SOMANETICS CORP
Form S-3/A
February 08, 2006

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As filed with the Securities and Exchange Commission on February 8, 2006.
Registration No. 333-131394

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Amendment
No. 1 To
FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

SOMANETICS CORPORATION

(Exact name of registrant as specified in its charter)

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

1653 East Maple Road
Troy, Michigan 48083-4208
(248) 689-3050
(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Bruce J. Barrett
President and Chief Executive Officer
Somanetics Corporation
1653 East Maple Road
Troy, Michigan 48083-4208
(248) 689-3050
(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. o

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box: o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. o

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. o

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Share(2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee(3)
Common Shares, par value $.01 per share	2,300,000	$23.145	$53,233,500	$5,695.99

(1) Includes 300,000 shares which the underwriters have the option to purchase to cover over-allotments, if any.

(2) Estimated solely for the purpose of computing the registration fee, based on the average of the high and low reported sale prices of the Registrant s common shares on February 7, 2006 as reported on The Nasdaq National Market, pursuant to Rule 457(c).

(3) $7,002.78 paid with the original filing.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED FEBRUARY 8, 2006

PROSPECTUS

2,000,000 Shares
Somanetics Corporation
Common Shares
$ 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 7, 2006 was $22.58 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	$	$
Underwriting Discount	$	$
Proceeds to Somanetics Corporation (before expenses)	$	$

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

Citigroup

SG Cowen & Co.
SunTrust Robinson Humphrey

, 2006

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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.

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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.

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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.

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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.

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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.

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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.

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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	$ 55,099
Working capital	18,044	59,995
Total assets	29,719	71,669
Total liabilities	1,878	1,878
Accumulated deficit	(37,131)	(37,131)
Total shareholders equity	27,841	69,791

(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 an assumed public offering price of $22.58 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

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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.

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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.

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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

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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.

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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

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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

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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

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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.

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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.

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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

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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.

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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.

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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.

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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.

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USE OF PROCEEDS

We estimate that we will receive approximately $41,950,400 in net proceeds from the 2,000,000 common shares that we are offering, or approximately $48,317,960 if the underwriters exercise their over-allotment option in full, based upon the estimated public offering price of $22.58 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.

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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 7, 2006)	$ 36.64	$ 21.98

On February 7, 2006, the last reported sales price for the common shares on The Nasdaq National Market was $22.58 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.

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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 an assumed public offering price of $22.58 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	106,795
Accumulated deficit	(37,131)	(37,131)
Total shareholders equity	27,841	69,791
Total capitalization	$ 27,841	$ 69,791

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.

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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.

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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 mar