SOMANETICS CORP
Form 424B4
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Table of Contents

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File No. 333-131394

PROSPECTUS

2,000,000 Shares
Somanetics Corporation
Common Shares
$24.00 per share

We are selling 2,000,000 common shares. We have granted the underwriters an option to purchase up to 300,000 additional common shares to cover over-allotments.

Our common shares are quoted on The Nasdaq National Market under the symbol SMTS. The last reported sale price of our common shares on The Nasdaq National Market on February 28, 2006 was $25.32 per share.

Investing in our common shares involves risks. See Risk Factors beginning on page 7.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Public Offering Price	$ 24.00	$ 48,000,000
Underwriting Discount	$ 1.44	$ 2,880,000
Proceeds to Somanetics Corporation (before expenses)	$ 22.56	$ 45,120,000

The underwriters expect to deliver the shares to purchasers on or about March 6, 2006.

Citigroup

Cowen & Company
SunTrust Robinson Humphrey

February 28, 2006

Table of Contents

The INVOS System

[Picture of operating room with INVOS System being used]

The INVOS System is a non-invasive patient monitoring system that continuously measures changes in the blood oxygen levels in the brain and somatic, or skeletal muscle, tissue.

The INVOS System is used with multiple single-use disposable SomaSensors, the sales of which represented approximately 75 percent of fiscal 2005 net revenues.

Financial Overview

[Graph of net revenues (five years) and gross margin as a percentage of net revenues (five years)]

Market Evolution

[Graphic of Company s entrance into various markets]

Disposable SomaSensors

[Picture of SomaSensors placed on man s head]

For multi-channel cerebral monitoring, SomaSensors are placed on both sides of a patient s forehead and are connected to the monitor.

[Illustration of how SomaSensor works]

Each SomaSensor contains a light source and two light detectors.

Light signals are received and analyzed to determine oxygen saturation of the blood in the area of the brain beneath the sensors, delivering a reading of changes in blood oxygen levels.

Next Generation Monitor

[Picture of next generation INVOS System]

Our next generation INVOS System monitor displays up to four data channels for continuous monitoring of changes in brain and somatic, or skeletal muscle, tissue oxygen saturation.

You should rely only on the information contained in or incorporated by reference in this prospectus. We have not authorized anyone to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front of this prospectus.

TABLE OF CONTENTS

Table of Contents

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Table of Contents

SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary may not contain all of the information that is important to you. Before investing in our common shares, you should read this prospectus carefully in its entirety, especially the description of risks of investing in our common shares set forth under Risk Factors, and our financial statements and related notes beginning on page F-1.

Somanetics Corporation Overview

We develop, manufacture and market the INVOS System, a non-invasive patient monitoring system that continuously measures changes in the blood oxygen levels in the brain. 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. Clinical studies have shown that when the INVOS System is used to monitor and provide information to help manage the regional brain blood oxygen saturation of patients, the occurrence of adverse clinical outcomes can be reduced, which can significantly improve patient outcomes and reduce hospital costs. The INVOS System consists of a portable monitoring system, including proprietary software, which is used with multiple single-use disposable sensors, called SomaSensors. During our fiscal year ended November 30, 2005, net revenues from SomaSensors comprised approximately 75 percent of our net revenues. As of November 30, 2005, we had an installed base of approximately 1,100 INVOS System monitors in the United States in approximately 500 hospitals, and during fiscal 2005 we sold approximately 213,000 SomaSensors worldwide.

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

We are currently sponsoring a prospective, randomized, blinded clinical trial involving diabetic patients over age 50 who are undergoing major general surgery. The study group will consist of patients whose surgeries are managed based on information provided by the INVOS System, and the control group will consist of similarly situated patients whose surgeries are not managed based on information provided by the INVOS System. The two groups will be compared across measures of patient outcomes and hospital costs, including length of hospital stay. Diabetics are at particular risk of oxygen imbalances because of a higher incidence of vascular disease. If results of this trial are positive, we intend to target more actively the sale of the INVOS System for use in diabetic patients undergoing major general surgeries, consistent with FDA requirements. We expect to begin this marketing in 2008. We are also evaluating sponsorship of other clinical trials which may allow us to more actively target the sale of the INVOS System for use in other patient populations. There are also numerous other independent clinical studies evaluating the use of the INVOS System.

Table of Contents

We sell the INVOS System through a direct sales team in the United States, consisting of salespersons and clinical specialists, the size of which has increased from 17 persons at the end of fiscal 2004 to 26 persons at the end of fiscal 2005, and 10 independent sales representative firms. Outside the United States, we market the INVOS System through independent distributors, including Tyco Healthcare in Europe, Canada, the Middle East and Africa, and Edwards Lifesciences Ltd. in Japan. We expect to increase significantly the size of our U.S. direct sales team in fiscal 2006 and are evaluating placing direct salespersons and clinical specialists in Europe to support Tyco Healthcare. Our net revenues have increased from $9.4 million in the fiscal year ended November 2003 to $20.5 million in fiscal 2005, representing a compounded annual growth rate of 47.6 percent. As a percentage of net revenues, our gross margin improved from 77 percent in fiscal 2003 to 87 percent in fiscal 2005.

Market Opportunity

We believe that in the United States in 2006 there will be approximately five million surgeries involving elderly patients who, due to the type of surgery, age of the patient or other factors, have a higher risk of developing post-operative complications. Such surgeries include cardiac surgeries, carotid surgeries and other major general surgeries involving elderly patients. In addition, we believe that there are other patient populations, such as non-elderly adult, pediatric and neonatal patients, undergoing major surgeries and patients undergoing ICU treatment or in other critical care situations that face a high risk of brain oxygen imbalances.

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. Once alerted to these imbalances, medical professionals can use this and other information to take corrective action through the introduction of medications, anesthetic agents or mechanical intervention, potentially improving patient outcomes and reducing the costs of care. Immediate and continuous information about changes in brain oxygen levels also provides immediate feedback regarding the adequacy of the selected therapy. Equally important, without information about brain oxygen levels, therapy that may not be necessary might be initiated in an attempt to ensure adequate brain oxygen levels and may have an adverse impact on patient safety and increase hospital costs.

We believe that it is uncommon for patients undergoing surgery to receive any sort of direct neuromonitoring of brain blood oxygen saturation, in part due to some of the shortcomings of the traditional technologies. When patients are monitored directly, several different methods are used to detect one or more of the factors affecting brain oxygen levels or the effects of brain oxygen imbalances. These methods include invasive jugular bulb catheter monitoring, transcranial Doppler, electroencephalograms, or EEGs, intracranial pressure monitoring and neurological examination. The use of these methods is limited because they are either expensive, difficult or impractical to use, invasive, not reliable under some circumstances, not organ specific, not able to measure more than one factor affecting oxygen imbalances in the brain or not able to provide continuous information.

In addition, hospitals in the United States have economic incentives to control health care costs. 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. In addition, lack of immediate knowledge about blood oxygen levels in areas such as the brain or somatic tissue can result in unnecessary medical treatments and associated costs. With the increasing focus by hospitals on avoiding unexpected costs, especially in the operating room, ICU and other critical care areas, we believe that there are significant incentives to evaluate and adopt new monitoring technologies which could provide information to improve patient care and reduce costs.

Table of Contents

Our Solution

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

Surgeons, anesthesiologists and other medical professionals can use the information provided by the INVOS System, in conjunction with other available information, to identify brain oxygen imbalances and take necessary corrective action, potentially improving patient outcomes and reducing the costs of care. Once the cause of a cerebral oxygen imbalance is identified and therapy is initiated, the INVOS System provides immediate feedback regarding the adequacy of the selected therapy. It can also provide medical professionals with an additional level of assurance when they make decisions regarding the need for therapy.

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

Our Strategy

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

Target Surgical Procedures and Other Critical Care Situations with a High Risk of Oxygen Imbalances. We target surgical procedures and other critical care situations with a high risk of oxygen imbalances. Some of our current and potential future markets include cardiac surgeries, carotid artery surgeries, pediatric and neonatal ICU applications and other major surgeries involving diabetic or elderly patients.

Sponsor Clinical Studies to Promote Expanded Acceptance of the INVOS System. We plan to sponsor clinical studies using the INVOS System to demonstrate its benefits. We use the results of clinical studies to help convince the medical community of the clinical importance of the information provided by the INVOS System. We also sponsor peer-to-peer educational opportunities and promote use of the INVOS System in regional centers of influence that we believe will influence its adoption by others.

Invest in Sales and Marketing Activities. We continue to increase our investment in our distribution network consisting of our direct sales employees, independent sales representative firms and distributors. We expect to increase significantly the size of our U.S. direct sales team in fiscal 2006 and are evaluating placing direct salespersons and clinical specialists in Europe to support Tyco Healthcare.

Table of Contents

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. We plan to support the interface and integration of our INVOS System technology with other medical device manufacturers to expand the installed base of INVOS System monitors and increase the demand for SomaSensors. We expect that such arrangements will provide another distribution channel for our INVOS System.

Develop Additional Applications and Markets for the INVOS System. We are developing a smaller SomaSensor for use with newborns, developing a product-line extension of the INVOS System for monitoring non-brain tissues and making other advances to the design and performance features of the INVOS System, including the SomaSensor. We are also evaluating additional potential market segments for our INVOS System, such as use in other major surgeries, in the adult ICU, in the emergency room, in ambulances, in the catheterization laboratory, for blood transfusions, for muscle ischemia, for cosmetic surgery, for non-surgical neurology or cardiology applications, for psychiatric applications and for sleep disorders. Pursuit of some of these potential market segments may require additional FDA clearance.

The CorRestore System

We also develop and market the CorRestore System, which includes a cardiac implant, which we call the CorRestore Patch, for use in cardiac repair and reconstruction, including heart surgeries called surgical ventricular restoration, or SVR. During SVR, the surgeon restores an enlarged, poorly functioning left ventricle to more normal size and function by inserting an implant, in most instances, or closing the defect directly. Sales of CorRestore Systems represented two percent of our fiscal 2005 net revenues.

Risk Factors

Our business is subject to numerous risks, as more fully described in the section entitled Risk Factors immediately following this prospectus summary on page 7.

Our Corporate Information

We were incorporated under the laws of the State of Michigan in 1982. Our principal executive offices are located at 1653 East Maple Road, Troy, Michigan 48083-4208, and our telephone number is (248) 689-3050. Our website address is www.somanetics.com. The information on, or that can be accessed through, our website is not a part of this prospectus. Unless the context indicates otherwise, as used in this prospectus, the terms Somanetics, Somanetics Corporation, the Company, we, us and our refer to Somanetics Corporation, a Michigan corporation. Somanetics®, INVOS®, SomaSensor®, Window to the Brain® and CorRestore® are our registered trademarks. Each of the other trademarks, trade names or service marks appearing in this prospectus belongs to its respective holder.

Table of Contents

The Offering

Common shares offered by us	2,000,000 shares
Common shares to be outstanding immediately after the offering	12,715,885 shares
Use of Proceeds	We expect to use the net proceeds of this offering to expand our direct sales team and other sales and marketing activities, to sponsor additional clinical trials, to expand our research and development efforts, and for working capital and general corporate purposes, including potential acquisitions of complementary products, technologies or businesses. See Use of Proceeds.
Nasdaq National Market Symbol	SMTS

The number of shares to be outstanding immediately after this offering do not include the following:

- 1,914,232 common shares issuable upon exercise of outstanding options granted under our stock option plans and independent of our stock option plans at an average exercise price of $4.59 per share;
- 505,785 common shares reserved for future grants and awards under our 1997 Stock Option Plan and 2005 Stock Incentive Plan; and
- 2,100,000 common shares issuable upon exercise of the warrants issued to CorRestore LLC and its agent Wolfe & Company in connection with our license agreement. The exercise of these warrants is dependent upon our cumulative net sales of CorRestore products. The sales requirements for exercise of these warrants have not been met to date, and we do not expect that they will be met before these warrants expire in November 2006.

Unless otherwise noted, the information in this prospectus assumes that the underwriters do not exercise their over-allotment option.

Table of Contents

Summary Financial Data

You should read the following summary financial data together with our financial statements and related notes and with Selected Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this prospectus. We have derived the statement of operations data for the years ended November 30, 2003, 2004 and 2005 and the balance sheet data as of November 30, 2005 from our audited financial statements, which appear elsewhere in this prospectus. Our historical results for any prior period are not necessarily indicative of results to be expected for any future period.

	Year Ended November 30,		
	2003	2004	2005
	(in thousands, except per share data)		
Statement of Operations Data:			
Net revenues	$ 9,361	$ 12,609	$ 20,509
Cost of sales	2,140	2,050	2,601
Gross margin	7,221	10,558	17,908
Operating expenses:			
Research, development and engineering	413	369	526
Selling, general and administrative	6,759	8,237	13,241
Total operating expenses(1)	7,172	8,606	13,767
Operating income	49	1,952	4,141
Other income:			
Interest income	23	55	310
Total other income	23	55	310
Income before income taxes	72	2,007	4,451
Income tax benefit(2)		6,700	3,300
Net income	$ 72	$ 8,707	$ 7,751
Net income per common share basic	$ 0.01	$ 0.89	$ 0.75
Net income per common share diluted	$ 0.01	$ 0.77	$ 0.66
Weighted average number of common shares outstanding basic	9,114	9,780	10,322
Weighted average number of common shares outstanding diluted	9,467	11,323	11,798

	As of November 30, 2005	
	Actual	As Adjusted(3)
	(in thousands)	
Balance Sheet Data:		
Cash and cash equivalents	$ 13,148	$ 57,768
Working capital	18,044	62,664
Total assets	29,719	74,339
Total liabilities	1,878	1,878
Accumulated deficit	(37,131)	(37,131)
Total shareholders equity	27,841	72,461

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

(2) Represents income recognized in fiscal 2004 and fiscal 2005 as a result of a reversal of a portion of our income tax valuation allowance.

(3) As adjusted to give effect to the sale of the 2,000,000 common shares offered by us in this offering at the public offering price of $24.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Table of Contents

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 and the other information included in this prospectus, before purchasing our common shares. The risks described below are not the only ones that we face. Additional risks that are not yet known to us or that we currently think are immaterial could also impair our business, financial condition or results of operations. If any of the following risks actually occurs, our business, financial condition or results of operations could be adversely affected. In such case, the trading price of our common shares could decline, and you may lose all or part of your investment.

Risks Relating to Our Business

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

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

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

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

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

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

Table of Contents

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

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

Tyco Healthcare, part of Tyco International Ltd., our international distributor in Europe, the Middle East, Africa and Canada for our INVOS System, accounted for 11 percent and 12 percent of our net revenues for fiscal 2005 and for fiscal 2003, respectively. Edwards Lifesciences Ltd., formerly Baxter Limited, our international distributor in Japan for our INVOS System, was our largest customer for fiscal 2004, although it accounted for less than 10 percent of our net revenues for fiscal 2004. The loss of either of these distributors could have an adverse effect on our business, financial condition and results of operations.

We plan to increase the number of our direct sales team personnel in the United States and reduce our dependence on our independent sales representative firms. As a result, we might terminate some of our existing independent sales representatives, which could result in claims by terminated sales representative firms. If we are required to pay any significant amounts to terminated sales representatives, our results of operations and financial condition would be adversely affected.

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

We are dependent on various suppliers for manufacturing the components for our INVOS System. Although we believe that most components are generally available from several potential suppliers, we depend on one supplier for one of our components. We are not aware of any validated alternative supplier for this component, although we are currently in the process of validating in accordance with FDA requirements a second source of supply. Moreover, we typically use one supplier for custom-designed components, including the unit enclosure, the printed circuit boards, other mechanical components and the SomaSensor. SomaSensors represented approximately 75 percent of our net revenues in fiscal 2005. Engaging additional or replacing existing suppliers of custom-designed components is costly and time consuming. We estimate that it would require approximately four to five months to change SomaSensor suppliers. We do not intend to maintain significant inventories of components, other than an approximate six-month supply of the one component for which we currently have no alternative supplier. If we fail to obtain custom-designed components from our sole suppliers, if we lose any of our present suppliers and cannot replace them on a timely basis when necessary, if there is an interruption of production at one or more of our suppliers, or if any supplier is otherwise unable or unwilling to meet our requirements at current prices or at all, our ability to manufacture and sell our products would be impaired or we might have to pay higher prices for our components or our clinical trials could be delayed. In addition, because we do not have long-term agreements with our suppliers, we might be subject to unexpected price increases which might adversely affect our profit margins.

Table of Contents

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

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

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

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

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

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

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

We have invested substantial resources to develop the INVOS System. We expect to continue to invest substantial resources to develop a smaller SomaSensor for use with newborns, product-line extension of the INVOS System for monitoring non-brain tissues and other advances to the design and performance

Table of Contents

features of the INVOS System, including the disposable SomaSensor. New products require extensive testing and regulatory clearance before they can be marketed, and substantial customer education concerning the product s use, advantages and effectiveness. We might not be able to develop commercially viable products. We might not be able to manage effectively our future growth, and if we fail to do so, our business, financial condition and results of operations would be adversely affected.

Patients might assert product liability claims against us.

Because we test, market and sell a patient monitoring device and a heart patch, patients might assert product liability claims against us. The INVOS System is used in operating rooms and other critical care hospital units with patients who might be seriously ill or might be undergoing dangerous procedures. The CorRestore Patch is used on seriously ill patients undergoing a dangerous procedure. On occasion, patients on whom the INVOS System is being used, or in whom a CorRestore Patch is implanted, may be injured or die as a result of their medical treatment or condition. We might be sued because of such injury or death, and regardless of whether we are ultimately determined to be liable or our products are determined to be defective and a contributing factor in such injury or death, we might incur significant legal expenses not covered by insurance. In addition, product liability litigation could damage our reputation and impair our ability to market our products, regardless of the outcome. Litigation could also impair our ability to retain product liability insurance or make our insurance more expensive. We have product liability insurance with a liability limit of $5,000,000. This insurance is costly and even though it has been obtained, we might not be able to retain it. Even if we are able to retain this insurance, it might not be sufficient to protect us in the event of a major defect in the INVOS System or the CorRestore Patch. If we are subject to an uninsured or inadequately insured product liability claim based on the performance of the INVOS System or the CorRestore Patch, our business, financial condition and results of operations could be adversely affected.

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

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

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

Medical devices may be marketed only for the indications for which they are approved or cleared. The FDA may fail to approve or clear indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products. Our clearances can be revoked if safety or effectiveness problems develop.

Table of Contents

The FDA might require us to obtain a new clearance to label or promote the INVOS System for specific patient subgroups, such as diabetics; if we fail to obtain such clearances, our sales and revenues may be adversely affected.

Our INVOS System 510(k) clearance states that the prospective clinical value of the INVOS System has not been demonstrated in patients with specific disease states. If we wish to label or promote more actively the INVOS System for specific types of patients, such as diabetics, the FDA may require us to obtain a new 510(k) clearance and would likely carefully scrutinize the data support for any such claim. The FDA may also determine that our current promotion of the INVOS System as suitable for use in diabetics constitutes promotion for an unapproved use and may take regulatory action against us and require us to cease and desist from such promotion until a new clearance or approval is obtained. 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 claim. Any of the above could delay our ability to market and sell new products or to promote the INVOS System for specific patient subgroups such as diabetics and would thereby have an adverse effect on our business, financial condition and results of operations.

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

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

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;

operating restrictions or partial suspension or total shutdown of production;

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

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

criminal prosecution.

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

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

Any modifications to one of our FDA-cleared devices that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or a premarket approval. We may be required to submit extensive pre-clinical and clinical data depending

Table of Contents

on the nature of the changes. We may not be able to obtain additional 510(k) clearances or premarket approvals for modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and operating results. We have made modifications to our devices in the past, such as changes to the SomaSensor, and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. We believe that these changes do not require the submission of a new 510(k) notice. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices, which could harm our operating results and require us to redesign our products.

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

We are currently required to demonstrate and maintain compliance with the FDA s Quality System Regulation, or QSR. The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. The FDA enforces the QSR through periodic unannounced inspections. We have been, and anticipate in the future being, subject to such inspections. Our failure to comply with the QSR or to take satisfactory corrective action in response to an adverse QSR inspection could result in enforcement actions, including a public warning letter, a shutdown of or restrictions on our manufacturing operations, delays in approving or clearing a product, refusal to permit the import or export of our products, a recall or seizure of our products, fines, injunctions, civil or criminal penalties, or other sanctions, any of which could cause our business and operating results to suffer.

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

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

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

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

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

We have recognized deferred tax assets relating to the expected future benefits of our net operating loss carryforwards. Our assessment of our deferred tax assets, and the reversal of part of our valuation

Table of Contents

allowance relating to those assets in fiscal 2005 and 2004, included assuming that our net revenues and pre-tax income will grow in future years consistent with the growth guidance given for fiscal 2006 and making allowance for the uncertainties surrounding, among things, our future rate of growth in net revenues, the rate of adoption of our products in the marketplace and the potential for competition to enter the marketplace. Given the assumptions inherent in our financial plans, it is possible to calculate a different value for our deferred tax assets by changing one or more of the variables in our assessment. In addition, changes in our actual or estimated future taxable income could change the value of our deferred tax asset, potentially resulting in a decrease in net income, which could adversely affect the price of our common shares.

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

Effective December 1, 2005, we became subject to new stock option accounting rules that require that compensation costs related to share-based payment transactions, including stock options, stock appreciation rights and restricted stock, be recognized in our financial statements. Previously, we accounted for stock-based compensation of employees using the intrinsic value method, which resulted in no compensation expense charged against income for stock option grants to employees for fiscal 2005, 2004 or 2003. In addition, in November 2005, we accelerated the vesting of all unvested stock options to eliminate compensation expense that we would otherwise have recognized in our results of operations after the adoption of the new stock option accounting rules when those options would have otherwise vested. Future grants of options, however, will require us to recognize compensation expense in our income statement, increasing our reported expenses for the same activities, which could adversely affect the price of our common shares.

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 typically approximately six to nine months. The process can be delayed as a result of hospital capital budgeting procedures. These delays could have an adverse effect on our business, financial condition and results of operations and cause variability in our operating results from quarter to quarter, which could cause fluctuations in the trading price of our common shares.

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 be adversely affected and our competitive position could be harmed.

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

For example, one of our significant patents is the subject of a reissue proceeding in the U.S. Patent and Trademark Office. Our reissue application was filed for the sole purpose of seeking to broaden certain claims. We cannot predict the outcome of this proceeding, which may result in some or all of the claims

being broadened, narrowed or rejected. Another of our patents may be expired for ultimately claiming priority to a patent that was filed more than 20 years ago. We believe that this patent does not have a claim of priority that extends back for more than 20 years, and that the patent is still extant and will expire on March 29, 2009. However, there is a risk that a court might find that the earliest effective filing date for this patent is more than 20 years ago, and rule that this patent is expired and unenforceable.

The validity of our patent claims depends, in part, on whether prior art references disclosed or rendered obvious our inventions as of the filing date of our patent applications. We may not have identified all prior art, 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 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 our patents are not valid, not enforceable or of a limited scope, we will not have the right to stop others from using our inventions.

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

We also cannot be certain that we were the first to invent, or the first to file patent applications relating to, our cerebral oximeter technologies. 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 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 we are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, we may incur substantial costs and our business prospects could be substantially harmed.

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

Table of Contents

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

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

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

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

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

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

Table of Contents

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 material 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 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 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 April 30, 2006. In addition, competition for qualified employees is intense, and if we are unable to attract, retain and motivate additional, highly-skilled employees required for the expansion of our operations, our business, financial condition and results of operations could be adversely affected. We cannot assure you that we will be able to retain our existing personnel or attract additional, qualified persons when required and on acceptable terms.

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

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

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

Since we acquired rights in the CorRestore System in 2000, we have had limited success in marketing the system. The CorRestore System competes against existing patches also used for cardiac reconstruction and repair that are significantly less expensive and at least one study indicates are effective. We also compete against alternative methods of treating congestive heart failure. Surgical Ventricular Restoration, or SVR, is in the early stages of its development and will likely require significant clinical studies before it is widely accepted. There are many larger companies in this industry that have significantly larger research and development budgets than ours. Competitors may be able to develop additional or better treatments

Table of Contents

for congestive heart failure and may be able to take advantage of the significant time and effort we have invested to gain medical acceptance of SVR surgeries.

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

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

Risks Relating to This Offering

We have broad discretion to determine how to allocate the net proceeds of this offering and may not use them effectively.

We intend to use the net proceeds of this offering primarily to expand our direct sales team and other sales and marketing activities, sponsor additional clinical trials and expand our research and development efforts and for working capital and general corporate purposes. A significant portion of the net proceeds of the offering may be allocated to working capital and general corporate purposes. We are raising money for these purposes to strengthen our balance sheet and provide us with greater flexibility in implementing our business plans and responding to future business conditions and opportunities. The amounts listed in Use of Proceeds for these purposes are estimates and the amounts actually spent for each of these purposes and the timing of these payments may vary depending on numerous factors. We will retain broad discretion to determine how to allocate the net proceeds of this offering and the timing of the payments. 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. Pending the application of such proceeds, we intend to keep sufficient net proceeds of sales of common shares in cash and bank accounts to avoid becoming an inadvertent investment company subject to regulation under the Investment Company Act of 1940. The remaining proceeds 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.

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

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

Table of Contents

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

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

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

changes in our quarterly financial condition or operating results;

changes in general conditions in the economy;

changes in the financial markets;

changes in the medical equipment industry;

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

the liquidity of the market for the common shares;

developments with respect to patents and proprietary rights;

publication of clinical research results regarding our products;

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

grants or exercises of stock options or warrants;

news announcements;

litigation involving us;

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

other developments affecting us or our competitors.

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

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

We have never paid cash dividends on our common shares and do not expect to pay dividends in the foreseeable future. We currently intend to retain any future earnings for use in our business. The payment of any future dividends will be determined by the board in light of the conditions then existing, including our financial condition and

requirements, future prospects, restrictions in financing agreements, business conditions and other factors deemed relevant by the board. As a result, capital appreciation, if any, of our common shares will be your sole source of gain for the foreseeable future.

Table of Contents

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

Future sales of substantial amounts of common shares in the public market or the perception that such sales could occur could adversely affect the market price of the common shares. Any substantial sale of common shares or even the possibility of such sales occurring may have an adverse effect on the market price of the common shares. We have outstanding options and warrants to purchase an aggregate of 4,014,232 common shares. We have also reserved up to an additional 505,785 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 and the lock-up agreements described below, these shares are freely tradeable. Our executive officers and directors, including Bruce J. Barrett, our largest shareholder, have agreed not to sell their shares for a period of 120 days after the date of this prospectus without the consent of Citigroup Global Markets Inc. Our directors and executive officers as a group beneficially own 1,962,137 common shares, including 1,654,943 common shares they have a right to acquire upon the exercise of options within 60 days of the date of this prospectus. As these restrictions on resale end, 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.

Table of Contents

FORWARD-LOOKING STATEMENTS

Some of the statements in this prospectus are forward-looking statements. These forward-looking statements include statements relating to our performance in the sections entitled Summary, Risk Factors, Management s Discussion and Analysis of Financial Condition and Results of Operations, Use of Proceeds and Business and elsewhere in this prospectus. 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, similar expressions, with respect to various matters.

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 prospectus in greater detail under the heading Risk Factors. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this prospectus. You should read this prospectus and the documents that we have filed as exhibits and incorporated by reference to the registration statement, of which this prospectus is a part, 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 prospectus are based on information available to us on the date of this prospectus. We do not undertake to update any forward-looking statements that may be made by us or on our behalf in this prospectus or otherwise.

Table of Contents

USE OF PROCEEDS

We estimate that we will receive approximately $44,620,000 in net proceeds from the 2,000,000 common shares that we are offering, or approximately $51,388,000 if the underwriters exercise their over-allotment option in full, based upon the public offering price of $24.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We estimate that we will use:

approximately $5 million of our net proceeds to accelerate the expansion of our direct sales team and other sales and marketing activities;

approximately $2 million of our net proceeds to sponsor additional clinical trials; and

approximately $1 million of our net proceeds to expand our research and development efforts.

We intend to use the remainder of our net proceeds for working capital and general corporate purposes. We may use a portion of our net proceeds to acquire complementary products, technologies or businesses. We currently have no agreements or commitments to complete any such transactions. The amounts and timing of our actual expenditures may vary significantly depending upon numerous factors, including our future revenues and cash generated by operations. Accordingly, we will retain broad discretion in the allocation of our net proceeds of this offering.

A significant portion of the net proceeds of the offering may be allocated to working capital and general corporate purposes. We are raising money for these purposes to strengthen our balance sheet and provide us with greater flexibility in implementing our business plans and responding to future business conditions and opportunities.

Pending the application of such proceeds, we intend to invest the proceeds in short-term, U.S. government or other investment grade, interest-bearing investments.

Table of Contents

PRICE RANGE OF COMMON SHARES AND DIVIDEND POLICY

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

	High	Low
Fiscal Year Ended November 30, 2004		
First Quarter	$ 10.00	$ 6.00
Second Quarter	15.86	8.77
Third Quarter	16.70	9.23
Fourth Quarter	14.98	10.65
Fiscal Year Ended November 30, 2005		
First Quarter	$ 16.00	$ 13.00
Second Quarter	18.85	12.50
Third Quarter	25.74	17.66
Fourth Quarter	36.95	21.51
Fiscal Year Ending November 30, 2006		
First Quarter (through February 28, 2006)	$ 36.64	$ 21.53

On February 28, 2006, the last reported sales price for the common shares on The Nasdaq National Market was $25.32 per share. As of February 6, 2006, we had 657 shareholders of record of our common shares.

We have never paid cash dividends on our common shares and do not expect to pay dividends in the foreseeable future. We currently intend to retain any future earnings for use in our business. The payment of any future dividends will be determined by the board in light of the conditions then existing, including our financial condition and requirements, future prospects, restrictions in any financing agreements, business conditions and other factors deemed relevant by the board.

Table of Contents

CAPITALIZATION

The following table sets forth our capitalization as of November 30, 2005 and as adjusted to give effect to the sale of 2,000,000 common shares that we are offering at the public offering price of $24.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. You should read this table together with Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes included elsewhere in this prospectus.

	As of November 30, 2005	
	Actual	As Adjusted
	(in thousands, except share data)	
Long-Term Debt		
Shareholders Equity:		
Preferred shares; authorized 1,000,000 shares of $0.01 par value; no shares issued or outstanding		
Common shares, authorized 20,000,000 shares of $0.01 par value; issued and outstanding, 10,715,885 as of November 30, 2005 and 12,715,885 shares, as adjusted	$ 107	$ 127
Additional paid-in capital	64,865	109,465
Accumulated deficit	(37,131)	(37,131)
Total shareholders equity	27,841	72,461
Total capitalization	$ 27,841	$ 72,461

The number of our common shares outstanding as of November 30, 2005 does not include:

1,914,232 common shares issuable upon exercise of outstanding options granted under our stock option plans and independent of our stock option plans at an average exercise price of $4.59 per share;

505,785 common shares reserved for future grants and awards under our 1997 Stock Option Plan and 2005 Stock Incentive Plan; and

2,100,000 common shares issuable upon exercise of the warrants issued to CorRestore LLC and its agent Wolfe & Company in connection with our license agreement. The exercise of these warrants is dependent upon our cumulative net sales of CorRestore products. The sales requirements for exercise of these warrants have not been met to date, and we do not expect that they will be met before these warrants expire in November 2006.

Table of Contents

SELECTED FINANCIAL DATA

You should read the following selected financial data together with our financial statements and related notes and with Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this prospectus. We have derived the statement of operations data for the years ended November 30, 2003, 2004 and 2005 and the balance sheet data as of November 30, 2004 and 2005 from our audited financial statements, which are included elsewhere in this prospectus. We have derived the statement of operations data for the years ended November 30, 2001 and 2002 and the balance sheet data as of November 30, 2001, 2002 and 2003 from our audited financial statements, which are not included in this prospectus. Our historical results for any prior period are not necessarily indicative of results to be expected for any future period.

	Year Ended November 30,				
	2001	2002	2003	2004	2005
	(in thousands, except per share data)				
Statement of Operations Data:					
Net revenues	$ 5,656	$ 6,706	$ 9,361	$ 12,609	$ 20,509
Cost of sales	2,094	2,049	2,140	2,050	2,601
Gross margin	3,561	4,657	7,221	10,558	17,908
Operating expenses:					
Research, development and engineering	778	571	413	369	526
Selling, general and administrative(1)	5,133	5,344	6,759	8,237	13,241
Total operating expenses	5,911	5,915	7,172	8,606	13,767
Operating income (loss)	(2,350)	(1,258)	49	1,952	4,141
Other income:					
Interest income	22	52	23	55	310
Interest expense and other	(3)	(1)			
Total other income	19	51	23	55	310
Income (loss) before income taxes	(2,331)	(1,207)	72	2,007	4,451
Income tax benefit(2)				6,700	3,300
Net income (loss)	$ (2,331)	$ (1,207)	$ 72	$ 8,707	$ 7,751
Net income (loss) per common share basic	$ (0.31)	$ (0.13)	$ 0.01	$ 0.89	$ 0.75
Net income (loss) per common share diluted	$ (0.31)	$ (0.13)	$ 0.01	$ 0.77	$ 0.66
Weighted average number of common shares outstanding basic	7,606	8,951	9,114	9,780	10,322
	7,606	8,951	9,467	11,323	11,798

Weighted average number of common shares outstanding diluted					

	As of November 30,				
	2001	**2002**	**2003**	**2004**	**2005**
			(in thousands)		
Balance Sheet Data:					
Cash and cash equivalents	$ 168	$ 2,382	$ 2,239	$ 7,070	$ 13,148
Working capital	1,724	4,047	4,480	9,311	18,044
Total assets	3,587	6,164	7,156	18,785	29,719
Total liabilities	575	664	991	1,232	1,878
Accumulated deficit	(52,445)	(53,661)	(53,589)	(44,882)	(37,131)
Total shareholders equity	3,013	5,501	6,165	17,553	27,841

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

(2) Represents income recognized in fiscal 2004 and fiscal 2005 as a result of a reversal of a portion of our income tax valuation allowance.

Table of Contents

MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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 prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, 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 prospectus 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.

Overview

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

In the first quarter of fiscal 2005, we initiated selling and marketing efforts for the INVOS System in the pediatric intensive care unit, or ICU. We plan to launch the product into the neonatal ICU in late 2006, after completing development of a smaller SomaSensor. We are currently sponsoring a clinical trial evaluating the use of the INVOS System on diabetic patients over age 50. If results of this trial are positive, we intend to target more actively the sale of the INVOS System for use in diabetic patients undergoing major surgeries, consistent with FDA requirements. We expect to begin this marketing in 2008.

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

We also develop and market the CorRestore System for use in cardiac repair and reconstruction. In June 2000, we entered into a license agreement for the CorRestore System. In November 2001, we received clearance from the FDA to market the CorRestore Patch in the United States, and in April 2003 we met the requirements under the European Medical Device Directive to use the CE Mark, thereby allowing us to market the product in the European Economic Community. However, in September 2004, the European Economic Community changed its regulations, limiting approval authority for animal tissue implant products sold in Europe to some independent registration agencies that do not include our registrar. Sales of CorRestore Systems represented two percent of our fiscal 2005 net revenues. We expect that as sales of our INVOS System increase, the CorRestore System will become an even less significant component of our business.

Net Revenues and Cost of Sales

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

Table of Contents

outside the United States contributed 16 percent to our fiscal 2005 net revenues. As a percentage of net revenues, the gross margins from our international sales are typically lower than gross margins from our U.S. sales, reflecting the difference between the prices we receive from distributors and from direct customers.

We recognize revenue when there is persuasive evidence of an arrangement with the customer, the product has been delivered, the sales price is fixed or determinable, and collectibility is reasonably assured. The product is considered delivered to the customer once we have shipped it, as this is when title and risk of loss have transferred. Payment terms are generally net 30 days for U.S. sales and net 60 days or longer for international sales.

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

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

Operating Expenses

Selling, general and administrative expenses generally consist of:

- salaries, wages and related expenses of our employees and consultants;
- sales and marketing expenses, such as employee sales commissions, commissions to independent sales representatives, travel, entertainment, advertising, education and training expenses, depreciation of demonstration monitors and attendance at selected medical conferences;
- clinical research expenses, such as costs of supporting clinical trials; and
- general and administrative expenses, such as the cost of corporate operations, professional services, insurance, warranty and royalty expenses, investor relations, depreciation and amortization, facilities expenses and other general operating expenses.

We have increased the size of our direct sales team from 17 persons at the end of fiscal 2004 to 26 persons at the end of fiscal 2005. We expect to increase significantly the size of our U.S. direct sales team in fiscal 2006 and are evaluating placing direct salespersons and clinical specialists in Europe to support Tyco Healthcare. We also expect our clinical research expenses to increase in fiscal 2006 as a result of sponsoring a clinical trial evaluating the use of the INVOS System on diabetic patients over age 50. As a result, we expect selling, general and administrative expenses to increase in fiscal 2006.

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.

Deferred Tax Assets and Impairment Charges

As of November 30, 2004, we adjusted our deferred tax asset valuation allowance resulting in the recognition of a deferred tax asset of $6,700,000 as a result of expected future tax benefits related to our net operating loss carryforwards. Recognition of this deferred tax asset resulted in a non-cash tax benefit on our statement of operations for fiscal 2004 of $6,700,000.

Table of Contents

For the fiscal year ended November 30, 2005:

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

We further adjusted our deferred tax asset valuation allowance resulting in the recognition of additional deferred tax assets due to expected future tax benefits related to our net operating loss carryforwards. Recognition of this additional deferred tax asset resulted in a non-cash tax benefit on our statement of operations for fiscal 2005 of $3,300,000.

Results of Operations

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

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

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

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

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

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

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

Effective December 1, 2005, we increased the suggested list price of the adult SomaSensor and the pediatric SomaSensor in the United States to $140.00 and $155.00, respectively. Although these prices may not apply to existing customers or to any existing sales quotations issued before the price increase was effective, we expect that the average selling price of SomaSensors in the United States will increase in

Table of Contents

fiscal 2006, primarily as a result of the addition of new customers at our suggested retail prices and increased sales of our pediatric SomaSensor.

Gross Margin. Gross margin as a percentage of net revenues was 87 percent for the fiscal year ended November 30, 2005 and 84 percent for the fiscal year ended November 30, 2004. The increase in gross margin as a percentage of net revenues is primarily attributable to the increase in the average selling price of SomaSensors in the United States and increased sales of the INVOS System monitors to pediatric hospitals in the United States.

Research, Development and Engineering Expenses. Our research, development and engineering expenses increased approximately $156,573, or 42 percent, from $369,106 in fiscal 2004 to $525,679 in fiscal 2005. The increase is primarily attributable to development costs associated with our next generation INVOS System monitor, scheduled to be launched in the first half of 2006. We expect our research, development and engineering expenses to increase in fiscal 2006, primarily as a result of our hiring additional research and development personnel.

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

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

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

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

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

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

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

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

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

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

We expect our selling, general and administrative expenses to increase in fiscal 2006, primarily as a result of our hiring additional direct sales personnel in fiscal 2005 and 2006, increased sales commissions payable to our independent sales representative firms, increased clinical research expense, and increased sales and marketing expenses.

Income Tax Benefit. As of November 30, 2005, we further adjusted our deferred tax asset valuation allowance resulting in the recognition of additional deferred tax assets as a result of expected future tax benefits related to our net

operating loss carryforwards. Recognition of this additional deferred tax asset

Table of Contents

resulted in a non-cash tax benefit on our statement of operations for fiscal 2005 of $3,300,000, and increased our net income for fiscal 2005 to $7,751,087, or $0.66 per diluted common share. As 2006 progresses and we assess our plans for future years, we will continue to review the appropriateness of adjusting our deferred tax asset valuation allowance and recognizing additional deferred tax assets.

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

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

an increase in U.S. sales of $3,100,634, or 42 percent, from $7,416,380 in fiscal 2003 to $10,517,014 in fiscal 2004. The increase in U.S. sales was primarily due to an increase in sales of the disposable SomaSensor of $2,967,150, or 49 percent, as a result of a 22 percent increase in SomaSensor unit sales and a 22 percent increase in SomaSensor average selling prices. This increase in our average selling prices is attributable to the addition of new customers at our higher suggested retail prices, which were effective September 1, 2003, increased sales of our small adult SomaSensor that was launched in the third quarter of fiscal 2003 and sells for a premium price compared to the adult SomaSensor, increased sales of our pediatric SomaSensor which also sells for a higher price than the adult SomaSensor, and the upgrade of certain customers to our most recent model INVOS System monitor in exchange for the customer agreeing to pay a higher price for the disposable SomaSensor. In addition, sales of the INVOS System monitor in the United States increased $332,779, or 49 percent, as a result of increased purchases by pediatric hospitals. These increases were partially offset by a decrease in CorRestore System revenues of $199,295, or 29 percent; and

an increase in international sales of $147,089, or 8 percent, from $1,944,513 in fiscal 2003 to $2,091,602 in fiscal 2004. The increase in international sales was primarily due to increased purchases of the INVOS System monitor and disposable SomaSensor by Edwards Lifesciences in Japan, which was partially offset by decreased purchases by Tyco Healthcare in Europe. In fiscal 2004, international sales represented 17 percent of our net revenues, compared to 21 percent of our net revenues in fiscal 2003. Purchases by Tyco Healthcare accounted for 12 percent of net revenues in fiscal 2003.

In the United States, we sold 111,406 SomaSensors in fiscal 2004. We placed 193 INVOS System monitors in the United States and 133 internationally in fiscal 2004, and our installed base of INVOS System monitors in the United States was approximately 800, in 380 hospitals, as of November 30, 2004.

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

	Fiscal Year Ended November 30,	
Product	**2004**	**2003**
SomaSensors	78%	71%
INVOS System Monitors	18%	21%
Total INVOS System	96%	92%
CorRestore Systems	4%	8%
Total	100%	100%

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

- a change in the sales mix with increased sales of the disposable SomaSensor, which has a higher gross margin percentage than the INVOS System monitor or CorRestore System;

Table of Contents

the increase in the average selling price of SomaSensors;

a significant reduction in the cost of our SomaSensor in May 2004 as a result of changes in our manufacturing process; and

the change in sales mix with increased sales in the United States, which have higher gross margins than our international sales to distributors.

Research, Development and Engineering Expenses. Our research, development and engineering expenses decreased $43,847, or 11 percent, from $412,953 in fiscal 2003 to $369,106 in fiscal 2004. The decrease is primarily attributable to $46,891 in decreased costs associated with the development of the CorRestore System and $24,516 in decreased costs associated with the development of the INVOS System monitor, partially offset by increased costs associated with the development of the disposable SomaSensor and increased engineering salaries.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $1,478,674, or 22 percent, from $6,758,637 for the fiscal year ended November 30, 2003 to $8,237,401 for the fiscal year ended November 30, 2004. The increase in selling, general and administrative expense is primarily attributable to:

a $398,329 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 28 employees for the fiscal year ended November 30, 2003 to an average of 32 employees for the fiscal year ended November 30, 2004);

a $393,196 increase in employee sales commissions as a result of increased sales and increased sales headcount during fiscal 2004;

a $352,948 increase in commissions paid to our independent sales representative firms as a result of increased sales;

a $226,588 increase in accrued incentive compensation expense due to our fiscal 2004 financial performance, primarily increased sales and net income, in accordance with the 2004 Incentive Compensation Plan;

a $117,416 increase in travel and selling-related expenses as a result of our increased sales headcount and increased sales and marketing activities;

$96,254 in costs associated with a 401(k) matching contribution program that we implemented in fiscal 2004; and

$95,998 in costs associated with the termination of some of our independent sales representative firms in the second quarter of fiscal 2004.

These increases were partially offset by a $169,522 decrease in customer education expenses for the CorRestore System.

Income Tax Benefit. As of November 30, 2004, we adjusted our deferred tax asset valuation allowance resulting in the recognition of a deferred tax asset of $6,700,000 as a result of expected future tax benefits related to our net operating loss carryforwards. Recognition of this deferred tax asset resulted in a non-cash tax benefit on our statement of operations for fiscal 2004, and increased our net income for fiscal 2004 to $8,706,576, or $0.77 per diluted common share.

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.

Table of Contents

Liquidity and Capital Resources

General

Our principal sources of operating funds have been the proceeds of equity investments from sales of our common shares and, in fiscal years 2004 and 2005, cash provided by operating activities. See Statements of Shareholders Equity of our financial statements included elsewhere in this prospectus.

As of November 30, 2005, we did not have any outstanding or available debt financing arrangements, we had working capital of $18.0 million and our primary source of liquidity was $13.1 million of cash and cash equivalents. Pending their ultimate use, we currently invest our available funds in bank savings accounts.

We believe that cash and cash equivalents on hand at November 30, 2005 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 (used in) operations during fiscal 2005, 2004 and 2003 was $3,687,653, $2,233,331 and ($630,577), respectively. In fiscal 2005, cash was provided primarily by:

$5,764,166 of net income before income taxes, non-cash intangible impairment expense, and non-cash depreciation and amortization expense;

a $462,485 increase in accrued liabilities, primarily as a result of the increased accrued incentive compensation and accrued sales commissions as a result of our fiscal 2005 financial performance, partially offset by reduced accrued 401(k) matching contributions as of the end of the fiscal year and decreased accrued professional fees; and

a $183,699 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 2005 was partially offset by:

a $1,509,196 increase in accounts receivable primarily as a result of higher fourth quarter sales in fiscal 2005 than in the fourth quarter of fiscal 2004, and the timing of more of the sales in fiscal 2005 towards the end of the fourth quarter;

a $859,312 increase in inventories, primarily due to the acquisition of SomaSensors and components associated with 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; and

a $365,410 increase in prepaid expenses, primarily due to the timing of the renewal of our product liability and general liability insurance policies, and increased prepaid expenses for trade shows and marketing programs.

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 $484,121 of costs from inventory for INVOS System monitors being used as demonstration units and no capital cost sales equipment at customers during fiscal 2005, compared to $565,962 in fiscal 2004. As of November 30, 2005, we have capitalized $1,916,655 in costs for INVOS System monitors being used as demonstration and no capital cost sales equipment, and these assets have a net book value of $1,096,730. We depreciate these assets over five years.

Table of Contents

Cash Flows From Investing Activities

Net cash used in investing activities in fiscal 2005, 2004 and 2003 was $134,637, $84,003 and $50,665, respectively. In fiscal 2005, these expenditures were primarily for computer equipment for our new employees and furniture and fixtures associated with leasehold improvements to our facilities.

Cash Flows From Financing Activities

Net cash provided by financing activities in fiscal 2005, 2004 and 2003 was $2,525,679, $2,681,022 and $538,626, respectively. During fiscal 2005, we issued 561,839 common shares as a result of stock option exercises, for proceeds of $2,525,679. During fiscal 2004, we issued 321,276 common shares as a result of stock option exercises by employees, directors and former employees, for proceeds of $1,541,022. In April 2004, CorRestore LLC exercised its warrant to purchase 380,000 of our newly-issued common shares, at $3.00 per share, for proceeds of $1,140,000. During fiscal 2003, we issued 148,371 common shares as a result of stock option exercises by employees, directors and former employees, for proceeds of $538,626.

Contractual Obligations

The following information is provided as of November 30, 2005 with respect to our known contractual obligations specified in the following table, aggregated by type of contractual obligation:

	Payments Due by Period				
Contractual Obligations	**Total**	**Less Than 1 Year**	**1-3 Years**	**3-5 Years**	**More Than 5 Years**
Long-term debt obligations					
Capital lease obligations					
Operating lease obligations	$ 590,200	$ 140,400	$ 288,700	$ 161,100	
Purchase obligations	2,010,000	2,010,000			
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

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 123 (revised), Share Based Payment. This Statement revises Statement No. 123, Accounting for Stock-Based Compensation, and requires that compensation costs related to share-based payment transactions, including stock options, be recognized in the financial statements. In November 2005, we approved the acceleration of vesting of all unvested stock options as of November 30, 2005. The primary purpose of this accelerated vesting was to eliminate compensation expense we would recognize in our results of operations upon the adoption of SFAS 123R, which is effective for our fiscal quarter beginning December 1, 2005. After the effects of the accelerated vesting, the initial adoption of SFAS 123R is expected to be immaterial. However, the issuance of additional stock compensation under the 2005 Stock Incentive Plan in future years will have an additional impact on our financial statements.

Critical Accounting Policies

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

Table of Contents

treatment of stock options issued to employees, our accounting treatment for income taxes, and our revenue recognition associated with our no capital cost sales program.

CorRestore Intangible Asset

In fiscal years 2000, 2001 and 2003, we recorded an intangible asset related to our acquisition of exclusive, worldwide, royalty-bearing licenses to specified rights relating to the CorRestore System and related products and accessories. License acquisition costs include our estimate of the fair value of ten-year vested stock options to purchase common shares granted to one of our directors in connection with negotiating and assisting us in completing the transaction, and our estimate of the fair value of the vested portion of five-year warrants to purchase common shares issued in the transaction. Consistent with the treatment of the vested warrants to purchase common shares, we intend to include in license acquisition costs, and additional paid in capital, the fair value of the vested portion of the unvested warrants to purchase common shares, estimated using the Black-Scholes valuation model, when and if they become vested. However, we do not expect any of these remaining warrants to become vested before their November 21, 2006 expiration date, based on sales of CorRestore products to date.

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

We have adopted Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets. This statement establishes accounting and reporting standards for goodwill and other intangible assets. The effect of adopting this Statement has been to discontinue amortizing our license acquisition costs related to our acquisition of exclusive, worldwide, royalty-bearing licenses to specified rights relating to the CorRestore System and related products and accessories described above because we believe these licenses have an indefinite life. Therefore, we recorded no amortization expense related to these license acquisition costs in fiscal 2005, 2004 or 2003. It is possible to determine a different life for these licenses, and if they had a definite life, we would amortize the intangible asset over the remaining useful life. However, we believe it is appropriate to use an indefinite life for these licenses. Indefinite lived intangible assets are reviewed annually for impairment at the end of our fiscal year, and whenever events or changes in circumstances indicate that the carrying value of the asset may not be recovered. We evaluate impairment by comparing the fair value of the intangible asset, determined using a cash flow method, with its carrying value.

In November 2005, we wrote off the remaining CorRestore license acquisition cost intangible asset and recorded an impairment expense of $929,093. We wrote this off based on the cash flow impairment analysis that was performed, the declining sales of CorRestore products and the uncertainty regarding future prospective, randomized clinical data. Management does not expect net positive future cash flow from the CorRestore product for the foreseeable future.

Employee Stock Options

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 123 (revised), Share Based Payment. This Statement requires that compensation costs related to share-based payment transactions, including stock options, stock appreciation rights and restricted stock be recognized in the financial statements. This Statement will be effective for our fiscal quarter beginning December 1, 2005.

Table of Contents

We currently account for stock-based compensation of employees using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations. Accordingly, compensation costs for stock options granted to employees are measured as the excess, if any, of the market price of our stock at the date of the grant over the amount an employee must pay to acquire the stock. No compensation expense has been charged against income for fiscal 2005, 2004 and 2003 for stock option grants to employees because our stock option grants are priced at the market value as of the date of grant.

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

Stock-based compensation of consultants and advisors is determined based on the fair value of the options or warrants on the grant date pursuant to the methodology of SFAS No. 123, estimated using the Black-Scholes model. The resulting amount is recognized as compensation expense and an increase in additional paid-in capital over the vesting period of the options or warrants. As a result, we recorded $11,221 of compensation expense, and an equal increase in additional paid in capital, for stock options vesting in favor of non-employees in fiscal 2005, and $8,471 of compensation expense in fiscal 2003.

During fiscal 2005, we granted 162,146 stock options to our employees and directors, in fiscal 2004 we granted 53,500 stock options to our employees and directors, and in fiscal 2003 we granted 471,000 stock options to our employees and directors.

Had we recognized compensation expense for our stock options that vested in fiscal 2005 using the fair value method of accounting based on the fair value of the options on the grant date using the Black-Scholes valuation model, we would have recorded $1,804,000 in compensation expense and realized pro forma net income of $5,958,308, or $0.51 per diluted common share. For fiscal 2004, had we recognized compensation expense for our stock options that vested in fiscal 2004, using the fair value method of accounting based on the fair value of the options on the grant date using the Black-Scholes valuation model, we would have recorded $796,000 in compensation expense and realized pro forma net income of $7,911,576, or $0.70 per diluted common share. For fiscal 2003, had we recognized compensation expense for stock options that vested in fiscal 2003, using the fair value method of accounting based on the fair value of the options on the grant date using the Black-Scholes valuation model, we would have recorded $962,000 in compensation expense and incurred a pro forma net loss of $880,943, or $0.09 per diluted common share.

Income Taxes

We have performed the required assessment of positive and negative evidence regarding realization of our deferred tax assets in accordance with SFAS No. 109, including our past operating results, the existence of cumulative losses over our history up to the most recent three fiscal years and our forecast for future net income. Our assessment of our deferred tax assets, and the reversal of part of our valuation allowance, included assuming that our net revenues and pre-tax income will grow in future years consistent with the growth guidance given for fiscal 2006 and making allowance for the uncertainties surrounding, among other things, our future rate of growth in net revenues, the rate of adoption of our products in the marketplace and the potential for competition to enter the marketplace. In reversing a portion of our valuation allowance, we have concluded that it is more likely than not that such assets will be realized.

During fiscal 2004, we adjusted our deferred tax asset valuation allowance resulting in the recognition of a deferred tax asset of $6,700,000 related to the expected future benefits of our net operating loss carryforwards, in accordance with Statement of Financial Accounting Standards No. 109, Accounting for

Table of Contents

Income Taxes. During fiscal 2005, we further adjusted our deferred tax asset valuation allowance resulting in the recognition of an additional net deferred tax asset of $3,300,000.

The effect of recognizing this asset on our balance sheet, and associated tax benefit on our statement of operations, is to increase our net income for fiscal 2005 to $7,751,087, or $0.66 per diluted common share, and to increase our net income for fiscal 2004 to $8,706,576, or $0.77 per diluted common share. Given the assumptions inherent in our financial plans, it is possible to calculate a different value for our deferred tax asset by changing one or more of the variables in our assessment. However, we believe that our evaluation of our financial plans was reasonable, and that the judgments and assumptions that we made at the time of developing the plan were appropriate.

No Capital Cost Sales Revenue Recognition

We offer to our customers in the United States a no capital cost sales program whereby we ship the INVOS System monitor to the customer at no charge. Under this program, we do not recognize any revenue upon the shipment of the INVOS System monitor. We recognize SomaSensor revenue when we receive purchase orders and ship the product to the customer. At the time of shipment of the monitor, we capitalize the INVOS System monitor as an asset and depreciate this asset over five years. We believe this is consistent with our stated revenue recognition policy, which is compliant with Staff Accounting Bulletin No. 104 and Emerging Issues Task Force No. 00-21, Revenue Arrangements with Multiple Deliverables.

Table of Contents

BUSINESS

Overview

We develop, manufacture and market the INVOS System, a non-invasive patient monitoring system that continuously measures changes in the blood oxygen levels in the brain. The brain is the organ least tolerant of oxygen deprivation. Without sufficient oxygen, brain damage may occur within minutes, which can result in paralysis, other disabilities or death. Brain oxygen information, therefore, is important, especially in surgical procedures requiring general anesthesia and in other critical care situations with a high risk of the brain getting less oxygen than it needs. The INVOS System consists of a portable monitoring system, including proprietary software, which is used with multiple single-use disposable sensors, called SomaSensors. During our fiscal year ended November 30, 2005, net revenues from SomaSensors comprised approximately 75 percent of our net revenues. As of November 30, 2005, we had an installed base of approximately 1,100 INVOS System monitors in the United States in approximately 500 hospitals, and during fiscal 2005 we sold approximately 213,000 SomaSensors worldwide.

Clinical studies have shown that when the INVOS System is used to monitor and provide information to help manage the regional brain blood oxygen saturation of patients, the occurrence of adverse clinical outcomes can be reduced, 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. 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 adverse clinical outcomes was reduced from 12.5 percent to two percent. Additionally, in 2004, the results of a large retrospective review showed a statistically significant greater than 50 percent reduction (2.01 percent versus 0.97 percent) in the incidence of permanent stroke when information from the INVOS System was used to help manage brain blood oxygen saturation of cardiac surgery patients. The results also showed a reduced length of hospital stay and reduced incidence of prolonged ventilation when the INVOS System was used.

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

We are currently sponsoring a prospective, randomized, blinded clinical trial involving diabetic patients over age 50 who are undergoing major general surgery. The study group will consist of patients whose surgeries are managed based on information provided by the INVOS System, and the control group will consist of similarly situated patients whose surgeries are not managed based on information provided by the INVOS System. The two groups will be compared across measures of patient outcomes and hospital costs, including length of hospital stay. Diabetics are at particular risk of oxygen imbalances because of a higher incidence of vascular disease. If results of this trial are positive, we intend to target more actively the sale of the INVOS System for use in diabetic patients undergoing major general surgeries, consistent with FDA requirements. We expect to begin this marketing in 2008. We are also

Table of Contents

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

We sell the INVOS System through a direct sales team in the United States, consisting of salespersons and clinical specialists, the size of which has increased from 17 persons at the end of fiscal 2004 to 26 persons at the end of fiscal 2005, and 10 independent sales representative firms. Outside the United States, we market the INVOS System through independent distributors, including Tyco Healthcare in Europe, Canada, the Middle East and Africa, and Edwards Lifesciences Ltd. in Japan. We expect to increase significantly the size of our U.S. direct sales team in fiscal 2006 and are evaluating placing direct salespersons and clinical specialists in Europe to support Tyco Healthcare. Our net revenues have increased from $9.4 million in the fiscal year ended November 2003 to $20.5 million in fiscal 2005, representing a compounded annual growth rate of 47.6 percent. As a percentage of net revenues, our gross margin improved from 77 percent in fiscal 2003 to 87 percent in fiscal 2005.

Industry

Market Opportunity

We believe that in the United States in 2006 there will be approximately five million surgeries involving elderly patients who, due to the type of surgery, age of the patient or other factors, have a higher risk of developing post-operative complications. Such surgeries include cardiac surgeries, carotid surgeries and other major general surgeries involving elderly patients. In addition, we believe that there are other patient populations, such as non-elderly adult, pediatric and neonatal patients, undergoing major surgeries and patients undergoing ICU treatment or in other critical care situations that face a high risk of brain oxygen imbalances.

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

Brain Oxygen Imbalances and Its Effects

Oxygen is carried to the brain by hemoglobin in the blood. Hemoglobin passes through the lungs, bonds with oxygen and is pumped by the heart through arteries and capillaries to the brain. Brain cells extract oxygen and the blood carries away carbon dioxide through the capillaries and veins back to the lungs.

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

Table of Contents

Brain oxygen information is important in surgical procedures requiring general anesthesia, in other critical care situations with a high risk of brain oxygen imbalances, as well as in the treatment of patients with head injuries or strokes. Once alerted to these imbalances, medical professionals can use this and other information to take corrective action through the introduction of medications, anesthetic agents or mechanical intervention, potentially improving patient outcomes and reducing the costs of care. Immediate and continuous information about changes in brain oxygen levels also provides immediate feedback regarding the adequacy of the selected therapy. Equally important, without information about brain oxygen levels, therapy that may not be necessary might be initiated in an attempt to ensure adequate brain oxygen levels and may have an adverse impact on patient safety and increase hospital costs.

Limitations of Traditional Monitoring Technologies

We believe that it is uncommon for patients undergoing surgery to receive any sort of direct neuromonitoring of brain blood oxygen saturation, in part due to some of the shortcomings of the traditional technologies. When patients are monitored directly, several different methods are used to detect one or more of the factors affecting brain oxygen levels or the effects of brain oxygen imbalances. These methods include invasive jugular bulb catheter monitoring, transcranial Doppler, electroencephalograms, or EEGs, intracranial pressure monitoring and neurological examination. These methods have not been widely adopted to monitor brain oxygen levels in critical care situations for a variety of reasons. The use of these methods is limited because they are either expensive, difficult or impractical to use, invasive, not reliable under some circumstances, not organ specific, not able to measure more than one factor affecting oxygen imbalances in the brain or not able to provide continuous information.

Our Solution

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

Surgeons, anesthesiologists and other medical professionals can use the information provided by the INVOS System, in conjunction with other available information, to identify brain oxygen imbalances and take necessary corrective action, potentially improving patient outcomes and reducing the costs of care. Once the cause of a cerebral oxygen imbalance is identified and therapy is initiated, the INVOS System provides immediate feedback regarding the adequacy of the selected therapy. It can also provide medical professionals with an additional level of assurance when they make decisions regarding the need for therapy.

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

Table of Contents

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

Features	Benefits
Non-invasive	Reduced risk to patients and medical professionals Consistent with market trend toward less invasive medical procedures
Continuous Information	Immediate information regarding brain oxygen imbalances to help guide therapeutic interventions Trend information, rather than at a single point in time
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 SomaSensor 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

The CorRestore System

In addition to the INVOS System, we also develop and market the CorRestore System, which includes a cardiac implant, which we call the CorRestore Patch, for use in cardiac repair and reconstruction, including heart surgeries called surgical ventricular restoration, or SVR. During SVR, the surgeon restores an enlarged, poorly functioning left ventricle to more normal size and function by inserting an implant, in most instances, or closing the defect directly. Sales of CorRestore Systems represented two percent of our fiscal 2005 net revenues.

Business Strategy

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

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

damage resulting from oxygen

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

Sponsor Clinical Studies to Promote Expanded Acceptance of the INVOS System. We believe that our INVOS System has been evaluated in over 400 presentations, study abstracts and published papers. During the second quarter of fiscal 2004, results of both the first prospective, randomized clinical trial and a larger retrospective review evaluating the INVOS System were presented, which we believe have contributed to the INVOS System gaining further market penetration. We plan to sponsor clinical studies using the INVOS System to demonstrate its benefits. We are currently sponsoring a prospective, randomized, blinded clinical trial involving diabetic patients over age 50 who are undergoing major general surgery. The study group will consist of patients whose surgeries are managed based on information provided by the INVOS System, and the control group will consist of similarly situated patients whose surgeries are not managed based on information provided by the INVOS System. The two groups will be compared across measures of patient outcomes and hospital costs, including length of hospital stay. Diabetics are at particular risk of oxygen imbalances because of a higher incidence of vascular disease. If results of this trial are positive, we intend to target more actively the sale of the INVOS System for use in diabetic patients undergoing major general surgeries, consistent with FDA requirements. We expect to begin this marketing in 2008. We are also evaluating sponsorship of other clinical trials which may allow us to more actively target the sale of the INVOS System for use in other patient populations. We use the results of clinical studies to help convince the medical community of the clinical importance of the information provided by the INVOS System. We also sponsor peer-to-peer educational opportunities and promote use of the INVOS System in regional centers of influence that we believe will influence its adoption by others.

Invest in Sales and Marketing Activities. We continue to increase our investment in our distribution network consisting of our direct sales employees, independent sales representative firms and distributors. We sell the INVOS System through a direct sales team in the United States, the size of which has increased from 17 persons at the end of fiscal 2004 to 26 persons at the end of fiscal 2005, and 10 independent sales representative firms. We expect to increase significantly the size of our U.S. direct sales team in fiscal 2006 and are evaluating placing direct salespersons and clinical specialists in Europe to support Tyco Healthcare. We also have a co-promotion relationship with Fresenius Medical Care Cardiovascular Resources, Inc. s North American Extracorporeal Alliance. We participate in trade shows and medical conferences, ongoing peer-to-peer educational programs and targeted public relations opportunities.

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

Develop Additional Applications and Markets for the INVOS System. We are developing a smaller SomaSensor for use with newborns, developing a product-line extension of the INVOS System for monitoring non-brain tissues and making other advances to the design and performance features of the INVOS System, including the SomaSensor. We are also evaluating additional potential market segments for our INVOS System, such as use in other major surgeries, in the adult ICU, in the emergency room, in ambulances, in the catheterization laboratory, for blood transfusions, for muscle ischemia, for cosmetic surgery, for non-surgical neurology or cardiology

40

Table of Contents

applications, for psychiatric applications and for sleep disorders. 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 software, which is used with multiple single-use disposable SomaSensors.

Monitor and Software. Our oximeter is a portable monitor that uses our proprietary software to analyze information received from the SomaSensors. It provides a continuous digital and trend display of an index of the oxygen saturation in the region of the body under the SomaSensors. The monitor includes menus for users to set high and low audible alarms, customize the display and retrieve data. Single-function keys allow users to silence alarms, mark important events, store data for up to 28 surgical procedures, and retrieve data by disk or through a USB link to a computer. The monitor measures approximately 9 inches wide, 8 inches high, and 8 inches deep and weighs approximately 14 pounds. Our next generation INVOS System monitor, which we expect to launch in the first half of 2006, measures approximately 11 inches wide, 9 inches high, and 6 inches deep and weighs approximately 11 pounds. We provide a one-year warranty on the monitor, and we offer service for the monitor for a fee after the warranty expires. As of November 30, 2005, we had an installed base of approximately 1,100 INVOS System monitors in the United States in approximately 500 hospitals.

SomaSensors. Each single-use SomaSensor contains a light source and two light detectors. For multi-channel cerebral monitoring, SomaSensors are placed on both sides of a patient s forehead and are connected to the monitor, which allows for monitoring both sides of the brain. Our next generation INVOS System monitor, which we expect to launch in the first half of 2006, can display information from four SomaSensors, which will allow for the simultaneous monitoring of changes in blood oxygen saturation in the brain and, in patients with or at risk for restricted blood flow, in somatic tissue. The number of sensors used will depend on the application. We expect that the INVOS System will be used to monitor simultaneously the brain and somatic tissue initially for patients in the pediatric and neonatal ICU, and will later also be used on adults and for monitoring somatic tissue alone. The SomaSensors contain information that is processed by the INVOS System allowing it to automatically calibrate each sensor. During our fiscal year ended November 30, 2005, net revenues from SomaSensors comprised approximately 75 percent of our net revenues. During fiscal 2005 we sold approximately 213,000 SomaSensors worldwide.

Overview of INVOS Technology

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

By identifying the hemoglobin and the oxygenated hemoglobin and measuring the relative amounts of each, oxygen saturation of hemoglobin can be measured. However, traditional optical spectroscopy was generally not useful when the substances to be measured were surrounded by, were behind or were near

Table of Contents

bone, muscle or other tissue, because they produce extraneous data that interferes with analysis of the data from the area being examined.

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

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

Applications and Market Segments

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

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

Pediatric and Neonatal ICU. We are not aware of any other FDA-cleared cerebral oximeter commercially available in the United States that is cleared for monitoring non-adult patients. In the first quarter of fiscal 2005, we initiated selling and marketing efforts for the INVOS System in the pediatric ICU. We plan to launch the product into the neonatal ICU in late 2006, after completing development of a smaller SomaSensor. Our next generation INVOS System monitor, which we expect to launch in the first half of 2006, can display information from four SomaSensors, which will allow for the simultaneous monitoring of changes in blood oxygen saturation in the brain and, in patients with or at risk for restricted blood flow, in somatic tissue. We expect that the INVOS System will be used to monitor simultaneously the brain and somatic tissue initially for patients in the pediatric and neonatal ICU.

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

Table of Contents

System for use in diabetic patients undergoing major general surgeries, consistent with FDA requirements. We expect to begin this marketing in 2008.

Other Applications. We are also evaluating sponsorship of other clinical trials which may allow us to more actively target the sale of the INVOS System for use in other patient populations. If the results of these trials are positive, following completion of these trials and publication of the results, we intend to target the sale of the INVOS System for use on elderly patients undergoing major surgeries. We are also evaluating additional potential market segments for our INVOS System, such as use in other major surgeries, in the adult ICU, in the emergency room, in ambulances, in the catheterization laboratory, for blood transfusions, for muscle ischemia, for cosmetic surgery, for non-surgical neurology or cardiology applications, for psychiatric applications and for sleep disorders. Pursuit of some of these potential market segments may require additional FDA clearance.

Clinical Development

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

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 the overall number of adverse clinical outcomes 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 have not been published in a peer-reviewed publication. We believe Dr. Murkin is preparing an article for presentation to a peer-reviewed publication.

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 (99 patients) was covered and patients treatments were managed routinely. In the intervention group (101 patients) the patients treatments were managed using information from the INVOS System, and the patients received a pre-determined series of interventions to maintain the INVOS System s index of regional cerebral blood oxygen saturation within 75 percent of baseline values taken at the beginning of the operation.

Independent observers assessed all of the patients for adverse 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 adverse outcomes. The intervention group experienced statistically significantly fewer adverse clinical outcomes than the control group: two patients in the intervention group experienced adverse clinical

Table of Contents

outcomes, compared to 12 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 percent) was statistically significantly less than in the control group (2.01 percent), despite a sicker population according to the higher NYHA class of the study group. Although the incidence of permanent stroke was lower in the study group, the incidence of all neurologic dysfunction, including stroke and transient ischemic attach, was similar in the two groups. The proportion of patients requiring prolonged ventilation also was statistically significantly smaller in the study group, 6.8 percent, compared to 10.6 percent in the control group. Total ventilator time was statistically significantly shorter in the study group (four hours) than the control group (five hours). The length of hospital stay was similar overall in the two groups, but was statistically significantly shorter in the study group when examined by pre-operative NYHA classifications of patients.

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

Table of Contents

Diabetic Patients Studies

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

Diabetic patients have impaired cerebral autoregulation and oxygenation during cardiopulmonary bypass surgery. This sub-study analyzed outcomes of two coronary artery bypass graft patient groups: an intervention group of diabetic and non-diabetic patients who were monitored with the INVOS System and received a pre-determined series of interventions to maintain the INVOS System s index of regional cerebral blood oxygen saturation within 75 percent of baseline values taken at the beginning of the operation and a control group of diabetic and non-diabetic patients who were monitored with the INVOS System, but the display was covered and the patients were managed routinely. Diabetic patients in the intervention group required shorter ventilation (nine hours versus 30 hours), shorter stays in the ICU (30 hours versus 69 hours) and shorter hospital stays (5.5 days versus 8.4 days) than diabetic patients in the control group. All of these differences were statistically significant. There were no statistically significant differences between the regional cerebral oxygen saturation levels of the diabetic patients in the intervention group and the levels of the non-diabetic patients in the intervention group.

We are currently sponsoring a prospective, randomized, blinded clinical trial involving diabetic patients over age 50 who are undergoing major general surgery. The study group will consist of patients whose surgeries are managed based on information provided by the INVOS System, and the control group will consist of similarly situated patients whose surgeries are not managed based on information provided by the INVOS System. The two groups will be compared across measures of patient outcomes and hospital costs, including length of hospital stay. The initial phase of this trial is being conducted at Duke University Medical Center and the neighboring Veteran s Administration Hospital. In the initial phase, which began in 2006, the investigators will determine the number of patients to study in each of the intervention and control groups so that the results are expected to be statistically significant. If results of this trial are positive, we intend to target more actively the sale of the INVOS System for use in diabetic patients undergoing major general surgeries, consistent with FDA requirements. We expect to begin this marketing in 2008.

Other Future Studies

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

The CorRestore System

We develop and market the CorRestore System for use in cardiac repair and reconstruction, including heart surgeries called surgical ventricular restoration, or SVR. During SVR, the surgeon restores an enlarged, poorly functioning left ventricle to more normal size and function by inserting an implant, in most instances, or closing the defect directly. Before the availability of the CorRestore System, SVR was generally performed using a patch formed by the surgeon from medical grade fabrics or bovine pericardium tissue. These hand-formed patches take time for the surgeon to make, can be difficult to insert, and can leak around the edges.

As a result of these problems, two heart surgeons and their company developed and patented the CorRestore System with the intent to make SVR easier for the surgeon, to standardize the operation and to provide a better seal on the edges of the patch to minimize leaking. The CorRestore System consists of

a non-circular bovine pericardium, or cow heart-sac, tissue patch with an integrated pericardial suture ring, as well as accessories for aiding the implantation of the patch.

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

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

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

License Agreement

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

In exchange for the licenses and consulting services, we agreed to the following compensation for CorRestore LLC and its agent, Joe B. Wolfe: (1) a royalty of 10 percent in the aggregate of our net sales of products subject to the licenses, for the term of the patent relating to the CorRestore System, (2) five-year warrants to purchase an aggregate of 400,000 common shares at $3.00 per share, which were exercised in full in 2004 and 2005, (3) five-year warrants to purchase an aggregate of 2,100,000 common shares at $3.00 per share, exercisable based on our cumulative net sales of the CorRestore System products (we do not expect the sales requirements for exercise of these warrants to be met before the November 2006 expiration date of these warrants), and (4) a consulting fee of $25,000 a year to each of the two inventors until we sell 1,000 CorRestore Patches.

CorRestore LLC and the inventors may terminate the licenses (1) if we materially breach specified covenants in the license agreement, (2) if our common shares are delisted from the Nasdaq Stock Market, and (3) in connection with specified bankruptcy and insolvency events. CorRestore LLC and the inventors may exclude specified countries from the geographic scope of the license to the extent we did not begin

Table of Contents

marketing the CorRestore System products or begin the process of obtaining necessary regulatory approval to sell CorRestore System products in that country by May 15, 2002. Countries may be excluded from the license only if we fail to cure the breach of this provision within 90 days after CorRestore LLC notifies us of the breach. We have not received any such notice.

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

Marketing, Sales and Distribution

Marketing

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

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

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

Sales and Distribution

We sell the INVOS System through a direct sales team in the United States, the size of which has increased from 17 persons at the end of fiscal 2004 to 26 persons at the end of fiscal 2005, and 10 independent sales representative firms. We expect to increase significantly the size of our U.S. direct sales team in fiscal 2006. We believe the selling cycle for the INVOS System is typically approximately six to nine months.

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

Outside the United States, we have distribution agreements with independent distributors covering 56 countries for the INVOS System. Our distributors for the INVOS System include Tyco Healthcare, part of Tyco International Ltd., in Europe, the Middle East, Africa and Canada, and Edwards Lifesciences Ltd., formerly Baxter Limited, in Japan. We are evaluating placing direct salespersons and clinical specialists in Europe to support Tyco Healthcare. We also have one international sales consultant. For fiscal 2005, approximately 16 percent of our net revenues were represented by international sales.

Table of Contents

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

We did not have any backlog of firm orders as of January 10, 2006 or as of January 10, 2005. We generally do not have a backlog of firm orders because we generally ship product upon receipt of a customer order.

For a description of sales to major customers, see Note 9 of Notes to Financial Statements included elsewhere in this prospectus. Tyco Healthcare was our largest customer in fiscal 2005 and 2003, and Edwards Lifesciences was our largest customer in fiscal 2004. We are dependent on our sales to Tyco Healthcare and Edwards Lifesciences, and the loss of either of them as a customer would have an adverse effect on our business, financial condition and results of operations in the near-term, until such time as they could be replaced as our distributor in the respective market.

Our international sales were $3,303,692 for the fiscal year ended November 30, 2005, $2,091,602 for the fiscal year ended November 30, 2004 and $1,944,513 for the fiscal year ended November 30, 2003 including approximately $2,202,000 in fiscal 2005, $944,000 in fiscal 2004 and $1,166,000 in fiscal 2003 to Tyco Healthcare, our distributor in Europe, the Middle East, Africa and Canada, and approximately $707,000 in fiscal 2005, $970,000 in fiscal 2004 and $616,000 in fiscal 2003 to Edwards Lifesciences Ltd., our distributor in Japan. See Note 9 of Notes to Financial Statements. For a description of the breakdown of sales between INVOS System monitors, SomaSensors and CorRestore Systems, see Management s Discussion and Analysis of Financial Condition and Results of Operations Results of Operations.

We sell the CorRestore System through our 26 direct salespersons and nine independent sales representative firms in the United States. In September 2004, the European Economic Community changed its regulations, limiting approval authority for animal tissue implant products sold in Europe to some independent registration agencies that do not include our registrar.

Research and Development

Our research and development activities are conducted internally by a staff consisting of five employees. We are developing a smaller SomaSensor for use with newborns, developing a product-line extension of the INVOS System for monitoring non-brain tissues and making other advances to the design and performance features of the INVOS System, including the SomaSensor. We are also working to interface our INVOS System with multi-functional monitors provided by other manufacturers. Our research, development and engineering expenditures were $525,679 during fiscal 2005, $369,106 during fiscal 2004, and $412,953 during fiscal 2003. We expect our research and development expenditures to increase as we add additional research and development staff in fiscal 2006.

Manufacturing

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

Table of Contents

We received ISO 13485 certification and met the requirements under the European Medical Device Directive to use the CE Mark, thereby allowing us to continue to market our INVOS System and SomaSensor in the European Economic Community. Our most recent ISO 13485 compliance surveillance audit occurred in August 2005.

Competition

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

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

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

We believe that a manufacturer s reputation for producing accurate, reliable, effective, sterile, patented and technically advanced products, clinical literature associated with leaders in the field, references from users, features (speed, safety, ease of use, patient and surgeon convenience and range of

Table of Contents

applicability), product effectiveness and price are the principal competitive factors in the medical products industry.

Proprietary Rights Information

We have 12 United States patents and three patents in various foreign countries. These patents expire on various dates from February 2006 to October 2019. We currently have two patent applications pending in the United States, including one reissuance application, and have patent applications in various foreign countries with respect to aspects of our technology relating to the interaction of light with tissue.

In September 2003, we were issued a new patent by the United States Patent and Trademark Office covering the application of non-invasive, near-infrared spectroscopy to measure continuously and substantially concurrently a blood metabolite (such as oxygen saturation) in at least two separate internal regions of the brain. This patent is now the subject of a reissue proceeding in the United States Patent and Trademark Office. We requested the reissuance of this patent because we believe that we are entitled to broader claims than those that were originally issued. However, the outcome of the reissue proceeding cannot be predicted, and the claims which ultimately issue may be broader in scope than the original claims, they may be narrower in scope than the original claims, or they may be rejected. The corresponding Australian patent for Multi-Channel, Noninvasive, Tissue Oximeter issued in December 2003, will expire in October 2019. This patent is pending in other markets outside the United States. We believe the design concepts covered in this patent are important to providing a clinically viable cerebral oximeter.

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

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 by our products of the claims of any issued patents, and no charge of patent infringement has been asserted against us.

In addition to our patent rights, we have obtained United States Trademark registrations for our trademarks SOMANETICS, INVOS, SOMASENSOR and WINDOW TO THE BRAIN. A United States service mark application for Enlightening Medicine, and a United States Trademark application for Reflecting the Color of Life, are pending. We have also obtained registrations of our basic mark, SOMANETICS, in eleven foreign countries.

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

The inventors of the CorRestore System and their company filed for a patent with respect to their patch, which was issued in the United States in February 2000 and expires in May 2018. The claims allowed relate primarily to the product design of a soft suture ring integrated with a patch. Subsequently five other United States patents have been issued to the inventors, also relating primarily to the product design of a soft suture ring integrated with a patch. Two of those issued patents also expire in May 2018 and the third one expires in July 2018. In addition, other United States and foreign patent applications are pending. We have also obtained United States Trademark registration for the trademark CorRestore.

Table of Contents

Government Regulation

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

product development;

product testing;

product labeling;

product storage;

premarket clearance or approval;

advertising and promotion; and

product sales and distribution.

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

510(k) Clearance Pathway. To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent in intended use and in safety and effectiveness to a previously 510(k) cleared device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet 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.

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

modification to the device, its labeling or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA.

Table of Contents

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.

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

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

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

fines, injunctions, and civil penalties;

recall or seizure of products;

operating restrictions, partial suspension or total shutdown of production;

refusing requests for 510(k) clearance or PMA approval of new products;

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

criminal prosecution.

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

If any of our current or future FDA clearances or approvals are rescinded or denied, sales of our applicable products in the United States would be prohibited during the period we do not have such clearances or approvals. In such cases we would consider shipping the product internationally and/or assembling it overseas if permissible and if we determine such product to be ready for commercial

Table of Contents

shipment. The FDA s current policy is that a medical device that is not in commercial distribution in the United States, but which needs 510(k) clearance to be commercially distributed in the United States, can be exported without submitting an export request and prior FDA clearance under certain conditions.

Congress has enacted the Medical Device User Fee Modernization Act of 2002. Among other things, this law has provisions which permit the assessment of user fees for product approvals and clearances. Given the recent enactment of this law, the effect of the law as it relates to us and our products is still unknown, other than that we will have to pay the FDA to review our 510(k) submissions. We do not currently have any 510(k) submissions pending.

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances.

Seasonality

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

Facilities

Our headquarters, manufacturing facility and warehouse space are located in a single building in Troy, Michigan. We lease approximately 23,000 square feet, including approximately 12,000 square feet of office space for sales and marketing, engineering, accounting and other administrative activities. Our lease expires on December 31, 2009. The minimum monthly lease payment will be approximately $11,700 for fiscal 2006, $11,900 for fiscal 2007, $12,200 for fiscal 2008 and $12,400 for fiscal 2009, excluding other occupancy costs. We believe that this facility is suitable and adequate for our needs now and for the foreseeable future and will allow for substantial expansion of our business and number of employees.

Employees

As of January 23, 2006, we had 49 full-time employees, including 29 in sales and marketing, five in research and development, six in general and administration and nine in manufacturing, quality and service. We also employed two part-time individuals in general and administration. In addition, we use three contract manufacturing employees, and we use one consultant. We believe that our future success is dependent, in large part, on our ability to attract and retain highly qualified managerial, sales, marketing and technical personnel. We expect to add additional sales and marketing and research and development employees in fiscal 2006. Our employees are not represented by a union or subject to a collective bargaining agreement. We believe that our relations with our employees are good.

Insurance

Because the INVOS System and the CorRestore System are intended to be used in hospital critical care units with patients who may be seriously ill or may be undergoing dangerous procedures, we might be exposed to serious potential product liability claims. We have obtained product liability insurance with a liability limit of $5,000,000. We also maintain coverage for property damage or loss, general liability, business interruption, travel-accident, directors and officers liability and workers compensation. We do not maintain key-man life insurance.

Litigation

We are not a party to any pending legal proceedings.

Table of Contents

MANAGEMENT

Directors and Executive Officers

Our executive officers and directors are as follows:

Name	Age	Position
Bruce J. Barrett	46	President, Chief Executive Officer and a Director
William M. Iacona	35	Vice President and Chief Financial Officer, Controller and Treasurer
Richard S. Scheuing	50	Vice President, Research and Development
Dominic J. Spadafore	46	Vice President, Sales and Marketing
Mary Ann Victor	48	Vice President and Chief Administrative Officer and Secretary
Ronald A. Widman	55	Vice President, Medical Affairs
Pamela A. Winters	47	Vice President, Operations
Dr. James I. Ausman(1)(2)(3)	68	Director
Daniel S. Follis(1)(2)(3)	68	Director
Robert R. Henry(1)(2)(3)	65	Director

(1) Member of the Compensation Committee.

(2) Member of the Audit Committee.

(3) Member of the Nominating Committee.

Bruce J. Barrett. Mr. 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.

William M. Iacona. Mr. Iacona has served as our Vice President and Chief Financial Officer since January 2006, as our Treasurer since February 2000 and as our Controller since April 1997. From December 2000 until January 2006, he served as our Vice President, Finance. Before joining us, he was in the Finance Department of Ameritech Advertising Services, a telephone directory company and a division of Ameritech Corporation (now SBC Communications), and was on the audit staff of Deloitte & Touche LLP, independent auditors. He is a certified public accountant and received a B.S. degree in accounting from the University of Detroit.

Richard S. Scheuing. Mr. Scheuing has served as our Vice President, Research and Development, since January 1998 and prior to that was our Director of Research and Development and Director of Mechanical Engineering. He is an inventor on five of our issued patents. Before joining us, he was Director of Mechanical Engineering for Irwin Magnetic Systems, Inc. and was a Development Engineer with the Sarns division of Minnesota Mining and Manufacturing Company, or 3M. He received a B.S. degree in mechanical engineering from the University of Michigan.

Dominic J. Spadafore. Mr. Spadafore has served as our Vice President, Sales and Marketing, since August 2002. Mr. Spadafore previously served, from July 2000 until July 2002, as National Sales and

Table of Contents

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

Mary Ann Victor. Ms. Victor has served as our Vice President and Chief Administrative Officer since January 2006 and as our Secretary since January 1998. From January 1998 until January 2006, she served as our Vice President, Communications and Administration. Prior to that she was our Director, Communications and Administration. Her prior experience includes various investor relations and public relations positions with publicly-held companies. She also is an attorney and practiced with the law firm Varnum Riddering Schmidt & Howlett. Ms. Victor received a B.S. in political science from the University of Michigan and a J.D. from the University of Detroit.

Ronald A. Widman. Mr. Widman has served as our Vice President, Medical Affairs, since January 1998 and prior to that was our Director of Medical Affairs and Marketing Manager. Prior to joining us in 1991, he was employed by Mennen Medical, Inc., a manufacturer and marketer of medical monitoring and diagnostic devices, where he held various positions in domestic and international medical product marketing. He is the author of several papers and articles related to medical care and monitoring devices.

Pamela A. Winters. Ms. Winters has served as our Vice President, Operations, since January 1998 and since joining Somanetics in 1991 has served as Director of Operations and Manager of Quality Assurance. Ms. Winters received a B.S. degree in management from the University of Phoenix.

James I. Ausman, M.D., Ph.D. Dr. Ausman has served as one of our directors since June 1994. Since July 2002, he has served as a consultant for Navigant Consulting, Inc. (formerly The Tiber Group), a healthcare strategic planning and market research company. He has been Professor of the Department of Neurosurgery at the University of Illinois at Chicago since 1991 and served as its head from 1991 until September 2001. From September 1978 until August 1991, he was Chairman of the Department of Neurosurgery at Henry Ford Hospital in Detroit. From December 1987 until July 1991, he served as Director of the Henry Ford Neurosurgical Institute, also at Henry Ford Hospital. In addition, he was Clinical Professor of Surgery, Section of Neurosurgery at the University of Michigan in Ann Arbor from 1980 until 1991. Dr. Ausman received a B.S. degree in chemistry and biology from Tufts University, a Doctorate of Medicine from Johns Hopkins University School of Medicine, a Masters of Arts in Physiology from the State University of New York at Buffalo, and a Ph.D. in Pharmacology from George Washington University. He has also received graduate training in neurosurgery at the University of Minnesota and has obtained board certification from the American Board of Neurological Surgery. He is now a Clinical Professor of Neurosurgery at the University of California at Los Angeles and, since 1994, has been the editor of Surgical Neurology. He serves as the medical expert for KMIR 6 TV in Palm Desert, California.

Daniel S. Follis. Mr. Follis has served as one of our directors since April 1989. Since 1981, he has served as President of Verschuren & Follis, Inc., which advises and administers The Infinity Fund, a limited partnership that invests in emerging growth companies. Since 1995 he has also served as President of Follis Corporation, a sales and marketing company engaged in media sales, television production, serving as a manufacturer s representative and investment management. Mr. Follis received a B.A. degree in business from Michigan State University.

Robert R. Henry. Mr. Henry has served as one of our directors since December 1998. He has been President of Robert R. Henry & Co., Inc., a financial consulting and investment firm, since 1989. Mr. Henry has been an advisory director of Morgan Stanley & Co. Incorporated since 1989, and from

Table of Contents

1977 to 1989 was a managing director of Morgan Stanley. He received an M.B.A. from Harvard Business School and a B.A. from Williams College.

Our officers serve at the discretion of the board of directors. Our directors serve staggered three-year terms. Our directors will hold office until the Annual Meeting of Shareholders to be held in 2006 for Messrs. Follis and Henry, the Annual Meeting of Shareholders to be held in 2007 for Mr. Barrett, and the Annual Meeting of Shareholders to be held in 2008 for Dr. Ausman, and until their successors are elected and qualified, or until their earlier death, resignation or removal. 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.

Board of Directors and Committees of the Board of Directors

Board of Directors

Our board of directors consists of Dr. Ausman, Mr. Follis, Mr. Henry and Mr. Barrett. Our board of directors has determined that Dr. Ausman, Mr. Follis and Mr. Henry are independent as defined in the listing standards of The Nasdaq Stock Market, Inc. Marketplace Rules, as those standards have been modified or supplemented.

Audit Committee

Our board of directors has established a separately-designated, standing Audit Committee that consists of three directors and is established for the purpose of overseeing our accounting and financial reporting processes and audits of our financial statements. Mr. Henry (Chairman), Dr. Ausman and Mr. Follis are the current members of this committee. Each of the members of our Audit Committee is independent as independence for audit committee members is defined in the listing standards of The Nasdaq Stock Market, Inc. Marketplace Rules, as those standards have been modified or supplemented, and SEC rules and regulations. The Audit Committee:

is directly responsible for the appointment, compensation, retention and oversight of the work of any registered public accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for us, including responsibility for the resolution of disagreements between management and the auditor regarding financial reporting; each such registered public accounting firm must report directly to the Audit Committee;

ensures that before the independent accountant is engaged by us to render audit or non-audit services, the engagement is approved by the Audit Committee or the engagement to render the service is entered into pursuant to pre-approval policies and procedures established by the Audit Committee; this pre-approval authority may be delegated to one or more members of the Audit Committee;

takes, or recommends that the full board takes, appropriate action to oversee the independence of our independent accountants;

oversees our independent accountants relationship by discussing with our independent accountants the nature, scope and rigor of the audit process, receiving and reviewing audit and other reports from the independent accountants and providing our independent accountants with full access to the committee and the board to report on any and all appropriate matters;

reviews and discusses the audited financial statements and the matters required to be discussed by SAS 61 with management and the independent accountants, including discussions concerning the independent accountant s judgments about the quality of our accounting principles, applications and practices as applied in our financial reporting;

recommends to the board whether the audited financial statements should be included in our Annual Report on Form 10-K;

Table of Contents

reviews with management and the independent accountants the quarterly financial information before we file our Form 10-Qs; this review is performed by the committee or its chairperson;

discusses with management and the independent accountants the quality and adequacy of our internal controls;

establishes procedures for (1) the receipt, retention, and treatment of complaints received by us regarding accounting, internal accounting controls, or auditing matters, and (2) confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters;

reviews related party transactions required to be disclosed in our proxy statement for potential conflict of interest situations and approves all such transactions;

discusses with management the status of pending litigation as it pertains to the financial statements and disclosure and other areas of oversight as the committee deems appropriate; and

reports committee activities to the full board.

Our board of directors has determined that Mr. Henry is an Audit Committee financial expert, as defined by the Securities and Exchange Commission, serving on our Audit Committee. Mr. Henry s experience that qualifies him as our Audit Committee financial expert includes investment banking experience serving as managing director of Morgan Stanley from 1977 to 1989, corporate securities underwriting experience with Morgan Stanley from 1965 to 1977 and an M.B.A. from Harvard Business School in 1964.

Compensation Committee

Our board of directors has a standing Compensation Committee which consists of three independent directors. Mr. Follis (Chairman), Dr. Ausman and Mr. Henry are the current members of this committee. The Compensation Committee makes recommendations to the board of directors with respect to compensation arrangements and plans for senior management, officers and directors of the Company and administers the Company s 1991 Incentive Stock Option Plan and 1997 Stock Option Plan, and 2005 Stock Incentive Plan.

Nominating Committee

Our board of directors has a standing Nominating Committee which consists of three directors. Dr. Ausman (Chairman), Mr. Henry and Mr. Follis are the current members of this committee. Each of the members of our Nominating Committee is independent as independence is defined in the listing standards of The Nasdaq Stock Market, Inc. Marketplace Rules, as those standards have been modified or supplemented. The Nominating Committee identifies individuals to become board members and selects, or recommends for the board s selection, director nominees to be presented for shareholder approval at the annual meeting of shareholders or to fill any vacancies.

Compensation Committee Interlocks and Insider Participation

During the fiscal year ended November 30, 2005, Dr. Ausman, Mr. Follis (Chairman) and Mr. Henry served as the members of our Compensation Committee. None of the members of our Compensation Committee was, during the fiscal year ended November 30, 2005, one of our officers or employees, or one of our former officers. None of the committee members had any relationship with us requiring disclosure by us pursuant to Securities and Exchange Commission rules regarding disclosure of related-party transactions.

Compensation of Directors

We refer to our directors who are not our officers or employees as Outside Directors. Effective June 1, 2005, each Outside Director receives a fee of $1,000 a month and reimbursement of reasonable

Table of Contents

expenses of attending board and board committee meetings. In addition, the board of directors may grant options to Outside Directors on a case by case basis. On May 4, 2005, we granted a total of 30,000 non-qualified stock options to our Outside Directors under the 2005 Stock Incentive Plan. The options are 10-year options, exercisable at $14.92 a share, the average of the high and low sales prices of the common shares on May 4, 2005. The options vested on November 30, 2005 and continue to be exercisable after termination of the director s service unless the director is terminated for cause. Until May 4, 2005, our Outside Directors received $1,000 for each board meeting attended in person, $250 for each telephonic board meeting attended and $250 for each board committee meeting attended on a date other than the date of a board meeting. The board had also determined to grant Outside Directors who continued to serve as our directors after each annual meeting of shareholders, 10-year options to purchase 3,500 common shares each year on the date of the annual meeting of shareholders, although such options were not granted in fiscal 2005. We also reimbursed Outside Directors for their reasonable expenses of attending board and board committee meetings.

Executive Compensation

Summary Compensation Table

The following table sets forth information for each of the fiscal years ended November 30, 2005, 2004 and 2003 concerning compensation of (1) all individuals serving as our Chief Executive Officer during the fiscal year ended November 30, 2005, and (2) our four most highly-compensated other executive officers in fiscal 2005 who were serving as executive officers as of November 30, 2005 and whose total annual salary and bonus exceeded $100,000:

Summary Compensation Table

				Long-Term Compensation Awards	
		Annual Compensation			
Name and Principal Position	**Year**	**Salary($)**	**Bonus($)**	**Securities Underlying Options(#)**	**All Other Compensation ($)(1)**
Bruce J. Barrett	2005	250,377	302,999	31,919	11,574
President and Chief Executive Officer	2004	238,415	184,653		11,374
	2003	225,500	103,253	132,000	3,174
Richard S. Scheuing	2005	119,853	76,030	12,220	7,855
Vice President, Research and	2004	114,811	49,162		6,574
Development	2003	111,100	19,002	56,000	
Dominic J. Spadafore	2005	136,097	190,376	11,680	11,015
Vice President, Sales and Marketing	2004	133,486	100,570		9,778
	2003	130,866	64,553	36,000	1,578
Mary Ann Victor	2005	117,699	93,360	12,861	9,297
Vice President and Chief	2004	111,384	57,861		7,689
Administrative Officer and Secretary	2003	106,400	29,005	56,000	897

Pamela A. Winters	2005	119,853	76,030	12,220	8,890
Vice President, Operations	2004	114,811	49,461		7,621
	2003	111,100	26,562	50,000	948

(1) Amounts for 2005 include (a) the following matching contributions paid by us into our 401(k) plan on behalf of the following persons: $8,400 for Mr. Barrett, $7,855 for Mr. Scheuing, $8,400 for Mr. Spadafore, $8,400 for Ms. Victor and $7,855 for Ms. Winters, and (b) the following premiums paid for additional disability insurance for the following persons: $3,174 for Mr. Barrett, $2,615 for Mr. Spadafore, $897 for Ms. Victor and $1,035 for Ms. Winters.

Table of Contents

Stock Option Grants

The following table sets forth information concerning individual grants of stock options made during the fiscal year ended November 30, 2005 to each of our executive officers named in the Summary Compensation Table above. Amounts in the following table represent potential realizable gains that could be achieved for the options if exercised at the end of the option term. The five percent and ten percent assumed annual rates of compounded stock price appreciation are calculated based on the requirements of the Securities and Exchange Commission and do not represent an estimate or projection of our future stock prices. These amounts represent certain assumed rates of appreciation in the value of our common shares from the fair market value on the date of grant. Actual gains, if any, on stock option exercises depend on the future performance of the common shares and overall stock market conditions. The amounts reflected in the following table may not necessarily be achieved.

Option Grants In Last Fiscal Year

	Individual Grants				Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term	
Name	Number of Securities Underlying Options Granted (#)(1)	% of Total Options Granted to Employees in Fiscal Year	Exercise Price ($/Sh)	Expiration Date	5%($)	10%($)
Bruce J. Barrett	31,919	24.2	13.55	4/21/15	271,998	689,298
Richard S. Scheuing	12,220	9.2	13.55	4/21/15	104,133	263,893
Dominic J. Spadafore	11,680	8.8	13.55	4/21/15	99,531	252,232
Mary Ann Victor	12,861	9.7	13.55	4/21/15	109,595	277,736
Pamela A. Winters	12,220	9.2	13.55	4/21/15	104,133	263,893

(1) The options listed in the table were non-qualified stock options granted to Messrs. Barrett, Scheuing and Spadafore, Ms. Victor and Ms. Winters in fiscal 2005 under our 2005 Stock Incentive Plan or 1997 Stock Option Plan, exercisable at the then current fair market value of the underlying common shares. Each of these options is exercisable in full beginning November 30, 2005. Each option also becomes 100 percent exercisable 10 days before or immediately upon specified changes in control. The portion of these options that is exercisable at the date of termination of employment remains exercisable until the expiration date of the option, unless termination is for cause.

If, upon exercise of any of the options described above, we must pay any amount for income tax withholding, in the Compensation Committee s or the board of directors sole discretion, either the optionee will pay such amount to us or we will appropriately reduce the number of common shares we deliver to the optionee to reimburse us for such payment. The Compensation Committee or the board may also permit the optionee to choose to have these shares withheld or to tender common shares the optionee already owns. The Compensation Committee or the board may also make such other arrangements with respect to income tax withholding as it shall determine.

Table of Contents

Aggregated Option Exercises and Fiscal Year-End Option Value Table

The following table sets forth information concerning each exercise of stock options during the fiscal year ended November 30, 2005 by each of the executive officers named in the Summary Compensation Table above and the value of unexercised options held by them as of November 30, 2005:

Aggregated Option Exercises in Last Fiscal Year and FY-End Option Values

Name	Shares Acquired on Exercise (#)	Value Realized ($)(1)	Number of Securities Underlying Unexercised Options at FY-End (#)		Value of Unexercised In-the-Money Options at FY-End ($)	
			Exercisable	Unexercisable	Exercisable	Unexercisable
Bruce J. Barrett	178,200	3,198,532	761,919		20,488,234	
Richard S. Scheuing	50,000	875,000	138,220		3,709,399	
Dominic J. Spadafore	30,000	723,100	117,680		3,178,185	
Mary Ann Victor	51,000	977,300	153,261		4,083,211	
Pamela A. Winters	75,750	1,620,713	163,220		4,257,089	

(1) Value Realized represents the fair value of the underlying securities on the exercise date, based on the average of the high and low sales prices on the date of exercise, minus the aggregate exercise price of the options.

Employment Contracts and Termination of Employment and Change-in-Control Arrangements

Bruce J. Barrett. Pursuant to an employment agreement entered into in May 1994, we employ Bruce J. Barrett as our President and Chief Executive Officer, or in such other position as the board of directors determines. His employment under the agreement expires on April 30, 2006. Mr. Barrett s annual salary is currently $258,544, which may be increased by the board of directors. Mr. Barrett is also entitled to participate in any bonus plan established by the Compensation Committee of the board of directors. Mr. Barrett is entitled to various fringe benefits under the agreement, including 12 months of compensation and six months of benefits if his employment under the agreement is terminated without cause or if the agreement expires without being renewed. Mr. Barrett has agreed not to compete with us during specified periods following the termination of his employment.

Dominic J. Spadafore. Pursuant to an employment agreement entered into in August 2002, we employ Dominic J. Spadafore as our Vice President, Sales and Marketing, or in such other position as the board of directors determines. His employment under the agreement expires upon his death, termination by us upon his disability or with or without cause or termination by Mr. Spadafore. Mr. Spadafore s annual salary is currently $142,015, which may be increased by the board of directors. Mr. Spadafore is also entitled to participate in commission incentive plans. Mr. Spadafore is entitled to various fringe benefits under the agreement.

As of June 13, 2005, we entered into an amended and restated employment agreement with Dominic J. Spadafore. The amendment and restatement primarily replaces provisions in his employment agreement to match those in the new Change in Control, Invention, Confidentiality, Non-Compete and Non-Solicitation Agreements entered into with five other executive officers and described below. The agreement now provides 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 of control of the Company that occurs by June 13, 2008. Mr. Spadafore has agreed not to compete with us and not to solicit our employees during specified periods following the termination of his employment, and he has agreed to various confidentiality obligations.

Change in Control, Invention, Confidentiality, Non-Compete and Non-Solicitation Agreements. In June 2005, we entered into Change in Control, Invention, Confidentiality, Non-Compete and Non-Solicitation Agreements with

five of our executive officers: William M. Iacona, Richard S. Scheuing, Mary Ann Victor, Ronald A. Widman and Pamela A. Winters. These agreements provide for severance

Table of Contents

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 of control of the Company that occurs by June 13, 2008, June 29, 2008 for Mr. Scheuing. The 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.

Stock Option Terms. All options granted under our stock option plans that are not already 100 percent exercisable immediately, including options granted to Messrs. Barrett, Scheuing and Spadafore, Ms. Victor and Ms. Winters, become 100 percent exercisable immediately ten days before or upon specified changes in control of the Company. On November 30, 2005, our board of directors accelerated all outstanding options that had not already vested.

Stock Option Plans

We have adopted the Somanetics Corporation 2005 Stock Incentive Plan. The plan allows us to grant stock options, including both incentive stock options and nonqualified stock options, restricted stock and restricted stock units to our officers, other employees, non-employee directors, consultants, advisors, independent contractors and agents to purchase up to an aggregate of 600,000 common shares. Options to purchase 99,716 common shares are outstanding under the plan, no options granted under the plan have been exercised and 500,284 common shares remain available for grants and awards under the plan. See Executive Compensation Option Grants Table. Under the plan, stock options to purchase no more than 300,000 common shares may be granted to any one participant in any calendar year. The plan also contains provisions to