# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

# Form 10-K

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

**For the fiscal year ended December 31, 2002**

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

**For the transition period from to**

**Commission file number: 0-24663**

# Aspect Medical Systems, Inc.

*(Exact name of Registrant as Specified in Its Charter)*

| **Delaware** | **04-2985553** |
|---|---|
| *(State or Other Jurisdiction of Incorporation or Organization)* | *(I.R.S. Employer Identification No.)* |
| **141 Needham Street Newton, Massachusetts** | **02464-1505** |
| *(Address of Principal Executive Offices)* | *(Zip Code)* |

**(617) 559-7000**
**Registrant's telephone number, including area code**

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

**Securities registered Pursuant to Section 12(g) of the Act:**

**Common Stock, $0.01 Par Value**
*(Title Of Class)*

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes ☐ No ☑

The aggregate market value of the voting stock held by non-affiliates of the registrant as of June 28, 2002 (based on the closing price as quoted by the Nasdaq National Market as of such date) was $57,464,808. The registrant had 19,381,010 shares of Common Stock, $0.01 par value per share, outstanding as of March 20, 2003.

**DOCUMENTS INCORPORATED BY REFERENCE**

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2002. Portions of such proxy statement are incorporated by reference into Part III of this Form 10-K.

## PART I

### Item 1. Business.

#### Overview

Aspect Medical Systems, Inc. was incorporated as a Delaware corporation in 1987. We develop, manufacture and market an anesthesia monitoring system that we call the BIS® system. The BIS system is based on our patented core technology, the Bispectral Index, which we refer to as the BIS index. The BIS system provides information that allows clinicians to better assess and manage a patient's level of consciousness in the operating room and intensive care settings and administer the precise amount of anesthesia needed by each patient. We developed the BIS system over 10 years, and it is the subject of 17 issued United States patents and eight pending United States patent applications. Our proprietary BIS system includes our BIS monitor, or our BIS Module Kit, which allows original equipment manufacturers to incorporate the BIS index into their monitoring products, and our single-use disposable BIS Sensors.

Our latest generation monitor, the A-2000® BIS Monitor, was cleared for marketing by the United States Food and Drug Administration, or the FDA, in February 1998. Our latest version of the BIS system, the BIS XP system, was cleared for marketing by the FDA in June 2001. The BIS XP system offers enhanced performance capabilities and expanded benefits as compared to the previous version of our BIS system, enabling more precise measurement of brain activity to assess the level of consciousness. The BIS XP system is designed to detect and filter interference from muscle artifact and is resistant to interference from electrocautery devices. Additionally, it is able to provide enhanced detection of near suppression, a brain wave pattern occasionally observed during deep anesthesia and cardiac cases. In addition to our A-2000 BIS Monitor, we offer original equipment manufacturers our BIS Module Kit for integration into equipment sold by the original equipment manufacturers.

As of December 31, 2002, the worldwide installed base of BIS monitors and modules was approximately 16,000 units. We estimate that BIS technology is installed in approximately 27% of all operating rooms in the United States, and is available in more than 160 countries. We estimate that over six million patients have been monitored using the BIS index during surgery.

Clinical trials and routine clinical use of the BIS system have shown that patient monitoring with the BIS system results in:

- a reduction in the amount of anesthetics used,
- faster wake-up from anesthesia,
- less patient time in the operating room and the post-anesthesia care unit following surgery,
- higher rates of outpatients bypassing the post-anesthesia care unit and proceeding to a less costly step-down recovery area directly from the operating room,
- improvements in the quality of recovery, and
- improvements in the means to assess the risk of surgical awareness, which is the unintentional regaining of consciousness during surgery.

We derive our revenue primarily from sales of monitors, BIS Module Kits, and related accessories, which we collectively refer to as Equipment, and sales of BIS Sensors. In 2002, 2001 and 2000, revenue from the sale of Equipment represented approximately 33%, 32% and 40%, respectively, of our revenue, and revenue from the sale of BIS Sensors represented approximately 67%, 68% and 60%, respectively, of our revenue.

We maintain a website with the address *www.aspectmedical.com*. We are not including the information contained on our website as a part of, or incorporating it by reference into, this Annual Report on Form 10-K. We make available free of charge through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, and amendments to these reports, as soon as reasonably

practicable after we electronically file such material with, or furnish such material to, the Securities and Exchange Commission.

**The Aspect Solution: Patient Monitoring with the BIS System**

We have developed the BIS monitoring system that is based on our proprietary BIS index. Our BIS system is comprised of our BIS monitor or BIS Module Kit and our single-use, disposable BIS Sensors. The BIS Sensors are applied to a patient's forehead to acquire the EEG, a measure of the electrical activity of the brain. The EEG is then analyzed by the BIS monitor or BIS Module Kit to produce the BIS index. The BIS index is a numerical index that correlates with levels of consciousness and is displayed as a number ranging between 100, indicating that the patient is awake, and zero, indicating an absence of brain activity. In October 1996, the FDA cleared the BIS index for marketing for use as a direct measure of anesthetic effect on the brain.

**Products**

The following chart summarizes our principal product offerings:

| Product | Initial Commercial Shipment | Description |
|---|---|---|
| BIS XP System | 2001 | Latest version of BIS system offering enhanced performance capabilities and expanded benefits as compared to the previous version of the BIS system, enabling more precise measurement of brain activity to assess the level of consciousness |
| BIS Module Kit — 4 Channel Support | 2001 | Same as standard BIS Module Kit plus 4 channel EEG monitoring capability |
| A-2000 BIS Monitor | 1998 | Small, lightweight, portable third-generation BIS monitor |
| BIS Module Kit | 1998 | Components of BIS monitoring technology that are integrated into equipment sold by original equipment manufacturers |
| BIS Extend Sensor | 2002 | Disposable product with electronic memory device for use with A-2000 BIS Monitor and BIS Module Kit that was specially designed for patients who are typically monitored for extended periods |
| BIS Pediatric Sensor | 2001 | Disposable product with electronic memory device for use with A-2000 BIS Monitor and BIS Module Kit that is smaller and easier to apply to children |
| BIS Quatro Sensor | 2001 | Disposable product with electronic memory device for use with A-2000 BIS Monitor and BIS Module Kit that offers enhanced performance in deep anesthetic states and improved robustness to interference from noise sources |

| Product | Initial Commercial Shipment | Description |
|---|---|---|
| BIS Sensor Plus | 2001 | Second-generation disposable product for use with the A-2000 BIS Monitor and BIS Module Kit |
| BIS Standard Sensor | 1997 | Disposable product for use with A-2000 BIS Monitor, A-1050 EEG Monitor with BIS and BIS Module Kit |

***BIS XP System***

We began commercial distribution of the BIS XP system in September 2001. The BIS XP system runs on the A-2000 BIS Monitor and BIS Module Kit platforms and offers enhanced performance capabilities and expanded benefits as compared to the previous version of our BIS system, enabling more precise measurement of brain activity to assess the level of consciousness. The BIS XP system is designed to detect and filter interference from muscle artifact and is resistant to interference from electrocautery devices. Additionally, it is able to provide enhanced detection of near suppression, a brain wave pattern occasionally observed during deep anesthesia and cardiac cases.

***A-2000 BIS Monitor***

We began commercial distribution of the A-2000 BIS Monitor, our third-generation monitor, in February 1998. The A-2000 BIS Monitor is a compact, lightweight, portable monitor designed to accommodate the space limitations and positioning requirements of surgical settings. The A-2000 BIS Monitor displays the BIS index and supporting information and includes our proprietary digital signal converter. This converter is a palm-sized module that serves as the interface between the BIS monitor and the BIS Sensors. The digital signal converter acquires the EEG signal from the BIS Sensors and converts the EEG signal to digital format. The EEG signal is then processed and the BIS index is displayed on the A-2000 BIS Monitor.

***BIS Module Kit***

In 1996, we introduced our BIS Module Kit, which is designed to facilitate the integration of the BIS index into equipment marketed by our original equipment manufacturers. The BIS Module Kit consists of two pieces, our proprietary digital signal converter and a small circuit board that resides in the original equipment manufacturer's system. The digital signal converter acquires the EEG signal from the BIS Sensors and converts the EEG signal to digital format. The circuit board then processes the EEG signal and outputs the BIS index to the original equipment manufacturer's system.

The common architecture of the BIS Module Kit facilitates integration of the BIS index into the original equipment manufacturer's system. Each original equipment manufacturer is required to obtain FDA and other appropriate regulatory clearance of its BIS module product.

***BIS Module Kit — 4 Channel Support***

In 2001, we introduced commercially the BIS Module Kit with 4 channel EEG monitoring capability to support a product introduction of one of our original equipment manufacturers.

***BIS Sensors***

*BIS Extend Sensor.* We created the BIS Extend Sensor, which was introduced commercially in 2002, for patients who are typically monitored for an extended period of time, such as in intensive care unit settings. We designed the BIS Extend Sensor with a surface that allows clinicians to record in writing the date and time of application, making it easier to track when a new sensor should be applied. The BIS Extend Sensor provides resistance to electrical artifact and is designed to detect and filter interference from muscle artifact caused by sources such as eye movement. The BIS Extend Sensor contains an electronic memory device that allows

information about the sensor, such as lot code, expiration date and type of sensor, to be stored on the sensor and to be retrieved by the BIS monitor or BIS Module Kit.

*BIS Pediatric Sensor.* The BIS Pediatric Sensor, which was introduced commercially in 2001, is smaller and easier to apply than our other BIS Sensors, and is visually appealing to children. The BIS Pediatric Sensor features an improved design for easy connection and enables the BIS system to automatically configure its settings for specific patient populations and applications. The BIS Pediatric Sensor contains an electronic memory device that allows information about the sensor, such as lot code, expiration date and type of sensor, to be stored on the sensor and to be retrieved by the BIS monitor or BIS Module Kit.

*BIS Quatro Sensor.* The BIS Quatro Sensor, which was introduced commercially in 2001, offers enhanced performance in deep anesthetic states and improved resistance to interference from noise sources, such as high frequency/electromyography conditions, in the operating room and intensive care unit. The BIS Quatro Sensor features an improved design as compared to the BIS Standard Sensor for easy connection and enables the BIS system to automatically configure its settings for specific patient populations and applications. The BIS Quatro Sensor contains an electronic memory device that allows information about the sensor, such as lot code, expiration date and type of sensor, to be stored on the sensor and to be retrieved by the BIS monitor or BIS Module Kit.

*BIS Sensor Plus.* The BIS Sensor Plus, which was introduced commercially in 2001, is a second-generation disposable product for use with the A-2000 BIS Monitor and BIS Module Kit. The BIS Sensor Plus features an improved design as compared to the BIS Standard Sensor for easy connection and enables the BIS system to automatically configure its settings for specific patient populations and applications. The BIS Sensor Plus contains an electronic memory device that allows information about the sensor, such as lot code, expiration date and type of sensor, to be stored on the sensor and to be retrieved by the BIS monitor or BIS Module Kit.

*BIS Standard Sensor.* We commenced commercial distribution of the BIS Standard Sensor in January 1997. The BIS Standard Sensor is a single-use, disposable product for use with the A-2000 BIS Monitor, the A-1050 EEG Monitor with BIS and the BIS Module Kit. The BIS Standard Sensor is not compatible with the BIS XP system because it does not contain the easy connection feature and electronic memory device of our other BIS Sensors. The BIS Standard Sensor provides a reliable and simple means of acquiring the EEG signal needed to generate the BIS index. The one-piece design allows quick and accurate placement on the patient's forehead. The BIS Standard Sensor connects to the monitor by a single-point proprietary connector.

Our Zipprep self-prepping technology is a key feature of each of our BIS Sensors. The technology is designed to minimize patient set-up time and establish effective electrical contact with the patient which enables consistent, accurate readings of the EEG signal. Prior to our development of the Zipprep technology, to obtain an EEG signal the user prepared a patient's skin by rubbing an abrasive cream over the forehead 10 to 20 times in order to remove the top layer of skin prior to applying the electrode.

**Technology**

We developed the BIS system, including our proprietary BIS index, over 10 years. The BIS index is a numerical index that quantitates the hypnotic component of anesthetic drug effect which correlates with the level of consciousness and is derived from an analysis of the EEG signal. In general, an EEG signal changes from a small-amplitude, high-frequency signal while a person is awake to a large-amplitude, low-frequency signal while a person is deeply anesthetized. Historically, researchers have used observations about these changes in the EEG signal to create mathematical algorithms to track the effects of anesthetics on the brain. However, these algorithms have not been widely adopted because studies have indicated that they generally do not provide sufficient clinically useful information to assess levels of consciousness with commonly used anesthetics and doses.

In developing the BIS index, we sought to improve these early EEG analyses in two ways. First, by using bispectral analysis, a mathematical tool that examines signals such as the EEG, we can extract new information from the EEG signal. Second, we developed proprietary processing algorithms that extract

information from bispectral analysis, power spectral analysis and time domain analysis. Geophysicists originally used bispectral analysis in the early 1960s to study ocean wave motion, atmospheric pressure changes and seismic activity. The advent of high-speed, low-cost digital signal processors has enabled the use of bispectral analysis for other applications. By using bispectral analysis, we are able to extract a distinctive fingerprint of the underlying signal structure of the EEG and represent it as a three-dimensional mathematical model.

We created the BIS index to quantify changes in the EEG that relate to the effects of anesthetics on the brain in order to assess levels of consciousness. Over a number of years, Aspect and others collected a large database of high fidelity EEG recordings and clinical assessments from volunteers and patients receiving a wide variety of anesthetics. Researchers used clinical assessments such as a sedation rating scale, picture or word recall memory tests and response to stimuli to define levels of consciousness. Using statistical methods, we identified features within the EEG that correlated with sedation and loss of consciousness. We then used proprietary statistical methods to combine these features to generate an interpretive numerical index, which we refer to as the BIS index. The BIS index ranges from 100, indicating that the patient is awake, to zero, indicating an absence of electrical brain activity.

**Clinical Development**

Our clinical research and regulatory affairs group is responsible for:

- establishing collaborative relationships with leading clinical researchers,
- encouraging publications related to the BIS index in scientific literature,
- assuring compliance with the FDA and other regulatory agencies' requirements,
- conducting clinical research with the goal of extending the application of patient monitoring with the BIS system to other settings and clinical uses, and
- collecting data for new product development.

We have a clinical database of over 5,000 cases for use in algorithm development and product validation based on trials that we conducted or sponsored or that third parties conducted.

In 1996, the FDA cleared the BIS index for marketing as a measure of anesthetic effect on the brain. The regulatory process involved studies we conducted on over 900 volunteers and patients. These studies characterized the relationships between the BIS index value and various clinical endpoints, including movement, response to incision, response to verbal command as a measure of consciousness in volunteers and patients, memory function, drug utilization and speed of patient recovery following surgery.

Although we have not systematically solicited reports of surgical awareness, clinicians have reported to us cases of possible surgical awareness during surgical procedures monitored with the BIS system. These reports may not include all cases of surgical awareness that might have occurred during procedures where patients were monitored with the BIS system. In most of the cases that were reported to us, when BIS index values were recorded at the time of awareness, high BIS index values were noted, indicating that the BIS index correctly identified the increased risk of awareness in these patients. It is possible that, in a small number of these reported cases, surgical awareness may not have been detected by monitoring with the BIS system.

We have not yet completed a prospective, randomized, controlled study to evaluate whether or not monitoring with the BIS system reduces the incidence of surgical awareness. However, we are currently sponsoring three multi-center, multinational studies to make an assessment as to the incidence of awareness during BIS monitoring. More than 28,000 patients were enrolled in these studies, which we conducted over a period of 18 months. Data collection for these studies was completed in the first quarter of 2003, and the results are currently being analyzed. One of the studies we are sponsoring, which involves 5,057 patients at two hospitals, has indicated that the use of the BIS index was associated with a significantly reduced incidence of awareness as compared with historical rates from the same two hospitals. Because data analysis from another prospective randomized study that we are sponsoring has not yet been completed, we cannot and do not claim

that patient monitoring with the BIS system will reduce the incidence of surgical awareness. Although our clinical research and practice experience suggests that surgical awareness is more likely to occur when BIS values are high, we do not believe that our experience demonstrates conclusively that patient monitoring with the BIS system will reduce the frequency of awareness.

We are also currently investigating the relationship between deep anesthetic levels as measured using the BIS system and one-year morbidity and mortality. One initial report (Weldon CB, Mahla ME, Van der Aa MT, Monk T. Advancing Age and Deeper Intraoperative Anesthetic Levels Are Associated with Higher First Year Death Rates. *Anesthesiology 2002; 96: A-1097*) suggests that deep anesthesia is associated with increased post-operative mortality in elderly patients undergoing general anesthesia. We believe that this initial finding needs to be confirmed in additional trials. We have initiated additional studies to confirm these findings.

**Sales, Marketing and Customers**

Our customers include anesthesia providers, hospitals, outpatient surgical centers and individual practitioners in office-based practice. We market and sell our products to our customers through:

- our direct sales force,
- distributors, and
- original equipment manufacturers.

For the fiscal year ended December 31, 2002, no one customer accounted for 10% or more of our total revenue.

***Domestic***

We market our BIS system in the United States primarily through a combination of a direct sales force, specialty distributors and original equipment manufacturers. As of December 31, 2002, our domestic sales force was comprised of 48 sales professionals, four clinical specialists and four inside sales representatives.

We augment our direct sales force with medical products distributors in selected markets, including Canada and locations in the United States. We also market our products through the sales organizations of our original equipment manufacturers and contracts with hospital group purchasing organizations.

We offer our customers the option either to purchase BIS monitors outright or to acquire BIS monitors pursuant to a sales-type lease agreement whereby the customer contractually commits to purchase a minimum number of BIS Sensors per BIS monitor per year. Under this agreement, our customers purchase BIS Sensors and the BIS monitor for the purchase price of the BIS Sensors plus an additional charge per BIS Sensor to pay for the purchase price of the BIS monitor and related financing costs over the term of the agreement. These customers are granted an option to purchase the BIS monitors at the end of the term of the agreement, which is typically three to five years. We believe that the sales-type lease arrangement in some cases reduces the time required for customers to adopt the BIS system because it provides them with an option to utilize their operating budget to fund the purchase.

Under certain circumstances, we also offer our customers the opportunity to use the BIS monitors under our Equipment Placement program, which we refer to as the EP program. Under the EP program, the customer is granted the right to use the BIS monitors for a mutually agreed upon period of time. During this period, the customer purchases BIS Sensors at a price that includes a premium above the list price of the BIS Sensors to cover the rental of the equipment, but without any minimum purchase commitments. At the end of the agreed upon period, these customers have the option of purchasing the BIS monitors, continuing to use them under the EP program or returning them to us. Although we believe that in certain circumstances the EP program may provide an effective method of allowing customers to evaluate and ultimately acquire the BIS technology from us or our original equipment manufacturers, we substantially reduced our focus on the EP program in 2002.

We focus our marketing initiatives on the various constituencies that may be involved in the decision-making process concerning the purchase of our products. For clinical audiences, we exhibit at tradeshows, sponsor speakers at professional meetings and develop articles for publication in conjunction with industry experts. In addition, we work with hospitals to publicize their adoption of patient monitoring with the BIS system in an effort to assist them in communicating their commitment to improving the quality and efficiency of patient care.

***Group Purchasing Agreements***

We have entered into several agreements with group purchasing organizations whereby the member healthcare organizations have the right to purchase BIS monitors and BIS Sensors under the pricing terms contained in the respective agreements. Under these agreements, the group purchasing organizations' field forces have agreed to work with our sales force to facilitate the adoption of BIS technology by their affiliated healthcare organizations. We have group purchasing agreements with the following group purchasing organizations:

| Group Purchasing Organization | Effective Date | Termination Provisions |
|---|---|---|
| Premier Purchasing Partners, L.P. | November 1, 2000 | Unless terminated earlier by either party by giving 90 days prior written notice, this agreement expires on May 31, 2003. |
| Consorta, Inc. | November 1, 2000 | Unless terminated earlier by either party by giving 90 days prior written notice, this agreement expires on October 31, 2005. |
| AmeriNet, Inc. | September 1, 2000 | August 31, 2003 |
| Healthtrust Purchasing Group, L.P. | September 1, 2000 | Unless terminated earlier by either party by giving 60 days prior written notice, this agreement expires on September 30, 2004. |
| Health Services Corporation of America | September 1, 2000 | This agreement expires on August 31, 2003. The term of the agreement automatically renews for one-year periods unless either party provides written notice of termination to the other party, at least 60 days prior to expiration of the agreement. |
| Novation | August 13, 1998 | Unless terminated earlier by Novation by giving at least 90 days prior written notice or by us by giving at least 180 days prior written notice, this agreement expires on December 31, 2003. Novation may elect to renew the agreement for up to two additional one-year periods. |

***International***

In 1998, we established our international operations and opened our international headquarters in Leiden, The Netherlands. We continue to develop our international sales and distribution program through a combination of distributors and marketing partners, including companies with which we have entered into original equipment manufacturer relationships. As of December 31, 2002, we employed 23 persons in our international organization. The majority of our international sales are denominated in United States dollars. See Note 15, "Segment Information and Enterprise Reporting," of the Notes to our Consolidated Financial Statements for domestic and international financial information.

We are increasingly subject to a number of challenges which specifically relate to our international business activities. These challenges include:

- failure of local laws to provide the same degree of protection against infringement of our intellectual property,
- protectionist laws and business practices that favor local competitors, which could slow our growth in international markets,
- difficulties in terminating or modifying distributor arrangements because of restrictions in markets outside the United States,
- less acceptance by foreign anesthesia providers of the use of disposable products similar to the BIS Sensors,
- delays in regulatory approval of our products,
- currency conversion issues arising from sales denominated in currencies other than the United States dollar,
- foreign currency exchange rate fluctuations,
- longer sales cycles to sell products like the BIS system to hospitals and outpatient surgical centers, which could slow our revenue growth from international sales, and
- longer accounts receivable payment cycles and difficulties in collecting accounts receivable.

***Distribution Agreements***

We have entered into a master distribution agreement, effective September 1, 2000, with Datex-Ohmeda Division of Instrumentarium Corporation, under which Datex-Ohmeda has agreed to act as a nonexclusive distributor of our A-2000 BIS Monitor, BIS Sensors and related products in a number of territories outside the United States. The master distribution agreement expires on November 1, 2003. The master distribution agreement will be replaced by country-specific agreements with Datex-Ohmeda sales subsidiaries and distributors in various countries. To date, several new distribution agreements have been finalized and we continue to negotiate new agreements in numerous other countries.

We entered into a distribution agreement, effective October 1, 1999 and amended effective March 1, 2001, with Philips Medizinsysteme Boeblingen GmbH (formerly Agilent Technologies, Inc., which was formerly part of Hewlett-Packard Company), under which Philips agreed to act as a nonexclusive distributor of our BIS Sensors in a number of territories outside the United States. This distribution agreement expired on September 30, 2001. Philips retains the right to distribute BIS Sensors under the OEM Development and Purchase Agreement described below.

We have entered into a distribution agreement, dated January 21, 1998, with Nihon Kohden Corporation, under which Nihon Kohden has agreed to act as an exclusive distributor of our BIS monitors and related products in Japan. This agreement expires on February 21, 2004. The term of the agreement automatically renews for one-year periods unless either party provides written notice of termination to the other party, at least three months prior to expiration of the agreement or any renewal period.

***Original Equipment Manufacturer Relationships***

We have entered into agreements with six patient monitoring or anesthesia equipment companies, Datex-Ohmeda Division of Instrumentarium Corporation, Dräger Medizintechnik GmbH, Philips Medizinsysteme Boeblingen GmbH (formerly Agilent Technologies, Inc., which was formerly part of Hewlett-Packard Company), GE Medical Systems — Information Technologies, Nihon Kohden Corporation and Spacelabs Medical, Inc., that provide for the integration of our BIS technology into their equipment. Spacelabs introduced a BIS module for its patient monitoring systems in October 1998, Philips introduced a BIS module for its patient monitoring systems in October 2000, GE Medical Systems and Datex-Ohmeda introduced a

BIS module in October 2001 and Nihon Kohden received Ministry of Health, Labor and Welfare approval of their BIS module in July 2002. We currently expect that a BIS module for Dräger will be available within the next year. We have also entered into an agreement with Boston Scientific Corporation, a worldwide developer, manufacturer and marketer of medical devices, to introduce new sedation management technology to interventional and specialty medical procedure suites.

*Boston Scientific Corporation.* Under a strategic alliance with Boston Scientific Corporation, including an OEM Product Development Agreement, dated August 7, 2002, between Aspect and Boston Scientific Corporation, we have agreed with Boston Scientific Corporation to introduce new sedation management technology for use in interventional and specialty medical procedure suites, including the gastrointestinal endoscopy suite, the interventional cardiology suite and the interventional radiology suite. The alliance will focus on the development and distribution of brain monitoring technology specifically designed to enhance the safety, efficiency and delivery of sedation to patients undergoing less-invasive medical procedures. As part of this alliance, the Company has granted Boston Scientific Corporation an option to distribute the newly developed technology for monitoring patients under sedation in a range of medical specialties. The term of this agreement shall continue until such time that Boston Scientific Corporation is no longer distributing our products, but shall in no event extend beyond December 31, 2012.

*Datex-Ohmeda Division of Instrumentarium Corporation.* Under an OEM Purchase Agreement, dated September 1, 2000, between Aspect and Datex-Ohmeda Division of Instrumentarium Corporation, Datex-Ohmeda agreed to integrate our BIS technology with Datex-Ohmeda's patient monitors. Unless terminated sooner, this agreement expires on December 31, 2005. The term of the agreement automatically renews for one-year periods unless either party provides written notice of termination to the other party, at least 12 months prior to expiration of the agreement. Under a separate agreement with Datex-Ohmeda, dated September 1, 2000, we agreed to supply certain sensor products to Datex-Ohmeda for certain monitoring products developed and introduced by Datex-Ohmeda. Unless terminated sooner, this agreement expires on December 31, 2005. The term of this agreement automatically renews for one-year periods unless either party provides written notice of termination to the other party, at least 12 months prior to expiration of the agreement. In December 2002, GE Medical Systems announced that GE Medical Systems and Instrumentarium Corporation have entered into a definitive combination agreement for GE Medical Systems to acquire Instrumentarium Corporation. We are currently evaluating the impact that this acquisition may have on our agreements and operations.

*GE Medical Systems — Information Technologies.* Under an OEM Development and Purchase Agreement, dated December 22, 1999, between Aspect and GE Medical Systems — Information Technologies, GE Medical Systems agreed to integrate our BIS technology with GE Medical Systems' patient monitors. Unless terminated sooner, the agreement expires December 31, 2004. The term of the agreement automatically renews for one-year periods unless either party provides written notice of termination to the other party, at least 60 days prior to the expiration of the agreement.

*Philips Medizinsysteme Boeblingen GmbH.* Under an OEM Development and Purchase Agreement, dated August 6, 1999, between Aspect and Philips, Philips agreed to integrate our BIS technology with Philips' patient monitors. Unless terminated sooner, this agreement expires on August 6, 2005. The term of the agreement automatically renews for one-year periods unless either party provides written notice of termination to the other party, at least 60 days prior to expiration of the agreement.

*Dräger Medizintechnik GmbH.* Under a Product Agreement with Dräger Medizintechnik GmbH, dated May 5, 1999, Dräger agreed to integrate our technology with Dräger's anesthesia equipment. Unless terminated sooner, this agreement will expire on December 31, 2005. This agreement automatically renews for successive one-year periods thereafter unless either party provides written notice of termination to the other party, at least twelve months prior to expiration of the renewal period.

*Nihon Kohden Corporation.* Under an International License Agreement, dated January 21, 1998, between Aspect and Nihon Kohden, we have licensed our technology to Nihon Kohden on a worldwide non-exclusive basis. Nihon Kohden has the right to incorporate our technology into its patient monitoring systems. Unless terminated sooner, the agreement expires four years following approval by the Japanese Ministry of

Health and Welfare of a Nihon Kohden patient monitor which integrates Aspect's BIS technology. Nihon Kohden obtained this approval in July 2002.

*Spacelabs Medical, Inc.* Pursuant to the terms of a Distribution and License Agreement, dated April 1, 1996, between Aspect and Spacelabs Medical, Inc., we have granted to Spacelabs a worldwide, non-exclusive license to the BIS index to develop, manufacture, market and sell Spacelabs monitoring equipment that incorporates the BIS index. Spacelabs also has the right to distribute our BIS Sensors on a non-exclusive basis throughout the world with the exception of the United States. Unless terminated sooner, this agreement expires in April 2006. In July 2002, Instrumentarium Corporation acquired Spacelabs Medical, Inc. This acquisition did not have a material impact on our agreements and our operations.

**Research and Development**

Our research and development efforts focus primarily on continuing to improve the function and features of the BIS system and enhancing our technical leadership in signal-processing technology for use in patient care. We intend to leverage the BIS technology for the development of new monitoring products and proprietary disposable sensors for new applications and to take advantage of new opportunities such as the intensive care unit and procedural sedation markets.

During the fiscal years ended December 31, 2002, 2001 and 2000, we spent approximately $7.8 million, $7.5 million and $5.7 million, respectively, in our research and development efforts, including clinical and regulatory expenses.

Our research and development department has four primary areas of responsibility:

- algorithm research,
- product development,
- pre-production quality assurance, and
- clinical engineering.

In 2001, we developed the BIS XP system, which offers enhanced performance capabilities and expanded benefits as compared to the previous version of our BIS system and the BIS Extend Sensor for patients, which are typically monitored for an extended period of time. We developed the BIS Extend Sensor with a surface that allows clinicians to record in writing the date and time of application, making it easier to track when a new sensor should be applied. We also continue to explore new signal-processing techniques to improve the quality of the BIS index. The BIS Sensor Plus, BIS Quatro, BIS Extend and BIS Pediatric Sensors contain an electronic memory device that allows information about the sensor, such as lot code, expiration date and type of sensor, to be stored on the sensor and to be retrieved by the BIS monitor when used.

We are also investigating other product areas that utilize our expertise in anesthesia delivery and monitoring of the brain. In 2001, we established a team that is investigating the use of the BIS monitoring platform to diagnose and track neurological disorders. We believe that because BIS technology quantifies changes in patients' brain wave activity, or EEG, and we have shown the BIS index correlates with memory function and changes in brain metabolism, it may be useful in detecting neurological disorders in patients. We are evaluating the application of the BIS technology to measure brain function, which may apply to detection of Alzheimer's disease, sleep cycles, seizure detection and/or other neurological disorders, including depression. Our recent research shows a correlation between the BIS index and the severity of dementia in patients with Alzheimer's disease and vascular dementia. This research complements our prior research demonstrating the correlation between the BIS index and the effects of pharmacological agents on the brain, changes in cerebral metabolic activity, and clinical measures of cognitive and memory function.

Additionally, on July 12, 2002, we entered into an agreement with the Regents of the University of California under which the Regents of the University of California granted to us an option to enter into a license agreement conveying to Aspect an exclusive license to commercialize brain monitoring technology for depression which was developed by the Neuropsychiatric Institute and David Geffen School of Medicine at

UCLA. We may exercise this option at anytime prior to July 12, 2003 by providing written notice to the Regents of the University of California. This option period may be extended by one year for an additional fee. Upon the exercise of our option, both parties have agreed to execute an exclusive license agreement, the terms of which have already been finalized.

**Manufacturing**

We use 12,000 square feet of our 61,000 square foot facility located in Newton, Massachusetts for manufacturing purposes. In this facility, we assemble all of our BIS monitors, and we produce substantially all of our BIS Sensors on two semi-automated production lines. Prior to 1998, we outsourced all BIS Sensor manufacturing. We currently outsource to third parties the production of our Zipprep EEG Electrodes.

Our production process for our BIS monitors consists of final assembly, integration and testing of standard and custom components. Our production process for our BIS Sensors consists of several manufacturing and assembly processes using custom components. Qualified sub-contractors, who have met our supplier certification process and are placed on an approved vendors list, produce certain custom components for our products. Some of the components that are necessary for the assembly of our BIS system, including some of the components used in our BIS Sensors, are currently provided to us by sole-source suppliers or a limited group of suppliers. We purchase components through purchase orders rather than long-term supply agreements and generally do not maintain large volumes of inventory. We have experienced shortages and delays in obtaining some of the components of our BIS system in the past, and we may experience similar delays or shortages in the future.

We maintain a quality-assurance program covering our manufacturing operations. Suppliers of purchased components are required to meet stated specifications. We certify suppliers prior to use by conducting audits and product inspections. We engage in ongoing evaluations of the performance of our suppliers by evaluating the results of inspections and tests as well as the timeliness of product deliveries. We employ numerous quality-assurance procedures during our in-house manufacturing processes to ensure finished products meet specification. Quality assurance procedures include operator training, process validation, equipment calibration, inspection and testing. All manufacturing procedures and processes are formally approved and updated using established revision control procedures. Documentation of in-process and final testing results is maintained in device history records for every unit. We also maintain an ongoing post-sale performance-monitoring program.

**Competition**

The medical device industry is subject to intense competition. We currently have three competitors in the U.S. market. The competitive devices are based on signal-processing of the EEG and are marketed by well-established medical products companies with significant resources. We believe that new competition will come from companies, including patient monitoring companies, currently marketing conventional EEG monitors utilizing standard signal-processing techniques such as spectral edge frequency analyses and median frequency analyses. We also believe that new competition will come from companies that market EEG monitors utilizing novel signal-processing technologies. Several potential competitive products are currently being marketed outside the United States although we do not believe that these products provide any significant advantages relative to our BIS technology. These other products and techniques include the use of auditory evoked potentials, heart rate variability, pupillary reflexes and skin blood flow measurement techniques. Additionally, a number of academic researchers worldwide are studying the potential use of other techniques to measure the effects of anesthetics.

We believe that the principal competitive factors that companies in the market for anesthesia-monitoring products must address include:

- improved patient outcomes,
- cost effectiveness,
- FDA approval/clearance,

- acceptance by leading anesthesia providers,
- ease of use for anesthesia providers,
- the publication of peer reviewed clinical studies,
- sales and marketing capability,
- timing and acceptance of product innovation,
- patent protection, and
- product quality.

**Patents and Proprietary Rights**

Medical technology companies place considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. We consider the protection of our proprietary technologies and products to be important to the success of our business and rely on a combination of patents, licenses, copyrights and trademarks to protect our technologies and products. Our policy is to prosecute and enforce our patents and proprietary technology. We intend to continue to file United States and foreign patent applications to protect technology, inventions and improvements that are considered important to the development of our business. We also rely upon trade secrets, know-how, continuing technological innovation and licensing opportunities to develop and maintain our competitive position.

Trade secret protection for our unpatented confidential and proprietary information is important to us. To protect our trade secrets, we generally require our employees, material consultants, scientific advisors, and parties to collaboration and licensing agreements to execute confidentiality agreements upon the commencement of employment, the consulting relationship, or the collaboration or licensing arrangement with us. However, others could either develop independently the same or similar information or obtain access to our proprietary information.

We have established a substantial proprietary position with respect to our products and our core signal processing technology, bispectral analysis, and its application to biological signals. The patent position of medical device companies is highly uncertain and involves complex legal and factual questions. There can be no assurance that any claims which are included in pending or future patent applications will be issued, that any issued patents will provide us with competitive advantage or will not be challenged by third parties, or that the existing or future patents of third parties will not have an adverse effect on our ability to commercialize our products. Furthermore, there can be no assurance that other companies will not independently develop similar products, duplicate any of our products or design around patents that may be issued to us. Litigation or administrative proceedings may be necessary to enforce any patents issued to us or to determine the scope and validity of others' proprietary rights in court or administrative proceedings.

We were issued our most recent patent on August 13, 2002. As of December 31, 2002, we held 17 United States patents and had filed eight additional United States patent applications. We also have numerous corresponding patents and pending patent applications in certain major industrial countries, including Canada,

the major European market countries, Australia, Japan, Mexico and Brazil. The following chart summarizes our United States patents and patent applications:

| Number of Issued Patents | Number of Patent Applications | Technology Covered | Patent Expiration Date |
|---|---|---|---|
| — | 3 | Closed loop delivery of anesthesia | |
| 4 | — | Application of Bispectral and higher order analysis and various statistical modeling technologies to EEG signals | March 13, 2007<br>April 30, 2008<br>June 14, 2011<br>October 17, 2012 |
| 2 | 2 | Methods of ensuring the reliability of the computed values | December 24, 2016<br>January 30, 2018 |
| — | 1 | Method of monitoring anesthetic state using changes in arterial compliance | |
| 1 | — | Method of evaluating BIS information to facilitate clinical decision making | August 18, 2018 |
| 2 | — | Application of bispectral analysis to electrocardiogram signals | May 15, 2007<br>June 4, 2008 |
| — | 1 | Method of assessment of neurological conditions using EEG Bispectrum | |
| 1 | — | Zipprep self-prepping disposable electrode technology | April 26, 2011 |
| 2 | — | Technology relating to the interface between the BIS Sensor and the BIS monitor | October 20, 2015<br>October 20, 2015 |
| 4 | 1 | BIS Sensor technology | October 11, 2016<br>October 11, 2016<br>June 19, 2018<br>June 9, 2019 |
| 1 | — | Signal acquisition technology for digital signal converter | January 17, 2012 |
| 17 | 8 | | |

We have also been granted a perpetual, royalty-free, non-exclusive license by Siemens Medical Systems, Inc. to a United States patent covering signal acquisition technology for digital signal converters. Additionally, on July 12, 2002, we entered into an agreement with the Regents of the University of California under which the Regents of the University of California granted to us an option to enter into a license agreement conveying to Aspect an exclusive license to commercialize brain monitoring technology for depression which was developed by the Neuropsychiatric Institute and David Geffen School of Medicine at UCLA. We may exercise this option at anytime prior to July 12, 2003 by providing written notice to the Regents of the University of California. This option period may be extended by one year for an additional fee. Upon the exercise of our option, both parties have agreed to execute an exclusive license agreement, the terms of which have already been finalized.

**Government Regulation**

The manufacture and sale of medical diagnostic devices intended for commercial distribution and use are subject to extensive government regulation in the United States and in other countries. Our existing products are regulated in the United States as medical devices by the FDA under the Federal Food, Drug, and Cosmetic Act, or FDC Act. Pursuant to the FDC Act, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, record keeping, advertising, distribution and production of medical devices. Noncompliance with applicable regulations can result in refusal of the government to grant clearance for devices, withdrawal of prior clearances or approvals, total or partial suspension of production, fines, injunctions, civil penalties, recall or seizure of products and criminal prosecution.

Generally, before we can introduce a new product in the United States, we must obtain FDA clearance of a premarket notification under Section 510(k) of the FDC Act, referred to as a 510(k) notification, or approval of a premarket approval application under Section 515 of the FDC Act. To date, we have received clearance of 510(k) notification from the FDA with respect to the following products:

- Zipprep EEG Electrodes (June 1994),
- A-1050 EEG Monitor with BIS (January 1996),
- BIS Standard Sensor (October 1996),
- BIS Clinical Utility Indication (October 1996),
- A-2000 BIS Monitor (February 1998),
- BIS Sensor Plus (January 2000),
- BIS Pediatric Sensor (October 2000),
- BIS XP Sensor family, including the BIS Quatro Sensor and BIS Extend Sensor (October 2000),
- BIS Module Kit (October 2000), and
- BIS XP system (June 2001).

Once we have received clearance of a 510(k) notification, any products we manufacture or distribute are subject to extensive and continuing regulation by the FDA, including compliance with current Good Manufacturing Practices regulations, record keeping requirements, reporting of adverse experience with the use of the device, post-market surveillance, and other actions deemed necessary by the FDA. A new 510(k) notification is also required when a medical device manufacturer makes a change or modification to a legally marketed device that could significantly affect the safety or effectiveness of the device, or where there is a major change or modification in the intended use of the device. When any change or modification is made to a device or its intended use, the manufacturer must make the initial determination whether the change or modification is of a kind that would necessitate the filing of a new 510(k) notification. The FDA's regulations provide only limited guidance for making this determination.

The FDC Act regulates our quality control and manufacturing procedures by requiring us to demonstrate and maintain compliance with current Good Manufacturing Practices regulations, including quality systems regulations, as specified by the FDA. This regulation requires, among other things, that:

- we use written procedures to control our product development and manufacturing process,
- we validate, by extensive and detailed testing of every aspect of the process, our ability to produce devices which meet our manufacturing specifications,
- we investigate deficiencies in the manufacturing process or in the products produced, and
- we maintain detailed record keeping.

The current Good Manufacturing Practices regulations are applicable to manufacturers that produce components specifically for use in a medical device, and require design controls and maintenance of service records.

The FDA monitors compliance with current Good Manufacturing Practices regulations by conducting periodic inspections of manufacturing facilities. If violations of applicable regulations are noted during FDA inspections of our manufacturing facilities, the continued marketing of our products may be adversely affected. During the last routine inspection of our manufacturing facility by the FDA, the FDA noted no adverse observations. We believe that we have continued to maintain manufacturing facilities and procedures that are fully compliant with all applicable government quality systems regulations and guidelines.

In June 1998, we obtained ISO 9001/EN 46001 international quality systems registration, a certification showing that our procedures and manufacturing facilities comply with standards for quality assurance and

manufacturing process control. Our compliance with this registration has been confirmed since June 1998 in semi-annual surveillance audits. The ISO 9001 certification, along with the EN 46001, the European Medical Device Directive certification, signifies compliance with the requirements enabling us to affix the CE Mark to our current products. The CE Mark denotes conformity with European standards for safety and allows certified devices to be placed on the market in all European Union countries. After June 1998, medical devices may not be sold in European Union countries unless they display the CE Mark.

We have established a dedicated regulatory and quality assurance group to maintain regulatory compliance and manage all of our quality-assurance activities. This group is responsible for the following activities:

- all regulatory submissions and communications,
- scheduling and performing company-wide audits,
- coordinating product update procedures and corrective actions,
- maintaining adherence to appropriate procedures and applicable requirements related to the FDA's quality systems regulations, and
- coordinating appropriate documentation for FDA and ISO 9001/EN 46001 review and audits.

**Third-Party Reimbursement**

Third-party payors, including Medicare, Medicaid, private health insurance carriers, managed care organizations, health care administration authorities in foreign countries and other organizations, may affect the pricing or demand for our products by regulating the maximum amount of reimbursement provided by these payors to the anesthesia providers, hospitals, outpatient surgical centers or physicians' offices where surgical procedures are performed.

We believe that anesthesia providers will not be separately reimbursed for patient-monitoring activities utilizing the BIS system. When facilities, such as hospitals or outpatient surgical centers, are reimbursed a fixed fee calculated on a per case, per stay, or per capita basis, the cost of monitoring with the BIS system will not be recovered by these providers unless the incremental costs of this monitoring are offset by savings in other costs, such as the costs of anesthetics or costs of the operating room or post-anesthesia care unit. This type of reimbursement policy has been adopted by Medicare, for example, for both inpatient and outpatient surgery. In such cases, patient monitoring with the BIS system may not result in sufficient savings to offset these costs. When reimbursement is based on charges or costs, patient monitoring with the BIS system may have the effect of reducing reimbursement because the charges or costs for surgical procedures, including operating room and post-anesthesia care unit charges and costs, may decline as a result of monitoring with the BIS system.

In January 2002, the Japanese Ministry of Health, Labor and Welfare granted reimbursement approval for use of our BIS monitors. Healthcare providers in Japan will be eligible to receive partial reimbursement of 1,000 yen each time BIS monitoring is used. BIS monitoring is the only commercially available consciousness monitoring technology in Japan.

**Employees**

As of December 31, 2002, we had 205 full-time employees worldwide, of which:

- 26 persons were engaged in research and development activities,
- 31 persons were engaged in manufacturing and engineering,
- 15 persons were engaged in clinical and regulatory affairs,
- 102 persons were engaged in sales and marketing and clinical support, and
- 31 persons were engaged in general and administrative functions.

None of our employees is covered by a collective bargaining agreement. We consider relations with our employees to be good.

**Scientific Advisors**

We seek advice from a number of leading scientists and physicians on scientific and medical matters, including experts in EEG monitoring, pharmacology and anesthesia management. These individuals advise us concerning a number of matters, including:

- our research and development programs,
- the design and implementation of our clinical research program,
- our publication strategies,
- the identification of market opportunities from the clinical perspective, and
- specific scientific and technical issues.

## Item 2. Properties.

We currently lease approximately 61,000 square feet of development, manufacturing, warehouse and administrative space in Newton, Massachusetts pursuant to a lease which expires on December 31, 2006. Our international organization is based in approximately 2,800 square feet of office space, which we lease in Leiden, The Netherlands. We believe our current facilities are sufficient to meet our needs through the fiscal year ending December 31, 2003 and that additional space will be available at a reasonable cost to meet our space needs thereafter.

## Item 3. Legal Proceedings.

We are not a party to any material threatened or pending legal proceedings.

## Item 4. Submission of Matters to a Vote of Security Holders.

No matter was submitted to a vote of security holders during the fourth quarter of the fiscal year ended December 31, 2002 through the solicitation of proxies or otherwise.

## PART II

### Item 5. Market for Registrant's Common Equity and Related Stockholder Matters.

**(a)** ***Market for Registrant's Common Equity***

Our common stock has been traded on the Nasdaq National Market under the symbol "ASPM" since January 28, 2000. The following table sets forth, for the years ended December 31, 2001 and 2002, the range of high and low sales prices for our common stock on the Nasdaq National Market. These prices do not include retail mark-up, mark-down or commissions and may not represent actual transactions.

| | High | Low |
|---|---|---|
| 2001: | | |
| Quarter Ended March 31, 2001 | $14.500 | $6.813 |
| Quarter Ended June 30, 2001 | $16.500 | $9.300 |
| Quarter Ended September 29, 2001 | $15.440 | $9.800 |
| Quarter Ended December 31, 2001 | $11.090 | $8.110 |
| 2002: | | |
| Quarter Ended March 30, 2002 | $11.520 | $7.910 |
| Quarter Ended June 29, 2002 | $10.899 | $3.550 |
| Quarter Ended September 28, 2002 | $ 4.550 | $2.170 |
| Quarter Ended December 31, 2002 | $ 5.500 | $2.410 |

On March 20, 2003, the last reported sales price of our common stock on the Nasdaq National Market was $4.00 per share. As of March 20, 2003, there were approximately 365 holders of record of our common stock.

**(b)** ***Initial Public Offering***

On February 2, 2000, we sold 3,500,000 shares of our common stock, at an initial public offering price of $15.00 per share, pursuant to a Registration Statement on Form S-1 (Registration No. 333-86295), which was declared effective by the Securities and Exchange Commission on January 27, 2000. On February 4, 2000, the underwriters exercised in full their over-allotment option to purchase an additional 525,000 shares of our common stock at $15.00 per share. The managing underwriters of our initial public offering were Morgan Stanley & Co. Incorporated, Deutsche Bank Securities Inc. and U.S. Bancorp Piper Jaffray Inc.

The aggregate gross proceeds raised in the offering were approximately $60.4 million. Our total expenses in connection with the offering were approximately $5.7 million, of which $4.2 million was for underwriting discounts and commissions and, based on our reasonable estimate, approximately $1.5 million was for other expenses. Our net proceeds from the offering were approximately $54.6 million. From January 27, 2000, through December 31, 2002, we used approximately $8.7 million of the net proceeds for the acquisition of machinery and equipment, leasehold improvements, furniture and fixtures, demonstration and evaluation equipment and new information systems. In addition, from January 27, 2000, through December 31, 2002, we used approximately $37.8 million of the net proceeds for general corporate purposes, including the funding of operating losses, working capital, product development, increasing our sales and marketing capabilities and expanding our international operations. As of December 31, 2002, we had approximately $8.1 million of proceeds remaining from the offering, and pending use of the proceeds, we have invested these funds in short-term, interest-bearing, investment-grade securities.

**(c)** ***Dividend Policy***

We have never paid or declared any cash dividends on our common stock or other securities and do not anticipate paying cash dividends in the foreseeable future. We currently intend to retain all future earnings, if any, for use in the operation and expansion of our business. Payment of future cash dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs and plans for expansion. Additionally, our revolving line of credit agreements with each of Fleet National Bank and Boston Scientific Corporation prohibit the declaration or payment of cash dividends without the consent of these lenders.

**Item 6. Selected Consolidated Financial Data.**

The following selected consolidated financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes and other financial information included elsewhere in this Annual Report on Form 10-K. The consolidated statements of operations data for the years ended December 31, 2002, 2001 and 2000, and the consolidated balance sheet data as of December 31, 2002 and 2001, are derived from our audited consolidated financial statements included in this Annual Report on Form 10-K. The consolidated statements of operations data for the years ended December 31, 1999 and 1998 and the consolidated balance sheet data as of December 31, 2000, 1999, and 1998 are derived from our audited consolidated financial statements not included in this Annual Report on Form 10-K. The historical results presented here are not necessarily indicative of future results.

| | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2002 | 2001 | 2000 | 1999 | 1998 |
| | (in thousands, except per share data) | | | | |
| **Consolidated Statements of Operations Data:** | | | | | |
| Revenue | $ 39,776 | $ 35,829 | $36,024 | $27,187 | $ 11,238 |
| Costs of revenue | 11,815 | 12,446 | 11,279 | 9,324 | 5,880 |
| Gross profit margin | 27,961 | 23,383 | 24,745 | 17,863 | 5,358 |
| Operating expenses: | | | | | |
| Research and development | 7,827 | 7,467 | 5,713 | 4,847 | 4,042 |
| Sales and marketing | 28,449 | 28,396 | 21,979 | 16,543 | 10,354 |
| General and administrative | 7,942 | 7,803 | 6,390 | 4,829 | 4,254 |
| Total operating expenses | 44,218 | 43,666 | 34,082 | 26,219 | 18,650 |
| Loss from operations | (16,257) | (20,283) | (9,337) | (8,356) | (13,292) |
| Interest income, net | 956 | 2,564 | 3,993 | 1,317 | 459 |
| Other expense | — | — | — | — | (774) |
| Net loss | $(15,301) | $(17,719) | $(5,344) | $(7,039) | $(13,607) |
| Net loss per share: | | | | | |
| Basic and diluted | $ (0.83) | $ (1.01) | $ (0.34) | $ (4.57) | $ (11.70) |
| Weighted average shares used in computing net loss per share: | | | | | |
| Basic and diluted | 18,450 | 17,614 | 15,755 | 1,539 | 1,163 |

| | December 31, | | | | |
|---|---|---|---|---|---|
| | 2002 | 2001 | 2000 | 1999 | 1998 |
| | (in thousands) | | | | |
| **Consolidated Balance Sheet Data:** | | | | | |
| Cash, cash equivalents and marketable securities | $31,765 | $36,358 | $58,489 | $14,535 | $21,273 |
| Restricted cash | 5,100 | 5,100 | — | — | — |
| Working capital | 36,734 | 41,266 | 58,455 | 12,279 | 19,104 |
| Total assets | 54,480 | 63,369 | 79,411 | 29,402 | 28,589 |
| Long-term debt | 1,015 | 964 | 2,617 | 3,872 | 1,441 |
| Total stockholders' equity | 36,797 | 48,056 | 63,974 | 13,079 | 19,688 |

## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

*This Annual Report on Form 10-K contains, in addition to historical information, forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934. These forward-looking statements involve risks and uncertainties and are not guarantees of future performance. Words such as "expect," "anticipate," "intend," "plan," "believe," "seek," "estimate" and variations of these words and similar expressions are intended to identify forward-looking statements. Our actual results could differ significantly from the results discussed in these forward-looking statements. In addition, subsequent events and developments may cause our expectations to change. While we may elect to update these forward-looking statements we specifically disclaim any obligation to do so, even if our expectations change. See the important factors in the cautionary statements below under the heading "Factors Affecting Future Operating Results" that we believe could cause our actual results to differ materially from the forward-looking statements we make.*

### Overview

We develop, manufacture and market an anesthesia monitoring system that we call the BIS system. The BIS system is based on our patented core technology, the Bispectral Index, which we refer to as the BIS index. The BIS system provides information that allows clinicians to better assess and manage a patient's level of consciousness in the operating room and intensive care settings and administer the precise amount of anesthesia needed by each patient. Our proprietary BIS system includes our BIS monitor, or our BIS Module Kit, which allows original equipment manufacturers to incorporate the BIS index into their monitoring products, and our single-use disposable BIS Sensors. We collectively refer to our group of disposable sensors, including the BIS Standard Sensor, BIS Sensor Plus, BIS Pediatric Sensor, BIS Quatro Sensor and BIS Extend Sensor as BIS Sensors.

We follow a system of fiscal quarters as opposed to calendar quarters. Under this system, the first three quarters of each fiscal year end on the Saturday closest to the end of the calendar quarter and the last quarter of the fiscal year always ends on December 31.

We derive our revenue primarily from sales of monitors, BIS Module Kits, and related accessories, which we collectively refer to as Equipment, and sales of BIS Sensors. In 2002, 2001 and 2000, revenue from the sale of Equipment represented approximately 33%, 32% and 40%, respectively, of our revenue, and revenue from the sale of BIS Sensors represented approximately 67%, 68% and 60%, respectively, of our revenue. We believe our ability to grow our revenue is directly related to our ability to sell our Equipment to healthcare organizations and influence our customers to purchase and use our BIS Sensors. We believe the increase in our installed base of Equipment resulting from the sale of BIS monitors and the sale of original equipment manufacturers' equipment incorporating our BIS Module Kit has been the primary reason for the growth in revenue from the sale of BIS Sensors. Our domestic per monitor sensor utilization rate has remained relatively flat for the last six fiscal quarters. We believe that although revenue from the sale of BIS Sensors increased from 2001 to 2002, it remained relatively flat as a percentage of total revenue because the growth came from the increase in our installed base rather than a combination of an increase in our installed base and an increase in our per monitor and per module sensor utilization rate.

We believe that in order to successfully grow our business, we need to continue to focus on both selling our Equipment and improving our per monitor and per module sensor utilization rate. To achieve this growth, we continue to implement new sales and marketing programs. We feel that as we grow our business, revenue from the sale of BIS Sensors should contribute an increasing percentage of total revenue. Additionally, we feel that over time, revenue from the sale of BIS Module Kits will increase as a percentage of total Equipment revenue as healthcare organizations avail themselves of the integrated solution offered by our original equipment manufacturers.

For those healthcare organizations desiring to purchase our BIS monitors, we offer two options. Our customers have the option either to purchase BIS monitors outright or to acquire BIS monitors pursuant to a sales-type lease agreement whereby the customer contractually commits to purchase a minimum number of BIS Sensors per BIS monitor per year. Under this agreement, our customers purchase BIS Sensors and the

BIS monitor for the purchase price of the BIS Sensors plus an additional charge per BIS Sensor to pay for the purchase price of the BIS monitor and related financing costs over the term of the agreement. These customers are granted an option to purchase the BIS monitors at the end of the term of the agreement, which is typically three to five years. Revenue related to BIS monitors sold pursuant to sales-type leases is recognized at the time of shipment of the BIS monitors. Sales-type leases accounted for approximately 4%, 3% and 6% of total revenue in 2002, 2001 and 2000, respectively.

Under certain circumstances, we also offer customers the opportunity to use the BIS monitors under our Equipment Placement program, which we refer to as the EP program. Under the EP program, the customer is granted the right to use the BIS monitors for a mutually agreed upon period of time. During this period, the customer purchases BIS Sensors at a price that includes a premium above the list price of the BIS Sensors to cover the rental of the equipment, but without any minimum purchase commitments. At the end of the agreed upon period, the customer has the option of purchasing the BIS monitors, continuing to use them under the EP program or returning them to us. Although we believe that in certain circumstances the EP program may provide an effective method of allowing customers to evaluate and ultimately acquire the BIS technology from us or our original equipment manufacturers, we substantially reduced our focus on the EP program in 2002.

Revenue from domestic sales in 2002, 2001 and 2000 was approximately $33.1 million, $28.2 million and $30.1 million, respectively, which represented approximately 83%, 79% and 84%, respectively, of our revenue. Revenue from international sales in 2002, 2001 and 2000 was approximately $6.7 million, $7.6 million and $5.9 million, respectively, which represented approximately 17%, 21% and 16%, respectively, of our revenue.

We have subsidiaries in The Netherlands and the United Kingdom, to facilitate the sale of our products into the international market. We are continuing to develop our international sales and distribution program through a combination of distributors and marketing partners, including companies with which we have entered into original equipment manufacturer relationships. In January 1998, we entered into a distribution agreement with Nihon Kohden Corporation to distribute BIS monitors in Japan. In March 2000, Nihon Kohden received approval from the Japanese Ministry of Health, Labor and Welfare for marketing in Japan our A-1050 EEG Monitor with BIS and in May 2001, received approval for marketing in Japan our A-2000 BIS Monitor. Nihon Kohden has requested but has not yet received approval to market the BIS XP system in Japan. In January 2002, the Japanese Ministry of Health, Labor and Welfare granted reimbursement approval for use of our BIS monitors. With this approval, healthcare providers in Japan are eligible to receive partial reimbursement of 1,000 Yen each time BIS monitoring is used. In July 2002, the Japanese Ministry of Health, Labor and Welfare approved our BIS module for marketing in Japan. Sales to Nihon Kohden represented approximately 22%, 26% and 39% of international revenue in 2002, 2001 and 2000, respectively.

We believe that maintaining and ultimately improving our gross margin and controlling the growth of our operating expenses are important factors for us to manage in order to successfully grow our business and achieve profitability. To maintain our gross margin we believe we need to continue to focus on increasing our average unit prices for both monitors and BIS Sensors as we did in 2002, increase revenue from the sale of BIS Sensors as a percentage of total revenue and continue to reduce the costs to manufacture our products. In 2002, we reduced our headcount. We believe this headcount reduction, in combination with other cost reductions implemented in 2002 and to be implemented in 2003, should drive us closer to our goal of achieving profitability.

Various factors may adversely affect our quarterly operating results through the first fiscal quarter of 2003 and the year ending December 31, 2003. Among these factors are: first, as we continue to shift the focus of our placements from BIS monitors to BIS modules, Equipment revenue may be adversely affected. Second, in Japan, Nihon Kohden is awaiting approval of the BIS XP system, and we believe customers may delay purchases of our products or may choose not to purchase our products pending this approval. Third, on November 1, 2003, our distribution agreement with Datex-Ohmeda expires and Equipment revenue in the international market may be adversely affected as the expiration date of the agreement approaches.

**Critical Accounting Policies**

Financial Reporting Release No. 60, which was released by the Securities and Exchange Commission, or SEC, in December 2001, proposes a rule that requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Note 2 of the Notes to Consolidated Financial Statements includes a summary of our significant accounting policies and methods used in the preparation of our financial statements. In preparing these financial statements, we have made estimates and judgments of certain amounts included in the financial statements. The application of these accounting policies involves the exercise of judgment and use of assumptions as to future uncertainties and, as a result, actual results could differ from these estimates. We do not believe there is a great likelihood that materially different amounts would be reported under different conditions or using different assumptions. We believe that our critical accounting policies are as follows:

*Revenue Recognition*

Our revenue is recognized in accordance with SEC Staff Accounting Bulletin, or SAB, No. 101, *Revenue Recognition in Financial Statements,* which provides guidance related to revenue recognition in financial statements. We recognize revenue from Equipment sales, disposable product sales and sales-type leases at the time of product shipment when collectibility is reasonably assured. Payments received prior to shipment are recorded as deferred revenue. We have entered into certain licensing and distribution agreements for which payments received in advance are also recorded as deferred revenue. Revenue under these agreements is recognized as earned in accordance with the terms of the respective agreements.

We do not record a provision for estimated sales returns because historically we have experienced only minimal returns that were not covered by warranty reserves. To the extent returns increase in future periods, we would be required to re-evaluate our revenue recognition policy in accordance with Statement of Financial Accounting Standards, or SFAS, No. 48, *Revenue Recognition When Right of Return Exists.*

*Accounts Receivable*

We determine our allowance for doubtful accounts by using estimates based on our historical collections experience, current trends, historical write-offs of our receivables, credit policy and a percentage of our accounts receivable by aging category. We also review the credit quality of our customer base as well as changes in our credit policies. We continuously monitor collections and payments from our customers. While credit losses have historically been within our expectations and the provisions established, we cannot guarantee that we will continue to experience the same credit loss rates that we have in the past. To the extent we experience a deterioration in our historical collections experience or increased credit losses, bad debt expense would likely increase in future periods.

*Inventories*

We value inventory at the lower of cost or estimated market, and determine cost on a first-in, first-out basis. We regularly review inventory quantities on hand and record a provision for excess or obsolete inventory primarily based on production history and on our estimated forecast of product demand. The medical industry in which we market our products is characterized by rapid product development and technological advances that could result in obsolescence of inventory. Additionally, our estimates of future product demand may prove to be inaccurate, in which case we will need to change our estimate of the provision required for excess and obsolete inventory. If revisions are deemed necessary, we would recognize the adjustments in our costs of revenue at the time of the determination. Therefore, although we continually update our forecasts of future product demand, any significant unanticipated changes in demand or technological developments could have a significant impact on the value of our inventory and our results of operations in future periods.

*Investment in Sales-Type Leases*

We follow SFAS No. 13, *Accounting For Leases,* for our investment in sales-type leases. Under our sales-type leases, customers purchase BIS Sensors and the BIS monitor for the purchase price of the BIS Sensors

plus an additional charge per BIS Sensor to pay for the purchase price of the BIS monitor and related financing costs over the term of the agreement. In accordance with SFAS No. 13, the minimum lease payment, consisting of the additional charge per BIS Sensor, less the unearned interest income, which is computed at the interest rate implicit in the lease, is recorded as net investment in sales-type leases. The cost of the BIS monitor acquired by the customer is recorded as costs of revenue in the same period.

In addition, we periodically review and assess the net realizability of our investment in sales-type leases. This review includes determining if a customer who entered into a sales-type lease is significantly underperforming relative to the customer's committed level of BIS Sensor purchases. If this review results in a lower estimate of the net realizable investment balance, an allowance for the unrealized amount is established in the period in which the estimate is changed and is charged to revenue. Therefore, if in any period where we determine that a significant number of customers who entered into sales-type leases are underperforming in their respective commitments, it could have an impact on our results of operations.

*Warranty*

Equipment that we sell is generally covered by a warranty period of one year. We accrue a warranty reserve for estimated costs to provide warranty services. Our estimate of costs to service our warranty obligations is based on our historical experience and expectation of future conditions. While our warranty costs have historically been within our expectations and the provisions established, to the extent we experience increased warranty claim activity or increased costs associated with servicing those claims, our warranty accrual will increase, and we would experience decreased gross profit.

**Results of Operations**

The following table presents, for the periods indicated, information expressed as a percentage of revenue. This information has been derived from our consolidated statements of operations included elsewhere in this Annual Report on Form 10-K. You should not draw any conclusions about our future results from the results of operations for any period.

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2002 | 2001 | 2000 |
| Revenue | 100% | 100% | 100% |
| Costs of revenue | 30 | 35 | 31 |
| Gross profit margin | 70 | 65 | 69 |
| Operating expenses: | | | |
| Research and development | 20 | 21 | 16 |
| Sales and marketing | 71 | 79 | 61 |
| General and administrative | 20 | 22 | 18 |
| Total operating expenses | 111 | 122 | 95 |
| Loss from operations | (41) | (57) | (26) |
| Interest income, net | 2 | 7 | 11 |
| Net loss | (39)% | (50)% | (15)% |

***Year Ended December 31, 2002 Compared to Year Ended December 31, 2001***

*Revenue.* Our revenue increased to approximately $39.8 million in 2002 from approximately $35.8 million in 2001, an increase of approximately 11%. Revenue from the sale of Equipment increased to approximately $13.1 million in 2002 from approximately $11.5 million in 2001, an increase of approximately 14%. We believe that the primary factor that contributed to the increase in revenue from the sale of Equipment in 2002 as compared to 2001 was that revenue from the sale of accessories, particularly sales of the

BIS XP system upgrade kits, increased approximately 117% in 2002 compared to 2001. Additionally, we had an approximately 8% increase in monitor revenue. The increase in monitor revenue resulted from an approximately 32% increase in the monitor average unit price partially offset by an approximately 11% decrease in monitor unit volume. The decrease in monitor unit volume was primarily related to a reduction of sales in Japan from 430 units in 2001 to 200 units in 2002 as Nihon Kohden delayed additional monitor purchases pending Japanese Ministry of Health, Labor and Welfare approval of our BIS XP system. The increase in the monitor average unit price reflects an approximately 60% increase in the domestic average selling price of monitors in 2002 compared to 2001. Offsetting the increase in monitor revenue was an approximately 37% decrease in revenue from the sale of modules which resulted from an approximately 37% decrease in module unit volume.

Revenue from the sale of BIS Sensors increased to approximately $26.7 million in 2002 from approximately $24.3 million in 2001, an increase of approximately 10%. The increase in revenue from the sale of BIS Sensors from 2001 to 2002 was primarily attributable to an approximately 8% increase in the number of BIS Sensors sold as a result of growth in the installed base of monitors and modules and a slight increase in the our average selling price of the BIS Sensors. Our installed base of monitors and modules increased approximately 18% to more than 16,000 units at December 31, 2002 compared to December 31, 2001.

Our gross profit margin was approximately 70% of revenue in 2002 as compared to a gross profit margin of approximately 65% of revenue in 2001. The increase in gross profit margin percentage for the year ended December 31, 2002 was a result of two factors. First, we experienced increased sales of our BIS Sensors as a percentage of total revenue. BIS Sensors have a higher gross margin than Equipment. Second, we experienced an increase in the average worldwide selling price of monitors of approximately 32% in the year ended December 31, 2002 compared to the year ended December 31, 2001. We expect our gross profit margin to increase slightly in 2003 as we expect revenue from the sale of BIS Sensors to increase as a percentage of total revenue.

*Research and Development.* Research and development expenses increased to approximately $7.8 million in 2002 from approximately $7.5 million in 2001, an increase of approximately 5%. This increase in research and development expenses was primarily attributable to increases in research and development personnel and related payroll and other expenses of approximately $735,000, which included approximately $194,000 related to the reduction in force announced in November 2002, consulting expenses of approximately $119,000 and approximately $33,000 in patent related expenses. These increases were offset by a decrease in product development expenses of approximately $190,000 as a result of the completion of the development of our BIS XP system and BIS Extend Sensor and a decrease in clinical studies expenses of approximately $150,000. We expect research and development expenses in 2003 to be comparable to that of 2002.

*Sales and Marketing.* Sales and marketing expenses remained flat at approximately $28.4 million in 2002 and 2001. During 2002, there were increases in expenses related to clinical education initiatives of approximately $168,000 and in operating expenses associated with our international subsidiaries of approximately $1.1 million, of which approximately $783,000 was personnel and related payroll and other expenses. The international personnel and related payroll expenses included approximately $520,000 of severance, including amounts related to the resignation in January 2002 of our vice president and managing director of international and the reduction of force announced in November 2002. These increases were offset by decreases in consulting expenses of approximately $710,000, expenses associated with increasing our name and brand awareness through advertising, public relations, tradeshows and the internet of approximately $293,000 and approximately $65,000 in sales and marketing personnel and related payroll and other expenses, net of approximately $72,000 related to the reduction in force. We expect sales and marketing expenses to decrease in 2003 as a result of cost reductions in various programs and improved control over discretionary spending.

*General and Administrative.* General and administrative expenses increased slightly to approximately $7.9 million in 2002 from approximately $7.8 million in 2001, an increase of approximately 2%. This increase in general and administrative expenses was attributable to increases in professional and consulting expenses of approximately $291,000, insurance expense of approximately $355,000 and general and administrative personnel and related payroll and other expenses of approximately $97,000. The increases in general and

administrative expenses were offset by decreases in investor relations expenses of approximately $137,000 and franchise, use and other tax expenses of approximately $185,000. We expect general and administrative expenses to decrease slightly during 2003 as compared to 2002 as a result of cost reductions implemented in 2002 and to be implemented in 2003.

*Interest Income, Net.* Net interest income decreased to approximately $956,000 in 2002 from approximately $2.6 million in 2001, a decrease of approximately 63%. Interest income decreased to approximately $1.2 million in 2002 from approximately $2.9 million in 2001, a decrease of approximately 59%. The decrease in interest income was primarily attributable to lower cash and investment balances resulting from continued operating losses and other uses of cash and lower interest rates on our investments as a result of general interest rate declines. Interest expense decreased to approximately $243,000 in 2002 from approximately $365,000 in 2001, a decrease of approximately 34%. The decrease in interest expense in 2002 was a result of the repayment of our equipment and term loans in May 2001, lower average outstanding debt obligations resulting from payments under our other debt obligations, and lower interest rates on our working capital line of credit as compared to the equipment and term loans. We expect net interest income to decline in 2003 as a result of continuing low interest rates and a lower cash and investment balance.

*Net Loss.* As a result of the factors discussed above, in 2002 we had a net loss of approximately $15.3 million as compared to a net loss of approximately $17.7 million in 2001.

***Year Ended December 31, 2001 Compared to Year Ended December 31, 2000***

*Revenue.* Our revenue decreased slightly to approximately $35.8 million in 2001 from approximately $36.0 million in 2000, a decrease of approximately 1%. Revenue from the sale of Equipment decreased to approximately $11.5 million in 2001 from approximately $14.6 million in 2000, a decrease of approximately 21%. The decrease in revenue from the sale of Equipment in 2001 as compared to 2000 was primarily attributable to a decrease of approximately 35% in the number of monitors sold, partially offset by the sale of BIS Module Kits in 2001. We did not sell any BIS Module Kits in 2000. We believe there were three primary factors that contributed to the decrease in Equipment revenue for the year ended December 31, 2001 as compared to the year ended December 31, 2000. During the first half of 2001, many of our customers received the right to use our monitors under our Equipment Placement program, which was introduced in the second half of 2000, and had an adverse impact on our revenue from the sale of Equipment for the year ended December 31, 2001 as compared to the year ended December 31, 2000. Under the Equipment Placement program, monitors are placed free of charge for customers that agree to purchase BIS Sensors for a premium price. Second, because of FDA approval of a competitive monitoring product in 2000, some domestic customers did not purchase our products in order to evaluate the competitive product. Third, revenue from Japan decreased approximately 15% for the year ended December 31, 2001 as compared to the year ended December 31, 2000 primarily because our Japanese distributor delayed purchases in the early part of 2001 while awaiting marketing approval for our A-2000 BIS Monitor from Japan's Ministry of Health, Labor and Welfare. This approval was received in May 2001. The decrease in revenue from the sale of Equipment for the year ended December 31, 2001, was offset in part by an increase in BIS Sensor revenue of approximately 14% as compared to the year ended December 31, 2000.

Revenue from the sale of BIS Sensors increased to approximately $24.3 million in 2001 from approximately $21.4 million in 2000, an increase of approximately 14%. The increase in revenue from the sale of BIS Sensors from the year ended December 31, 2000 to the year ended December 31, 2001 was primarily attributable to a 14% increase in the number of BIS Sensors sold as a result of growth in the installed base of monitors and modules.

Our gross profit margin was approximately 65% of revenue in 2001 as compared to a gross profit margin of approximately 69% of revenue in 2000. The decrease in the gross profit margin for the year ended December 31, 2001 was primarily the result of five factors. First, we had increased cost of revenue related to the additional depreciation on monitors placed under our Equipment Placement program and monitors used by customers for evaluation purposes. Second, we had a lower gross margin percentage on the BIS Module Kits and accessories as compared to monitors and BIS Sensors. Third, we experienced an increase in the

amount of manufacturing overhead cost due to reduced monitor production in the second half of 2001. In addition, we had a lower gross profit margin as a result of the introduction of the BIS XP upgrade kits as we sold them at a special introductory price to encourage early adoption of the BIS XP system. Finally, in the second half of 2001, we had increased manufacturing inefficiencies due to the transition to the BIS XP system.

*Research and Development.* Research and development expenses increased to approximately $7.5 million in 2001 from approximately $5.7 million in 2000, an increase of approximately 31%. This increase in research and development expenses was primarily attributable to an increase in research and development personnel and related payroll and other expenses of approximately $678,000, which represented approximately 39% of the increase, and an increase in clinical study expenses of approximately $412,000, which accounted for approximately 24% of the increase, including the three multi-center, multinational studies to determine the incidence of awareness during BIS monitoring that we sponsored. In addition, the increase in research and development expenses for the year ended December 31, 2001 as compared to the year ended December 31, 2000, was attributable to increased costs incurred in connection with the continued product development efforts related to the BIS Quatro Sensor, BIS Extend Sensor and BIS Pediatric Sensor, the BIS Module Kit and product improvement efforts related to the BIS XP system and its introduction to the critical care area.

*Sales and Marketing.* Sales and marketing expenses increased to approximately $28.4 million in 2001 from approximately $22.0 million in 2000, an increase of approximately 29%. This increase in sales and marketing expenses primarily attributable to an increase in sales and marketing personnel and related payroll and other expenses, which represented approximately 40% of the increase, an increase in expenses associated with increasing name and brand awareness through advertising, public relations and the internet, which accounted for approximately 17% of the increase, an increase in consulting expenses primarily relating to our investment in new sales and marketing programs, which represented approximately 9% of the increase, an increase in operating expenses associated with our international subsidiaries, which accounted for approximately 12% of the increase, and an increase in fees and commissions related to the agreements with group purchasing organizations, original equipment manufacturers and distributors, which represented approximately 7% of the increase.

*General and Administrative.* General and administrative expenses increased to approximately $7.8 million in 2001 from approximately $6.4 million in 2000, an increase of approximately 22%. This increase in general and administrative expenses was attributable to an increase in general and administrative personnel and related payroll and other expenses, which represented approximately 11% of the increase. The increase also included an increase in expenses related to legal services, audit and tax services, insurance expenses, and other professional services, which represented approximately 51% of the increase. We also had an increase in franchise taxes, which represented approximately 20% of the increase, due to our increased presence in states that assess franchise taxes on companies without net income.

*Interest Income, Net.* Net interest income decreased to approximately $2.6 million in 2001 from approximately $4.0 million in 2000, a decrease of approximately 36%. Interest income decreased to approximately $2.9 million in 2001 from approximately $4.7 million in 2000, a decrease of approximately 38%. The decrease in interest income was primarily attributable to lower cash and investments balances resulting from continued operating losses and other uses of cash and lower interest rates on our investments as a result of general interest rate declines. Interest expense decreased to approximately $365,000 in 2001 from approximately $713,000 in 2000, a decrease of approximately 49%. The decrease in interest expense in 2001 was a result of the repayment of our equipment and term loans in May 2001, lower average outstanding debt obligations resulting from payments under our other debt obligations, and lower interest rates on our working capital line of credit as compared to the equipment and term loans.

*Net Loss.* As a result of the factors discussed above, in 2001 we had a net loss of approximately $17.7 million as compared to a net loss of approximately $5.3 million in 2000, an increase of approximately 232%.

**Quarterly Results of Operations**

The following table sets forth unaudited selected operating results for each of the eight fiscal quarters in the two fiscal years ended December 31, 2002. We believe that the following selected quarterly information includes all adjustments (consisting only of normal, recurring adjustments) that we consider necessary to present this information fairly. This financial information should be read in conjunction with the financial statements and related notes included elsewhere in this Annual Report on Form 10-K. Our results of operations have fluctuated in the past and are likely to continue to fluctuate significantly from quarter to quarter in the future. Therefore, results of operations for any previous periods are not necessarily indicative of results of operations to be recorded in the future.

| | Quarter Ended | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | March 31, 2001 | June 30, 2001 | September 29, 2001 | December 31, 2001 | March 30, 2002 | June 29, 2002 | September 28, 2002 | December 31, 2002 |
| Revenue | $ 8,863 | $ 8,973 | $ 8,528 | $ 9,465 | $ 9,687 | $10,051 | $ 9,995 | $10,043 |
| Gross margin | 6,092 | 6,093 | 5,477 | 5,721 | 6,169 | 7,027 | 7,192 | 7,573 |
| Operating expenses | 10,812 | 11,084 | 10,823 | 10,948 | 11,143 | 10,917 | 10,828 | 11,330 |
| Net loss | (3,797) | (4,267) | (4,837) | (4,818) | (4,699) | (3,662) | (3,406) | (3,534) |

**Liquidity and Capital Resources**

Our liquidity requirements have historically consisted of research and development expenses, sales and marketing expenses, capital expenditures, working capital and general corporate expenses. From our inception through January 2000, we financed our operations primarily from the sale of our convertible preferred stock. Through December 31, 2002, we raised approximately $77.6 million from private equity financings and have received approximately $3.4 million in equipment financing and approximately $4.9 million of financing related to our investments in sales-type leases. We also received approximately $2.8 million of financing under a term loan in December 1999. The outstanding principal on the equipment and term loans was paid in May 2001. In February 2000, we closed our initial public offering of an aggregate of 4,025,000 shares of common stock and received net proceeds of approximately $54.6 million. In May 2001, we entered into an agreement with Fleet National Bank for a $5.0 million revolving line of credit which expires in May 2004. The revolving line of credit agreement contains restrictive covenants that require us to maintain liquidity and net worth ratios and is secured by certain of our investments which are shown as restricted cash on our consolidated balance sheets. We are required to maintain restricted cash and securities with a net equity value equal to 102% of the $5.0 million commitment.

In August 2002, we entered into a strategic alliance with Boston Scientific Corporation whereby we sold 1,428,572 shares of our common stock at a purchase price per share of $7.00 to Boston Scientific Corporation pursuant to a stock purchase agreement. Gross cash proceeds from this sale of common stock were $10,000,004. Upon the closing date of the stock purchase agreement, approximately $6,300,000 of the aggregate purchase price was recorded as deferred revenue in our consolidated balance sheet. This amount represents the difference between the purchase price of $7.00 per share and the closing price of our common stock on the date of sale. The deferred revenue will be recognized ratably over the term of the OEM product development and distribution agreement that we entered into with Boston Scientific Corporation in August 2002.

In August 2002, we also entered into an agreement with Boston Scientific Corporation for a revolving line of credit. We are entitled to borrow up to $5.0 million under the revolving line of credit which expires in August 2007 and may be extended at the discretion of Boston Scientific Corporation. Interest on any borrowings under this revolving line of credit is at a rate equal to the LIBOR rate at which Boston Scientific Corporation, under its own revolving credit facility, is entitled to borrow funds plus any additional amounts payable thereon by Boston Scientific Corporation under such revolving credit facility, plus eighty basis points. Our revolving line of credit with Boston Scientific Corporation is secured by our inventory and certain of our accounts receivable and contains certain restrictive covenants covering the collateral. At December 31, 2002, there was no outstanding balance under this revolving line of credit.

We expect to meet our short-term liquidity needs through the use of cash and short-term investments on hand at December 31, 2002.

We believe that the financial resources available to us, including our current working capital and availability under our revolving lines of credit will be sufficient to finance our planned operations and capital expenditures through the end of 2004. However, our future liquidity and capital requirements will depend upon numerous factors, including the resources required to further develop our marketing and sales organization domestically and internationally, to finance our research and development programs, to implement new marketing programs, to finance our sales-type lease program and EP program and to meet market demand for our products.

Working capital at December 31, 2002 was approximately $36.7 million compared to approximately $41.3 million at December 31, 2001. The decrease in working capital from December 31, 2001 to December 31, 2002 was primarily attributable to our continued net loss of approximately $15.3 million, offset by gross proceeds of approximately $10.0 million received from the sale of our common stock in connection with the strategic alliance entered into in August 2002.

We used approximately $4.7 million of cash for operations in 2002. Cash used for operations during this period was primarily driven by operating losses, an increase in our investment in sales-type leases of approximately $734,000 and a decrease in accounts payable and accrued liabilities of approximately $627,000. These were offset by decreases in accounts receivable of approximately $829,000 and inventory of approximately $2.8 million due to improved inventory management and production forecasts, and an increase in deferred revenue of approximately $5.9 million. The increase in deferred revenue is related to proceeds received in connection with the strategic alliance entered into in August 2002. Of the approximately $10.0 million received from Boston Scientific Corporation, approximately $6.3 million was recorded as deferred revenue and represents the portion of the purchase price of the shares of our common stock sold to Boston Scientific Corporation in excess of the closing price of our common stock on the date of the sale. We used approximately $26.0 million for operations during the three years ended December 31, 2002 which was primarily driven by operating losses.

We received approximately $801,000 of cash from investing activities in 2002. The cash received from investing activities in 2002 was primarily the result of the sales and maturities of our investments in marketable securities. We received approximately $1.8 million, net, of proceeds from sales and maturities of marketable securities and invested approximately $1.0 million primarily for improvements to our information systems. We used approximately $33.3 million for investing activities during the three years ended December 31, 2002. We invested approximately $19.2 million, net, in marketable securities, approximately $8.0 million in manufacturing equipment, leasehold improvements, furniture and fixtures, demonstration and evaluation equipment and new information systems, approximately $1.0 million, net, in loans to related parties and increased restricted cash by $5.1 million during the three years ended December 31, 2002.

We received approximately $1.1 million of cash from financing activities in 2002 primarily as a result of proceeds from the sale of our common stock in connection with a strategic alliance entered into in August 2002 and proceeds from the sales of our investment in sales-type leases, partially offset by payments of principal on debt and the pay down of our working capital line of credit. We received approximately $57.3 million of cash from financing activities during the three years ended December 31, 2002. Cash provided by financing activities during this period was primarily the result of the closing of our initial public offering, proceeds from the sale of shares of our common stock in connection with a strategic alliance and the sale of a portion of our investments in sales-type leases offset by payments on our equipment loan, term loan and debt related to our investment in sales-type leases.

In May 2001, we paid the outstanding principal on both the equipment portion and term loan portion of our loan agreement with Imperial Bank and terminated the agreement. Following this termination, we entered into an agreement with Fleet National Bank for a revolving line of credit. The revolving line of credit is for $5.0 million and expires in May 2004 and, subject to annual review by the bank, may be extended at the discretion of Fleet National Bank. Interest on any borrowings under the revolving line of credit is, at our election, either the prime rate or at LIBOR plus 2.25%. At December 31, 2002, the interest rate on the line of

credit was 4.25%. The revolving line of credit agreement contains restrictive covenants that require us to maintain liquidity and net worth ratios and is secured by certain of our investments which are shown as restricted cash on our consolidated balance sheet. We are required to maintain restricted cash and securities with a net equity value equal to 102% of the $5.0 million commitment. Up to $1.5 million of the $5.0 million revolving line of credit is available for standby letters of credit. There was no outstanding balance under the line of credit at December 31, 2002. At December 31, 2002, we had standby letters of credit outstanding in the amount of approximately $295,000.

We guarantee certain operating lease obligations of our subsidiaries of approximately $293,000 for the lease of office space and automobiles.

In July 1999, we entered into an agreement under which we can sell a portion of our existing and future investments in sales-type leases to Americorp Financial, Inc. Through December 31, 2002, we sold approximately $4.9 million of our investments in sales-type leases. In accordance with SFAS No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities — A replacement of FASB Statement No. 125*, the proceeds from these sales are classified as debt. Payments on the outstanding principal under this debt match the timing of the payments due on the underlying investments in sales-type leases. At December 31, 2002, approximately $1.9 million is recorded as debt on our consolidated balance sheet.

We had capital expenditures of approximately $1.0 million for the year ended December 31, 2002 which related primarily to improvements to our information systems. At December 31, 2002, we did not have any commitments for capital expenditures however, we anticipate that the level of capital expenditures in 2003 will remain comparable to or increase slightly from the level of capital expenditures during the year ended December 31, 2002.

We have summarized below our contractual cash obligations as of December 31, 2002.

| | Payments Due By Period | | | | |
|---|---|---|---|---|---|
| **Contractual Obligations** | **Total** | **Less Than One Year** | **One to Three Years** | **Four to Five Years** | **After Five Years** |
| Operating leases | $4,425,435 | $1,250,234 | $2,180,005 | $ 995,196 | $ — |
| Debt related to the sale of investment in sales type leases | 1,902,639 | 887,538 | 979,547 | 35,554 | — |
| Total contractual cash obligations | $6,328,074 | $2,137,772 | $3,159,552 | $1,030,750 | $ — |

**Income Taxes**

We have net operating loss and research and development tax credit carryforwards for federal income tax purposes of approximately $79,106,000 and $1,888,000, respectively, at December 31, 2002 that began expiring in 2002 and will continue to expire through 2022 if not utilized.

The net operating loss and research and development tax credit carryforwards are subject to review by the Internal Revenue Service. Ownership changes, as defined under Section 382 in the Internal Revenue Code, may limit the amount of these tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on our value immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years.

**Effects of Inflation**

We believe that inflation and changing prices over the past three years have not had a significant impact on our revenue or on our results of operations.

**Conversion to Euro**

Twelve of the 15 members of the European Union have adopted the Euro as their legal currency. Our current information systems allow us to process Euro-denominated transactions. We are also assessing the business implications of the conversion to the Euro, including long-term competitive implications and the effect of market risk with respect to financial instruments. The majority of our international sales are denominated in U.S. dollars. We do not believe the Euro has had a significant effect on our business, financial condition or results of operations. However, the expenses and capital spending of our international subsidiaries are transacted in the respective country's local currency. As a result, changes in foreign currency exchange rates or weak economic conditions in foreign markets could affect our financial condition or results of operations.

**Recent Accounting Pronouncements**

In June 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities.* SFAS 146 requires that a liability for a cost associated with an exit or disposal activity be recognized and measured, initially at fair value, only when the liability is incurred; therefore, nullifying Emerging Issues Task Force, or EITF, Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)*, which required a liability for an exit cost to be recognized at the date of an entity's commitment to an exit plan. This change in accounting would be expected to result in a delayed recognition of certain types of costs, especially facility closure costs. The provisions of SFAS 146 are effective for exit or disposal activities that are initiated after December 31, 2002. Since SFAS 146 is effective only for new exit or disposal activities, adoption of this standard will not affect amounts currently reported in our consolidated financial statements. However, the adoption of SFAS 146 could affect the types and timing of costs included in any future business consolidation and restructuring programs. We adopted SFAS 146 as of January 1, 2003.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation — Transition and Disclosure.* SFAS 148 amends SFAS 123 and APB No. 28, *Interim Financial Reporting,* to present alternative methods of transition for an entity that voluntarily adopts the fair value based method of accounting for stock-based employee compensation, and provides modifications to the disclosure provisions to require prominent disclosure about the effects on reported net income of an entity's accounting policy decisions with respect to stock-based employee compensation in quarterly and annual financial statements. At this time, we have not voluntarily adopted the fair value method of accounting under SFAS 123. However, appropriate disclosures about the effects on reported net loss of our accounting policy with respect to stock-based employee compensation is reported in our consolidated financial statements.

In November 2002, the FASB issued Financial Interpretation No. 45, or FIN 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others.* FIN 45 requires a guarantor to disclose (a) the nature of the guarantee, and the events or circumstances that would require the guarantor to perform under the guarantee; (b) the maximum potential amount of future payments under the guarantee; (c) the carrying amount of the liability, if any, for the guarantor's obligations under the guarantee; and (d) the nature and extent of any recourse provisions or available collateral that would enable the guarantor to recover the amounts paid under the guarantee. FIN 45 also clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability at fair value for the obligations it has undertaken in issuing the guarantee, including its ongoing obligation to stand ready to perform over the term of the guarantee in the event that the specified triggering events or conditions occur. The initial recognition and initial measurement provision of FIN 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. FIN 45 also addresses the disclosure requirements regarding product warranties. Instead of disclosing the maximum potential amount of future payments under the product warranty guarantee, a guarantor is required to disclose its accounting policy and methodology used in determining its liability for product warranties, as well as, a tabular reconciliation of the changes in the guarantor's product warranty liability for the reporting period. We adopted FIN 45 as of January 1, 2003. We do not expect FIN 45 to have a material impact on our results of operations, cash flows or financial position.

**Factors Affecting Future Operating Results**

This Annual Report on Form 10-K includes forward-looking statements, including information relating to our ability to achieve profitability, information with respect to market acceptance of our BIS system, continued growth in sales of our BIS monitors, BIS Module Kits and BIS Sensors, our dependence on the BIS system, our ability to remain competitive and achieve future growth, information with respect to other plans and strategies for our business and factors that may influence our revenue for each fiscal quarter in 2003 and for the year ending December 31, 2003. The following important factors represent current challenges to us that create risk and uncertainty. Failure to adequately overcome any of the following challenges could have a material adverse effect on our results of operations, business or financial condition.

***We will not be profitable if hospitals and anesthesia providers do not buy and use our BIS system in sufficient quantities.***

Our customers may determine that the cost of the BIS system exceeds cost savings in drugs, personnel and post-anesthesia care recovery resulting from use of the BIS system. In addition, hospitals and anesthesia providers may not accept the BIS system as an accurate means of assessing a patient's level of consciousness during surgery or in the intensive care unit. If extensive or frequent malfunctions occur, these providers may also conclude that the BIS system is unreliable. If hospitals and anesthesia providers do not accept the BIS system as cost-effective, accurate and reliable, they will not buy and use the BIS system in sufficient quantities to enable us to be profitable.

The success of our business also depends in a large part on continued use of the BIS system by our customers and, accordingly, sales by us of BIS Sensors. We expect that over time sales of BIS Sensors will increase as a percentage of our revenue as compared to sales of Equipment as we build our installed base of monitors and modules. Nevertheless, sales of BIS Sensors as a percentage of revenue decreased slightly during 2002 as compared to 2001. If use of our BIS system, and accordingly, sales of our BIS Sensors, do not increase, it could adversely affect our revenue.

***We depend on our BIS system for substantially all of our revenue, and if the BIS system does not gain widespread market acceptance, then our revenue will not grow.***

We began selling our current BIS system in early 1998 and introduced the latest version, the BIS XP system, at the end of the third fiscal quarter of 2001. In 2002, we introduced commercially the BIS Extend Sensor for patients who are monitored over an extended period of time, such as in intensive care settings. To date, we have not achieved widespread market acceptance of the BIS system for use in the operating room or in the intensive care unit. Because we depend on our BIS system for substantially all of our revenue and we have no other significant products, if we fail to achieve widespread market acceptance for the BIS system, we will not be able to sustain or grow our product revenue.

***Various market factors may adversely affect our quarterly operating results through the first fiscal quarter of 2003 and for the year ending December 31, 2003.***

In addition to the factors identified herein, various other factors may adversely affect our quarterly operating results through the first fiscal quarter of 2003 and for the year ending December 31, 2003. First, we continue to shift the focus of our placements from BIS monitors to BIS modules which may lead to a reduction in Equipment revenue. Second, in Japan, Nihon Kohden is awaiting approval of the BIS XP system from the Japanese Ministry of Health, Labor and Welfare which may cause possible delays in purchasing decisions by customers in Japan, or these potential customers may choose not to purchase our products. Third, on November 1, 2003, our distribution agreement with Datex-Ohmeda expires, possibly resulting in lost sales from international distributors as the expiration of the Datex-Ohmeda distribution agreement approaches. These factors may adversely impact our revenue through the first fiscal quarter of 2003 and the year ending December 31, 2003. The continuation of difficult worldwide economic conditions, reductions in hospital purchasing programs, and the cost of transitioning our installed base to the new BIS XP system may also

adversely impact our revenue and operating results through the first fiscal quarter of 2003 and for the year ending December 31, 2003.

***Fluctuations in our quarterly operating results could cause our stock price to decrease.***

Our operating results have fluctuated significantly from quarter to quarter in the past and are likely to vary in the future. These fluctuations are due to several factors relating to the sale of our products, including:

- the timing and volume of customer orders for our BIS system,
- the introduction of the BIS XP system,
- implementation of, and our reduced focus on, our EP program,
- use of and demand for our BIS Sensors,
- customer cancellations,
- introduction of competitive products,
- changes in management,
- turnover in our direct sales force,
- effectiveness of new marketing and sales programs,
- reductions in orders by our distributors and original equipment manufacturers, and
- the timing and amount of our expenses.

Because of these fluctuations, it is likely that in some future quarter or quarters our operating results could again fall below the expectations of securities analysts or investors. If our quarterly operating results are below expectations in the future, the market price of our common stock would also likely decrease. In addition, because we do not have a significant backlog of customer orders for our BIS system, revenue in any quarter depends on orders received in that quarter. Our quarterly results may also be adversely affected because some customers may have inadequate financial resources to purchase our products or may fail to pay for our products after receiving them. In particular, hospitals are increasingly experiencing financial constraints, consolidations and reorganizations as a result of cost containment measures and declining third-party reimbursement for services, which may result in decreased product orders or an increase in bad debts in any quarter.

***If approval of our BIS XP system is not obtained in Japan, our revenue and operating results could be adversely affected.***

In Japan, Nihon Kohden is awaiting approval of the BIS XP system from the Japanese Ministry of Health, Labor and Welfare. Until approval is obtained, customers in Japan may delay or reconsider their purchasing decisions with respect to our products. As a result, if approval for this product is not obtained in Japan in the near future, or at all, it could limit the growth of our international revenue.

***We may need additional financing for our future capital needs and may not be able to raise additional funds on terms acceptable to us, or at all.***

We believe that the financial resources available to us, including our current working capital and availability under our revolving lines of credit, will be sufficient to finance our planned operations and capital expenditures through the end of 2004. If we are unable to increase our revenue and achieve positive cash flow, we will need to raise additional funds. We may also need additional financing if:

- we need additional cash to fund research and development costs of products currently under development,
- we decide to expand faster than currently planned,

- we develop new or enhanced services or products ahead of schedule,
- we decide to undertake new sales and/or marketing initiatives,
- we are required to defend or enforce our intellectual property rights,
- sales of our products do not meet our expectations in the United States or internationally,
- we need to respond to competitive pressures, or
- we decide to acquire complementary products, businesses or technologies.

We can provide no assurance that we will be able to raise additional funds on terms acceptable to us, if at all. If future financing is not available or is not available on acceptable terms, we may not be able to fund our future needs which would significantly limit our ability to implement our business plan. In addition, we may have to issue securities that may have rights, preferences and privileges senior to our common stock.

***Cases of surgical awareness during monitoring with the BIS system could limit market acceptance of BIS systems and could expose us to product liability claims.***

Clinicians have reported to us cases of possible surgical awareness during surgical procedures monitored with the BIS system. In most of the cases that were reported to us, when BIS index values were recorded at the time of awareness, high BIS index values were noted, indicating that the BIS index correctly identified the increased risk of awareness in these patients. However, in a small number of these reported cases, surgical awareness may not have been detected by monitoring with the BIS system. Not all cases of surgical awareness during surgical procedures monitored with the BIS system may be reported to us, and we have not systematically solicited reports of surgical awareness. Anesthesia providers and hospitals may elect not to purchase and use BIS systems if there is adverse publicity resulting from the report of cases of surgical awareness that were not detected during procedures monitored with the BIS system. If anesthesia providers and hospitals do not purchase and use the BIS system, then we may not sustain or grow our product revenue. Although we do not claim that patient monitoring with the BIS system will reduce the incidence of surgical awareness, we may be subject to product liability claims for cases of surgical awareness during surgical procedures monitored with the BIS system. These claims could require us to spend significant time and money in litigation or to pay significant damages.

We are currently evaluating the data that was collected in our three multi-center, multinational studies to assess the incidence of awareness during BIS monitoring. If the results of these studies do not conclusively demonstrate that patient monitoring with the BIS system will reduce the incidence of surgical awareness, our business could be adversely affected.

***We may not be able to compete with new products or alternative techniques developed by others, which could impair our ability to remain competitive and achieve future growth.***

The medical industry in which we market our products is characterized by rapid product development and technological advances. Our competitors have introduced commercially three FDA-approved anesthesia monitoring products. If we do not compete effectively with these monitoring products, our revenue will be adversely affected. Our current or planned products are at risk of obsolescence from:

- other new monitoring products, based on new or improved technologies,
- new products or technologies used on patients or in the operating room during surgery in lieu of monitoring devices,
- electrical or mechanical interference from new or existing products or technologies,
- alternative techniques for evaluating the effects of anesthesia,

- significant changes in the methods of delivering anesthesia, and

- the development of new anesthetic agents.

We may not be able to improve our products or develop new products or technologies quickly enough to maintain a competitive position in our markets and continue to grow our business.

***If we do not successfully develop and introduce enhanced or new products we could lose revenue opportunities and customers.***

As the market for our BIS system matures, we need to develop and introduce new products for anesthesia monitoring or other applications. In 2002, we introduced commercially the BIS Extend Sensor for patients who are typically monitored for an extended period of time, such as in intensive care unit settings. We do not know whether the use of the BIS system and the BIS Extend Sensor for use in the intensive care unit will achieve market acceptance. In addition, we have begun to research the use of BIS monitoring to diagnose and track neurological diseases. We face at least the following two risks:

- we may not successfully adapt the BIS system to function properly for procedural sedation, when used with anesthetics we have not tested or with patient populations we have not studied, such as infants, and

- our technology is complex, and we may not be able to develop it further for applications outside anesthesia monitoring, such as the diagnosis and tracking of neurological diseases.

If we do not successfully adapt the BIS system for new products and applications both within and outside the field of anesthesia monitoring, or if such products and applications are developed but not successfully commercialized, then we could lose revenue opportunities and customers.

***If we do not develop and implement a successful sales and marketing strategy, we will not expand our business.***

In the third quarter of 2002, we experienced a change in the management of our North American field operations. If the transition to new management is not effective, we may not be able to sustain or grow our product revenue. Throughout 2002, we experienced high turnover in our direct sales force. If our new sales representatives do not acquire the technological skills to sell our products in a timely and successful manner or we continue to experience high turnover in our direct sales force, we may not be able to sustain and grow our product revenue. On an ongoing basis we develop and introduce new sales and marketing programs. If we do not implement these new sales and marketing programs in a timely and successful manner, we may not be able to achieve the level of market awareness and sales required to expand our business. In January 2002, we transitioned to new management in our international operations, and as a result of the transition, we combined our international, commercial and clinical groups. If this international reorganization is not successful, we may not be able to expand our international business. We have only limited sales and marketing experience both in the United States and internationally and may not be successful in developing and implementing our strategy. We need to:

- provide or assure that distributors and original equipment manufacturers provide the technical and educational support customers need to use the BIS system successfully,

- promote frequent use of the BIS system so that sales of our disposable BIS Sensors increase,

- establish and implement successful marketing and sales programs that encourage our customers to purchase our products or the products that are made by original equipment manufacturers incorporating our technology,

- manage geographically dispersed operations, and
- modify our products and marketing and sales programs for foreign markets.

***In order to reach the level of sales we need to achieve profitability, we need to further develop our direct and indirect sales channels.***

In order to increase our sales, we need to continue to strengthen our relationships with our domestic and international distributors and continue to add international distributors. We need to also continue to strengthen our relationships with our original equipment manufacturers and other sales channels and increase sales through these channels. In addition, due to the high turnover in our direct sales force, we need to hire and train more sales representatives. On an ongoing basis we develop and implement new sales and marketing programs and clinical education programs to promote the use of the BIS system by our customers. If we do not further develop our direct and indirect sales channels and successfully implement the new sales and marketing programs and clinical education programs that encourage our customers to purchase and use our products, we will not reach the level of sales necessary to achieve profitability.

***Our third-party distribution and original equipment manufacturer relationships could negatively affect our profitability, cause sales of our products to decline and be difficult to terminate if we are dissatisfied.***

Sales through distributors could be less profitable than direct sales. Sales of our products through multiple channels could also confuse customers and cause the sale of our products to decline. We do not control our original equipment manufacturers and distribution partners. Our partners could sell competing products, may not incorporate our technology into their products in a timely manner and may devote insufficient sales efforts to our products. Our partners are generally not required to purchase minimum quantities. As a result, even if we are dissatisfied with the performance of our partners, we may be unable to terminate our agreements with these partners or enter into alternative arrangements.

***We may not be able to generate enough additional revenue from our international expansion to offset the costs associated with establishing and maintaining foreign operations.***

A component of our growth strategy is to expand our presence in foreign markets. We conduct international business primarily in Europe and Japan and we are attempting to increase the number of countries in which we do business. It is costly to establish international facilities and operations and to promote the BIS system in international markets. We have encountered barriers to the sale of our BIS system outside the United States, including less acceptance by anesthesia providers for use of disposable products, such as BIS Sensors, delays in regulatory approvals outside of the United States, particularly in Japan, and difficulties selling through indirect sales channels. In addition, we have little experience in marketing and distributing products for these markets. Revenue from international activities may not offset the expense of establishing and maintaining these foreign operations.

***We may not be able to meet the unique operational, legal and financial challenges that we will encounter in our international operations, which may limit the growth of our business.***

We are increasingly subject to a number of challenges which specifically relate to our international business activities. These challenges include:

- failure of local laws to provide the same degree of protection against infringement of our intellectual property,
- protectionist laws and business practices that favor local competitors, which could slow our growth in international markets,
- difficulties in terminating or modifying distributor arrangements because of restrictions in markets outside the United States,

- less acceptance by foreign anesthesia providers of the use of disposable products similar to the BIS Sensors,
- delays in regulatory approval of our products,
- currency conversion issues arising from sales denominated in currencies other than the United States dollar,
- foreign currency exchange rate fluctuations,
- longer sales cycles to sell products like the BIS system to hospitals and outpatient surgical centers, which could slow our revenue growth from international sales, and
- longer accounts receivable payment cycles and difficulties in collecting accounts receivable.

If we are unable to meet and overcome these challenges, our international operations may not be successful which would limit the growth of our business.

***We may experience customer dissatisfaction and our reputation could suffer if we fail to manufacture enough products to meet our customers' demands.***

We rely on third-party manufacturers to assemble and manufacture the components of our BIS monitors, BIS Module Kits and a portion of our BIS Sensors. We manufacture substantially all BIS Sensors in our own manufacturing facility. We have only one manufacturing facility. If we fail to produce enough products at our own manufacturing facility or at a third-party manufacturing facility or experience a termination or modification of any manufacturing arrangement with a third party, we may be unable to deliver products to our customers on a timely basis. Our failure to deliver products on a timely basis could lead to customer dissatisfaction and damage our reputation.

***Our reliance on sole-source suppliers could adversely affect our ability to meet our customers' demands for our products in a timely manner or within budget.***

Some of the components that are necessary for the assembly of our BIS system, including some of the components used in our BIS Sensors, are currently provided to us by sole-source suppliers or a limited group of suppliers. We purchase components through purchase orders rather than long-term supply agreements and generally do not maintain large volumes of inventory. We have experienced shortages and delays in obtaining some of the components of our BIS systems in the past, and we may experience similar delays or shortages in the future. The disruption or termination of the supply of components could cause a significant increase in the costs of these components, which could affect our profitability. A disruption or termination in the supply of components could also result in our inability to meet demand for our products, which could lead to customer dissatisfaction and damage our reputation. Furthermore, if we are required to change the manufacturer of a key component of the BIS system, we may be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could delay our ability to manufacture BIS systems in a timely manner or within budget.

***We may be required to bring litigation to enforce our intellectual property rights, which may result in substantial expense and may divert our attention from the implementation of our business strategy.***

We believe that the success of our business depends, in part, on obtaining patent protection for our products, defending our patents once obtained and preserving our trade secrets. We rely on a combination of contractual provisions, confidentiality procedures and patent, trademark and trade secret laws to protect the proprietary aspects of our technology. These legal measures afford only limited protection and competitors may gain access to our intellectual property and proprietary information. Litigation may be necessary to enforce our intellectual property rights, to protect our trade secrets and to determine the validity and scope of our proprietary rights. Any litigation could result in substantial expense and diversion of our attention from the growth of the business and may not be adequate to protect our intellectual property rights.

***We may be sued by third parties which claim that our products infringe on their intellectual property rights, particularly because there is substantial uncertainty about the validity and breadth of medical device patents.***

We may be exposed to litigation by third parties based on claims that our products infringe the intellectual property rights of others. This risk is exacerbated by the fact that the validity and breadth of claims covered in medical technology patents involve complex legal and factual questions for which important legal principles are unresolved. Any litigation or claims against us, whether or not valid, could result in substantial costs, could place a significant strain on our financial resources and could harm our reputation. In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease selling, incorporating or using any of our products that incorporate the challenged intellectual property, which would adversely affect our revenue,
- obtain a license from the holder of the infringed intellectual property right, which license may not be available on reasonable terms, if at all, and
- redesign our products, which would be costly and time-consuming.

***We could be exposed to significant product liability claims which could divert management attention and adversely affect our cash balances, our ability to obtain and maintain insurance coverage at satisfactory rates or in adequate amounts and our reputation.***

The manufacture and sale of our products expose us to product liability claims and product recalls, including those which may arise from misuse or malfunction of, or design flaws in, our products or use of our products with components or systems not manufactured or sold by us. Product liability claims or product recalls, regardless of their ultimate outcome, could require us to spend significant time and money in litigation or to pay significant damages. We currently maintain insurance; however, it may not cover the costs of any product liability claims made against us. Furthermore, we may not be able to obtain insurance in the future at satisfactory rates or in adequate amounts. In addition, publicity pertaining to the misuse or malfunction of, or design flaws in, our products could impair our ability to successfully market and sell our products.

***Several class action lawsuits have been filed against the underwriters of our initial public offering which may result in negative publicity and potential litigation against us that would be costly to defend and the outcome of which is uncertain and may harm our business.***

The underwriters of our initial public offering are named as defendants in several class action complaints which have been filed allegedly on behalf of certain persons who purchased shares of our common stock between January 28, 2000 and December 6, 2000. These complaints allege violations of the Securities Act of 1933 and the Securities Exchange Act of 1934. Primarily they allege that there was undisclosed compensation received by our underwriters in connection with our initial public offering. While we and our officers and directors have not been named as defendants in these suits, based on comparable lawsuits filed against other companies, there can be no assurance that we and our officers and directors will not be named in similar complaints in the future. In addition, the underwriters may assert that we are liable for some or all of any liability that they are found to have to the plaintiffs, pursuant to the indemnification provisions of an underwriting agreement we entered into as part of the initial public offering, or otherwise.

We can provide no assurance as to the outcome of these complaints or any potential suit against us or our officers and directors. Any conclusion of these matters in a manner adverse to us could have a material adverse affect on our financial position and results of operations. In addition, the costs to us of defending any litigation or other proceeding, even if resolved in our favor, could be substantial. Such litigation could also substantially divert the attention of our management and our resources in general. Uncertainties resulting from the initiation and continuation of any litigation or other proceedings and the negative publicity associated with this litigation could harm our ability to compete in the marketplace.

***Boston Scientific Corporation may be able to impact corporate actions requiring stockholder approval because it owns a significant amount of our common stock, and, if our strategic alliance with Boston Scientific Corporation is not successful, our operating results will be adversely affected.***

As of March 10, 2003, Boston Scientific Corporation owned approximately 17% of our outstanding common stock. We have an agreement with Boston Scientific Corporation, pursuant to which Boston Scientific Corporation has agreed not to acquire any shares of our common stock in excess of 25% of the outstanding shares of common stock prior to December 31, 2004 without our prior approval. If Boston Scientific Corporation increases its ownership of our outstanding common stock, it may impact corporate actions requiring stockholder approval. In addition, on August 7, 2002, we formed a strategic alliance with Boston Scientific Corporation. In connection with this strategic alliance, we entered into an agreement pursuant to which we granted Boston Scientific Corporation an option to distribute newly developed technology for monitoring patients under sedation in a range of less-invasive medical specialties. If such products are not successfully developed, marketed and sold under the agreement in a manner consistent with our expectations, the growth of our business and our operating results will be adversely affected. Even if we successfully develop new sedation management technology for less-invasive medical procedures, Aspect and Boston Scientific Corporation may not successfully market and sell this new technology.

***If the estimates we make, and the assumptions on which we rely in preparing our financial statements prove inaccurate, our actual results may vary from those reflected in our projections and accruals.***

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges accrued by us, such as those made in connection with our restructurings, and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. There can be no assurance, however, that our estimates, or the assumptions underlying them, will be correct.

***We may not reserve amounts adequate to cover product obsolescence, claims and returns, which could result in unanticipated expenses and fluctuations in operating results.***

Depending on factors such as the timing of our introduction of new products which utilize our BIS technology, as well as warranty claims and product returns, we may need to reserve amounts in excess of those currently reserved for product obsolescence, excess inventory, warranty claims and product returns. These reserves may not be adequate to cover all costs associated with these items. If these reserves are inadequate, we would be required to incur unanticipated expenses which could result in unexpected fluctuations in quarterly operating results.

***We may not be able to compete effectively, which could result in price reductions and decreased demand for our products.***

We are facing increased competition in the domestic level of consciousness monitoring market as a result of three competitors' monitoring systems which have been approved by the FDA. These products are marketed by well-established medical products companies with significant resources. We may not be able to compete effectively with these and other potential competitors. We may also face substantial competition from companies which may develop sensor products that compete with our proprietary BIS Sensors for use with our BIS monitors or with third-party monitoring systems or anesthesia delivery systems that incorporate the BIS index. We also expect to face competition from companies currently marketing conventional electroencephalogram, or EEG, monitors using standard and novel signal-processing techniques. Other companies may develop anesthesia-monitoring systems that perform better than the BIS system and/or sell for less. In addition, one or more of our competitors may develop products that are substantially equivalent to our FDA-approved products, in which case they may be able to use our products as predicate devices to more quickly obtain FDA approval of their competing products. Medical device companies developing these and other competitive products may have greater financial, technical, marketing and other resources than we do.

Competition in the sale of anesthesia-monitoring systems could result in price reductions, fewer orders, reduced gross margins and loss of market share.

***Our ability to market and sell our products and generate revenue depends upon receipt of domestic and foreign regulatory approval of our products and manufacturing operations.***

Before we can market new products in the United States, we must obtain clearance from the United States Food and Drug Administration, or FDA. If the FDA concludes that any of our products do not meet the requirements to obtain clearance of a premarket notification under Section 510(k) of the Food, Drug and Cosmetic Act, then we would be required to file a premarket approval application. The approval process for a premarket approval application is lengthy, expensive and typically requires extensive preclinical and clinical trial data. We may not obtain clearance of a 510(k) notification or approval of a premarket approval application with respect to any of our products on a timely basis, if at all. If we fail to obtain timely clearance or approval for our products, we will not be able to market and sell our products, which will limit our ability to generate revenue. We may also be required to obtain clearance of a 510(k) notification from the FDA before we can market certain previously marketed products which we modify after they have been cleared. We have made certain enhancements to our currently marketed products which we have determined do not necessitate the filing of a new 510(k) notification. However, if the FDA does not agree with our determination, it will require us to file a new 510(k) notification for the modification and we may be prohibited from marketing the modified device until we obtain FDA clearance.

The FDA also requires us to adhere to current Good Manufacturing Practices regulations, which include production design controls, testing, quality control, storage and documentation procedures. The FDA may at any time inspect our facilities to determine whether adequate compliance has been achieved. Compliance with current Good Manufacturing Practices regulations for medical devices is difficult and costly. In addition, we may not continue to be compliant as a result of future changes in, or interpretations of, regulations by the FDA or other regulatory agencies. If we do not achieve continued compliance, the FDA may withdraw marketing clearance or require product recall. When any change or modification is made to a device or its intended use, the manufacturer may be required to reassess compliance with current Good Manufacturing Practices regulations, which may cause interruptions or delays in the marketing and sale of our products.

Sales of our products outside the United States are subject to foreign regulatory requirements that vary from country to country. The time required to obtain approvals from foreign countries may be longer than that required for FDA approval, and requirements for foreign licensing may differ from FDA requirements.

The federal, state and foreign laws and regulations regarding the manufacture and sale of our products are subject to future changes, as are administrative interpretations of regulatory agencies. If we fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, including product seizures, recalls, withdrawal of clearances or approvals and civil and criminal penalties.

***If we do not retain our senior management and other key employees, we may not be able to successfully implement our business strategy.***

Our president and chief executive officer, Nassib Chamoun, joined us at our inception in 1987. Our chairman, J. Breckenridge Eagle, began serving as a director in 1988. Many other members of our management and key employees have extensive experience with us and other companies in the medical device industry. Our success is substantially dependent on the ability, experience and performance of these members of our senior management and other key employees. Because of their ability and experience, if we lose one or more of the members of our senior management or other key employees, our ability to successfully implement our business strategy could be seriously harmed.

***If we do not attract and retain skilled personnel, we will not be able to expand our business.***

Our products are based on complex signal-processing technology. Accordingly, we require skilled personnel to develop, manufacture, sell and support our products. Our future success will depend largely on our ability to continue to hire, train, retain and motivate additional skilled personnel, particularly sales

representatives who are responsible for customer education and training and post-installation customer support. Consequently, if we are not able to attract and retain skilled personnel, we will not be able to expand our business.

***Failure of users of the BIS system to obtain adequate reimbursement from third-party payors could limit market acceptance of the BIS system, which could prevent us from achieving profitability.***

Anesthesia providers are generally not reimbursed separately for patient monitoring activities utilizing the BIS system. For hospitals and outpatient surgical centers, when reimbursement is based on charges or costs, patient monitoring with the BIS system may reduce reimbursements for surgical procedures, because charges or costs may decline as a result of monitoring with the BIS system. Failure by hospitals and other users of the BIS system to obtain adequate reimbursement from third-party payors, or any reduction in the reimbursement by third-party payors to hospitals and other users as a result of using the BIS system could limit market acceptance of the BIS system, which could prevent us from achieving profitability.

**Item 7A. Qualitative and Quantitative Disclosures About Market Risk.**

We are exposed to financial market risks, including changes in foreign currency exchange rates and interest rates. Most of our revenue, expenses and capital spending are transacted in U.S. dollars. However, the expenses and capital spending of our international subsidiaries are transacted in the respective country's local currency. As a result, changes in foreign currency exchange rates or weak economic conditions in foreign markets could affect our financial results. We do not use derivative instruments to hedge our foreign exchange risk. Our exposure to market risk for changes in interest rates relates primarily to our cash and cash equivalent balances, marketable securities, investment in sales-type leases and line of credit agreements. The majority of our investments are in short-term instruments and subject to fluctuations in U.S. interest rates. Due to the nature of our short-term investments, we believe that there is no material market risk.

**Item 8. Financial Statements and Supplementary Data.**

The information required by this item may be found on pages F-1 through F-25 of this Annual Report on Form 10-K.

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

The Audit Committee of our Board of Directors annually considers and recommends to the Board of Directors the selection of our independent auditors. As recommended by the Audit Committee, the Board of Directors, on June 13, 2002, dismissed our independent accountants, Arthur Andersen LLP, and on June 19, 2002, engaged Ernst & Young LLP to serve as our independent auditors and to audit our consolidated financial statements for the fiscal year ended December 31, 2002.

Arthur Andersen's reports on our consolidated financial statements for the fiscal years ended December 31, 2001 and December 31, 2000 did not contain an adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles.

During the fiscal years ended December 31, 2001 and December 31, 2000, and the subsequent interim period through the date of Arthur Andersen's dismissal, there were (i) no disagreements with Arthur Andersen on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure which, if not resolved to Arthur Andersen's satisfaction, would have caused Arthur Andersen to make reference to the subject matter of such disagreement in connection with its report on our consolidated financial statements for such years, and (ii) no reportable events, as listed in Item 304(a)(1)(v) of Regulation S-K.

During the fiscal years ended December 31, 2001 and December 31, 2000, and the subsequent interim period through the date of Ernst & Young's engagement, we had not consulted Ernst & Young regarding either (i) the application of accounting principles to a specified transaction, either completed or proposed; or the type of audit opinion that might be rendered on our consolidated financial statements, and neither a

written report was provided to us or oral advice was provided that Ernst & Young concluded was an important factor considered by us in reaching a decision as to the accounting, auditing or financial reporting issue; or (ii) any matter that was either the subject of a disagreement (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions to Item 304 of Regulation S-K), or a reportable event (as described in Item 304(a)(1)(v) of Regulation S-K).

## PART III

### Item 10. Directors and Executive Officers of the Registrant.

The information with respect to directors required under this item is incorporated by reference to the information set forth under the section entitled *"Election of Directors"* in our proxy statement for our 2003 Annual Meeting of Stockholders to be held on May 20, 2003. Information relating to certain filings of Forms 3, 4 and 5 is contained in our 2003 proxy statement under the section entitled *"Section 16(a) Beneficial Ownership Reporting Compliance"* and is incorporated herein by reference.

### Item 11. Executive Compensation.

The information required under this item is incorporated by reference to the section entitled *"Compensation of Executive Officers"* and *"Compensation Committee Interlocks and Insider Participation"* in our 2003 proxy statement.

The sections entitled *"Report of the Compensation Committee"* and *"Comparative Stock Performance Graph"* in our 2003 proxy statement are not incorporated herein by reference.

### Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required under this item is incorporated by reference to the section entitled *"Stock Ownership Information"* and *"Securities Authorized for Issuance Under Equity Compensation Plans"* in our 2003 proxy statement.

### Item 13. Certain Relationships and Related Transactions.

The information required under this item is incorporated by reference to the section entitled *"Certain Relationships and Related Transactions"* in our 2003 proxy statement.

### Item 14. Controls and Procedures.

(a) Evaluation of Disclosure Controls and Procedures.

Within the 90-day period prior to the filing of this Annual Report on Form 10-K, an evaluation was carried out under the supervision and with the participation of our management, including our Chief Executive Officer, or CEO, and Chief Financial Officer, or CFO, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on that evaluation, our CEO and CFO have concluded that our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and are operating in an effective manner.

(b) Changes in Internal Controls.

There were no significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the date of their most recent evaluation.

## PART IV

### Item 15. Exhibits, Financial Statement Schedules, and Reports on Form 8-K.

(a) Consolidated Financial Statements.

For a list of the consolidated financial information included herein, see Index to the Consolidated Financial Statements on page F-1.

(b) Reports on Form 8-K.

We did not file any reports on Form 8-K during the quarter ended December 31, 2002.

(c) List of Exhibits.

The exhibits listed in the Exhibit Index immediately preceding the exhibits are filed as part of this Annual Report on Form 10-K. Exhibits which are incorporated herein by reference may be inspected and copied at the public reference facilities maintained by the SEC at Room 1024, Washington, D.C. 20549. Copies of such material may be obtained by mail from the Public Reference Section of the SEC at Judiciary Plaza, 450 Fifth Street, N.W., Washington, D.C. 20549, at prescribed rates. The SEC also maintains a Website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC at the address *"http://www.sec.gov."*

(d) Financial Statement Schedules.

All schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the accompanying Consolidated Financial Statements or notes thereto.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ASPECT MEDICAL SYSTEMS, INC.

Date: March 28, 2003

By: /s/ J. NEAL ARMSTRONG
J. Neal Armstrong
Vice President and Chief Financial Officer

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

| Signature | Title | Date |
|---|---|---|
| /s/ NASSIB G. CHAMOUN<br>Nassib G. Chamoun | President, Chief Executive Officer and Director (Principal Executive Officer) | March 28, 2003 |
| /s/ J. BRECKENRIDGE EAGLE<br>J. Breckenridge Eagle | Chairman of the Board of Directors | March 28, 2003 |
| /s/ J. NEAL ARMSTRONG<br>J. Neal Armstrong | Vice President and Chief Financial Officer (Principal Financial and Accounting Officer) | March 28, 2003 |
| /s/ BOUDEWIJN L.P.M. BOLLEN<br>Boudewijn L.P.M. Bollen | President of International Operations and Director | March 28, 2003 |
| /s/ STEPHEN E. COIT<br>Stephen E. Coit | Director | March 28, 2003 |
| /s/ EDWIN M. KANIA<br>Edwin M. Kania | Director | March 28, 2003 |
| /s/ LESTER J. LLOYD<br>Lester J. Lloyd | Director | March 28, 2003 |
| /s/ JAMES J. MAHONEY, JR.<br>James J. Mahoney, Jr. | Director | March 28, 2003 |
| /s/ RICHARD J. MEELIA<br>Richard J. Meelia | Director | March 28, 2003 |
| /s/ DONALD R. STANSKI, M.D.<br>Donald R. Stanski, M.D. | Director | March 28, 2003 |

## CERTIFICATIONS

I, Nassib G. Chamoun, certify that:

1. I have reviewed this annual report on Form 10-K of Aspect Medical Systems, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

   a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

   c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ NASSIB G. CHAMOUN

Nassib G. Chamoun
*Chief Executive Officer*

Dated: March 28, 2003

## CERTIFICATIONS

I, J. Neal Armstrong, certify that:

1. I have reviewed this annual report on Form 10-K of Aspect Medical Systems, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

   a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

   c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ J. Neal Armstrong

J. Neal Armstrong
*Chief Financial Officer*

Dated: March 28, 2003

**ASPECT MEDICAL SYSTEMS, INC.**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

## REPORT OF INDEPENDENT AUDITORS

The Board of Directors and Stockholders of
Aspect Medical Systems, Inc.:

We have audited the accompanying consolidated balance sheet of Aspect Medical Systems, Inc. as of December 31, 2002, and the related statement of operations, stockholders' equity, and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit. The consolidated financial statements of Aspect Medical Systems, Inc. as of December 31, 2001, and for each of the three years in the period ended December 31, 2001 were audited by other auditors who have ceased operations and whose report dated January 28, 2002, expressed an unqualified opinion on those statements.

We conducted our audit in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the 2002 consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Aspect Medical Systems, Inc. at December 31, 2002, and the results of its operations and cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States.

/s/ Ernst & Young LLP

Boston, Massachusetts
January 23, 2003

NOTE: THIS IS A COPY OF THE AUDIT REPORT PREVIOUSLY ISSUED BY ARTHUR ANDERSEN LLP IN CONNECTION WITH ASPECT MEDICAL SYSTEMS, INC.'S FORM 10-K FILING FOR THE FISCAL YEAR ENDED DECEMBER 31, 2001. THE INCLUSION OF THIS PREVIOUSLY ISSUED ARTHUR ANDERSEN LLP REPORT IS PURSUANT TO THE "TEMPORARY FINAL RULE AND FINAL RULE REQUIREMENTS FOR ARTHUR ANDERSEN LLP AUDITING CLIENTS," ISSUED BY THE SECURITIES AND EXCHANGE COMMISSION IN MARCH 2002. NOTE THAT THE PREVIOUSLY ISSUED ARTHUR ANDERSEN LLP REPORT INCLUDES REFERENCES TO CERTAIN FISCAL YEARS WHICH ARE NOT REQUIRED TO BE PRESENTED IN THE ACCOMPANYING CONSOLIDATED FINANCIAL STATEMENTS AS OF AND FOR THE YEAR ENDED DECEMBER 31, 2002. THIS AUDIT REPORT HAS NOT BEEN REISSUED BY ARTHUR ANDERSEN LLP IN CONNECTION WITH THIS FILING ON FORM 10-K.

## REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To Aspect Medical Systems, Inc.:

We have audited the accompanying consolidated balance sheets of Aspect Medical Systems, Inc. (a Delaware corporation) and subsidiaries as of December 31, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Aspect Medical Systems, Inc. and subsidiaries as of December 31, 2001 and 2000, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

/s/ ARTHUR ANDERSEN LLP

Boston, Massachusetts
January 28, 2002

## ASPECT MEDICAL SYSTEMS, INC.

## CONSOLIDATED BALANCE SHEETS

| | December 31, 2002 | December 31, 2001 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 11,542,833 | $ 14,325,348 |
| Restricted cash | 5,100,000 | 5,100,000 |
| Marketable securities | 20,222,500 | 22,032,628 |
| Accounts receivable, net of allowances of $408,000 and $522,000 at December 31, 2002 and 2001, respectively | 4,666,098 | 5,395,096 |
| Current portion of investment in sales-type leases | 1,859,237 | 1,473,260 |
| Inventory, net | 2,333,385 | 5,108,166 |
| Other current assets | 1,319,091 | 1,182,385 |
| Total current assets | 47,043,144 | 54,616,883 |
| Property and equipment, net | 4,121,560 | 5,695,436 |
| Long-term investment in sales-type leases | 2,282,751 | 1,934,699 |
| Long-term portion of notes receivable from related parties | 1,032,572 | 1,122,026 |
| Total assets | $ 54,480,027 | $ 63,369,044 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Working capital line of credit | $ — | $ 3,000,000 |
| Current portion of long-term debt | 887,538 | 829,947 |
| Accounts payable | 1,246,567 | 1,563,990 |
| Accrued liabilities | 7,127,091 | 7,436,236 |
| Deferred revenue | 1,047,651 | 521,119 |
| Total current liabilities | 10,308,847 | 13,351,292 |
| Long-term portion of deferred revenue | 6,359,210 | 997,813 |
| Long-term debt | 1,015,101 | 963,813 |
| Commitments and contingencies (Note 12) | | |
| Stockholders' equity: | | |
| Preferred Stock, $.01 par value; 5,000,000 shares authorized, no shares issued or outstanding | — | — |
| Common Stock, $.01 par value; 60,000,000 shares authorized, 19,370,823 and 17,791,967 shares issued and outstanding at December 31, 2002 and 2001, respectively | 193,708 | 177,920 |
| Additional paid-in capital | 130,606,576 | 126,655,623 |
| Notes receivable from employees and directors | (271,049) | (335,777) |
| Deferred compensation | — | (23,162) |
| Accumulated other comprehensive income | 20,900 | 33,617 |
| Accumulated deficit | (93,753,266) | (78,452,095) |
| Total stockholders' equity | 36,796,869 | 48,056,126 |
| Total liabilities and stockholders' equity | $ 54,480,027 | $ 63,369,044 |

The accompanying notes are an integral part of these consolidated financial statements.

## ASPECT MEDICAL SYSTEMS, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2002 | 2001 | 2000 |
| Revenue | $ 39,776,394 | $ 35,828,851 | $36,023,564 |
| Costs of revenue | 11,815,387 | 12,445,938 | 11,279,031 |
| Gross profit margin | 27,961,007 | 23,382,913 | 24,744,533 |
| Operating expenses: | | | |
| Research and development | 7,826,874 | 7,466,621 | 5,712,687 |
| Sales and marketing | 28,449,042 | 28,396,057 | 21,978,802 |
| General and administrative | 7,941,829 | 7,803,506 | 6,389,948 |
| Total operating expenses | 44,217,745 | 43,666,184 | 34,081,437 |
| Loss from operations | (16,256,738) | (20,283,271) | (9,336,904) |
| Interest income | 1,198,519 | 2,930,140 | 4,705,236 |
| Interest expense | (242,952) | (365,428) | (712,666) |
| Net loss | $(15,301,171) | $(17,718,559) | $(5,344,334) |
| Net loss per share: | | | |
| Basic and diluted | $ (0.83) | $ (1.01) | $ (0.34) |
| Weighted average shares used in computing net loss per share: | | | |
| Basic and diluted | 18,450,002 | 17,614,036 | 15,754,831 |

The accompanying notes are an integral part of these consolidated financial statements.

## ASPECT MEDICAL SYSTEMS, INC.

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

| | Comprehensive Income (Loss) | Convertible Preferred Stock | | Common Stock | | Additional Paid-in Capital | Notes Receivable From Employees and Directors | Deferred Compensation | Accumulated Other Comprehensive Income | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Shares | Amount | Shares | Par Value | | | | | | |
| Balance, December 31, 1999 | $ — | 11,067,238 | $ 67,560,365 | 1,815,840 | $ 18,158 | $ 1,420,331 | $(305,324) | $(225,111) | $ — | $(55,389,202) | $ 13,079,217 |
| Conversion of preferred stock into common stock upon closing of initial public offering | — | (11,067,238) | (67,560,365) | 11,067,238 | 110,673 | 67,449,692 | — | — | — | — | — |
| Issuance of common stock upon closing of initial public offering | — | — | — | 4,025,000 | 40,250 | 54,602,033 | — | — | — | — | 54,642,283 |
| Issuance of common stock upon exercise of common stock options | — | — | — | 446,273 | 4,463 | 1,040,148 | (234,420) | — | — | — | 810,191 |
| Issuance of common stock upon exercise of warrants stock options | — | — | — | 22,906 | 229 | 150,940 | — | — | — | — | 151,169 |
| Payments on notes receivable from employees and directors | — | — | — | — | — | — | 28,957 | — | — | — | 28,957 |
| Deferred compensation related to stock options | — | — | — | — | — | 392,942 | — | (392,942) | — | — | — |
| Amortization of deferred compensation related to stock options | — | — | — | — | — | — | — | 543,010 | — | — | 543,010 |
| Comprehensive loss: | | | | | | | | | | | |
| Net loss | (5,344,334) | — | — | — | — | — | — | — | — | (5,344,334) | (5,344,334) |
| Other comprehensive income — | | | | | | | | | | | |
| Unrealized gain on marketable securities | 63,029 | — | — | — | — | — | — | — | 63,029 | — | 63,029 |
| Comprehensive loss: | (5,281,305) | — | — | — | — | — | — | — | — | — | — |
| Balance, December 31, 2000 | | — | — | 17,377,257 | 173,773 | 125,056,086 | (510,787) | (75,043) | 63,029 | (60,733,536) | 63,973,522 |
| Issuance of common stock upon exercise of common stock options | — | — | — | 414,710 | 4,147 | 1,586,047 | — | — | — | — | 1,590,194 |
| Payments on notes receivable from employees and directors | — | — | — | — | — | — | 175,010 | — | — | — | 175,010 |
| Deferred compensation related to stock options | — | — | — | — | — | 13,490 | — | (13,490) | — | — | — |
| Amortization of deferred compensation related to stock options | — | — | — | — | — | — | — | 65,371 | — | — | 65,371 |
| Comprehensive loss: | | | | | | | | | | | |
| Net loss | (17,718,559) | — | — | — | — | — | — | — | — | (17,718,559) | (17,718,559) |
| Other comprehensive loss — | | | | | | | | | | | |
| Unrealized loss on marketable securities | (29,412) | — | — | — | — | — | — | — | (29,412) | — | (29,412) |
| Comprehensive loss: | $(17,747,971) | — | — | — | — | — | — | — | — | — | — |
| Balance, December 31, 2001 | | — | $ — | 17,791,967 | $177,920 | $126,655,623 | $(335,777) | $ (23,162) | $ 33,617 | $(78,452,095) | $ 48,056,126 |

## ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY — (Continued)

| | Comprehensive Income (Loss) | Convertible Preferred Stock | | Common Stock | | Additional Paid-in Capital | Notes Receivable From Employees and Directors | Deferred Compensation | Accumulated Other Comprehensive Income | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Shares | Amount | Shares | Par Value | | | | | | |
| Issuance of common stock in connection with a strategic alliance, net of issuance costs of approximately $170,000 | $ — | — | $ — | 1,428,572 | $ 14,285 | $ 3,515,775 | $ — | $ — | $ — | $ — | $ 3,530,060 |
| Issuance of common stock upon exercise of common stock options | — | — | — | 150,284 | 1,503 | 426,899 | — | — | — | — | 428,402 |
| Payments on notes receivable from employees and directors | — | — | — | — | — | — | 64,728 | — | — | — | 64,728 |
| Deferred compensation related to stock options | — | — | — | — | — | 8,033 | — | (8,033) | — | — | — |
| Amortization of deferred compensation related to stock options | — | — | — | — | — | 246 | — | 31,195 | — | — | 31,441 |
| Comprehensive loss: | | | | | | | | | | | |
| Net loss | (15,301,171) | — | — | — | — | — | — | — | — | (15,301,171) | (15,301,171) |
| Other comprehensive loss — | | | | | | | | | | | |
| Unrealized loss on marketable securities | (12,717) | — | — | — | — | — | — | — | (12,717) | — | (12,717) |
| Comprehensive loss: | $(15,313,888) | — | — | — | — | — | — | — | — | — | — |
| Balance, December 31, 2002 | | — | $ — | 19,370,823 | $193,708 | $130,606,576 | $(271,049) | $ — | $ 20,900 | $(93,753,266) | $ 36,796,869 |



The accompanying notes are an integral part of these consolidated financial statements.

## ASPECT MEDICAL SYSTEMS, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2002 | 2001 | 2000 |
| Cash flows from operating activities: | | | |
| Net loss | $(15,301,171) | $(17,718,559) | $ (5,344,334) |
| Adjustments to reconcile net loss to net cash used for operating activities — | | | |
| Depreciation and amortization | 2,619,515 | 2,942,027 | 1,767,050 |
| Provision for doubtful accounts | (100,000) | 100,000 | 15,000 |
| Compensation expense related to stock options | 31,441 | 65,371 | 543,010 |
| Changes in assets and liabilities — | | | |
| Decrease (increase) in accounts receivable | 828,998 | (1,829,524) | 619,663 |
| Decrease (increase) in inventory | 2,774,781 | (343,687) | (3,249,777) |
| (Increase) decrease in other assets | (96,099) | 197,869 | (418,324) |
| (Increase) decrease in investment in sales-type leases | (734,029) | 734,492 | 453,581 |
| (Decrease) increase in accounts payable | (317,423) | (313,305) | 308,202 |
| (Decrease) increase in accrued liabilities | (309,145) | 962,349 | 536,333 |
| Increase (decrease) increase in deferred revenue | 5,887,929 | (420,233) | (878,569) |
| Net cash used for operating activities | (4,715,203) | (15,623,200) | (5,648,165) |
| Cash flows from investing activities: | | | |
| Loans to related parties | (50,000) | (1,155,500) | (125,000) |
| Payments on loans to related parties | 98,847 | 195,817 | 6,750 |
| Acquisition of property and equipment | (1,045,639) | (1,830,271) | (5,124,990) |
| Increase in restricted cash | — | (5,100,000) | — |
| Purchases of marketable securities | (21,601,392) | (29,081,621) | (59,899,296) |
| Proceeds from sales and maturities of marketable securities | 23,398,803 | 41,731,907 | 26,250,000 |
| Net cash provided by (used for) investing activities | 800,619 | 4,760,332 | (38,892,536) |
| Cash flows from financing activities: | | | |
| Proceeds from working capital line of credit | — | 3,000,000 | — |
| Payment on working capital line of credit | (3,000,000) | — | — |
| Principal payments on equipment loan | — | (720,670) | (720,672) |
| Principal payments on term loan | — | (1,884,933) | (942,462) |
| Proceeds from sale of investment in sales-type leases | 1,072,735 | 341,420 | 1,614,065 |
| Principal payments on debt related to investment in sales-type leases | (963,856) | (1,089,422) | (801,577) |
| Proceeds from issuance of common stock | 3,958,462 | 1,590,194 | 55,603,643 |
| Payments received on notes receivable from employees and directors | 64,728 | 175,010 | 28,957 |
| Net cash provided by financing activities | 1,132,069 | 1,411,599 | 54,781,954 |
| Net (decrease) increase in cash and cash equivalents | (2,782,515) | (9,451,269) | 10,241,253 |
| Cash and cash equivalents, beginning of period | 14,325,348 | 23,776,617 | 13,535,364 |
| Cash and cash equivalents, end of period | $ 11,542,833 | $ 14,325,348 | $ 23,776,617 |
| Supplemental disclosure of cash flow information: | | | |
| Interest paid | $ 242,031 | $ 403,632 | $ 728,203 |
| Supplemental disclosure of non-cash financing activities: | | | |
| Conversion of preferred stock into common stock | $ — | $ — | $ 67,560,365 |
| Cashless exercise of warrants | $ — | $ — | $ 135,075 |

The accompanying notes are an integral part of these consolidated financial statements.

## (1) Description of Operations

Aspect Medical Systems, Inc. and its subsidiaries (the "Company") develop, manufacture and market an anesthesia monitoring system called the BIS® system. The BIS system provides information that allows clinicians to better assess and manage a patient's level of consciousness in the operating room and intensive care settings and administer the amount of anesthesia needed by each patient. The Company's BIS system incorporates the Company's proprietary disposable BIS Sensors and the Company's BIS monitor or BIS Module Kit. The Company's latest generation BIS monitor, the A-2000 BIS Monitor, was cleared for marketing by the United States Food and Drug Administration ("FDA") in February 1998. The Company's latest version of the BIS system, the BIS XP system, was cleared for marketing by the FDA in June 2001. The BIS system is based on the Company's patented core technology, the BIS index.

The Company incurred net losses of $15,301,171, $17,718,559 and $5,344,334 for the years ended December 31, 2002, 2001 and 2000, respectively. At December 31, 2002, the Company had an accumulated deficit of $93,753,266. The principal risks that may affect the business, results of operations and financial condition of the Company include the Company's ability to raise sufficient capital to fund operations, the ability to effectively market and sell the Company's products, market acceptance of the Company's technology and products, limited sales and marketing experience, the reliance on a single product family, manufacturing risks, the dependence on single source or limited suppliers, technological risks and other risks.

## (2) Summary of Significant Accounting Policies

A summary of the significant accounting policies used by the Company in the preparation of its financial statements follows:

### *Principles of Consolidation*

The consolidated financial statements include the accounts of the Company and all wholly-owned subsidiaries. All material intercompany accounts and transactions have been eliminated.

### *Foreign Currency Translation*

The functional currency of the Company's international subsidiaries is the U.S. dollar; therefore, transaction gains and losses from such entities are recorded in the consolidated statements of operations. Foreign currency transaction gains and losses have not been material.

### *Cash, Cash Equivalents and Marketable Securities*

The Company invests its excess cash in money market accounts, certificates of deposit, U.S. Treasury bills, high-grade commercial paper and debt obligations of various government agencies. The Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents.

The Company accounts for its investments in marketable securities in accordance with Statement of Financial Accounting Standards ("SFAS") No. 115, *Accounting for Certain Investments in Debt and Equity Securities.* In accordance with SFAS No. 115, the Company has classified all of its investments in marketable securities as available-for-sale at December 31, 2002 and 2001. The marketable securities are reported at fair value, with any unrealized gains and losses excluded from earnings and reported as a separate component of stockholders' equity as other comprehensive income (loss).

***Revenue Recognition***

The Company recognizes revenue from equipment sales, disposable product sales and sales-type leases at the time of product shipment when collectibility is reasonably assured. Payments received prior to shipment are recorded as deferred revenue. The Company has entered into certain licensing and distribution agreements for which payments received in advance are recorded as deferred revenue (see Note 10). Revenue under these agreements is recognized as earned per the terms of the respective agreements. The Company does not record a provision for estimated sales returns because historically the Company has experienced only minimal returns that were not covered by warranty reserves. All shipping and handling costs are included in cost of revenue.

In August 2002, the Company sold 1,428,572 shares of its common stock at $7.00 per share to Boston Scientific Corporation pursuant to a stock purchase agreement. Gross cash proceeds from this sale of common stock were $10,000,004. Upon the closing date of the stock purchase agreement approximately $6,300,000 of the aggregate purchase price was recorded as deferred revenue in the accompanying consolidated balance sheet. This amount represents the difference between the purchase price of $7.00 per share and the closing price of the Company's common stock on the date of the sale. The deferred revenue will be recognized ratably over the term of the OEM product development and distribution agreement that the Company entered into with Boston Scientific Corporation in August 2002. The term of this agreement continues until such time that Boston Scientific Corporation is no longer distributing the Company's products, but in no event will extend beyond December 31, 2012 (see Note 18).

***Research and Development Costs***

The Company charges research and development costs to operations as incurred. Research and development costs include costs associated with new product development, product improvements and extensions, clinical studies and project consulting expenses.

***Accounts Receivable***

Estimates are used in determining the Company's allowance for doubtful accounts based on the Company's historical collections experience, historical write-offs of its receivables, current trends, credit policy and a percentage of the Company's accounts receivable by aging category. The Company also reviews the credit quality of its customer base as well as changes in the Company's credit policies. The Company continually monitors collections and payments from its customers.

***Inventory***

The Company values inventory at the lower of cost or estimated market, and determines cost on a first-in, first-out basis. The Company regularly reviews inventory quantities on hand and records a provision for excess or obsolete inventory primarily based on production history and on its estimated forecast of product demand. The medical industry in which the Company markets its products is characterized by rapid product development and technological advances that could result in obsolescence of inventory. Additionally, the Company's estimates of future product demand may prove to be inaccurate, in which case it will need to change its estimate of the provision required for excess and obsolete inventory. If revisions are deemed necessary, the Company would recognize the adjustments in its costs of revenue at the time of the determination.

***Investment in Sales-Type Leases***

The Company follows SFAS No. 13, *Accounting For Leases,* for its investment in sales-type leases. Under the Company's sales-type leases, customers purchase BIS Sensors and the BIS monitor for the purchase price of the BIS Sensors plus an additional charge per BIS Sensor to pay for the purchase price of

the BIS monitor and related financing costs over the term of the agreement. In accordance with SFAS No. 13, the minimum lease payment, consisting of the additional charge per BIS Sensor, less the unearned interest income, which is computed at the interest rate implicit in the lease, is recorded as net investment in sales-type leases. The cost of the BIS monitor acquired by the customer is recorded as costs of revenue in the same period.

In addition, the Company periodically reviews and assesses the net realizability of its investment in sales-type leases. This review includes determining if a customer who entered into a sales-type lease is significantly underperforming relative to the customer's committed level of BIS Sensor purchases. If this review results in a lower estimate of the net realizable investment balance, an allowance for the unrealized amount is established in the period in which the estimate is changed and is charged to revenue.

***Warranty***

Equipment that the Company sells is generally covered by a warranty period of one year. The Company accrues a warranty reserve for estimated costs to provide warranty services. The Company's estimate of costs to service its warranty obligations is based on historical experience and an expectation of future conditions. Warranty expense for the years ended December 31, 2002, 2001 and 2000, and accrued warranty cost, included in accrued liabilities in the consolidated balance sheets at December 31, 2002 and 2001, was as follows:

| | Product Warranty |
|---|---|
| Balance as of January 1, 2000 | $1,348,000 |
| Warranty expense | 382,000 |
| Deductions and other | (255,000) |
| Balance as of December 31, 2000 | 1,475,000 |
| Warranty expense | (43,800) |
| Deductions and other | (341,080) |
| Balance as of December 31, 2001 | 1,090,120 |
| Warranty expense | (599,800) |
| Deductions and other | (122,522) |
| Balance as of December 31, 2002 | $ 367,798 |

***Advertising Costs***

Advertising costs are expensed as incurred. These costs are included in sales and marketing expense in the consolidated statements of operations. Advertising costs for the years ended December 31, 2002, 2001 and 2000 were approximately $672,000, $626,000 and $175,000, respectively.

***Property and Equipment***

Property and equipment is recorded at cost and depreciated using the straight-line method over the estimated useful lives of the related equipment. Equipment held under capital leases is stated at the lower of the fair market value of the equipment or the present value of the minimum lease payments at the inception of the lease and is amortized on a straight-line basis over the shorter of the lives of the related assets or the term of the leases. Maintenance and repair expenditures are charged to expense as incurred.

***Income Taxes***

The Company accounts for income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes.* Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences, utilizing currently enacted tax rates, of temporary differences between the carrying amounts and the tax basis of assets and liabilities. Deferred tax assets are recognized, net of any valuation allowance, for the estimated future tax effects of deductible temporary differences and tax operating loss and credit carryforwards.

***Concentration of Credit Risk and Single or Limited Source Suppliers***

Financial instruments that potentially expose the Company to concentrations of credit risk primarily consist of cash, cash equivalents, accounts receivable, investment in sales-type lease receivables and marketable securities. To minimize the financial statement risk with respect to accounts receivable and investment in sales-type lease receivables, the Company maintains reserves for potential credit losses and such losses, in the aggregate, have not exceeded management's expectations. The Company maintains cash, cash equivalents and investments in marketable securities with various financial institutions. The Company performs periodic evaluations of the relative credit quality of investments and Company policy is designed to limit exposure to any one institution or type of investment. The primary objective of the Company's investment strategy is the safety of the principal invested. The Company does not maintain foreign exchange contracts or other off-balance sheet financial investments.

The Company currently obtains certain key components of its products from single or limited sources. The Company purchases components pursuant to purchase orders rather than long-term supply agreements and generally does not maintain large volumes of inventory. The Company has experienced shortages and delays in obtaining certain components of its products in the past. There can be no assurance that the Company will not experience similar delays or shortages in the future. The disruption or termination of the supply of components or a significant increase in the costs of these components from these sources could have a material adverse effect on the Company's business, financial position and results of operations.

***Fair Value of Financial Instruments***

The estimated fair market values of the Company's financial instruments, which include cash equivalents, marketable securities, accounts receivable, investment in sales-type leases, accounts payable and long-term debt, approximate their carrying values.

***Net Loss Per Share***

The Company follows SFAS No. 128, *Earnings per Share.* Basic net loss per share represents net loss available to common stockholders divided by the weighted average number of common shares outstanding. The Company has excluded all shares of restricted common stock that are subject to repurchase by the Company from the weighted average number of common shares outstanding. Diluted net loss per share is the same as basic net loss per share as the inclusion of common stock issuable pursuant to the exercise of stock options, warrants and the conversion of convertible preferred stock would be antidilutive. For the years ended December 31, 2002, 2001, and 2000, the Company has excluded from the calculation of the Company's diluted earnings per share approximately 590,000, 1,049,000 and 3,162,000 shares, respectively, related to restricted common stock subject to repurchase and common stock issuable pursuant to the exercise of stock options, warrants and the conversion of convertible preferred stock because the inclusion of these shares would have been antidilutive as a result of the Company's net loss position for each of the three years then ended.

***Comprehensive Income (Loss)***

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Other than the Company's net loss, the only other element of comprehensive income (loss) impacting the Company is the unrealized gains (losses) on its marketable securities for all years presented.

***Stock-Based Compensation***

SFAS No. 123, *Accounting for Stock-Based Compensation,* requires the measurement of the fair value of stock options or warrants to be included in the statement of income or disclosed in the notes to financial statements. The Company accounts for stock-based compensation for employees under APB Opinion No. 25 and follows the disclosure-only alternative under SFAS No. 123. The Company has computed the weighted-average fair value of options granted in 2002, 2001 and 2000 using the Black-Scholes option-pricing model prescribed by SFAS No. 123. The following table shows the weighted average assumptions used in the applicable periods and the weighted average fair market value of the options granted in each period.

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2002 | 2001 | 2000 |
| Risk-free interest rate | 4.40% | 5.04% | 6.51% |
| Expected dividend yield | — | — | — |
| Expected life of options | 5 years | 5 years | 5 years |
| Expected volatility | 75% | 75% | 75% |
| Weighted average fair market value of options granted | $6.10 | $8.84 | $15.14 |

If the Company had recognized compensation cost for these awards consistent with SFAS No. 123, the Company's net loss and pro forma net loss per common share would have been increased to the following pro forma amounts:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2002 | 2001 | 2000 |
| Net loss: | | | |
| Net loss as reported | $(15,301,171) | $(17,718,559) | $(5,344,334) |
| Add: Stock-based compensation expense included in reported net loss | 31,441 | 65,371 | 543,010 |
| Deduct: Stock-based compensation expense determined under fair value based method for all awards | (7,775,610) | (7,066,156) | (4,827,821) |
| Pro forma net loss | $(23,045,340) | $(24,719,344) | $(9,629,145) |
| Net loss per share: | | | |
| Basic and diluted net loss per common share: | | | |
| As reported | $ (0.83) | $ (1.01) | $ (0.34) |
| Pro forma | $ (1.25) | $ (1.40) | $ (0.61) |

The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option-pricing models require the input of highly subjective assumptions, including expected stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair

value of its employee stock options. Also, because options vest over several years and the Company expects to grant options in future years, the above pro forma results of applying the provisions of SFAS No. 123 are not necessarily representative of the pro forma results in future years.

***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

***Reclassifications***

Certain amounts in the prior years' financial statements have been reclassified to conform with the current-year presentation.

***Recent Accounting Pronouncements***

In June 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities.* SFAS 146 requires that a liability for a cost associated with an exit or disposal activity be recognized and measured, initially at fair value, only when the liability is incurred; therefore, nullifying Emerging Issues Task Force, or EITF, Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)*, which required a liability for an exit cost to be recognized at the date of an entity's commitment to an exit plan. This change in accounting would be expected to result in a delayed recognition of certain types of costs, especially facility closure costs. The provisions of SFAS 146 are effective for exit or disposal activities that are initiated after December 31, 2002. Since SFAS 146 is effective only for new exit or disposal activities, adoption of this standard will not affect amounts currently reported in the Company's consolidated financial statements. However, the adoption of SFAS 146 could affect the types and timing of costs included in any future business consolidation and restructuring programs. The Company adopted SFAS 146 as of January 1, 2003.

In December 2002, the FASB issue SFAS No. 148, *Accounting for Stock-Based Compensation — Transition and Disclosure.* SFAS 148 amends SFAS 123 and APB No. 28, *Interim Financial Reporting* to present alternative methods of transition for an entity that voluntarily adopts the fair value based method of accounting for stock-based employee compensation, and provides modifications to the disclosure provisions to require prominent disclosure about the effects on reported net income of an entity's accounting policy decisions with respect to stock-based employee compensation in quarterly and annual financial statements. At this time, the Company has not voluntarily adopted the fair value method of accounting under SFAS 123. However, appropriate disclosures about the effects on reported net loss of the Company's accounting policy with respect to stock-based employee compensation are provided in these financial statements.

In November 2002, the FASB issued Financial Interpretation No. 45, ("FIN 45"), *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others.* FIN 45 requires a guarantor to disclose (a) the nature of the guarantee, and the events or circumstances that would require the guarantor to perform under the guarantee; (b) the maximum potential amount of future payments under the guarantee; (c) the carrying amount of the liability, if any, for the guarantor's obligations under the guarantee; and (d) the nature and extent of any recourse provisions or available collateral that would enable the guarantor to recover the amounts paid under the guarantee. FIN 45 also clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability at fair value for the obligations it has undertaken in issuing the guarantee, including its ongoing obligation to stand ready to

perform over the term of the guarantee in the event that the specified triggering events or conditions occur. The initial recognition and initial measurement provision of FIN 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. FIN 45 also addresses the disclosure requirements regarding product warranties. Instead of disclosing the maximum potential amount of future payments under the product warranty guarantee, a guarantor is required to disclose its accounting policy and methodology used in determining its liability for product warranties, as well as, a tabular reconciliation of the changes in the guarantor's product warranty liability for the reporting period, which the Company has provided in Note 2. The Company adopted FIN 45 as of January 1, 2003.

**(3) Cash Equivalents, Restricted Cash and Marketable Securities**

Cash and cash equivalents consist of the following:

| | December 31, | |
|---|---|---|
| | 2002 | 2001 |
| Cash | $ 8,795,587 | $13,325,776 |
| Commercial paper | 2,747,246 | 999,572 |
| | $11,542,833 | $14,325,348 |

At December 31, 2002, the Company maintained $5,100,000 of restricted cash as part of its revolving line of credit agreement (see Note 17).

Available-for-sale marketable securities at December 31, 2002 and 2001 consist of the following:

| | Amortized Cost | Unrealized Gains | Unrealized Losses | Fair Value |
|---|---|---|---|---|
| December 31, 2002 — | | | | |
| Corporate obligations | $20,201,600 | $118,244 | $ (97,344) | $20,222,500 |
| | $20,201,600 | $118,244 | $ (97,344) | $20,222,500 |
| December 31, 2001 — | | | | |
| U.S. Government debt securities | $ 9,004,730 | $ — | $ — | $ 9,004,730 |
| Corporate obligations | 12,994,281 | 469,507 | (435,890) | 13,027,898 |
| | $21,999,011 | $469,507 | $(435,890) | $22,032,628 |

All available-for-sale marketable securities have contractual maturities of one to two years.

The cost of securities sold is determined based on the specific identification method for purposes of recording realized gains and losses. Gross realized gains and losses on the sales of investments have not been material.

**(4) Investment in Sales-Type Leases**

The Company leases equipment to customers under sales-type leases. The components of the Company's net investment in sales-type leases are as follows:

| | December 31, | |
|---|---|---|
| | 2002 | 2001 |
| Total minimum lease payments receivable | $5,091,303 | $4,199,380 |
| Less — unearned interest | 949,315 | 791,421 |
| Net investment in sales-type leases | 4,141,988 | 3,407,959 |
| Less — current portion | 1,859,237 | 1,473,260 |
| | $2,282,751 | $1,934,699 |

Future minimum lease payments due under non-cancelable leases as of December 31, 2002 are as follows:

| Year Ending December 31, | |
|---|---|
| 2003 | $2,053,885 |
| 2004 | 1,429,359 |
| 2005 | 890,722 |
| 2006 | 536,300 |
| 2007 | 181,037 |
| | $5,091,303 |

**(5) Inventory**

Inventory consists of the following:

| | December 31, | |
|---|---|---|
| | 2002 | 2001 |
| Raw materials | $1,060,709 | $2,891,400 |
| Work-in-progress | 129,673 | 90,076 |
| Finished goods | 1,143,003 | 2,126,690 |
| | $2,333,385 | $5,108,166 |

## (6) Property and Equipment

Property and equipment consist of the following:

| | Useful Life in Years | December 31, 2002 | December 31, 2001 |
|---|---|---|---|
| Construction in progress | — | $ 51,152 | $ 397,022 |
| Computer equipment | 3 | 4,882,427 | 4,093,037 |
| Demonstration, evaluation and rental equipment | 2 | 65,013 | 1,074,746 |
| Machinery and equipment | 3 to 5 | 4,364,911 | 4,050,004 |
| Furniture and fixtures | 3 | 1,855,067 | 1,841,667 |
| Leasehold improvements | Shorter of the lease or useful life of the asset | 1,629,620 | 1,629,620 |
| | | 12,848,190 | 13,086,096 |
| Accumulated depreciation and amortization | | (8,726,630) | (7,390,660) |
| | | $ 4,121,560 | $ 5,695,436 |

## (7) Income Taxes

Deferred income tax assets consist of the following:

| | December 31, 2002 | December 31, 2001 |
|---|---|---|
| Net operating loss carryforwards | $ 29,664,000 | $ 24,061,000 |
| Tax credit carryforwards | 2,288,000 | 2,600,000 |
| Other | 4,316,000 | 2,882,000 |
| Gross deferred tax assets | 36,268,000 | 29,543,000 |
| Valuation allowance | (36,268,000) | (29,543,000) |
| Net deferred tax asset | $ — | $ — |

The Company has provided a full valuation allowance against its gross deferred tax assets at December 31, 2002 and 2001 because the future realizability of such assets is uncertain. The change in the valuation allowance was $6,725,000 from December 31, 2001 to December 31, 2002. Should the Company achieve profitability in the future, various components of the gross deferred tax assets would be available to offset future income tax liabilities and expenses.

The Company has net operating loss and research and development tax credit carryforwards for federal income tax purposes of approximately $79,106,000 and $1,888,000, respectively, at December 31, 2002, that began expiring in 2002 and will continue to expire through 2022 if not utilized. The net operating loss and research and development tax credit carryforwards are subject to review by the Internal Revenue Service. Ownership changes, as defined under Section 382 in the Internal Revenue Code, may limit the amount of these tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the Company's value immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years.

## (8) Stockholders' Equity

### *Convertible Preferred Stock*

On February 2, 2000, upon the closing of the Company's initial public offering, all 11,067,238 shares of the Company's convertible preferred stock automatically converted into 11,067,238 shares of common stock.

### *Warrants*

In December 1998, the Company issued warrants to purchase 192,902 shares of common stock in association with the issuance of convertible preferred stock. The warrants had an exercise price of $12.50 per share and warrants to purchase 160,110 shares of common stock expired unexercised on February 2, 2003, the third anniversary of the closing of the Company's initial public offering. The Company allocated the proceeds received between the preferred stock and the warrants based on the estimated fair market values of the convertible preferred stock and the warrants.

During 2000, the Company issued a total of 22,906 shares of common stock pursuant to the exercise of warrants issued by the Company in December 1998. The exercise price of the warrants was $12.50 per share of common stock; however, 10,806 shares of common stock were issued pursuant to a cashless exercise provision contained in the warrants. As a result, the Company received no consideration upon the exercise of those warrants and approximately $151,250 of consideration for the other 12,100 shares of common stock.

### *Common Stock*

On February 2, 2000, the Company completed the initial public offering of its common stock. Upon the closing of the initial public offering, the Company issued 3,500,000 shares of its common stock at an offering price of $15.00 per share. On February 4, 2000, the underwriters exercised in full their over-allotment option to purchase an additional 525,000 shares at $15.00 per share. Cash proceeds from the sale of the 4,025,000 shares of common stock, net of the underwriters' discount and offering expenses, totaled approximately $54,642,000.

At December 31, 2002, the Company has reserved 5,926,518 shares of common stock for issuance under the Company's stock option plans, 193,379 shares of common stock for issuance under the Company's 1999 Employee Stock Purchase Plan and 160,110 shares of common stock for issuance upon the exercise of outstanding warrants.

## (9) Stock Option Plans

The Company's stock option plans provided for the grant, at the discretion of the Board of Directors, of options for the purchase of up to 8,560,000 shares of common stock to employees, directors and advisors. Option prices are determined by the Board of Directors. Stock options and restricted common stock generally vest over two to four years and provide for the acceleration of vesting upon a change of control of the Company. At December 31, 2002, 1,827,406 shares of common stock were available for future grant under the Company's stock option plans.

A summary of stock option activity is as follows:

| | Number of Shares | Option Exercise Prices | Weighted Average Option Price per Share |
|---|---|---|---|
| Outstanding, December 31, 1999 | 2,695,680 | $ .20-45.83 | $ 4.60 |
| Granted | 1,326,187 | 4.20-47.88 | 20.34 |
| Exercised | (431,215) | .20-45.83 | 2.16 |
| Canceled | (183,921) | .20-28.63 | 9.36 |
| Outstanding, December 31, 2000 | 3,406,731 | .20-47.88 | 10.77 |
| Granted | 955,668 | 9.50-13.79 | 12.04 |
| Exercised | (382,737) | .20-12.63 | 3.48 |
| Canceled | (569,884) | .80-47.88 | 15.49 |
| Outstanding, December 31, 2001 | 3,409,778 | .20-47.88 | 11.16 |
| Granted | 1,323,700 | 2.51-10.55 | 7.40 |
| Exercised | (90,694) | .20-10.20 | 2.39 |
| Canceled | (543,672) | 2.80-28.63 | 10.52 |
| Outstanding, December 31, 2002 | 4,099,112 | $ .20-47.88 | $10.23 |
| Exercisable, December 31, 2002 | 2,327,699 | $ .20-47.88 | $10.03 |

During 1997 and 1998, the Company accelerated the vesting of certain employees' and directors' stock options. These employees and directors exercised options to acquire 1,495,470 shares of common stock. The option exercise price was paid in the form of cash of $45,735 and by delivery to the Company of full recourse promissory notes of $336,580. These promissory notes bear interest at 5.28% per annum and are payable over periods ranging up to five years. The shares of common stock were subject to a repurchase right by the Company. As of December 31, 2002, no shares remained subject to repurchase and $158,674 of these loans remained outstanding.

During 2000, one employee exercised stock options to purchase 143,511 shares of common stock with a full recourse promissory note of $234,420. The loan is payable over five years and bears interest at a rate of 8% per annum. As of December 31, 2002, $112,375 of this loan remained outstanding. These loans are included as a reduction of stockholders' equity in the accompanying consolidated balance sheets.

A summary of outstanding and exercisable options as of December 31, 2002 is as follows:

| | Outstanding | | | Exercisable | |
|---|---|---|---|---|---|
| Exercise Price | Number | Weighted Average Remaining Contractual Life | Weighted Average Exercise Price | Number | Weighted Average Exercise Price |
| $ 0.20 – $ 2.80 | 461,341 | 5.07 | $ 1.27 | 430,357 | $ 1.17 |
| 3.26 – 3.85 | 348,859 | 9.58 | 3.77 | 6,000 | 3.85 |
| 4.20 | 411,377 | 5.54 | 4.20 | 411,377 | 4.20 |
| 4.96 – 8.56 | 510,114 | 7.79 | 7.00 | 260,643 | 7.47 |
| 9.40 – 9.80 | 171,816 | 9.06 | 9.72 | 43,122 | 9.70 |
| 10.00 | 456,279 | 9.03 | 10.00 | 115,743 | 10.00 |
| 10.19 – 10.55 | 482,091 | 7.24 | 10.27 | 352,545 | 10.22 |
| 11.00 – 12.50 | 587,430 | 8.30 | 12.01 | 287,910 | 12.00 |
| 12.63 – 15.00 | 96,320 | 7.91 | 13.23 | 53,372 | 13.42 |
| 23.63 – 47.88 | 573,485 | 7.45 | 26.52 | 366,630 | 26.74 |
| $ 0.20 – $47.88 | 4,099,112 | 7.57 | $10.23 | 2,327,699 | $10.03 |

In 2002, 2001 and 2000, the Company recorded additional deferred compensation of approximately $8,000, $13,500, and $393,000, respectively, which represents the estimated fair value of stock options granted to non-employees.

***1991 Amended and Restated Stock Option Plan***

The Company's 1991 Amended and Restated Stock Option Plan provides for the granting, at the discretion of the Board of Directors, of options for the purchase of up to 3,360,000 shares of common stock to employees, directors and advisors. Option prices are determined by the Board of Directors.

***1998 Stock Incentive Plan***

The Company's 1998 Stock Incentive Plan (the "1998 Incentive Plan") was adopted by the Board of Directors on July 8, 1998. The Board of Directors has authorized the Compensation Committee to administer the 1998 Incentive Plan, including the granting of options to executive officers. At December 31, 2002, the 1998 Incentive Plan provided for the granting, at the discretion of the Compensation Committee, of options for the purchase of up to 3,000,000 shares of common stock (subject to adjustment in the event of stock splits and other similar events) to employees, directors and advisors. Option prices are determined by the Compensation Committee, but cannot be less than 100% of fair market value for incentive stock options.

***1998 Director Stock Option Plan***

In February 1998, the Company adopted the 1998 Director Stock Option Plan (the "Director Plan"). Under the terms of this plan, directors of the Company who are not employees of the Company are eligible to receive nonstatutory options to purchase shares of common stock. At December 31, 2002, a total of 200,000 shares of common stock could be issued upon exercise of options under this plan. The initial options granted under the Director Plan are exercisable as to 50% of the shares pursuant to the option as of the date of grant and as to one-sixth of the shares on the first, second and third anniversaries of the date of grant, provided that the optionee continues to serve as a director and provide for the acceleration of vesting upon a change of control of the Company. Additional options granted will be exercisable in three equal annual installments on each of the first, second and third anniversaries of the date of grant, provided that the optionee continues to

serve as a director. Options granted under the Director Plan terminate on the earlier of (i) ten years from the date of grant, or (ii) sixty days after the optionee ceases to serve as a director.

*1999 Employee Stock Purchase Plan*

In December 1999, the Company adopted its 1999 Employee Stock Purchase Plan (the "Purchase Plan"). The Purchase Plan allows eligible employees the right to purchase shares of common stock at the lower of 85% of the closing price per share of common stock on the first or last day of an offering period. Each offering period is six months. An aggregate of 300,000 shares of common stock have been reserved for issuance pursuant to the Purchase Plan. As of December 31, 2002, 106,621 shares of the Company's common stock had been issued under the Purchase Plan.

*2001 Stock Incentive Plan*

The Company's 2001 Stock Incentive Plan (the "2001 Incentive Plan") was adopted by the Company's Board of Directors on March 19, 2001 and approved by the Company's stockholders on May 22, 2001. The Board of Directors has authorized the Compensation Committee to administer the 2001 Incentive Plan, including the granting of options to executive officers. At December 31, 2002, the 2001 Incentive Plan provided for the granting, at the discretion of the Compensation Committee, of options for the purchase of up to 2,000,000 shares of common stock (subject to adjustment in the event of stock splits and other similar events) to employees, directors and advisors. Option prices are determined by the Compensation Committee, but cannot be less than 100% of fair market value for incentive stock options.

**(10) Distribution and Licensing Agreements**

The Company has entered into various distribution, licensing and royalty agreements relating to its products with distributors and original equipment manufacturers covering both the domestic and international markets. These agreements have original terms ranging from two to ten years. In connection with these agreements, approximately $7,385,000 and $1,519,000 in revenue was deferred as of December 31, 2002 and 2001, respectively. The deferred revenue includes prepaid license and royalty fees. The deferred revenue is recognized upon product shipment and as license and royalty fees are earned. License and royalty fees are related to future technological developments and will be recognized upon shipment of units incorporating the technology.

**(11) 401(k) Savings Plan**

The Company has a 401(k) savings plan in which substantially all domestic employees can participate. Employer contributions are at the discretion of the Board of Directors and vest ratably over five years. The Company made no contributions to the plan during the years ended December 31, 2002, 2001 and 2000.

**(12) Commitments and Contingencies**

*Leases*

The Company leases approximately 61,000 square feet of development, production and administrative space in Newton, Massachusetts under an operating lease that expires in December 2006. The Company's international organization leases approximately 2,800 square feet of office space in Leiden, The Netherlands under an operating lease that expires in February 2004. Rent expense was approximately $966,000, $967,000

and $1,150,000 in 2002, 2001 and 2000, respectively. Future gross minimum lease commitments for all non-cancelable operating leases as of December 31, 2002 are as follows:

| Year Ending December 31, | |
|---|---|
| 2003 | $1,250,234 |
| 2004 | 1,166,829 |
| 2005 | 1,013,176 |
| 2006 | 995,196 |
| Total minimum lease payments | $4,425,435 |

**(13) Other Related Party Transactions**

In addition to the related party transactions discussed in Note 9, the Company has made other loans to certain employees and a consultant of the Company. Through December 31, 2001, the Company loaned, on a full recourse basis, an aggregate of $1,441,000, to an officer, certain employees and a consultant of the Company. In May 2002, the Company loaned, on a full recourse basis, $50,000 to another officer of the Company. On September 27, 2002, that officer left the employ of the Company and the note and accrued interest became due and payable. The loans are evidenced by promissory notes bearing interest with rates ranging from 5.00% to 8.00% per annum. The loans are payable over periods ranging from one to five years and in each case are secured by assets of the borrower, including shares of the Company's common stock owned by the borrower. The long-term portion of the loans is included in long-term notes receivable from related parties and the short-term portion of approximately $128,000 and $87,000 at December 31, 2002 and 2001, respectively, is included in other current assets in the accompanying consolidated balance sheets. The aggregate outstanding balance on these loans at December 31, 2002 and 2001 was approximately $1,160,000 and $1,209,000, respectively.

In January 2002, the Company entered into a consulting agreement with one of its directors to provide consulting, advisory and neuroscience business planning services to the Company. As of December 31, 2002, the Company has paid approximately $9,000 to this director under this consulting agreement.

**(14) Accrued Liabilities**

Accrued liabilities consist of the following:

| | December 31, | |
|---|---|---|
| | 2002 | 2001 |
| Payroll and payroll-related | $3,975,418 | $3,467,479 |
| Professional services | 372,287 | 241,817 |
| Warranty | 367,798 | 1,090,120 |
| Other | 2,411,588 | 2,636,820 |
| | $7,127,091 | $7,436,236 |

**(15) Segment Information and Enterprise Reporting**

The Company operates in one reportable segment as it has one family of anesthesia monitoring systems. The Company does not disaggregate financial information by product or geographically, other than export sales by region and sales by product, for management purposes. Substantially all of the Company's assets are located within the United States. All of the Company's products are manufactured in the United States.

Revenue by geographic destination and as a percentage of total revenue is as follows:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2002 | 2001 | 2000 |
| **Geographic Area by Destination** | | | |
| Domestic | $33,089,108 | $28,164,957 | $30,085,477 |
| International | 6,687,286 | 7,663,894 | 5,938,087 |
| | $39,776,394 | $35,828,851 | $36,023,564 |

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2002 | 2001 | 2000 |
| **Geographic Area by Destination** | | | |
| Domestic | 83% | 79% | 84% |
| International | 17 | 21 | 16 |
| | 100% | 100% | 100% |

The Company did not have sales in any individual country, other than the United States, that accounted for more than 10% of the Company's total revenue for the years ended December 31, 2002, 2001 and 2000.

**(16) Valuation and Qualifying Accounts**

The following table sets forth activity in the Company's allowance for doubtful accounts:

| | Balance at Beginning of Period | Charges (Credits) to Expenses | Deductions | Balance at End of Period |
|---|---|---|---|---|
| Year Ended — | | | | |
| December 31, 2000 | $407,000 | $ 15,000 | $ — | $422,000 |
| December 31, 2001 | 422,000 | 100,000 | — | 522,000 |
| December 31, 2002 | 522,000 | (100,000) | 14,000 | 408,000 |

**(17) Loan Agreements**

In May 2001, the Company paid the outstanding principal on both the equipment portion and term loan portion of its December 1999 loan agreement with a commercial bank and terminated the agreement. Following the termination of this loan agreement, the Company entered into an agreement with another commercial bank for a revolving line of credit. The Company is entitled to borrow up to $5,000,000 under the revolving line of credit, which expires in May 2004, and, subject to annual review by the commercial bank, may be extended at the discretion of the commercial bank. Interest on any borrowings under the revolving line of credit is, at the election of the Company, either the prime rate or at LIBOR plus 2.25%. Up to $1,500,000 of the $5,000,000 revolving line of credit is available for standby letters of credit. At December 31, 2002, the Company had outstanding standby letters of credit totaling $295,000.

The revolving line of credit agreement contains restrictive covenants that require the Company to maintain liquidity and net worth ratios and is secured by certain investments of the Company, which are shown as restricted cash in the accompanying consolidated balance sheets, in an amount equal to 102% of the $5,000,000 commitment, or $5,100,000. At December 31, 2002, there was no outstanding balance under the revolving line of credit, and the Company was in compliance with all covenants contained in the revolving line of credit agreement. At December 31, 2002, the interest rate on the revolving line of credit was 4.25%.

The Company also has entered into an agreement for a $5,000,000 revolving line of credit with Boston Scientific Corporation in connection with a strategic alliance entered into in August 2002 (see Note 18).

In July 1999, the Company entered into an agreement under which it can sell a portion of its existing and future investments in sales-type leases to a third-party finance company. Through December 31, 2002, the Company sold approximately $4.9 million of investments in sales-type leases. In accordance with SFAS No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities — A Replacement of FASB Statement No. 125*, the proceeds from these sales have been classified as debt in the accompanying consolidated balance sheets. This debt bears interest at rates ranging from 11.0% to 12.5%. Payments on the outstanding principal under this debt match the timing of the payments due on the underlying investments in sales-type leases.

Future principal payments under the Company's sales-type lease debt agreements are as follows:

| Year Ending December 31, | |
|---|---|
| 2003 | $ 887,538 |
| 2004 | 593,678 |
| 2005 | 276,538 |
| 2006 | 109,331 |
| 2007 | 35,554 |
| Total principal payments | $1,902,639 |

**(18) Strategic Alliance with Boston Scientific Corporation**

On August 7, 2002, the Company formed a strategic alliance with Boston Scientific Corporation, ("BSC"). In connection with this strategic alliance, the Company sold 1,428,572 shares of the Company's common stock at a purchase price per share of $7.00 to BSC pursuant to a stock purchase agreement and granted BSC an option to distribute newly developed technology for monitoring patients under sedation in a range of less-invasive medical specialties. Gross cash proceeds from this sale of common stock were $10,000,004. Approximately $6,100,000 of the aggregate purchase price was recorded as deferred revenue in the accompanying consolidated balance sheet at December 31, 2002, which represents the portion of the purchase price in excess of the closing price of the Company's common stock on August 7, 2002. The deferred revenue will be recognized ratably over the term of the OEM product development and distribution agreement that the Company entered into with BSC in August 2002. The term of the agreement continues until such time that BSC is no longer distributing the Company's products, but in no event will extend beyond December 31, 2012.

As part of the strategic alliance with BSC, the Company also entered into an agreement pursuant to which BSC has agreed to provide the Company a $5,000,000 revolving line of credit which expires in August 2007 and may be extended at the discretion of BSC. Interest on any borrowings under this revolving line of credit is at a rate equal to the LIBOR rate at which BSC, under its own revolving credit facility, is entitled to borrow funds plus any additional amounts payable thereon by BSC under such revolving credit facility, plus eighty basis points. The Company's revolving line of credit with BSC is secured by the Company's inventory and certain of the Company's accounts receivable and contains certain restrictive covenants with respect to the collateral. At December 31, 2002, there was no outstanding balance under this revolving line of credit, and the Company was in compliance with all covenants contained in the revolving line of credit agreement.

**(19) Summarized Quarterly Financial Data (Unaudited)**

The tables that follow summarize unaudited quarterly financial data for the years ended December 31, 2002 and December 31, 2001:

| | For the Quarter Ended | | | |
|---|---|---|---|---|
| | March 30, 2002 | June 29, 2002 | September 28, 2002 | December 31, 2002 |
| Revenue | $ 9,686,566 | $10,051,223 | $ 9,995,213 | $10,043,392 |
| Gross margin | 6,169,030 | 7,027,172 | 7,191,934 | 7,572,871 |
| Operating expenses | 11,143,113 | 10,917,212 | 10,827,372 | 11,330,048 |
| Net loss | $(4,699,518) | $(3,661,838) | $(3,406,117) | $(3,533,698) |
| Basic and diluted net loss per share | $ (0.26) | $ (0.20) | $ (0.18) | $ (0.18) |

| | For the Quarter Ended | | | |
|---|---|---|---|---|
| | March 31, 2001 | June 30, 2001 | September 29, 2001 | December 31, 2001 |
| Revenue | $ 8,862,820 | $ 8,973,021 | $ 8,528,080 | $ 9,464,930 |
| Gross margin | 6,092,208 | 6,092,496 | 5,477,003 | 5,721,206 |
| Operating expenses | 10,811,639 | 11,083,420 | 10,822,913 | 10,948,212 |
| Net loss | $(3,797,207) | $(4,266,505) | $(4,837,108) | $(4,817,739) |
| Basic and diluted net loss per share | $ (0.22) | $ (0.24) | $ (0.27) | $ (0.27) |

## EXHIBIT INDEX

| Exhibit No. | Exhibit |
|---|---|
| 3(i).1 | Restated Certificate of Incorporation is incorporated herein by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-86295). |
| 3(ii).1 | Amended and Restated By-Laws are incorporated herein by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the period ended March 31, 2001 (File No. 0-24663). |
| 4.1 | Specimen common stock certificate is incorporated herein by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-86295). |
| 4.2 | See Exhibits 3(i).1 and 3(ii).1 for provisions of the Registrant's certificate of incorporation and by-laws defining the rights of holders of common stock. |
| 10.1 | 1998 Director Stock Option Plan, as amended, is incorporated herein by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-86295). |
| 10.2† | International Distribution Agreement, dated as of January 21, 1998, by and between the Registrant and Nihon Kohden Corporation is incorporated herein by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-86295). |
| 10.3† | International License Agreement, dated as of January 21, 1998, by and between the Registrant and Nihon Kohden Corporation is incorporated herein by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-86295). |
| 10.4 | License Agreement, dated as of October 31, 1995, by and between the Registrant and Siemens Medical Systems, Inc. is incorporated herein by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-86295). |
| 10.5† | Product Agreement, dated May 5, 1999, by and between the Registrant and Drager Medizintechnik GmbH is incorporated herein by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (File No. 333-86295). |
| 10.6† | OEM Development and Purchase Agreement, dated August 6, 1999, by and between the Registrant and Philips Medizinsysteme Boeblingen GmbH (formerly Agilent Technologies, Inc.) is incorporated herein by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (File No. 333-86295). |
| 10.7† | Letter Agreement, dated August 27, 1999, by and between the Registrant and Philips Medizinsysteme Boeblingen GmbH (formerly Agilent Technologies, Inc.) is incorporated herein by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-86295). |
| 10.8† | Distribution and License Agreement, dated as of April 1, 1996, between SpaceLabs Medical, Inc. and the Registrant is incorporated herein by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-86295). |
| 10.9 | Promissory Note, dated February 18, 1997, as amended on April 14, 1997, made in favor of the Registrant by Nassib G. Chamoun, together with Pledge Agreement, dated as of February 18, 1997, as amended on April 14, 1997, by and between the Registrant and Nassib G. Chamoun are incorporated herein by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-86295). |
| 10.10 | Promissory Note, dated May 1, 1997, made in favor of the Registrant by Nassib G. Chamoun, together with Pledge Agreement, dated as of May 1, 1997, by and between the Registrant and Nassib G. Chamoun are incorporated herein by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 (File No. 333-86295). |
| 10.11 | Promissory Note, dated May 1, 1997, made in favor of the Registrant by Nassib G. Chamoun, together with Pledge Agreement, dated as of May 1, 1997, by and between the Registrant and Nassib G. Chamoun are incorporated herein by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1 (File No. 333-86295). |

| Exhibit No. | Exhibit |
|---|---|
| 10.12 | Form of Promissory Note made in favor of the Registrant by certain directors and executive officers, together with Form of Pledge Agreement, by and between the Registrant and certain directors and executive officers, together with a schedule of material terms are incorporated herein by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1 (File No. 333-86295). |
| 10.13 | Promissory Note, dated April 10, 1998, made in favor of the Registrant by Jeffrey Barrett, together with Pledge Agreement, dated as of April 10, 1998, by and between the Registrant and Jeffrey Barrett are incorporated herein by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1 (File No. 333-86295). |
| 10.14 | Fourth Amended and Restated Registration Rights Agreement, dated December 17, 1998, by and among the Registrant and the several purchasers named on the signature pages thereto is Registrant's Registration Statement on Form S-1 (File No. 333-86295). |
| 10.15 | Form of Warrant to purchase the Registrant's common stock, together with schedule of warrantholders are incorporated herein by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form S-1 (File No. 333-86295). |
| 10.16† | Supplier Agreement, dated August 13, 1999, between Novation, LLC and the Registrant is incorporated herein by reference to Exhibit 10.24 to the Registrant's Registration Statement on Form S-1 (File No. 333-86295). |
| 10.17† | Medical Products Distribution Agreement, dated October 1, 1999, between Philips Medizinsysteme Boeblingen GmbH (formerly Agilent Technologies, Inc.) and the Registrant is incorporated herein by reference to Exhibit 10.25 to the Registrant's Registration Statement on Form S-1 (File No. 333-86295). |
| 10.18† | Amendment, dated March 1, 2001, to Medical Products Distribution Agreement, dated October 1, 1999, between Philips Medizinsysteme Boeblingen GmbH and the Registrant is incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the period ended September 29, 2001 (File No. 0-24663). |
| 10.19† | OEM Development and Purchase Agreement, dated December 22, 1999, by and between the Registrant and GE Marquette Medical Systems, Inc. is incorporated herein by reference to Exhibit 10.26 to the Registrant's Registration Statement on Form S-1 (File No. 333-86295). |
| 10.20† | Master Distribution Agreement, dated September 1, 2000, by and between the Registrant and Datex-Ohmeda Division of Instrumentarium Corporation is incorporated herein by reference to Exhibit 10.21 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2000 (File No. 0-24663). |
| 10.21 | Promissory Note, dated July 13, 2000, made in favor of the Registrant by Nassib Chamoun, together with Pledge Agreement, dated as of July 13, 2000, by and between the Registrant and Nassib Chamoun is incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the period ended March 31, 2000 (File No. 0-24663). |
| 10.22 | Sublease Agreement, dated as of October 15, 1999, by and between Newton Technology Park LLC and the Registrant is incorporated herein by reference to Exhibit 10.24 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2000 (Commission File No. 0-24663 Iomega). |
| 10.23 | Promissory Note, dated April 10, 2001, made in favor of Registrant by Nassib G. Chamoun, together with Pledge Agreement, dated as of April 10, 2001, by and between the Registrant and Nassib G. Chamoun is incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the period ended March 31, 2001 (File No. 0-24663). |
| 10.24 | Revolving Credit Facility, dated as of May 16, 2001, by and between the Registrant and Fleet National Bank, together with Promissory Note, dated May 16, 2001, by and between the Registrant and Fleet National Bank and Pledge Agreement, dated as of May 16, 2001, by and between the Registrant and Fleet National Bank is incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the period ended June 30, 2001 (File No. 0-24663). |

| Exhibit No. | Exhibit |
|---|---|
| 10.25 | First Amendment, dated December 21, 2001, to Loan Agreement, dated as of May 16, 2001, by and between the Registrant and Fleet National Bank is incorporated herein by reference to Exhibit 10.26 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001 (File No. 0-24663). |
| 10.26† | Addendum No. 1, effective January 1, 2002, to OEM Development and Purchase Agreement, dated December 22, 1999, by and between the Registrant and GE Medical Systems, Inc. is incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the period ended March 30, 2002 (File No. 0-24663). |
| 10.27 | Advisory Board Agreement, dated as of January 23, 2002, by and between Stephen E. Coit and the Registrant is incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the period ended March 30, 2002 (File No. 0-24663). |
| 10.28 | Amendment Number 1, dated June 10, 2002, to the Master Distribution Agreement, dated September 1, 2000, by and between the Registrant and Datex-Ohmeda Division of Instrumentarium Corporation is incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the period ended June 29, 2002 (File No. 0-24663). |
| 10.29 | Stock Purchase Agreement, dated as of August 7, 2002, by and between the Registrant and Boston Scientific Corporation is incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated August 7, 2002 (File No. 0-24663). |
| 10.30 | Registration Rights Agreement, dated as of August 7, 2002, by and between the Registrant and Boston Scientific Corporation is incorporated herein by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K dated August 7, 2002 (File No. 0-24663). |
| 10.31 | Loan Agreement, dated August 7, 2002, by and between the Registrant and Boston Scientific Corporation, together with Security Agreement, dated August 7, 2002, by and between the Registrant and Boston Scientific Corporation and Promissory Note dated as of August 7, 2002, made by the Registrant in favor of Boston Scientific Corporation are incorporated herein by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K dated August 7, 2002 (File No. 0-24663). |
| 10.32† | OEM Product Development Agreement, dated as of August 7, 2002, by and between the Registrant and Boston Scientific Corporation is incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the period ended September 28, 2002 (File No. 0-24663). |
| 10.33 | Third Amendment, dated March 21, 2003, to Loan Agreement, dated as of May 16, 2001, by and between the Registrant and Fleet National Bank. |
| 21.1 | Subsidiaries of the Registrant. |
| 23.1 | Consent of Ernst & Young LLP. |
| 23.2 | Notice Regarding Consent of Arthur Andersen LLP. |
| 99.1 | Certification by Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 99.2 | Certification by Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |

† Confidential treatment has been requested as to certain portions of this Exhibit. Such portions have been omitted and filed separately with the Securities and Exchange Commission.