,449,420. All of the shares were purchased by us in open-market transactions pursuant to this publicly-announced share repurchase program. The program does not have an expiration date, except upon purchase of the maximum authorized dollar amount of our common shares.

**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, 2009, 2008 and 2007 and the balance sheet data as of November 30, 2009 and 2008 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, 2006 and 2005 and the balance sheet data as of November 30, 2007, 2006 and 2005 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.

	Year Ended November 30,				
	2009	2008 (4)	2007	2006	2005
	(in thousands, except per share data)				
Statement of Operations Data:					
Net revenues	\$ 50,014	\$ 47,455	\$ 38,586	\$ 28,701	\$ 20,509
Cost of sales	6,581	6,249	4,726	3,566	2,601
Gross margin	43,433	41,206	33,860	25,135	17,908
Operating expenses:					
Research, development and engineering (1)	3,947	1,259	669	1,582	526
Selling, general and administrative (2)	29,621	26,166	22,269	16,485	13,241
Total operating expenses	33,568	27,425	22,938	18,067	13,767
Operating income	9,865	13,781	10,922	7,068	4,141
Other income:					
Interest income	1,063	2,630	4,008	2,582	310
Total other income	1,063	2,630	4,008	2,582	310
Income before income taxes	\$ 10,928	\$ 16,411	\$ 14,930	\$ 9,650	\$ 4,451
Income tax (expense) benefit (3)	(4,110)	(5,965)	(5,248)	750	3,300
Net income	\$ 6,818	\$ 10,446	\$ 9,682	\$ 10,400	\$ 7,751
Net income per common share    basic	\$ .57	\$ .82	\$ .73	\$ .83	\$ .75
Net income per common share    diluted	\$ .53	\$ .76	\$ .67	\$ .75	\$ .66
Weighted average number of common shares outstanding    basic	12,069	12,671	13,213	12,463	10,322
Weighted average number of common shares outstanding    diluted	12,936	13,672	14,384	13,824	11,798

**As of November 30,**

	2009	2008 (4)	2007 (in thousands)	2006	2005
<b>Balance Sheet Data:</b>					
Cash, cash equivalents, securities and investments	\$ 79,733	\$69,996	\$ 85,804	\$ 71,571	\$ 13,148
Working capital	64,251	65,640	62,998	57,968	18,044
Total assets	101,288	87,968	104,984	92,423	29,719
Total liabilities	3,255	3,120	2,819	2,205	1,878
Retained Earnings (Accumulated deficit)	216	(6,603)	(17,049)	(26,731)	(37,131)
Total shareholders' equity	98,033	84,848	102,165	90,218	27,841

(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, and a \$2,000,000 expense in fiscal 2009 in connection with our Exclusive Sublicensing Agreement with Raba Equity Partners II, LLC and our Development and Exclusive License Agreement with an inventor and his company.

(2) Includes an impairment expense of \$929,093 in fiscal 2005 in connection with the write-off of an intangible asset.

- (3) Fiscal 2006 and 2005 amounts are net of a fourth quarter reversal of a portion of our income tax valuation allowance in the amount of \$4,068,613 and \$4,837,420, respectively.
- (4) Fiscal 2008 amounts reflect 1) our acquisition of substantially all of the assets of ICU Data Systems, Inc. in November 2008, and 2) our common share repurchase program. See Notes 2 and 8 of Notes to Financial Statements in Item 8.

**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 provides accurate, real-time blood oxygen measurements in the brain and elsewhere in the body in tissues beneath the sensor in patients greater than 2.5 kilograms, and continuously measures changes in blood oxygen levels for individuals of any weight. Our four-channel cerebral and somatic INVOS System monitor can display information from four disposable sensors simultaneously. The INVOS System is the only commercially-available cerebral/somatic Oximeter proven to improve outcomes. In May 2008, we received 510(k) clearance from the FDA to market our INVOS System to monitor changes in blood oxygen saturation in any tissues beneath the sensor, not limited to brain and somatic tissue, in any individual. In April 2009, we received 510(k) clearance from the FDA to expand the indications for use to reflect the INVOS System's ability to provide accurate, immediate blood oxygen saturation measurements in patients greater than 2.5 kilograms at risk for restricted or no blood flow, in addition to our previous FDA clearance to measure changes in blood oxygen saturation in any individual. In addition, this most recent 510(k) clearance expanded the labeling for our INVOS System to include the following new marketing claims:

The measurement of regional cerebral oxygen saturation (rSO<sub>2</sub>) is an indication of whether oxygen delivery to the brain is adequate. Prolonged declines in rSO<sub>2</sub> are indicative of, or may result in, potential brain injury.

When used as an indication of compromised cerebral oxygenation, interventions to return the patient's rSO<sub>2</sub> to baseline using the INVOS System have been shown to improve outcomes after surgery.

In neonates, infants and children, cerebral and somatic rSO<sub>2</sub> provide noninvasive indications of oxygen changes in the cerebral and peripheral circulatory systems and may provide an early indication of oxygen deficits associated with impending shock states and anaerobiosis.

In November 2008, we acquired substantially all of the assets of ICU Data Systems, Inc., a technology development company, for approximately \$2,000,000 in cash plus the assumption of specified liabilities. ICU Data Systems has developed a patented technology that integrates data from a broad array of hospital bedside devices, such as physiological monitors, ventilators and infusion devices, into a single bedside display for comparison, data management and storage. We launched our newly-acquired data integration technology, as a stand-alone device that we call Vital Sync, in the third quarter of fiscal 2009. The INVOS System is one of many devices whose data can be integrated into the stand-alone device. To support the addition of the derived parameter features to the system, or calculated parameters based on the combination of two or more discrete parameters, we have filed a new FDA 510(k) premarket notification in the fourth quarter of fiscal 2009. In addition, we expect to invest to combine the ICU Data Systems and INVOS System technologies in a single product in fiscal 2010. Upon completion of development of a single product combining the Vital Sync System with our INVOS System technology, we also plan to pursue a new FDA 510(k) clearance for this integrated device for a launch currently expected in mid-2011.

## **Table of Contents**

### ***Net Revenues and Cost of Sales***

We derive our revenues primarily from sales of INVOS Systems, although we derived modest revenues in fiscal 2009 from sales of our Vital Sync System, which we launched as a stand-alone device in the third quarter of 2009 through our direct sales team. In the United States, such sales are made primarily to hospitals through our direct sales team and an independent sales representative firm. Outside the United States, we have distribution agreements with independent distributors for the INVOS System, including Covidien in Europe, Canada, the Middle East and South Africa, and Edwards Lifesciences Ltd. in Japan. Our cost of sales represent the cost of producing monitors and disposable sensors. Revenues from outside the United States contributed 20% to our fiscal 2009 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 collectability 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 sensors. We intend that disposable sensors will form the basis of a recurring revenue stream. In addition, 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. 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. We recognize sensor revenue when we receive purchase orders and ship the product to the customer.

### ***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, stock compensation, insurance, warranty and royalty expenses, investor relations, depreciation and amortization, facilities expenses and other general operating expenses.

We have increased the size of our U.S. direct sales team from 55 persons at the end of fiscal 2008 to 63 persons at the end of fiscal 2009. We expect to increase the size of our U.S. direct sales team in fiscal 2010 and have hired and may hire additional direct salespersons and clinical specialists in Europe to support Covidien. We also expect selling, general and administrative expenses to increase in fiscal 2010, primarily as a result of the lease agreement that we have entered into for our new corporate headquarters and assembly and storage facility, and the patent infringement action that we have filed against CAS Medical Systems, Inc.

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.

We expect our research, development and engineering expenses to increase in fiscal 2010 from the level in 2009, excluding the \$2,000,000 expense under our Exclusive Sublicense Agreement and Development and Exclusive License Agreement, described below. We expect this increase primarily as a result of the hiring of





**Table of Contents**

additional research and development personnel, development costs associated with the integration of the INVOS System and Vital Sync System, development costs associated with our Exclusive Sublicense Agreement with Raba Equity Partners II, LLC ( Raba coreFoundry ), development costs associated with our Contract Development Agreement with Shirley Research Corporation, and development costs associated with advances to the design and performance features of the INVOS System, including the disposable sensor.

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

For the fiscal year ended November 30, 2007, we recognized income tax expense at an estimated effective tax rate of 35% on our statement of operations. This income tax expense included a non-cash tax expense on our statement of operations for fiscal 2007 of \$5,076,276. In November 2007, we wrote off obsolete inventory of \$180,521.

For the fiscal year ended November 30, 2008, we recognized income tax expense at an estimated effective tax rate of 36% on our statement of operations. This income tax expense included a non-cash tax expense on our statement of operations for fiscal 2008 of \$5,586,906. In addition, during fiscal 2008 we recognized deferred tax assets related to the previous exercise of stock options of approximately \$1,012,000. These assets were recognized in additional paid in capital on our balance sheet because they were utilized and reduced current taxes payable in 2008.

For the fiscal year ended November 30, 2009, we recognized income tax expense at an estimated effective tax rate of 38% on our statement of operations. This income tax expense included a non-cash tax expense on our statement of operations for fiscal 2009 of \$3,715,516. In addition, during fiscal 2009, we recognized deferred tax assets primarily related to the previous exercise of stock options of approximately \$4,580,000. These assets were recognized in additional paid in capital on our balance sheet because they were utilized and reduced current taxes payable in 2009.

**Results of Operations*****Fiscal Year Ended November 30, 2009 Compared to Fiscal Year Ended November 30, 2008***

**Net Revenues.** Our net revenues increased \$2,558,117, or 5%, from \$47,455,617 in the fiscal year ended November 30, 2008 to \$50,013,734 in the fiscal year ended November 30, 2009. The increase in net revenues is primarily attributable to:

an increase in U.S. sales of \$2,124,351, or 6%, from \$38,035,145 in fiscal 2008 to \$40,159,496 in fiscal 2009. The increase in U.S. sales was primarily due to an increase in sales of the disposable sensor of \$4,737,655, or 16%, primarily as a result of a 12% increase in sensor unit sales. This increase was partially offset by a decrease in sales of the INVOS System monitor in the United States of \$2,737,468, or 36%, primarily as a result of the current economic downturn in the United States that is affecting hospital budget spending and lengthening the sales cycle for our INVOS System monitor; and

an increase in international sales of \$433,766, or 5%, from \$9,420,472 in fiscal 2008 to \$9,854,238 in fiscal 2009. The increase in international sales was primarily due to increased sales of our disposable sensor of \$1,174,742, or 30%, primarily as a result of increased purchases of approximately \$832,000 by Covidien in Europe and \$235,000 by Edwards Lifesciences in Japan. This increase was partially offset by a decrease in sales of the INVOS System monitor internationally of \$740,976, or 13%, primarily due to reduced purchases by Covidien in Europe as a result of the current economic downturn internationally that is affecting hospital budget spending and lengthening the sales cycle for our INVOS System monitor. In fiscal 2009 and fiscal 2008, international sales represented 20% of our net revenues. Purchases by Covidien accounted for 13% of net revenues in fiscal 2009, compared to 14% in fiscal 2008.

In the United States, we sold 323,156 disposable sensors in fiscal 2009, and internationally, we sold 178,870. We placed 404 INVOS System monitors in the United States and 525 internationally in fiscal 2009, and our installed base of INVOS System monitors in the United States was 2,927, in 782 hospitals, as of November 30, 2009.

**Table of Contents**

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

<b>Product</b>	<b>Fiscal Year Ended November 30,</b>	
	<b>2009</b>	<b>2008</b>
Sensors	81%	72%
INVOS System Monitors	19%	28%
Total	100%	100%

We believe that the current economic downturn in the United States and abroad could continue to significantly lengthen the sales cycle for our products and reduce the growth in our net revenues in fiscal 2010. We expect international net revenues to increase beginning in February 2010 as a result of new prices negotiated as part of our distribution agreement extension with Covidien.

**Gross Margin.** Gross margin as a percentage of net revenues was 87% for the fiscal year ended November 30, 2009 and November 30, 2008. During fiscal 2009, we realized a 3% increase in the average selling price of disposable sensors in the United States as a result of increased sales of our pediatric sensor, which sells for a higher price than the adult sensor. The increase in average selling prices described above was primarily offset by decreased sales of the INVOS System monitor to pediatric hospitals in the United States during fiscal 2009. We expect international gross margins to increase beginning in February 2010 as a result of new prices negotiated as part of our distribution agreement extension with Covidien.

**Research, Development and Engineering Expenses.** Our research, development and engineering expenses increased \$2,688,282, or 213%, from \$1,259,227 in fiscal 2008 to \$3,947,509 in fiscal 2009. The increase is primarily attributable to \$1,800,000 in up-front, non-refundable payments in connection with our Exclusive Sublicense Agreement we entered into with Raba Equity Partners II, LLC ( Raba coreFoundry ) in the fourth quarter of fiscal 2009 and a \$200,000 up-front, non-refundable payment in connection with our Development and Exclusive License Agreement with an inventor and his company in the fourth quarter of fiscal 2009. The increase is also attributable to an increase in salaries of \$412,829, primarily due to the addition of research and development personnel in fiscal 2008 and 2009, and increased development costs and expenses associated with our Contract Development Agreement with Shirley Research Corporation and the development of our Vital Sync System of \$229,106. We expect our research, development and engineering expenses to increase in fiscal 2010 from the level in 2009, excluding the \$2,000,000 expense under our Exclusive Sublicense Agreement, and Development and Exclusive License Agreement, described below. We expect this increase primarily as a result of the hiring of additional research and development personnel, development costs associated with the integration of the INVOS System and Vital Sync System, development costs associated with our Exclusive Sublicense Agreement with Raba Equity Partners II, LLC ( Raba coreFoundry ), development costs associated with our Contract Development Agreement with Shirley Research Corporation, and development costs associated with advances to the design and performance features of the INVOS System, including the disposable sensor.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses increased \$3,454,498, or 13%, from \$26,166,120 for the fiscal year ended November 30, 2008 to \$29,620,618 for the fiscal year ended November 30, 2009, primarily due to:

a \$2,261,456 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 105 employees for the fiscal year ended November 30, 2008 to an average of 123 employees for the fiscal year ended November 30, 2009) and an increase in employee insurance premiums and salaries of existing employees;

an \$782,640 increase in travel, marketing and selling-related expenses as a result of our increased sales personnel and increased sales and marketing activities, including trade shows, sales training and advertising expenses;

a \$359,477 increase in professional service fees, primarily due to increased legal and accounting fees associated with the establishment of Somanetics International BV and the related branches and operations, and legal fees associated with the patent infringement action that we have filed against CAS Medical Systems, Inc., in addition to other corporate and intellectual property matters;

## **Table of Contents**

a \$291,558 increase in office and administrative expenses, primarily due to the addition of new employees during fiscal 2009 and the establishment of Somanetics International BV and the hiring of employees in the related branches and operations, and costs associated with terminating our CorRestore license;

a \$278,088 increase in stock compensation expense due to stock compensation issued to our officers, employees, directors and one of our consultants in fiscal 2008 and 2009;

a \$217,112 increase in accrued incentive compensation expense due to our fiscal year 2009 financial performance, primarily sales and operating income compared to targets in accordance with the 2009 incentive compensation plans;

a \$187,451 increase in clinical research expenses, primarily as a result of educational grants and clinical trials evaluating the use of our INVOS System; and

a \$182,197 increase in recruiting and training, primarily as a result of an increase in the number of employees, principally in sales and marketing.

These increases were partially offset by a \$635,653 decrease in commissions paid to our independent sales representative firms as a result of fewer independent sales representative firms in fiscal 2009, and a \$523,298 decrease in commissions paid to our sales employees as a result of lower than expected fiscal 2009 sales.

We expect our selling, general and administrative expenses to increase in fiscal 2010, primarily as a result of our hiring additional direct sales personnel in fiscal 2009 and 2010, as a result of the lease agreement that we have entered into for our new corporate headquarters and assembly and storage facility, and the patent infringement action that we filed against CAS Medical Systems, Inc.

**Other Income.** During fiscal 2009, interest income decreased to \$1,063,147, from \$2,629,967 in fiscal 2008, primarily due to decreased interest rates, in addition to the use of cash for the repurchase of common shares in 2008, and our decreased cash and cash equivalents balances. These decreases were partially offset by our increased investment balances and cash provided by operating activities.

**Income Taxes.** As of November 30, 2009, we recognized income tax expense at an estimated effective tax rate of 38% on our statement of operations. In addition, during fiscal 2009 we recognized deferred tax assets primarily related to the exercise of stock options of approximately \$4,580,000. These assets were recognized as an increase in additional paid in capital on our balance sheet because they were utilized and reduced current taxes payable. As of November 30, 2008, we recognized income tax expense at an estimated effective tax rate of 36% on our statement of operations.

### ***Fiscal Year Ended November 30, 2008 Compared to Fiscal Year Ended November 30, 2007***

**Net Revenues.** Our net revenues increased \$8,869,785, or 23%, from \$38,585,832 in the fiscal year ended November 30, 2007 to \$47,455,617 in the fiscal year ended November 30, 2008. The increase in net revenues is primarily attributable to:

an increase in U.S. sales of \$6,474,215, or 21%, from \$31,560,930 in fiscal 2007 to \$38,035,145 in fiscal 2008. The increase in U.S. sales was primarily due to an increase in sales of the disposable sensor of \$5,619,820, or 23%, primarily as a result of a 16% increase in sensor unit sales. In addition, sales of the INVOS System monitor in the United States increased \$932,969, or 14%, primarily as a result of increased purchases by pediatric hospitals; and

an increase in international sales of \$2,395,570, or 34%, from \$7,024,902 in fiscal 2007 to \$9,420,472 in fiscal 2008. The increase in international sales was primarily due to increased purchases of our INVOS System monitor and disposable sensors of \$1,655,456 by Covidien in Europe, and \$686,471 by Edwards Lifesciences in Japan. In fiscal 2008, international sales represented 20% of our net revenues, compared to 18% of our net revenues in fiscal 2007. Purchases by Covidien accounted for 14% of net revenues in fiscal 2008, compared to 13% in fiscal 2007.

In the United States, we sold 288,797 disposable sensors in fiscal 2008, and internationally, we sold 135,850. We placed 517 INVOS System monitors in the United States and 621 internationally in fiscal 2008, and

**Table of Contents**

our installed base of INVOS System monitors in the United States was 2,523, in 714 hospitals, as of November 30, 2008.

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

<b>Product</b>	<b>Fiscal Year Ended November 30,</b>	
	<b>2008</b>	<b>2007</b>
Sensors	72%	73%
INVOS System Monitors	28%	27%
Total	100%	100%

**Gross Margin.** Gross margin as a percentage of net revenues was 87% for the fiscal year ended November 30, 2008 and 88% for the fiscal year ended November 30, 2007. The decrease in our gross margin percentage is primarily attributable to increased international sales, due to lower margins we receive on sales to our international distributors. This decrease was partially offset by a 6% increase in the average selling price of disposable sensors in the United States, which is attributable to increased sales of our pediatric sensors, which sell for a higher price than the adult sensor.

**Research, Development and Engineering Expenses.** Our research, development and engineering expenses increased \$590,412, or 88%, from \$668,815 in fiscal 2007 to \$1,259,227 in fiscal 2008. The increase is primarily attributable to an increase in salaries of \$279,487 due to the addition of research and development personnel in fiscal 2007 and 2008, and increased costs associated with advances to the design and performance features of our INVOS System monitor and disposable sensors of \$214,803.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses increased \$3,896,936, or 17%, from \$22,269,184 for the fiscal year ended November 30, 2007 to \$26,166,120 for the fiscal year ended November 30, 2008, primarily due to:

a \$2,275,304 increase in salaries, wages, commissions and related expenses, primarily as a result of an increase in the number of employees, principally in sales and marketing (from an average of 88 employees for the fiscal year ended November 30, 2007 to an average of 105 employees for the fiscal year ended November 30, 2008) and an increase in salaries of existing employees;

an \$673,212 increase in travel, marketing and selling-related expenses as a result of our increased sales personnel and increased sales and marketing activities, including sales training and trade shows;

a \$557,282 increase in stock compensation expense due to stock compensation issued to our officers, employees, directors and one of our consultants in fiscal 2006, 2007 and 2008;

a \$465,769 increase in professional service fees, primarily due to increased legal, auditing and tax fees;

a \$217,099 increase in accrued incentive compensation expense due to our fiscal year 2008 financial performance, primarily increased sales and operating income in accordance with the 2008 incentive compensation plans; and

a \$173,672 increase in office and facility expenses primarily as a result of increased employees.

These increases were partially offset by a \$273,905 decrease in commissions paid to our independent sales representative firms as a result of fewer independent sales representative firms in fiscal 2008, and a \$182,919 decrease in clinical research expense primarily as a result of a grant made in fiscal 2007 for the support of neonatal research.

**Other Income.** During fiscal 2008, interest income decreased to \$2,629,967, from \$4,008,537 in fiscal 2007, primarily due to decreased interest rates, decreased investment balances, and the use of cash for the repurchase of

common shares, partially offset by our increased cash and cash equivalents balances as a result of cash provided by operating activities and maturities and redemptions of investments.

**Income Taxes.** As of November 30, 2008, we recognized income tax expense at an estimated effective tax rate of 36% on our statement of operations. In addition, during fiscal 2008 we recognized deferred tax assets related



## **Table of Contents**

to the exercise of stock options of approximately \$1,012,000. These assets were recognized in additional paid in capital on our balance sheet because they were utilized and reduced current taxes payable. As of November 30, 2007, we recognized income tax expense at an estimated effective tax rate of 35% on our statement of operations.

### ***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 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.

As of November 30, 2009, we did not have any outstanding or available debt financing arrangements, we had working capital of \$64.3 million and our primary sources of liquidity were \$29.0 million of cash and cash equivalents, \$24.8 million of marketable securities and \$26.0 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.

In April 2008, our Board of Directors authorized the repurchase of up to \$15 million of our common shares. Purchases may be made from time to time in the open market or in privately negotiated transactions. The prices, timing and amount of, and purposes for, any purchases will be determined by management. In May 2008, our Board of Directors authorized the repurchase of up to an additional \$15 million of our common shares, and in July 2008, our Board of Directors authorized the repurchase of up to an additional \$15 million of our common shares, for a total of \$45 million of our common shares under the repurchase program. During fiscal 2008, we repurchased 1,805,129 common shares at an average price of \$17.42 per share and an aggregate cost of \$31,449,420, leaving \$13,550,580 in dollar value of shares that may yet be purchased under the repurchase program. In the first quarter of 2010, we have resumed purchases of our common shares under our share repurchase program.

We launched our newly-acquired data integration technology, as a stand-alone device that we call Vital Sync , in the third quarter of fiscal 2009. To support the addition of the derived parameter features to the system, or calculated parameters based on the combination of two or more discrete parameters, we have filed a new FDA 510(k) premarket notification in the fourth quarter of fiscal 2009. In addition, we expect to invest to combine the ICU Data Systems and INVOS System technologies in a single product in fiscal 2010. Upon completion of development of a single product combining the Vital Sync System with our INVOS System technology, we also plan to pursue a new FDA 510(k) clearance for this integrated device for a launch currently expected in mid-2011. We expect our research, development and engineering expenses to increase in fiscal 2010 as a result of development costs associated with the integration of the INVOS System and Vital Sync System.

We entered into a Contract Development and Exclusive Licensing Agreement with NeuroPhysics Corporation as of September 18, 2006. The agreement provided 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 terminated this agreement in February 2009, except for various provisions regarding our ownership of the technology related to the potential new products. In February 2009, we entered into a similar agreement with Shirley Research Corporation and Hugh F. Stoddart and Hugh A. Stoddart, and have agreed to pay monthly development and consulting fees of \$15,000 a month during the term of the agreement and a royalty on future sales of the new products.

## **Table of Contents**

On August 7, 2009, we filed a patent infringement action against CAS Medical Systems, Inc. in the United States District Court for the Eastern District of Michigan. The complaint asserts that CAS Medical's FORE-SIGHT® Cerebral Oximeter willfully infringes upon one or more of Somanetics' patents. The complaint also asserts that CAS Medical has engaged in unfair competition and false advertising, by making false or misleading statements in connection with its advertising and promotion of FORE-SIGHT, and false or misleading statements related to Somanetics' products. The complaint seeks, among other things, compensation for damages and an injunction against CAS Medical from infringing upon Somanetics' patents. CAS Medical Systems, Inc. has answered the complaint denying that it infringes any asserted patent and asserting defenses and counterclaims, including those for patent invalidity and/or unenforceability, and antitrust violations. We expect our selling, general and administrative expenses to increase in fiscal 2010, in part as a result of this patent infringement action.

In October 2009, we entered into an Exclusive Sublicense Agreement with Raba Equity Partners II, LLC ( "Raba coreFoundry "). We paid Raba coreFoundry up-front, non-refundable payments of \$1.8 million and will pay a royalty on future revenue associated with products using the licensed technology. The up-front payment was accounted for as a research and development expense in the fourth quarter of fiscal 2009. We plan to file a new 510(k) premarket notification with the FDA to support marketing the new module in the U.S. and pursue a product launch in the first half of 2011.

In November 2009, we entered into a Development and Exclusive Agreement with an inventor and his company to develop and market a product that uses INVOS technology and methods and means described in the inventor's patent to monitor, detect and assess acute compartment syndrome in parts of the human body. We paid the inventor's company an up-front, non-refundable payment of \$200,000 and will pay an additional \$300,000 upon obtaining 510(k) clearance for the product and a royalty on future revenue associated with products using the licensed technology. The up-front payment was accounted for as research and development expenses in the fourth quarter of fiscal 2009. The U.S. Department of Defense has provided a grant for the research and development of a monitor and sensors to monitor, detect and assess compartment syndrome. As part of the agreement, over a three-year period, we expect to receive approximately \$2.1 million for product and prototype sales and research and development fees, derived from the grant, for its work to develop the compartment syndrome product.

See Operating Expenses above for a description of our expected increased research and development commitments expected in fiscal 2010 as a result of these agreements.

We believe that cash, cash equivalents, marketable securities and long-term investments on hand at November 30, 2009 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 2009, 2008 and 2007 was \$5,539,819, \$15,874,473 and \$13,081,989, respectively. In fiscal 2009, cash was provided primarily by:

\$8,646,991 of income before income taxes and non-cash depreciation, amortization, stock compensation expense and excess tax benefits from stock option exercises; and

a \$195,439 increase in accounts payable, primarily as a result of increased inventory and operating expenses, partially offset by more timely payments made to vendors.

Cash provided by operations in fiscal 2009 was partially offset by:

a \$1,384,230 increase in inventories, primarily due to lower than expected fiscal 2009 sales and the acquisition of components associated with our disposable sensors 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 \$1,016,839 increase in accounts receivable, primarily as a result of higher fourth quarter sales in fiscal 2009 than in the fourth quarter of fiscal 2008, the timing of more of the sales in the fourth quarter of fiscal



**Table of Contents**

2009 towards the end of the quarter than in the fourth quarter of fiscal 2008 and less timely collections in fiscal 2009 than in fiscal 2008;

a \$489,990 increase in prepaid expenses, primarily due to prepaid expenses related to our planned move into our new corporate headquarters and assembly and storage facility in December 2009;

a \$230,000 increase in deferred income tax benefits as a result of payments made for estimated alternative minimum tax that we expect will result in future tax credits when we use our net operating loss carryforwards;

a \$121,432 increase in accrued interest income, primarily due to our increased marketable securities and long-term investment balances, partially offset by decreased interest rates; and

a \$60,120 decrease in accrued liabilities, primarily as a result of a decrease in accrued state, local and property taxes as a result of payments made in 2009, and a decrease in accrued sales commissions as a result of lower than expected 2009 sales, partially offset by an increase in accrued legal fees associated with the patent infringement action that we have filed against CAS Medical Systems, Inc., and an increase in accrued incentive compensation due to our fiscal year 2009 financial performance, primarily sales and operating income compared to targets in accordance with the 2009 incentive compensation plans.

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

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 \$722,121 of costs from inventory for INVOS System monitors being used as demonstration units and no capital cost sales equipment at customers during fiscal 2009, compared to \$644,814 in fiscal 2008. As of November 30, 2009, we have capitalized \$4,285,163 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 \$1,868,706. We depreciate these assets over five years.

We believe that the current economic downturn in the United States and abroad could lengthen our collection cycle for our accounts receivable and, as a result, increase our accounts receivable balances.

***Cash Flows From Investing Activities***

Net cash used in investing activities in fiscal 2009 and 2007 was \$18,491,637 and \$10,127,748, respectively, and net cash provided by investing activities in fiscal 2008 was \$17,220,458. In fiscal 2009, we invested \$58,528,869 in marketable securities and long-term investments, partially offset by maturities of marketable securities and long-term investments of \$40,590,275.

***Cash Flows From Financing Activities***

Net cash provided by financing activities in fiscal 2009 and 2007 was \$4,749,950 and \$1,483,867, respectively, and net cash used in financing activities in fiscal 2008 was \$29,101,767. During fiscal 2009, we received \$4,579,947 in excess tax benefits from the previous exercise of stock options, and \$170,003 in proceeds from the issuance of 52,800 common shares as a result of the exercise of stock options in 2009 by our employees, directors and an officer.

In the first quarter of 2010, we have resumed purchases of our common shares under our share repurchase program.

**Table of Contents****Contractual Obligations**

The following information is provided as of November 30, 2009 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			
		Less than 1 year	1-3 years	3-5 years	More than 5 years
Long-term debt obligations					
Capital lease obligations					
Operating lease obligations	\$3,412,000	\$ 365,000	\$911,500	\$957,600	\$1,177,800
Purchase obligations	6,225,700	6,218,700	7,000		
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**

On July 1, 2009, the Financial Accounting Standards Board ( FASB ) Accounting Standards Codification ( Codification or ASC ) became the single source of authoritative U.S. GAAP (other than rules and interpretive releases of the U.S. Securities and Exchange Commission). The Codification is topically based with topics organized by ASC number and updated with Accounting Standards Updates ( ASUs ). ASUs replace accounting guidance that was historically issued as Statements of Financial Accounting Standards ( SFAS ), FASB Interpretations ( FIN ), FASB Staff Positions ( FSP ), Emerging Issues Task Force ( EITF ) Abstracts and other types of accounting standards. The Codification became effective during our fourth quarter of fiscal 2009, and disclosures within this Annual Report on Form 10-K have been updated to reflect the change.

**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, our revenue recognition associated with our no capital cost sales program and our recognition of a technology acquisition cost intangible asset and goodwill.

***Stock Compensation***

Generally accepted accounting principles, or GAAP, 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. The issuance of stock compensation under the 2005 Stock Incentive Plan in fiscal 2009, 2008, 2007 and 2006 had an impact on our financial statements.

During fiscal 2009, we granted 68,250 stock options to our employees, directors and an officer, and we issued 17,588 restricted common shares to our employees and an officer. During fiscal 2008, we granted 253,000 stock options to our employees, directors and officers, and we issued 75,273 restricted common shares to our officers and employees. During fiscal 2007, we granted 96,000 stock options to our employees, directors and one of our officers, and we issued 9,000 restricted common shares to one of 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 2009, 2008, 2007 and 2006, we have recorded \$1,616,678 in fiscal 2009, \$1,338,590 in fiscal 2008, and \$781,308 in fiscal 2007 in stock compensation expense.

As of November 30, 2009, there was \$4,437,246 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 3 years. As of November 30, 2008, there was \$5,247,791 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 years. As of November 30, 2007, there was \$3,606,518 of total unrecognized compensation cost related to nonvested share-based compensation awards granted under the 2005 Plan. That cost was expected to be recognized over a weighted average period of 4 years. No modifications were made to any share awards that required an accounting charge, and no cash was paid for share-based liabilities during fiscal 2009, 2008 or 2007.

The fair value of each option grant was estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions for fiscal 2009, 2008 and 2007: expected volatility (the measure by which the stock price has fluctuated or is expected to fluctuate during the period) 53.97% (59.30% for 2008 and 47.00% for 2007), risk-free interest rate (approximate U.S. Treasury yield in effect at the time of grant) of 2.50% (2.35% for 2008 and 5.00% for 2007), expected lives of approximately 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. Different assumptions could significantly change the calculated grant date fair value and, therefore, the amount of stock compensation expense we recognize over the vesting period of the awards. We believe, however, that our estimates are appropriate.

### ***Income Taxes***

We have performed the required assessment of positive and negative evidence regarding realization of our deferred tax assets in accordance with GAAP, including our past operating results, the existence of cumulative losses over our history up to the most recent seven fiscal years, and our forecast for future net income. Our assessment of our deferred tax assets included making assumptions about our net revenues and pre-tax income in future years, making allowance for the uncertainties regarding, among other things, our future net revenues, the rate of adoption of our products in the marketplace and the competition in the marketplace. As of November 30, 2009, we have concluded that it is more likely than not that approximately \$2,847,000 of such assets will be realized. The remaining tax benefits of \$2,590,000 relating to stock option exercises will not be recognized on our financial statements until they reduce current taxes payable. The benefit, when recognized, will increase additional paid in capital. During fiscal 2009, we recognized deferred tax assets of approximately \$4,580,000 in additional paid in capital because they were utilized and reduced current taxes payable.

For the fiscal year ended November 30, 2009, we recorded income tax expense at an estimated effective tax rate of 38%, for the year ended November 30, 2008 we recorded income tax expense at an estimated effective tax rate of 36%, and for the year ended November 30, 2007 we recorded income tax expense at an estimated effective tax rate of 35%.

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 shipment of the INVOS System monitor. 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 recognize sensor revenue when we receive purchase orders and ship the product to the customer. We believe this is consistent with our stated revenue recognition policy, which is compliant with the Financial Accounting Standards Board ( FASB ) Accounting

**Table of Contents**

Standards Codification ( ASC ) 605 Revenue Recognition and Securities and Exchange Commission Staff Accounting Bulletin ( SAB ) No. 104.

***Technology Acquisition Costs Intangible Asset and Goodwill***

Technology acquisition costs and goodwill are related to our November 2008 acquisition of substantially all of the assets of ICU Data Systems, Inc., a technology development company, for approximately \$2,000,000 in cash plus the assumption of specified liabilities. Goodwill represents the amount by which the purchase price of the acquired business exceeds the estimated fair value of the net tangible and separately identifiable intangible assets of the acquired business, in addition to transaction costs recorded at cost. Goodwill is not amortized, but is tested at least annually for impairment. The technology acquisition costs intangible asset has an estimated useful life of 20 years, based on several patents that we have filed related to the technology, and is being amortized on a straight-line basis over the estimated useful life. Intangible assets and goodwill are reviewed annually for impairment at the end of our fiscal year, and whenever events or changes in circumstances indicate that the carrying value of the asset may not be recovered. We evaluate impairment by comparing the fair value of the intangible asset, determined using a cash flow method, with its carrying value.

We estimated the value of the technology acquisition costs intangible asset based on a valuation model that included estimating the future cash flows of the technology and discounting the net cash flows back to their present value using an appropriate risk-adjusted rate of return (discount rate). The discount rate used was determined at the time of the acquisition in accordance with accepted valuation methods. Our assessment of the estimated fair value included making assumptions about the expected net revenues and operating income related to the acquired technology in future years, making allowance for the uncertainties regarding, among other things, the time and cost associated with the further advancement of the design and performance of the technology, the rate of adoption of the technology, and the potential for competition related to the technology. As of November 30, 2009, the carrying value of the technology acquisition costs intangible asset was \$234,003, and the carrying value of the goodwill was \$1,783,712.

Given the assumptions inherent in our valuation model, it is possible to calculate a different value for our technology acquisition costs intangible asset by changing one or more of the variables within our model. However, we believe that our evaluation of our valuation model was reasonable, and that the judgments and assumptions that we made in our valuation model were appropriate.

**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 and treasury bills. 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 and treasury bills with varying maturity dates with the intention of holding them until maturity.

**November 30, 2009**  
**Expected Maturity Dates By Fiscal Year**

	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>Thereafter</b>	<b>Total</b>	<b>Fair Value</b>
<b>Investments:</b>								
Marketable Securities and Long-term Investments:								
Fixed Rate (\$)	24,763,854	20,000,000	1,010,681	4,994,314			50,768,849	51,155,992
Average interest rate	.94%	1.84%	2.35%	5.05%	N/A	N/A	1.73%	

**November 30, 2008**  
**Expected Maturity Dates By Fiscal Year**

	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>Thereafter</b>	<b>Total</b>	<b>Fair Value</b>
<b>Investments:</b>								
Marketable Securities and Long-term Investments:								
Fixed Rate (\$)	19,992,545	3,845,241		4,000,000	4,992,469		32,830,255	32,823,806
Average interest rate	.53%	4.72%	N/A	5.00%	5.05%	N/A	2.25%	

During fiscal 2009, we invested approximately \$8,000,000 of our cash in two new bonds with maturity dates in fiscal 2009, \$27,500,000 of our cash in four new bonds with maturity dates in fiscal 2010, \$22,000,000 of our cash in two new bonds with maturity dates in fiscal 2011 and \$1,000,000 of our cash in one new bond with a maturity date in fiscal 2012. Two bonds and two of our treasury bills matured for approximately \$28,000,000, three of our bonds that were due to mature in 2010, 2011 and 2012 were called for approximately \$11,000,000, and one of our bonds due to mature in 2010 returned approximately \$1,500,000 in principal in 2009.



**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, 2009. 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 have concluded that, as of November 30, 2009, 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 a report on the financial statements and on the effectiveness of the Company's internal control over financial reporting, which is included on the next page.  
January 21, 2010

**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, 2009 and 2008, and the related statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended November 30, 2009. We also have audited the Company's internal control over financial reporting as of November 30, 2009, 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 these financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on these financial statements and an opinion on the Company's internal control over financial reporting 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 and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide 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.

**Table of Contents**

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Somanetics Corporation as of November 30, 2009 and 2008, and the results of its operations and its cash flows for each of the three years in the period ended November 30, 2009, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of November 30, 2009, based on the criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

/s/ DELOITTE & TOUCHE LLP

Detroit, Michigan

February 3, 2010

**Table of Contents****SOMANETICS CORPORATION  
BALANCE SHEETS**

	November 30,	
	2009	2008
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents (Note 2)	\$ 28,964,273	\$ 37,166,141
Marketable securities	24,763,854	19,992,545
Accounts receivable	8,878,942	7,862,103
Inventory (Note 2)	3,622,531	2,960,422
Prepaid expenses	1,087,450	597,460
Accrued interest receivable	138,099	16,667
Deferred tax asset – current (Note 5)	51,060	164,615
 Total current assets	 67,506,209	 68,759,953
 <b>PROPERTY AND EQUIPMENT: (Note 2)</b>		
Demonstration and no capital cost sales equipment at customers	4,285,163	3,919,296
Machinery and equipment	1,886,582	1,638,597
Furniture and fixtures	545,796	504,485
Leasehold improvements	197,450	197,450
 Total	 6,914,991	 6,259,828
Less accumulated depreciation and amortization	(3,966,645)	(3,418,697)
 Net property and equipment	 2,948,346	 2,841,131
 <b>OTHER ASSETS:</b>		
Long-term investments	26,004,995	12,837,710
Deferred tax asset – non-current (Note 5)	2,795,963	1,587,977
Intangible assets, net (Note 2)	234,003	246,318
Goodwill (Note 2)	1,783,712	1,679,713
Other	15,000	15,000
 Total other assets	 30,833,673	 16,366,718
 <b>TOTAL ASSETS</b>	 <b>\$ 101,288,228</b>	 <b>\$ 87,967,802</b>
 <b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 1,466,497	\$ 1,271,058
Accrued liabilities (Notes 4 and 6)	1,788,552	1,848,672
 Total current liabilities	 3,255,049	 3,119,730
 <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, 12,104,462 shares at November 30, 2009, and 12,034,074 shares at November 30, 2008

Additional paid-in capital

Retained Earnings (Accumulated deficit)

Total shareholders' equity

TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY

121,045	120,341
97,696,229	91,330,305
215,905	(6,602,574)
98,033,179	84,848,072
\$ 101,288,228	\$ 87,967,802

See notes to financial statements

57

**Table of Contents****SOMANETICS CORPORATION  
STATEMENTS OF OPERATIONS**

	For the Years Ended November 30,		
	2009	2008	2007
NET REVENUES (Notes 2 and 9)	\$ 50,013,734	\$ 47,455,617	\$ 38,585,832
COST OF SALES	6,580,766	6,249,256	4,726,146
Gross margin	43,432,968	41,206,361	33,859,686
OPERATING EXPENSES:			
Research, development and engineering (Note 2)	3,947,509	1,259,227	668,815
Selling, general and administrative	29,620,618	26,166,120	22,269,184
Total operating expenses	33,568,127	27,425,347	22,937,999
OPERATING INCOME	9,864,841	13,781,014	10,921,687
OTHER INCOME:			
Interest income	1,063,147	2,629,967	4,008,537
Total other income	1,063,147	2,629,967	4,008,537
INCOME BEFORE INCOME TAXES	\$ 10,927,988	\$ 16,410,981	\$ 14,930,224
INCOME TAX EXPENSE (Note 5)	(4,109,508)	(5,964,734)	(5,247,943)
NET INCOME	\$ 6,818,480	\$ 10,446,247	\$ 9,682,281
NET INCOME PER COMMON SHARE BASIC (Note 2)	\$ .57	\$ .82	\$ .73
NET INCOME PER COMMON SHARE DILUTED (Note 2)	\$ .53	\$ .76	\$ .67
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING BASIC (Note 2)	12,069,361	12,671,452	13,213,428
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING DILUTED (Note 2)	12,935,886	13,671,730	14,384,445

See notes to financial statements

Table of Contents

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

	<b>Common Shares</b>	<b>Share Value</b>	<b>Additional Paid-In Capital</b>	<b>Retained Earnings (Accumulated Deficit)</b>	<b>Total Shareholders' Equity</b>	<b>Comprehensive Income</b>
Balance at December 1, 2006	13,163,627	\$ 131,636	\$ 116,817,012	\$ (26,731,103)	\$ 90,217,545	
For cash, exercise of stock options	271,334	2,714	1,481,153		1,483,867	
Stock compensation expense			781,308		781,308	
Restricted share grant	9,000	90	(90)			
Net income and comprehensive income				9,682,281	9,682,281	\$ 9,682,281
Balance at November 30, 2007	13,443,961	\$ 134,440	\$ 119,079,383	\$ (17,048,822)	\$ 102,165,001	
For cash, exercise of stock options	319,969	3,199	1,332,129		1,335,328	
Stock compensation expense			1,338,590		1,338,590	
Restricted share grant	75,273	753	(753)			
Repurchase of common shares	(1,805,129)	(18,051)	(31,431,369)		(31,449,420)	
Income tax benefit from stock option exercises			1,012,325		1,012,325	
Net income and comprehensive income				10,446,247	10,446,247	\$ 10,446,247
Balance at November 30, 2008	12,034,074	\$ 120,341	\$ 91,330,305	\$ (6,602,574)	\$ 84,848,072	
For cash, exercise of stock options	52,800	528	169,475		170,003	
Stock compensation expense			1,616,678		1,616,678	
Restricted share grant	17,588	176	(176)			
Income tax benefit from stock option exercises			4,579,947		4,579,947	
Net income and comprehensive income				6,818,480	6,818,480	\$ 6,818,480
Balance at November 30, 2009	12,104,462	\$ 121,045	\$ 97,696,229	\$ 215,905	\$ 98,033,179	

See notes to financial statements

**Table of Contents****SOMANETICS CORPORATION  
STATEMENTS OF CASH FLOWS**

	<b>For the Years Ended November 30,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net income	\$ 6,818,480	\$ 10,446,247	\$ 9,682,281
Adjustments to reconcile net income to net cash provided by operations:			
Income tax expense (benefit)	3,715,516	5,586,906	5,076,276
Depreciation and amortization	1,076,264	951,906	806,034
Stock compensation expense	1,616,678	1,338,590	781,308
Excess tax benefits from stock option exercises	(4,579,947)	(1,012,325)	
Changes in assets and liabilities net of effects from purchase of ICU Data Systems, Inc.:			
Accounts receivable (increase)	(1,016,839)	(375,532)	(2,746,528)
Accrued interest receivable (increase) decrease	(121,432)	534,450	(199,451)
Inventory (increase)	(1,384,230)	(1,606,952)	(658,895)
Deferred income tax benefit (increase)	(230,000)	(252,488)	(400,960)
Prepaid expenses (increase)	(489,990)	(36,575)	(66,063)
Accounts payable increase	195,439	153,055	72,276
Accrued liabilities (decrease) increase	(60,120)	147,191	541,711
Accrued income tax expense decrease			194,000
Net cash provided by operating activities	5,539,819	15,874,473	13,081,989
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchases of marketable securities and long-term investments	(58,528,869)	(35,021,241)	(63,795,275)
Proceeds from maturities of marketable securities and long-term investments	40,590,275	54,822,160	54,000,000
Payment for purchase of ICU Data Systems, Inc.	(104,000)	(1,926,031)	
Acquisition of property and equipment	(449,043)	(654,430)	(332,473)
Net cash (used in) provided by investing activities	(18,491,637)	17,220,458	(10,127,748)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Repurchase of common shares		(31,449,420)	
Excess tax benefits from stock option exercises	4,579,947	1,012,325	
Proceeds from issuance of common shares due to exercise of stock options	170,003	1,335,328	1,483,867
Net cash provided by (used in) financing activities	4,749,950	(29,101,767)	1,483,867
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(8,201,868)</b>	<b>3,993,164</b>	<b>4,438,108</b>



CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	37,166,141	33,172,977	28,734,869
--	------------	------------	------------

CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 28,964,273	\$ 37,166,141	\$ 33,172,977
--	---------------	---------------	---------------

Supplemental Disclosure of Non cash investing activities:

Demonstration and no capital cost sales equipment capitalized from inventory (Note 2)	\$ 722,121	\$ 644,814	\$ 833,069
---	------------	------------	------------

Supplemental Disclosure of Taxes paid: Federal and state income taxes (Note 5)	\$ 653,992	\$ 600,317	\$ 572,627
--	------------	------------	------------

See notes to financial statements

**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 provides accurate, real-time blood oxygen measurements in the brain and elsewhere in the body in tissues beneath the sensor in patients greater than 2.5 kilograms, and continuously measures changes in blood oxygen levels for individuals of any weight. The INVOS System measurement is made by transmitting low-intensity visible and near-infrared light through a portion of the body with disposable sensors, and detecting the manner in which the exposed substance interacts with light at specific wavelengths. The INVOS System is the only commercially-available cerebral/somatic Oximeter proven to improve outcomes. The principal markets for our products are the United States, Europe, and Japan.

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 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 May 2008, we received 510(k) clearance from the FDA to market our INVOS System to monitor changes in blood oxygen saturation in any tissues beneath the sensor, not limited to brain and somatic tissue, in any individual. In April 2009, we received 510(k) clearance from the FDA to expand the indications for use to reflect the INVOS System's ability to provide accurate, immediate blood oxygen saturation measurements in patients greater than 2.5 kilograms at risk for restricted or no blood flow, in addition to our previous FDA clearance to measure changes in blood oxygen saturation in any individual. In addition, this most recent 510(k) clearance expanded the labeling for our INVOS System to include new marketing claims.

In November 2008, we acquired substantially all of the assets of ICU Data Systems, Inc., a company that has developed a patented technology that integrates data from a broad array of hospital bedside devices, such as physiological monitors, ventilators and infusion devices, into a single bedside display for comparison, data management and storage. We launched our newly-acquired data integration technology, as a stand-alone device that we call Vital Sync, in the third quarter of fiscal 2009. The INVOS System is one of many devices whose data can be integrated into the stand-alone device. To support the addition of the derived parameter features to the system, or calculated parameters based on the combination of two or more discrete parameters, we have filed a new FDA 510(k) premarket notification in the fourth quarter of fiscal 2009. In addition, we expect to invest to combine the ICU Data Systems and INVOS System technologies in a single product in fiscal 2010. Upon completion of development of a single product combining the Vital Sync System with our INVOS System technology, we also plan to pursue a new FDA 510(k) clearance for this integrated device for a launch currently expected in mid-2011.

**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 and treasury bills, classified as held to maturity, maturing approximately nine months to five years from the date of acquisition, are stated at an amortized cost of \$50,768,849, and have a market value of \$51,155,992 at November 30, 2009.

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

Table of Contents

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

	<b>November 30,</b>	
	<b>2009</b>	<b>2008</b>
Purchased components	\$ 2,358,037	\$ 2,141,050
Finished goods	1,042,205	587,808
Work in process	222,289	231,564
 Total	 \$ 3,622,531	 \$ 2,960,422

*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 ten years. Depreciation expense was \$1,063,948, \$948,809 and \$799,122 for the fiscal years ended November 30, 2009, November 30, 2008 and November 30, 2007, 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, 2009, we have capitalized \$4,285,163 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 \$1,868,706. As of November 30, 2008, we have capitalized \$3,919,296 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 \$1,820,503. 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 and Goodwill* consist of technology acquisition costs and goodwill. The carrying amount and accumulated amortization of these technology acquisition costs are as follows:

	<b>November 30,</b>	
	<b>2009</b>	<b>2008</b>
Technology acquisition costs	\$ 246,318	\$ 246,318
Less: accumulated amortization	(12,315)	
 Total	 \$ 234,003	 \$ 246,318

Amortization expense was \$12,315 for fiscal year ended November 30, 2009 for our technology acquisition costs intangible asset. Amortization expense of \$3,097 for the fiscal year ended November 30, 2008 and \$6,912 for the fiscal year ended November 30, 2007 related to an intangible asset that has a net book value of zero at November 30, 2009.

Technology acquisition costs and goodwill are related to our November 2008 acquisition of substantially all of the assets of ICU Data Systems, Inc., a technology development company, for approximately \$2,000,000 in cash plus the assumption of specified liabilities. Goodwill represents the amount by which the purchase price of the acquired business exceeds the estimated fair value of the net tangible and separately identifiable intangible assets of the acquired business, in addition to transaction costs recorded at cost. Goodwill is not amortized, but is tested at least annually for impairment. The technology acquisition costs intangible asset has an estimated useful life of 20 years, based on several patents that we have filed related to the technology, and will be amortized on a straight-line basis over the estimated useful life. Intangible assets and goodwill are reviewed annually for impairment at the end of our fiscal year, and whenever events or changes in circumstances indicate that the carrying value of the asset may not be recovered. We evaluate impairment by comparing the fair value of the intangible asset, determined using a cash flow method, with its carrying value.

No amortization expense was recorded related to the technology acquisition costs intangible asset for 2008 because the transaction closed in November 2008. Amortization expense for each of the next 20 fiscal years related to the technology acquisition costs intangible asset is expected to be approximately \$12,300. As of November 30, 2008, the carrying value of the technology acquisition costs intangible asset was \$246,318, and the carrying value of the

**Table of Contents**

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

goodwill was \$1,679,713. As of November 30, 2009, the carrying value of the technology acquisition costs intangible asset was \$234,003, and the carrying value of the goodwill was \$1,783,712. The increase in goodwill during fiscal 2009 related to an additional payment in conjunction with our acquisition of substantially all of the assets of ICU Data Systems, Inc.

We estimated the value of the technology acquisition costs intangible asset based on a valuation model that included estimating the future cash flows of the technology and discounting the net cash flows back to their present value using an appropriate risk-adjusted rate of return (discount rate). The discount rate used was determined at the time of the acquisition in accordance with accepted valuation methods. Our assessment of the estimated fair value included making assumptions about the expected net revenues and operating income related to the acquired technology in future years, making allowance for the uncertainties regarding, among other things, the time and cost associated with the further advancement of the design and performance of the technology to ready it for market launch, the rate of adoption of the technology once it is launched into the marketplace, and the potential for competition related to the launched technology.

*Revenue Recognition*, including direct sales, sales through sales representatives and sales to international distributors, occurs for our products when there is persuasive evidence of an arrangement with the customer, the product has been delivered, the sales price is fixed or determinable, and collectability 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. We have considered the Financial Accounting Standards Board ( FASB ) Accounting Standards Codification ( ASC ) 605 Revenue Recognition and Securities and Exchange Commission Staff Accounting Bulletin ( SAB ) No. 104 in determining our revenue recognition policy.

*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, 2009, November 30, 2008 and November 30, 2007, includes the potential dilution that could occur for common shares issuable under stock options. As of November 30, 2009, 2008 and 2007, the difference between weighted average shares diluted and weighted average shares basic is calculated as follows:

	2009	2008	2007
Weighted average shares basic	12,069,361	12,671,452	13,213,428
Add: effect of dilutive common shares	866,525	1,000,278	1,171,017

Weighted average shares diluted	12,935,886	13,671,730	14,384,445
---------------------------------	------------	------------	------------

At November 30, 2009, there were 458,750 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 market price per share of our common shares. At November 30, 2008 and 2007, there were no stock options outstanding that were excluded from the computation of net income per common share diluted. In addition, at November 30, 2009, we had outstanding 1,814,637 stock options to purchase common shares, as of November 30, 2008, we had outstanding 1,822,187 stock options to purchase common shares and as of November 30, 2007, we had outstanding 1,895,656 stock options to purchase common shares.

*Common Share Repurchase Program* In April 2008, our Board of Directors authorized the repurchase of up to \$15 million of our common shares. Purchases may be made from time to time in the open market or in privately negotiated transactions. The prices, timing and amount of, and purposes for, any purchases will be determined by management. In May 2008, our Board of Directors authorized the repurchase of up to an additional \$15 million of our common shares, and in July 2008, our Board of Directors authorized the repurchase of up to an additional \$15 million of our common shares, for a total of \$45 million of our common shares under the repurchase program. During fiscal 2008, we repurchased 1,805,129 common shares at an average price of \$17.42 per share and an aggregate cost of \$31,449,420. All of the shares were purchased by us in open-market transactions pursuant to this



**Table of Contents**

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

publicly-announced share repurchase program. The program does not have an expiration date, except upon purchase of the maximum authorized dollar amount of our common shares.

*Accounting Pronouncements* On July 1, 2009, the Financial Accounting Standards Board ( FASB ) Accounting Standards Codification ( Codification or ASC ) became the single source of authoritative U.S. GAAP (other than rules and interpretive releases of the U.S. Securities and Exchange Commission). The Codification is topically based with topics organized by ASC number and updated with Accounting Standards Updates ( ASUs ). ASUs replace accounting guidance that was historically issued as Statements of Financial Accounting Standards ( SFAS ), FASB Interpretations ( FIN ), FASB Staff Positions ( FSP ), Emerging Issues Task Force ( EITF ) Abstracts and other types of accounting standards. The Codification became effective during our fourth quarter of fiscal 2009, and disclosures within this Annual Report on Form 10-K have been updated to reflect the change.

*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**

During fiscal 2009, we issued 52,800 common shares as a result of stock option exercises by our employees, directors and an officer for gross proceeds to us of \$170,003. During fiscal 2008, we issued 319,969 common shares as a result of stock option exercises by our employees and directors for gross proceeds to us of \$1,335,328. During fiscal 2007, we issued 271,334 common shares as a result of stock option exercises by our employees, a former director and a consultant for gross proceeds to us of \$1,483,867.

Common shares reserved for future issuance upon exercise of stock options as discussed above at November 30, 2009, are as follows:

1991 Incentive Stock Option Plan	14,663
1997 Stock Option Plan	1,023,508
2005 Stock Incentive Plan	1,026,139
Options Granted Independent of Option Plans	55,000
 Total shares reserved for future issuance	 2,119,310

### **4. Accrued Liabilities**

Accrued liabilities consist of the following:

	<b>November 30,</b>	
	<b>2009</b>	<b>2008</b>
Incentive Compensation	\$ 1,185,225	\$ 978,520
Sales Commissions	425,969	637,516
Professional Fees	159,458	39,500
Warranty	17,900	19,440
Taxes		121,683
Clinical Research		51,671
401(k) Match		342
 Total	 \$ 1,788,552	 \$ 1,848,672

### **5. Income Taxes**

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



**Table of Contents**

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

tax benefit of net operating loss carryforwards and research and general business tax credit carryforwards. We had deferred tax assets of approximately \$5,437,000 as of November 30, 2009, which include approximately \$2,590,000 related to the exercise of stock options, which will not be recognized as deferred tax assets on our balance sheet until such time as they are utilized and reduce current taxes payable. If realized in the future, these tax benefits will be recognized in additional paid in capital. During fiscal 2009, we recognized deferred tax assets of approximately \$4,580,000 in additional paid in capital because they were utilized and reduced current taxes payable. The change in the valuation related to future stock option tax benefits is attributable to current year tax deductions from stock options exercised. We had deferred tax assets of approximately \$8,706,000 as of November 30, 2008, which include approximately \$6,953,000 related to the exercise of stock options, as described above. We have used a statutory federal income tax rate of 34% when calculating our deferred tax assets. We paid income taxes in fiscal 2009, 2008 and 2007 of approximately \$230,000, \$252,000 and \$401,000 respectively for alternative minimum tax due. The amounts paid for alternative minimum tax in fiscal 2009, 2008 and 2007 have been recorded as tax credit carryforward deferred tax assets on our balance sheet, as shown below.

The components of deferred income tax assets as of November 30, 2009 and 2008 were as follows:

	<b>November 30,</b>	
	<b>2009</b>	<b>2008</b>
	<b>(in thousands)</b>	
Net operating loss carryforwards	\$ 2,641	\$ 7,119
Stock compensation expense	1,475	885
Other	66	85
Basis difference of fixed assets and intangibles	196	(212)
Alternative minimum tax credit carryforward	883	653
Research and general business tax credit carryforwards	176	176
Subtotal	5,437	8,706
Reduction for future stock option tax benefits valuation	(2,590)	(6,953)
Deferred tax asset	\$ 2,847	\$ 1,753

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

	<b>For the Fiscal Year Ended November 30,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
Taxes at U.S. statutory rate 34%	\$ 3,715,516	\$ 5,579,734	\$ 5,076,276
State and local income taxes	338,826	325,763	122,347
Nondeductible meals and entertainment	55,166	59,237	49,320
Income tax expense from continuing operations	\$ 4,109,508	\$ 5,964,734	\$ 5,247,943
Effective tax rate	37.6%	36.3%	35.1%

The components of current and deferred federal and state income tax expense are as follows:

**For the Fiscal Year Ended November 30,**

Edgar Filing: SOMANETICS CORP - Form 10-K

	<b>2009</b>	<b>2008</b>	<b>2007</b>
Federal income tax expense    current	\$ 230,000	\$ 252,488	\$ 206,960
Federal income tax expense    deferred	3,510,516	5,360,450	4,891,042
State income tax expense    current	338,826	325,763	122,347
State income tax expense    deferred	30,166	26,033	27,594
Income tax expense from continuing operations	\$ 4,109,508	\$ 5,964,734	\$ 5,247,943

**Table of Contents**

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

We have performed the required assessment of positive and negative evidence regarding realization of our deferred tax assets in accordance with generally accepted accounting principles, including our past operating results, the existence of cumulative losses over our history up to the most recent seven fiscal years, and our forecast for future net income. Our assessment of our deferred tax assets included making assumptions about our net revenues and pre-tax income in future years, making allowance for the uncertainties regarding, among other things, our future net revenues, the rate of adoption of our products in the marketplace and the competition in the marketplace. As of November 30, 2009, we have concluded that it is more likely than not that approximately \$2,847,000 of such assets will be realized. The remaining tax benefits of \$2,590,000 relating to stock option exercises will not be recognized on our financial statements until they reduce current taxes payable. The benefit, when recognized, will increase additional paid in capital.

For the fiscal year ended November 30, 2009, we recognized income tax expense in our statement of operations of \$4,109,508, which consisted of income tax expense recorded at an estimated effective tax rate of 38%. For the fiscal year ended November 30, 2008, we recognized an income tax expense of \$5,964,734, which consisted of income tax expense recorded at an estimated effective tax rate of 36%. In addition, for the fiscal year ended November 30, 2007, we recognized an income tax expense of \$5,247,943, which consisted of income tax expense recorded at an estimated effective tax rate of 35%.

As of November 30, 2009, net operating loss carryforwards of approximately \$7.6 million were available for Federal income tax purposes for future years. Research and business general tax credits of approximately \$176,000 are also available to offset future taxes, and alternative minimum tax credits of approximately \$883,000 are also available to offset future taxes. These losses and credits expire, if unused, at various dates from 2010 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**

On July 22, 2009, Somanetics entered into a new lease agreement for an approximately 48,000 square foot, stand-alone office, assembly and storage facility. The lease term began December 15, 2009, and expires March 31, 2017 and grants Somanetics two consecutive options to renew the lease for a term of five years each. The minimum monthly lease payment during the term through March 31, 2011 will be approximately \$36,900 (except that rent is abated for the first three months of the term), excluding other occupancy costs, and it will increase to approximately \$42,800 during the term of the lease, excluding other occupancy costs. Rent expense will be recorded on a straight-line basis over the lease term including consideration of lease incentives. Somanetics also pays other occupancy costs relating to the premises, including utilities, taxes and insurance.

The new premises replace our existing headquarters, office, assembly and warehouse space in Troy, Michigan, which we currently lease under a lease that expires March 31, 2010. In addition, on November 14, 2008, we assumed a lease for approximately 900 square feet of office space used primarily for engineering activities. This lease is on a month-to-month basis until terminated by lessor or tenant.

Operating lease expense for the years ended November 30, 2009, 2008 and 2007 was approximately \$201,500, \$168,200, and \$164,300, respectively. Approximate future minimum lease commitments are as follows:

**Table of Contents**

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

**Year ending November 30,**

2010	\$ 365,100
2011	450,100
2012	461,400
2013	472,900
2014	484,700
2015	497,000
2016	509,600
2017	171,200
<b>Total</b>	<b>\$ 3,412,000</b>

We have executed purchase orders for inventory components representing purchase obligations of approximately \$6,225,700 as of November 30, 2009.

In December 1991, we amended and restated our profit sharing plan to include a 401(k) plan covering substantially all employees. Under provisions of the plan, participants may contribute, annually, between 1% and 25% of their compensation. In November 2004, our board of directors approved matching contributions to the 401(k) Plan equal to \$2 for every \$1 contributed by Company employees to the 401(k) Plan at each payroll date on or after January 1, 2005, up to a Company contribution of 4% of the employee's compensation, and continuing until terminated by further action of the board of directors. In addition, at the discretion of the board of directors, we may make other annual discretionary contributions to the plan. Matching contributions made for fiscal 2009, 2008 and 2007 were approximately \$463,000, \$428,000 and \$338,000, respectively.

As of November 30, 2009, we have amended and restated employment agreements or amended and restated change in control agreements with all of our officers. The employment agreement with our Senior Vice President, U.S. Sales and Marketing and the change in control agreements with seven 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 17, 2011. In addition, on June 17, 2008, we amended and restated our employment agreement with our President and Chief Executive Officer that was scheduled to expire April 30, 2009. The amended and restated agreement provides for severance benefits consisting of fringe benefits for one year (two years if termination is in connection with a Change in Control) and a lump sum payment equal to one year's salary (two years if termination is in connection with a Change in Control), plus the target bonus for the year of termination (which must be at least 65% of his salary) (two times the target bonus if termination is in connection with a Change in Control), plus a pro rata bonus through the date of termination upon termination of his employment without cause or for good reason. His amended and restated employment agreement expires June 17, 2011, unless earlier terminated as provided in the agreement, except that the term is automatically extended for additional one-year periods effective one year before it would otherwise expire (i.e., so that the remaining term will be two years), unless either party provides the other with notice that the term will not be extended and such notice provided at least one year before the term would otherwise expire. 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 obligations. The estimated financial exposure of these employment agreements, upon a change of control of the Company and termination of all of the executives without cause, is approximately \$2,446,000.

We entered into a Contract Development and Exclusive Licensing Agreement with NeuroPhysics Corporation as of September 18, 2006. The agreement provided 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. We terminated this agreement in February 2009, except for various provisions regarding our ownership of the technology related to the potential new products. In February 2009, we entered into a similar agreement with Shirley Research Corporation and Hugh F. Stoddart and Hugh A. Stoddart, and have agreed to pay monthly development and consulting fees of \$15,000 a month during the term of the agreement and a royalty on future sales of the new products.

**Table of Contents**

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

In November 2009, we entered into a Development and Exclusive Agreement with an inventor and his company to develop and market a product that uses INVOS technology and methods and means described in the inventor's patent to monitor, detect and assess acute compartment syndrome in parts of the human body. We paid the inventor's company an up-front, non-refundable payment of \$200,000 and will pay an additional \$300,000 upon obtaining 510(k) clearance for the product and a royalty on future revenue associated with products using the licensed technology.

On August 7, 2009, Somanetics filed a patent infringement action against CAS Medical Systems, Inc. in the United States District Court for the Eastern District of Michigan. The complaint asserts that CAS Medical's FORE-SIGHT® Cerebral Oximeter willfully infringes upon one or more of Somanetics' patents. The complaint also asserts that CAS Medical has engaged in unfair competition and false advertising, by making false or misleading statements in connection with its advertising and promotion of FORE-SIGHT, and false or misleading statements related to Somanetics' products. The complaint seeks, among other things, compensation for damages and an injunction against CAS Medical from infringing upon Somanetics' patents. CAS Medical Systems, Inc. has answered the complaint denying that it infringes any asserted patent and asserting defenses and counterclaims, including those for patent invalidity and/or unenforceability, and antitrust violations.

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. On April 19, 2007, our shareholders 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.

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 1,200,000 common shares. In addition, we granted options to employees independent of the plans. Options granted generally have a 10-year life, and vest over a three-year period, except the options granted in fiscal 2005 vested on November 30, 2005 and the options and restricted stock granted in fiscal 2006, fiscal 2007, fiscal 2008 and fiscal 2009 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, 2009, 2008 and 2007 are listed below.

At November 30, 2009, no additional options may be granted under the 1991 plan or the 1997 plan, and 304,673 common shares were available to be granted or awarded under the 2005 plan.

During fiscal 2009, we granted 68,250 stock options to employees, directors and an officer, at the market price on the date of grant, during fiscal 2008, we granted 253,000 stock options to our employees, directors and officers, at the market price on the date of grant, and during fiscal 2007, we granted 96,000 stock options to our employees, directors and one of our officers, at the market price on the date of grant. During fiscal 2009, we also issued 8,588 restricted common shares to our employees in January 2009 and 9,000 restricted common shares to an officer in April 2009 valued at the market price on the date of grant of \$16.31 and \$14.77 respectively. During fiscal 2008, we also issued 5,273 restricted common shares to our employees in January 2008 and 70,000 restricted common shares to our officers in March 2008 valued at the market price on the date of grant of \$21.81 and \$12.61 respectively. During fiscal 2007, we issued 9,000 restricted common shares to our officers valued at the market price on the date of grant of \$18.93. These stock options and restricted shares vest and are expensed in the financial statements over five years. During fiscal 2009, 117,400 stock options and 30,455 restricted common shares vested, during fiscal 2008, 66,800 stock options and 15,400 restricted common shares vested, and during fiscal 2007, 47,800 stock options and 13,600 restricted common shares vested. As a result of the stock options and restricted common



**Table of Contents**

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

shares that we granted during fiscal 2006, 2007, 2008 and 2009, we have recorded \$1,616,678 in stock compensation expense in fiscal 2009. As a result of the stock options and restricted common shares that we granted during fiscal 2006, 2007 and 2008, we have recorded \$1,338,590 in stock compensation expense in fiscal 2008. As a result of the stock options and restricted common shares that we granted during fiscal 2006 and 2007, we recorded \$781,308 in stock compensation expense in fiscal 2007.

As of November 30, 2009, there was \$4,437,246 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 3 years. As of November 30, 2008, there was \$5,247,791 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 years. As of November 30, 2007, there was \$3,606,518 of total unrecognized compensation cost related to nonvested share-based compensation awards granted under the 2005 Plan. That cost was expected to be recognized over a weighted average period of 4 years.

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 2009, 2008 and 2007: expected volatility (the measure by which the stock price has fluctuated or is expected to fluctuate during the period) of 53.97% for 2009 (59.30% for 2008 and 47.00% for 2007), risk-free interest rate (approximate U.S. Treasury yield in effect at the time of grant) of 2.50% for 2009 (2.35% for 2008 and 5.0% for 2007), expected lives of 6 years for 2009 (6 years for 2008 and 2007) and dividend yield of 0%. 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, 2009, 2008 and 2007 is as follows:

	2009		2008		2007	
	Common Shares	Weighted Average Exercise Price	Common Shares	Weighted Average Exercise Price	Common Shares	Weighted Average Exercise Price
Options outstanding December 1,	1,822,187	\$ 8.12	1,895,656	\$ 6.75	2,071,990	\$ 6.01
Options granted	68,250	14.77	253,000	13.56	96,000	19.25
Options exercised	(52,800)	3.22	(319,969)	4.17	(271,334)	5.47
Options canceled	(23,000)	18.15	(6,500)	14.92	(1,000)	18.85
Options outstanding November 30,	1,814,637	8.38	1,822,187	8.12	1,895,656	6.75
Options exercisable November 30,	1,411,587	\$ 6.42	1,352,587	\$ 5.51	1,609,456	\$ 4.76

As of November 30, 2009, the aggregate intrinsic value of stock options outstanding was \$12,067,394, and the aggregate intrinsic value of stock options exercisable was \$11,799,187. As of November 30, 2008, the aggregate intrinsic value of stock options outstanding was \$17,165,002, and the aggregate intrinsic value of stock options exercisable was \$16,271,622. As of November 30, 2007, the aggregate intrinsic value of stock options outstanding was \$25,136,399, and the aggregate intrinsic value of stock options exercisable was \$24,544,204. The total intrinsic value of options exercised during fiscal 2009, 2008 and 2007 was \$568,889, \$5,589,429 and \$3,707,681, respectively.



**Table of Contents**

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

A summary of the price ranges of our stock options outstanding and exercisable as of November 30, 2009 is as follows:

Range of Exercise	Options	Options outstanding		Options	Options exercisable	
		Weighted Average Exercise	Weighted Average Remaining Life		Weighted Average Exercise	Weighted Average Remaining Life
Prices	Outstanding	Price	(years)	Exercisable	Price	(years)
\$1.70 - \$10.00	1,014,638	\$ 2.90	2.34	1,014,638	\$ 2.90	2.34
\$10.01 - \$15.00	439,503	13.36	7.38	213,253	13.47	6.03
\$15.01 - \$19.93	360,496	17.74	7.03	183,696	17.70	6.86
Total	1,814,637	\$ 8.38	4.49	1,411,587	\$ 6.42	3.49

The weighted-average grant-date fair value of options granted during fiscal 2009, 2008 and 2007 was \$7.81, \$7.83 and \$9.97, respectively. The total fair value of shares vested during fiscal 2009, 2008 and 2007 was \$1,532,494, \$936,463 and \$713,021, 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 2009, 2008 and 2007.

## **8. Acquisitions**

In November 2008, we acquired substantially all of the assets of ICU Data Systems, Inc., a technology development company, for approximately \$2,000,000 in cash plus the assumption of specified liabilities.

Upon our acquisition of ICU Data Systems, Inc.'s assets in November 2008, the purchase price was allocated among the net tangible assets, other identifiable intangible assets and goodwill, as required by the relevant accounting standards. The value assigned to the identified intangible asset was based on a valuation model that included estimating the future cash flows of the technology and discounting the net cash flows back to their present value using an appropriate risk-adjusted rate of return (discount rate). See Note 2. The discount rate used was determined at the time of the acquisition in accordance with accepted valuation methods. Our assessment of the estimated fair value included making assumptions about the expected net revenues and operating income related to the acquired technology in future years, making allowance for the uncertainties regarding, among other things, the time and cost associated with the further advancement of the design and performance of the technology to ready it for market launch, the rate of adoption of the technology once it is launched into the marketplace, and the potential for competition related to the launched technology.

Goodwill represents the amount by which the purchase price of the acquired business exceeds the estimated fair value of the net tangible and separately identifiable intangible assets of the acquired business, in addition to transaction costs recorded at cost. Goodwill is not amortized, but is tested at least annually for impairment. The technology acquisition costs intangible asset has an estimated useful life of 20 years, based on several patents related to the technology, and will be amortized on a straight-line basis over the estimated useful life. Intangible assets and goodwill are reviewed annually for impairment at the end of our fiscal year, and whenever events or changes in circumstances indicate that the carrying value of the asset may not be recovered. The company evaluates impairment by comparing the fair value of the intangible asset, determined using a cash flow method, with its carrying value. As of November 30, 2009, the carrying value of the technology acquisition costs intangible asset was \$234,003, and the carrying value of the goodwill was \$1,783,712.

## **9. Major Customers and Foreign Sales**

Covidien, our international distributor in Europe, the Middle East, South Africa and Canada for our INVOS System, accounted for 13% of net revenues for the fiscal years ended November 30, 2009 and November 30, 2007,

and 14% of net revenues for the fiscal year ended November 30, 2008.

**Table of Contents**

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

Additionally, foreign net revenues for the fiscal year ended November 30, 2009 were \$9,854,238, for the fiscal year ended November 30, 2008 were \$9,420,472, and for the fiscal year ended November 30, 2007 were \$7,024,902.

**10. Segment Information**

We operate our business in one reportable segment, the development, manufacture and marketing of medical devices. Our products have similar characteristics, customers, distribution and marketing strategies, and are subject to similar regulatory requirements. In making operating and strategic decisions, our management evaluates net revenues based on the worldwide net revenues of our products, and also profitability on an enterprise-wide basis due to shared costs. Approximately 100% of our net revenues in fiscal 2009, 2008 and 2007 were derived from our INVOS System product line.

**11. Subsequent Events**

On January 20, 2010, 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 1,200,000 shares to 1,800,000 shares, subject to shareholder approval at the 2010 Annual Meeting of Shareholders.

During the first quarter of 2010, we have repurchased 157,440 common shares for approximately \$2,532,000 under our share repurchase program.

We evaluated all subsequent events from the date of the balance sheet through February 3, 2010, which represents the date these financial statements are being filed with the SEC. Except as described in the preceding paragraph, there were no events or transactions occurring during this subsequent event reporting period which require recognition or disclosure in the financial statements.

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

The following is a summary of our quarterly operating results for the fiscal years ended November 30, 2009 and 2008:

		Quarter			
		First	Second	Third	Fourth*
<b>Year Ended November 30, 2009</b>					
Net revenues		\$ 11,155,354	\$ 11,831,560	\$ 12,513,135	\$ 14,513,685
Gross margin		9,574,873	10,227,805	10,970,234	12,660,056
Net income		1,302,179	1,777,565	2,229,046	1,509,690
Net income per common share	basic	\$ 0.11	\$ 0.15	\$ 0.18	\$ 0.13
Net income per common share	diluted	\$ 0.10	\$ 0.14	\$ 0.17	\$ 0.12
<b>Year Ended November 30, 2008</b>					
Net revenues		\$ 8,693,274	\$ 12,740,063	\$ 12,367,988	\$ 13,654,292
Gross margin		7,676,450	11,060,807	10,650,130	11,818,974
Net income		1,028,429	3,052,252	3,046,454	3,319,112
Net income per common share	basic	\$ 0.08	\$ 0.23	\$ 0.25	\$ 0.28
Net income per common share	diluted	\$ 0.07	\$ 0.21	\$ 0.23	\$ 0.25

\* Fourth quarter 2009 research, development and engineering expenses included \$2,000,000 of up-front, non-refundable payments in connection with two license agreements entered into in that quarter.

**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, 2009. Based on their evaluation, our principal executive and principal financial officers have concluded that these controls and procedures are effective as of November 30, 2009. See Item 8 of this report for Management's Report on Internal Control Over Financial Reporting and our Independent Registered Public Accounting Firm's 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, 2009 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) 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.

**ITEM 9B. OTHER INFORMATION**

None.

**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 captions Election of Directors and Biographical Information in our Proxy Statement in connection with the 2010 Annual Meeting of Shareholders scheduled to be held April 21, 2010, 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 2010 Annual Meeting of Shareholders scheduled to be held April 21, 2010, 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 2010 Annual Meeting of Shareholders scheduled to be held April 21, 2010, 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 2010 Annual Meeting of Shareholders scheduled to be held April 21, 2010, 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 2010 Annual Meeting of Shareholders scheduled to be held April 21, 2010, 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 2010 Annual Meeting of Shareholders scheduled to be held April 21, 2010, 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 2010 Annual Meeting of Shareholders scheduled to be held April 21, 2010, 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 2010 Annual Meeting of Shareholders scheduled to be held April 21, 2010, 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 Principal Holders of Our Voting Securities and Election of Directors in our Proxy Statement in connection with the 2010 Annual Meeting of Shareholders scheduled to be held April 21, 2010, 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 2010 Annual Meeting of Shareholders scheduled to be held April 21, 2010, 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 2010 Annual Meeting of Shareholders scheduled to be held April 21, 2010, and is incorporated in this Item 13 by reference. The information required by this Item 13 concerning director



**Table of Contents**

independence will be set forth under the caption "Corporate Governance - Independence" in our Proxy Statement in connection with the 2010 Annual Meeting of Shareholders scheduled to be held April 21, 2010, 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 2010 Annual Meeting of Shareholders scheduled to be held April 21, 2010, and is incorporated in this Item 14 by reference.

75

---



**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, 2009  
and 2008

Statements of Operations For Each of  
the Three Years in the Period Ended  
November 30, 2009

Statements of Shareholders Equity  
For Each of the Three Years in the  
Period Ended November 30, 2009

Statements of Cash Flows For Each  
of the Three Years in the Period  
Ended November 30, 2009

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 78 to 80 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 3, 2010

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

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

Signature	Title	Date
/s/ BRUCE J. BARRETT	President and Chief Executive Officer and a Director	February 3, 2010
<b>Bruce J. Barrett</b>	(Principal Executive Officer)	
/s/ WILLIAM M. IACONA	Vice President and Chief Financial Officer,	February 3, 2010
<b>William M. Iacona</b>	Controller, and Treasurer (Principal Financial Officer and Principal Accounting Officer)	
/s/ JAMES I. AUSMAN	Director	February 2, 2010
<b>James I. Ausman, M.D., Ph.D.</b>		
/s/ DANIEL S. FOLLIS	Director	February 2, 2010
<b>Daniel S. Follis</b>		
/s/ JOHN P. JUMPER	Director	February 2, 2010
<b>John P. Jumper</b>		
/s/ RICHARD R. SORENSEN	Director	February 2, 2010
<b>Richard R. Sorensen</b>		

**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 Current Report on Form 8-K dated November 2, 2007 and filed November 5, 2007.
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	Seventh Amendment, between Somanetics Corporation and First Industrial Mortgage Partnership, L.P., dated April 16, 2009, incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended May 31, 2009.
10.10	Lease, dated as of July 22, 2009, between Kirts Office Center Associates, L.L.C. and Somanetics Corporation, incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K

Edgar Filing: SOMANETICS CORP - Form 10-K

dated July 22, 2009 and filed on July 27, 2009.

- \*10.11 Somanetics Corporation Amended and Restated 1991 Incentive Stock Option Plan, incorporated by reference to Exhibit 10.5 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1991.
- \*10.12 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.
- \*10.13 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.
- \*10.14 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.
- \*10.15 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.
- \*10.16 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

**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit</b>	<b>Description</b>
	ended November 30, 1998.
*10.17	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.
*10.18	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.
*10.19	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.
*10.20	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.
*10.21	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
*10.22	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.
*10.23	Second Amendment to Somanetics Corporation 2005 Stock Incentive Plan, incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, dated January 20, 2010 and filed January 26, 2010.
*10.24	Somanetics Corporation 2009 Executive Officer Incentive Compensation Plan, incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, dated January 21, 2009 and filed January 23, 2009.
*10.25	Somanetics Corporation 2010 Executive Officer Incentive Compensation Plan, incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, dated January 20, 2010 and filed January 26, 2010.
*10.26	Amended and Restated Employment Agreement between Somanetics Corporation and Bruce J. Barrett, dated as of June 17, 2008, incorporated by reference to Exhibit 99.3 to the Company's Current Report on Form 8-K, dated June 17, 2008 and filed June 23, 2008.
*10.27	Amended and Restated Employment Agreement between Somanetics Corporation and Dominic J. Spadafore, dated as of June 17, 2008, incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K, dated June 17, 2008 and filed June 23, 2008.
*10.28	

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

Form of Amended and Restated Change in Control Agreement, between Somanetics Corporation and executive officers, dated as of June 17, 2008, incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K, dated June 17, 2008 and filed June 23, 2008.

- \*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.
- \*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

**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit</b>	<b>Description</b>
	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	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.
*10.39	Summary of Outside Director Compensation, incorporated by reference to Item 8.01 to the Company's Current Report on Form 8-K dated May 7, 2009 and filed May 8, 2009.
10.40	Contract Development Agreement, dated as of February 6, 2009 among Somanetics Corporation, Shirley Research 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 February 6, 2009 and filed February 10, 2009.
10.41	Current Form of Somanetics Corporation Confidentiality Agreement used for testing hospitals and clinics, incorporated by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K for the fiscal year ended November 30, 1992.
10.42	Current Form of Somanetics Corporation Confidentiality Agreement used for the Company's employees and agents, incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended August 31, 1992.
14.1	Somanetics Corporation Code of Business Conduct and Ethics, as re-adopted December 8, 2009.
21.1	Subsidiaries of the Registrant.
23.1	Consent of Deloitte & Touche LLP.
31.1	Certifications of Chief Executive Officer Pursuant to Rule 13a-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certifications of Chief Financial Officer Pursuant to Rule 13a-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.