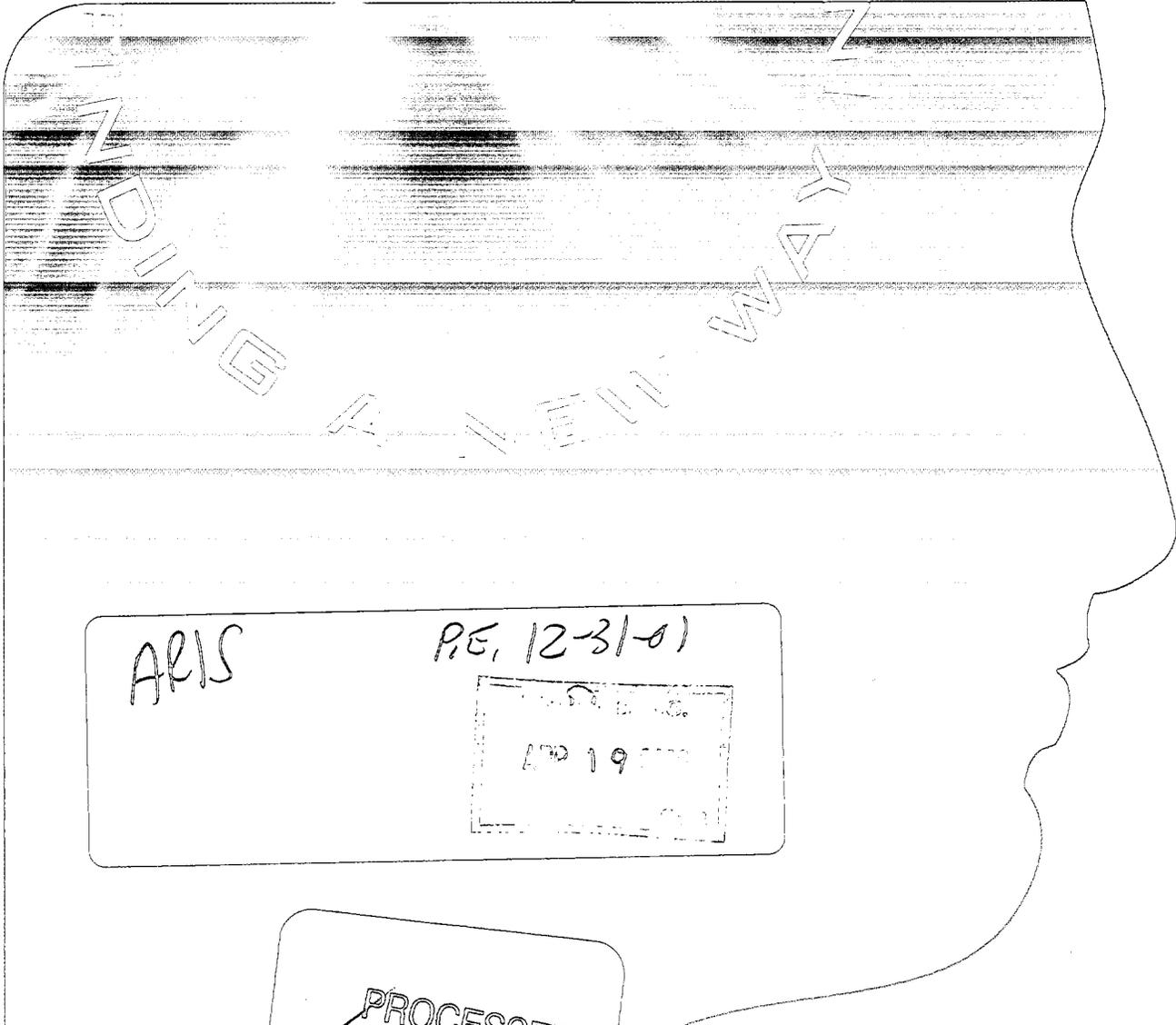


THE HUMAN BRAIN

ASPECT MEDICAL SYSTEMS ANNUAL REPORT 2001

FNC



FINDING A NEW WAY

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ASPECT

MEDICAL SYSTEMS, INC.

(NASDAQ: ASPM) WAS

FOUNDED IN 1987 TO DEVELOP

A TECHNOLOGY TO MEASURE AN

UNKNOWN ELEMENT OF PATIENT STATUS:

THE EFFECTS OF DRUGS ON THE BRAIN.

IN 1996, AFTER MILLIONS OF DOLLARS

OF INVESTMENT IN R&D, ASPECT LAUNCHED

BISPECTRAL INDEX (BIS®) TECHNOLOGY - THE FIRST

FDA CLEARED MEASURE OF ANESTHETIC EFFECTS

ON THE BRAIN. SINCE THE LAUNCH, ASPECT HAS

RAPIDLY ESTABLISHED ITSELF AS THE GLOBAL

MARKET LEADER. BIS TECHNOLOGY HAS BEEN USED

TO ASSESS MORE THAN 4.5 MILLION PATIENTS

AND HAS BEEN THE SUBJECT OF MORE THAN 850

PUBLISHED ARTICLES AND ABSTRACTS. IT IS

CURRENTLY IN USE IN THE ORS AND ICUS OF MORE

THAN 60 PERCENT OF THE BEST-RANKED

HOSPITALS WITH OPERATING ROOMS IN THE UNITED

STATES (U.S. NEWS & WORLD REPORT),

AND IS AVAILABLE IN MORE THAN

160 COUNTRIES. BASED IN NEWTON,

MASSACHUSETTS, ASPECT EMPLOYS

MORE THAN 220 PEOPLE

WORLDWIDE.

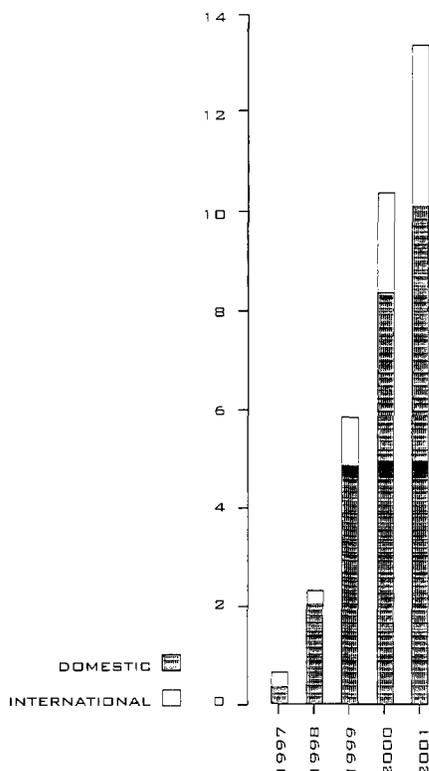
THE BRAIN'S CAPABILITY APPEARS TO BE ENDLESS. SO ARE OUR OPPORTUNITIES TO UN

YEAR ENDED DECEMBER 31,	2001	2000	1999	1998	1997
Revenue	\$ 35,829	\$ 36,024	\$ 27,187	\$ 11,238	\$ 3,068
Gross profit	23,383	24,745	17,863	5,358	(534)
Gross profit percentage	65.3%	68.7%	65.7%	47.7%	(17.4)%
Expenses:					
Research & development	7,467	5,713	4,847	4,042	2,603
Sales & marketing	28,396	21,979	16,543	10,354	4,813
General & administrative	<u>7,803</u>	<u>6,390</u>	<u>4,829</u>	<u>4,254</u>	<u>2,358</u>
Total expenses	43,666	34,082	26,219	18,650	9,774
Loss from operations	(20,283)	(9,337)	(8,356)	(13,292)	(10,308)
Interest income, net	2,564	3,993	1,317	459	422
Other expense	-	-	-	(774)	-
Net loss	<u><u>\$(17,719)</u></u>	<u><u>\$ (5,344)</u></u>	<u><u>\$ (7,039)</u></u>	<u><u>\$(13,607)</u></u>	<u><u>\$(9,886)</u></u>
Net loss per share:					
Basic and diluted	<u><u>\$ (1.01)</u></u>	<u><u>\$ (0.34)</u></u>	<u><u>\$ (4.57)</u></u>	<u><u>\$ (11.70)</u></u>	<u><u>\$(15.63)</u></u>
Weighted average shares used in computing net loss per share:					
Basic and diluted	17,614	15,755	1,539	1,163	632

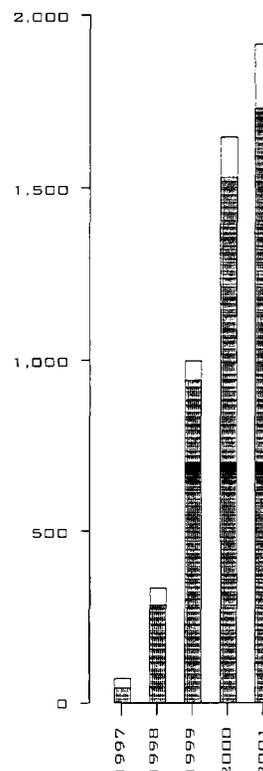
CONSOLIDATED BALANCE SHEET DATA (in thousands)

Cash, cash equivalents, restricted cash and marketable securities					
	\$ 41,458	\$ 58,489	\$ 14,535	\$ 21,273	\$ 4,981
Working capital	41,266	58,455	12,279	19,104	3,572
Total assets	63,369	79,411	29,402	28,589	7,603
Long-term debt	964	2,617	3,872	1,441	118
Total stockholders' equity	48,056	63,974	13,079	19,688	4,067

MONITOR & MODULE
INSTALLED BASE (IN THOUSANDS)



SENSOR SHIPMENTS
(IN THOUSANDS)



Aspect's live or work – is preceded by a much longer period of evolution, a period when innovation and increasing acceptance is nurtured through the combined efforts and experience of technology developers and users.

In the lifetime of any successful innovation or technology there comes a “tipping point,” the moment at which an idea, or a product, becomes a necessity. And once it becomes a part of our routine, it is difficult to recall how dramatically it changed the way we once did things.

Aspect's BIS technology, developed to measure the effects of anesthetics and sedatives on the brain, is, I believe, fast approaching the tipping point. Why? Because the improvements to patient care made possible by BIS are real, they are measurable, and they are profound; and because BIS is showing great promise beyond the operating room (OR) where it now allows doctors and nurses to measure with great precision the effects of anesthesia and sedatives on the brain.

Our mission at Aspect is simple: to help medical professionals deliver the best possible patient care by providing brain monitoring technologies that enhance clinical decision-making.

At the same time, Aspect faces a challenge that almost all new technologies face in the marketplace – how to communicate the benefits of BIS to those who have not yet used it, and how to overcome the natural resistance of practitioners who are comfortable with their current methods of practice.

Aspect has reached the early adopters – those innovators who quickly embrace new, promising technologies – with 26% of all operating rooms in the United States equipped with BIS monitoring, and approximately 8.5% of all patients receiving general anesthesia or deep sedation being monitored with BIS. Now, we must reach out to the larger community of anesthesia providers who are not yet using BIS technology, and demonstrate to them the myriad ways BIS can enhance and enrich their current methods of practice. We must also demonstrate the value of our technology outside the OR, for example in the critical care setting and in other procedure rooms where sedatives are routinely used. To do so, we have assembled a team of skilled professionals with decades of experience leading companies, such as ours, through this stage of growth.

A number of key developments in 2001 were part of our evolution. Last year Aspect:

SUCCESSFULLY LAUNCHED into the operating room market the next generation BIS XP monitoring system, which is resistant to artifact and electrocautery devices. In January 2002, BIS XP was also used as the platform for launching BIS into the sizeable critical care market.

COMPLETED the development of a new family of sensors designed to operate with the XP system including:

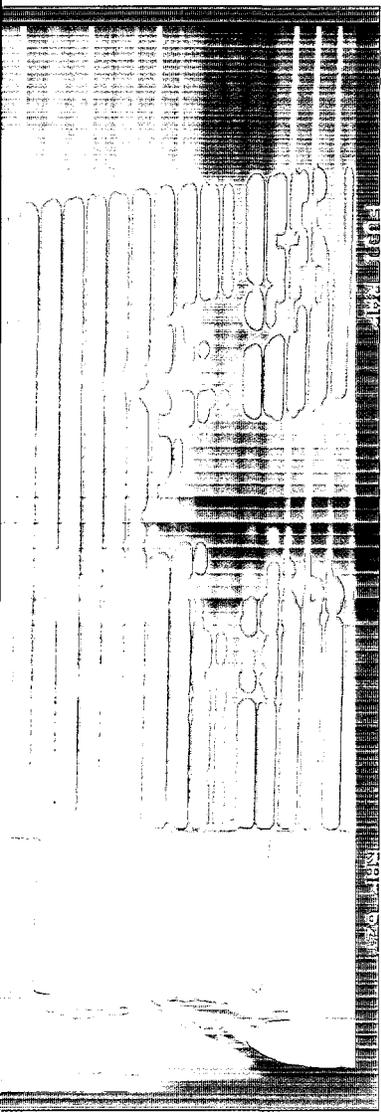


BIS Extend, specially designed for patients who are typically monitored for an extended period of time, such as patients in the ICU.

BIS Pediatric, the first and only commercially available sensor specifically designed for consciousness monitoring in children.

BIS Quatro, an enhanced version of our standard sensor product that is used primarily in the operating room.

INCREASED our worldwide installed base of BIS monitors and modules by approximately 30%.



WORKED IN CONCERT with our marketing partner in Japan, Nihon Kohden, to receive approval from the Japanese Ministry of Health, Labour & Welfare (MHLW) to market the A-2000 BIS monitor. This led the way to approval from the MHLW in January 2002 for reimbursement for use of the BIS monitor in Japan.

INTRODUCED new BIS module solutions to the market with our OEM partners. Combined, these manufacturers equip more than 90% of all operating rooms and intensive care units worldwide with patient monitoring solutions, giving BIS technology considerable market access.

LAUNCHED a formal neurodiagnostics research program to explore how extensions of our technology may apply in the diagnosis and tracking of neurological diseases such as Alzheimer's and depression.

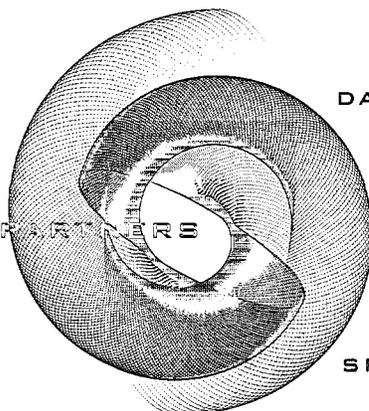
We believe that these important developments position us well for the year ahead. The market opportunity and the promise of Aspect's technology for monitoring the effects of drugs and disease on the brain are significant. I am proud of our accomplishments, optimistic about our future, and committed to delivering the promise of BIS technology to every patient for whom monitoring of the brain can improve the quality of their medical care.

Sincerely,

NASSIB G. CHAMOUN

CEO, PRESIDENT & FOUNDER, ASPECT MEDICAL SYSTEMS

ASPECT MEDICAL SYSTEMS OEM PARTNERS



DATEX-OHMEDA

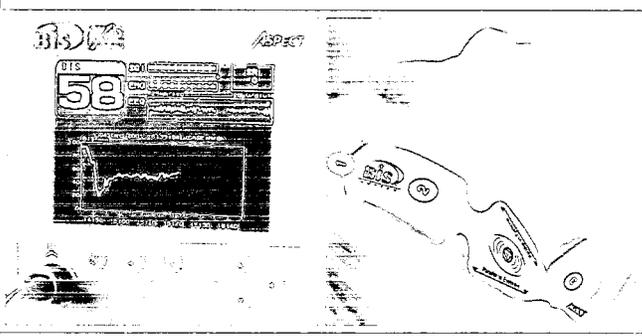
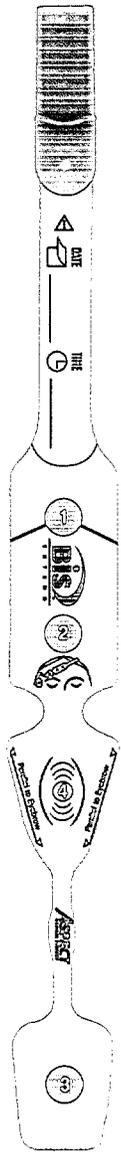
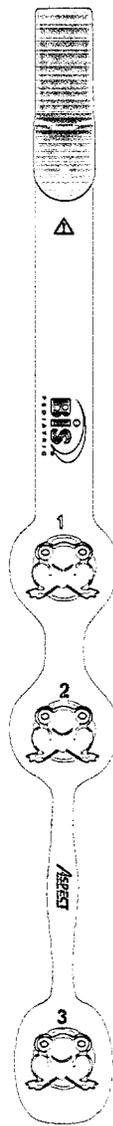
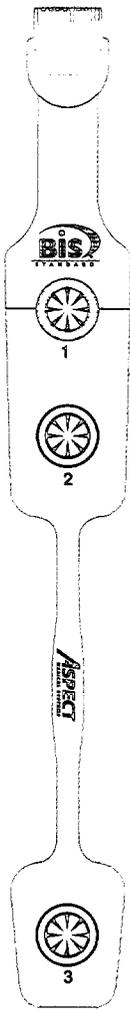
DRÄGER

GE MEDICAL SYSTEMS
INFORMATION TECHNOLOGY

NIHON KOHDEN

PHILIPS

SPACELABS MEDICAL



ASPECT HISTORY

- 1991 FIRST ARTICLES PUBLISHED
- 1992 FDA CLEARANCE: A-1000 EEG MONITOR
- 1994 FDA CLEARANCE: ZIPPREP EEG ELECTRODE
- 1996 FDA CLEARANCE: A-1050 EEG MONITOR
- 1996 FDA CLEARANCE: BIS SENSOR
- 1996 FDA CLEARANCE: A-1000 | A-1050 EEG MONITOR WITH
- 1998 FDA CLEARANCE: A-2000 BIS MONITOR
- 1998 ASPECT OPENS INTERNATIONAL HEADQUARTERS IN LEIDEN, THE NETHERLANDS
- 1999 1 MILLION PATIENTS MONITORED
- 2000 FDA CLEARANCE: PEDIATRIC SENSOR
- 2000 FDA CLEARANCE: XP SENSOR
- 2000 FDA CLEARANCE: BIS ENGINE AND MODULE
- 2001 1,000TH HOSPITAL ADOPTS BIS
- 2001 4.5 MILLION PATIENTS MONITORED
- 2001 LAUNCH OF XP TECHNOLOGY
- 2001 850 ARTICLES & ABSTRACTS PUBLISHED
- 2001 NEURODIAGNOSTICS INITIATIVE COMMENCES

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, 2001

- 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

*(State or Other Jurisdiction of
Incorporation or Organization)*

04-2985553

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

141 Needham Street,
Newton, Massachusetts
(Address of Principal Executive Offices)

02464-1505
(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.

The aggregate market value of the voting stock held by non-affiliates of the registrant as of March 15, 2002 (based on the closing price as quoted by the Nasdaq National Market as of such date) was \$129,225,000. The registrant had 17,837,206 shares of Common Stock, \$0.01 par value per share, outstanding as of March 15, 2002.

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, 2001. 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 15 issued patents and six pending United States patent applications. Our proprietary BIS system includes our BIS monitor, or 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 the BIS Standard Sensor, BIS Sensor Plus, BIS Pediatric Sensor, BIS Quatro Sensor, which we formerly called the BIS XP Sensor, and BIS Extend Sensor as 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 expanded performance capabilities and expanded benefits, enabling more precise measurement of brain activity to assess the level of consciousness as compared to earlier versions of the BIS system. Our other monitor products are the A-1000 Monitor, the A-1050 EEG Monitor with BIS and the BIS Module Kit. After the introduction of the A-2000 BIS Monitor, we ceased active marketing in the United States of the A-1050 EEG Monitor with BIS. In addition to the disposable BIS Sensors, we offer the Zipprep EEG Electrode.

As of December 31, 2001, the worldwide installed base of BIS monitors and modules was approximately 13,400. We estimate that BIS technology is installed in approximately 26% of all operating rooms in the United States. Based on a U.S. News and World Report hospital ranking, we also estimate that BIS technology is currently in use in more than 60% of the best U.S. hospitals with operating rooms and is available in more than 160 countries. We estimate that over 4.5 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 2001, 2000 and 1999, revenue from the sale of Equipment represented approximately 32%, 40% and 53%, respectively, of our revenue, and revenue from the sale of BIS Sensors represented approximately 68%, 60% and 47%, respectively, of our revenue.

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 proprietary product offerings:

<u>Product</u>	<u>Initial Commercial Shipment</u>	<u>Description</u>
BIS XP System	2001	Latest version of BIS system offering expanded 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 third-generation BIS monitor
BIS Module Kit	1998	Components of BIS monitoring technology that are integrated into monitors sold by original equipment manufacturers
A-1050 EEG Monitor with BIS	1996	Second-generation monitor with BIS index and simplified user interface
BIS Extend Sensor	2002	Disposable product with electronic memory device for use with A-2000 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 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 and BIS Module Kit that offers enhanced performance in deep anesthetic states and improved robustness to interference from noise sources

<u>Product</u>	<u>Initial Commercial Shipment</u>	<u>Description</u>
BIS Sensor Plus	2001	Second-generation disposable product for use with the A-2000 and BIS Module Kit
BIS Standard Sensor	1997	Disposable product for use with A-2000, A-1050 and BIS Module Kit
Zipprep EEG Electrode	1995	EEG electrode with our Zipprep technology

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 expanded 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 seen 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 monitoring products 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 we 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. This memory device 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 we 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. This memory device 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 we introduced commercially in 2001, offers enhanced performance in deep anesthetic states and improved resistance to interference from noise sources, such as high frequency/EMG 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. This memory device 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 we 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. This memory device 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 as it does not contain the easy connection feature and electronic memory device that our other BIS Sensors contain. 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 correlates with levels 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 patients and volunteers 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 the scientific literature,
- coordinating with the FDA and other regulatory agencies,
- 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 subjects. 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 completed a prospective, randomized, controlled study to evaluate whether or not monitoring with the BIS system reduces the incidence of surgical awareness. A controlled study to evaluate whether monitoring with the BIS system reduces the frequency of surgical awareness in the general population would require a sample size of up to 50,000 patients, which may not be practicable. However, we are currently sponsoring three multi-center, multinational studies to make an assessment as to the incidence of awareness during BIS monitoring. Because these studies have not been completed, we cannot and do not claim that patient monitoring with the BIS system will reduce the incidence of surgical awareness. Although our experience suggests that surgical awareness is more likely to occur when BIS values are high, we do not

believe that our experience proves conclusively that patient monitoring with the BIS system will reduce the frequency of awareness.

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, 2001, 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 and specialty distributors. As of December 31, 2001, our domestic sales force was comprised of 44 sales professionals and 8 clinical specialists. We have developed a financial model which is used by sales representatives to assist administrators in evaluating the economic impact of patient monitoring with the BIS system at their facility. We believe that our clinical specialists play a key role in the ongoing process of developing support for the BIS technology both before and after the sale of BIS systems.

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

We offer customers the option either to purchase the BIS monitors outright or to acquire the 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, 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 monitor 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 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 this agreed upon period of time, these customers have the option of purchasing the BIS monitors, continuing to use them under the EP program or returning them to us. We believe that the EP program will, in certain circumstances, provide an effective method of allowing customers to evaluate and ultimately acquire the BIS technology from us or our original equipment manufacturers.

We conduct several activities for the different constituencies that may be involved in the decision-making process. For clinical audiences, we exhibit at tradeshow, 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

Premier Purchasing Partners, L.P. We have entered into an agreement, effective November 1, 2000, with Premier Purchasing Partners, L.P., the group purchasing program of one of the nation's leading hospital and healthcare system alliances. Under this agreement, the more than 1,800 hospitals and healthcare facilities affiliated with Premier have the right to purchase BIS monitors and BIS Sensors under the pricing terms contained in the agreement. Under this agreement, Premier's field force has agreed to work with our sales force to facilitate the adoption of BIS technology by their affiliated healthcare organizations. Unless terminated earlier by either party by giving 90 days prior written notice, this agreement expires on February 28, 2003.

Consorta, Inc. We have entered into an agreement, effective November 1, 2000, with Consorta, Inc. Consorta's shareholder health care systems operate more than half of all Catholic hospitals in the United States. The Consorta membership encompasses more than 300 acute care facilities, representing nearly 50,000 beds and 700 alternate care sites. Under this agreement, the Consorta membership has the right to purchase BIS monitors and BIS Sensors under the pricing terms contained in the agreement. Under this agreement, Consorta's field force has agreed to work with our sales force to facilitate the adoption of BIS technology by their member healthcare organizations. Unless terminated earlier by either party by giving 90 days prior written notice, this agreement expires on October 31, 2005.

AmeriNet, Inc. We have entered into an agreement, effective September 1, 2000, with AmeriNet, Inc., the nation's largest membership-based health care group purchasing organization. AmeriNet represents 13,989 member facilities in all 50 states, including hospitals, medical group practices, nursing homes, surgery centers, managed care organizations, pharmacies and integrated delivery networks. Under this agreement, AmeriNet's membership has the right to purchase BIS monitors and BIS Sensors under the pricing terms contained in the agreement. Under this agreement, AmeriNet's field force has agreed to work with our sales force to facilitate the adoption of BIS technology by their member healthcare organizations. This agreement expires on August 31, 2003.

Healthtrust Purchasing Group, L.P. We have entered into an agreement, effective September 1, 2000, with Healthtrust Purchasing Group, L.P. Healthtrust Purchasing Group serves over 330 hospitals and more than 125 surgery centers, representing five percent of the nation's operating rooms. Under this agreement, Healthtrust Purchasing Group's participants have the right to purchase BIS monitors and BIS Sensors under the pricing terms contained in the agreement. 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. We have entered into a single source agreement, effective September 1, 2000, with Health Services Corporation of America, a leading group purchasing organization dedicated to improving purchasing to improve healthcare. Health Services Corporation of America's 2,000 plus members include hospitals, health systems, integrated delivery networks, and other healthcare facilities across the United States. Under this agreement, Health Services Corporation of America's membership has the right to purchase BIS monitors and BIS Sensors under the pricing terms contained in the agreement. Under this agreement, Health Services Corporation of America's field force has agreed to work with our sales force to facilitate the adoption of BIS technology by their member healthcare organizations. 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. We have entered into an agreement, dated August 13, 1998, with Novation, the supply cost management company for VHA Inc. and the University Hospital Consortium, two national health care alliances. Under this agreement, the approximately 1,900 member healthcare organizations of VHA and the University Hospital Consortium have the right to purchase BIS monitors and BIS Sensors under the pricing terms contained in the agreement. Under this agreement, Novation's field force has agreed to work with our sales force to facilitate the adoption of BIS technology by their member healthcare organizations. 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 August 30, 2002. Novation may elect to renew the agreement for up to two additional one-year periods.

International

In late 1998, we established our international operations and opened our international headquarters in Leiden, The Netherlands. We are developing 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. We expect to complement our international third-party distribution program through direct sales to select customers and to support these customers with clinical specialists. As of December 31, 2001, we employed 30 persons in our international organization. The majority of our international sales are denominated in United States dollars. See Note 17 of the notes to our consolidated financial statements for domestic and international financial information.

Distribution Agreements

We entered into a 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. On or after September 1, 2002, either party may terminate this agreement by giving 14 months prior written notice.

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. A new distribution agreement is currently being negotiated. Philips retains the right to distribute BIS Sensors under an OEM Development and Purchase Agreement until such time that we enter into a new distribution agreement with Philips.

We 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, 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 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 and GE Medical Systems and Datex-Ohmeda introduced a BIS module in October 2001, though Datex-Ohmeda has not yet begun shipping to end-users. We currently expect that BIS modules for Datex-Ohmeda, Dräger and Nihon Kohden will be available within the next one to two years.

Datex-Ohmeda Division of Instrumentarium Corporation. Under an OEM Purchase Agreement, dated September 1, 2000, between Aspect and Datex-Ohmeda Division of Instrumentarium Corporation, we have agreed with Datex-Ohmeda 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 if and when certain

monitoring products are 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.

GE Medical Systems — Information Technologies. Under an OEM Development and Purchase Agreement, dated December 22, 1999, between Aspect and GE Medical Systems — Information Technologies, we have agreed with GE Medical Systems 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, we have agreed with Philips 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, we have 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.

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.

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, 2001, 2000 and 1999, we spent approximately \$7.5 million, \$5.7 million and \$4.8 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.

Algorithm research involves developing signal-processing techniques to analyze the EEG and other electrical signals generated by the body. Our product development activities include developing and maintaining the hardware and software, including signal-processing software employed in the BIS systems, and coordinating with external resources, particularly with respect to mechanical engineering and industrial design. Disposable-product research and development combines expertise in materials science, disposable-products design, electrode technology and design for manufacturing to develop our disposable products, including the BIS Sensor products. Pre-production quality-assurance activities include testing our products to ensure that they meet FDA guidelines, other applicable regulatory and international quality standards and internal verification and validation protocols. Our clinical engineering activities include optimizing products for use in the clinical environment.

In 2001, we developed the BIS XP system which offers expanded 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. This memory device 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. During 2001, we established a team that is seeking to extend the use of the BIS monitoring platform to diagnose and track neurological diseases. We believe that in patients who suffer from neurological diseases, BIS technology may help detect disease because it quantifies changes in brain wave activity, or EEG, and has been shown to correlate with memory and changes in brain metabolism. We are evaluating the application of the BIS index to measure additional states of the brain, which may apply to detection of Alzheimer's disease, sleep cycles, seizure detection and/or other neurological states, including depression.

Additional studies, some of which we sponsored, are being conducted, or have been completed, to assess the performance of the BIS index in the presence of certain anesthetics, such as ketamine, and patient populations such as infants, not included in the clinical development of the BIS algorithms.

Manufacturing

We use 19,000 square feet of our 61,000 square foot facility located in Newton, Massachusetts for manufacturing and warehousing 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 Ziprep 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. 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 separate sole 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 a single competitor in the US market. The competitive device is based on signal-processing of the EEG and is marketed by a well-established medical products company. 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. We believe that one or more companies will seek to market competitive products based on auditory evoked potentials in the United States. Additionally, a number of academic researchers worldwide are studying the potential use of other techniques to measure the effects of anesthetics. These other products and techniques include the use of auditory evoked potentials, heart rate variability, pupillary reflexes and skin blood flow measurement techniques.

We believe that the principal competitive factors in the market for anesthesia-monitoring products 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

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. 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. We were issued our most recent patent on January 14, 2002. As of that date, we held 15 United States patents and had filed six 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 and Japan. The following chart summarizes our United States patents and patent applications:

Number of Issued Patents	Number of Patent Applications	Technology Covered	Patent Expiration Date
—	1	Closed loop delivery of anesthesia	
4	—	Application of Bispectral and higher order analysis and various statistical modeling technologies to EEG signals	March 13, 2007 April 30, 2008 June 14, 2011 October 17, 2012
2	2	Methods of ensuring the reliability of the computed values	December 24, 2016 January 30, 2018
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 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 October 20, 2015
2	2	BIS Sensor technology	October 11, 2016 June 9, 2019
<u>1</u>	<u>—</u>	Signal acquisition technology for digital signal converter	January 17, 2012
<u>15</u>	<u>6</u>		

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.

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. In August 1996, the FDA conducted a routine inspection of our manufacturing facility to ensure compliance with current Good Manufacturing Practices regulations. The FDA noted no adverse observations during that inspection. 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 expect that anesthesia providers will not be separately reimbursed for patient-monitoring activities utilizing the BIS system. When providers, 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, 2001, we had 226 full-time employees worldwide, of which:

- 28 persons were engaged in research and development activities,
- 41 persons were engaged in manufacturing and engineering,
- 16 persons were engaged in clinical and regulatory affairs,
- 110 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, 2002 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, 2001 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, 2000 and 2001, 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.

	<u>High</u>	<u>Low</u>
2000:		
Quarter Ended April 1, 2000	\$66.500	\$21.563
Quarter Ended July 1, 2000	\$49.109	\$21.250
Quarter Ended September 30, 2000	\$28.563	\$ 9.750
Quarter Ended December 31, 2000	\$12.313	\$ 7.563
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

On March 15, 2002, the last reported sales price of our common stock on the Nasdaq National Market was \$10.00 per share. As of March 15, 2002, there were approximately 366 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, 2001, we used approximately \$7.0 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, 2001, we used approximately \$28.1 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, 2001, we had approximately \$19.5 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 agreement with Fleet National Bank prohibits the declaration or payment of cash dividends without the consent of the bank.

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, 2001, 2000 and 1999, and the consolidated balance sheet data as of December 31, 2001 and 2000, 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, 1998 and 1997 and the consolidated balance sheet data as of December 31, 1999, 1998 and 1997 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,				
	2001	2000	1999	1998	1997
	(in thousands, except per share data)				
Consolidated Statements of Operations Data:					
Revenue	\$ 35,829	\$36,024	\$27,187	\$ 11,238	\$ 3,068
Costs and expenses:					
Costs of revenue	12,446	11,279	9,324	5,880	3,602
Research and development	7,467	5,713	4,847	4,042	2,603
Sales and marketing	28,396	21,979	16,543	10,354	4,813
General and administrative	7,803	6,390	4,829	4,254	2,358
Total costs and expenses	56,112	45,361	35,543	24,530	13,376
Loss from operations	(20,283)	(9,337)	(8,356)	(13,292)	(10,308)
Interest income, net	2,564	3,993	1,317	459	422
Other expense	—	—	—	(774)	—
Net loss	<u>\$ (17,719)</u>	<u>\$ (5,344)</u>	<u>\$ (7,039)</u>	<u>\$ (13,607)</u>	<u>\$ (9,886)</u>
Net loss per share:					
Basic and diluted	<u>\$ (1.01)</u>	<u>\$ (0.34)</u>	<u>\$ (4.57)</u>	<u>\$ (11.70)</u>	<u>\$ (15.63)</u>
Weighted average shares used in computing net loss per share:					
Basic and diluted	17,614	15,755	1,539	1,163	632
	December 31,				
	2001	2000	1999	1998	1997
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable securities	\$ 36,358	\$58,489	\$14,535	\$ 21,273	\$ 4,981
Restricted cash	5,100	—	—	—	—
Working capital	41,266	58,455	12,279	19,104	3,572
Total assets	63,369	79,411	29,402	28,589	7,603
Long-term debt	964	2,617	3,872	1,441	118
Total stockholders' equity	48,056	63,974	13,079	19,688	4,067

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, as amended. These forward-looking statements involve risks and uncertainties and are not guarantees of future performance. 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 "Factors Affecting Future Operating Results" below.

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 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 BIS Module Kit, which allows original equipment manufacturers to incorporate the BIS index into their monitoring products, and our disposable BIS Sensors. We collectively refer to the BIS Standard Sensor, BIS Sensor Plus, BIS Pediatric Sensor, BIS Quatro Sensor, which we formerly called the BIS XP Sensor, and BIS Extend Sensor as BIS Sensors. Our latest generation monitor, the A-2000 BIS Monitor, was cleared for marketing by 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 expanded performance capabilities and expanded benefits, 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 seen during deep anesthesia and cardiac cases. Our other monitor products are the A-1000 Monitor, the A-1050 EEG Monitor with BIS and the BIS Module Kit. After the introduction of the A-2000 BIS Monitor, we ceased active marketing of the A-1050 EEG Monitor with BIS domestically. In addition to the disposable BIS Sensors, we offer the Zipprep EEG Electrode.

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 offer customers the option either to purchase the BIS monitors outright or to acquire the 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, 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. The customer is granted an option to purchase the BIS monitor 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 3%, 6% and 15% of total revenue in 2001, 2000 and 1999, 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.

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 2001, 2000 and 1999, revenue from the sale of Equipment represented approximately 32%, 40% and 53%, respectively, of our revenue, and revenue from

the sale of BIS Sensors represented approximately 68%, 60% and 47%, respectively, of our revenue. We believe that revenue from the sale of BIS Sensors will continue to increase as a result of our growing installed base and the introduction of the BIS Pediatric Sensor, BIS Quatro Sensor and BIS Extend Sensor. However, revenue from the sale of BIS Sensors may decline as a percentage of revenue in 2002 because we believe that revenue from Equipment sales may increase as result of the commercial introduction of the BIS XP system in September 2001, the introduction of the BIS technology into the critical care area, our continuing focus on reducing of the free placement of monitors in the medical community, the shipments of BIS Module Kits to our original equipment manufacturers and marketing clearance received from Japan's Ministry of Health, Labor and Welfare in May 2001 to sell the A-2000 BIS Monitor in Japan.

Revenue from domestic sales in 2001, 2000 and 1999 was approximately \$28.2 million, \$30.1 million and \$24.6 million, respectively, which represented approximately 79%, 84% and 91%, respectively, of our revenue. Revenue from international sales in 2001, 2000 and 1999 was approximately \$7.6 million, \$5.9 million and \$2.6 million, respectively, which represented approximately 21%, 16% and 9%, respectively, of our revenue.

In December 1998 and March 1999, we established subsidiaries in The Netherlands and the United Kingdom, respectively, to facilitate our entry into the international market. We are developing 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. We expect to enhance our international third-party distribution program through direct sales efforts and to support our customers with clinical specialists. In January 1998, we entered into a distribution agreement with Nihon Kohden Corporation to distribute BIS monitors in Japan. In March 2000, the Japanese Ministry of Health, Labor and Welfare approved our A-1050 EEG Monitor with BIS for marketing in Japan. In May 2001, the Japanese Ministry of Health, Labor and Welfare approved our A-2000 BIS Monitor for marketing in Japan. Sales to Nihon Kohden represented approximately 26%, 39% and 3% of international revenue in 2001, 2000 and 1999, respectively.

Various factors may adversely affect our quarterly operating results through the second fiscal quarter of 2002 and the year ending December 31, 2002. We are facing increased competition in the domestic level of consciousness monitoring market as a result of the FDA's approval in 2000 of a competitor's monitoring system. Second, during the third fiscal quarter of 2001, we began the reorganization of our sales and clinical organizations. Third, we have underestimated the amount of clinical education necessary to bring our installed base up to expected sensor utilization levels. Fourth, we have recently transitioned leadership of our international operations. These factors and others may adversely impact our operating results.

Critical Accounting Policies

Financial Reporting Release No. 60, which was released by the Securities and Exchange Commission, or SEC, in December 2001, 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 our best estimates and judgments of certain amounts included in the financial statements, giving due consideration to materiality. 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. 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

recorded as deferred revenue. Revenue under these agreements is recognized as earned per 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. To the extent returns increase in future periods, we will be required to record a provision for estimated sales returns resulting in decreased net revenue.

Accounts Receivable

Estimates are used in determining our allowance for doubtful accounts based on our historical collections experience, current trends, credit policy and a percentage of our accounts receivable by aging category. In determining these percentages, we look at historical write-offs of our receivables. We also look at 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.

Inventories

We value inventory at the lower of cost or estimated market, cost being determined on a first-in, first-out basis. We regularly review inventory quantities on hand and record a provision for excess and obsolete inventory based primarily 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 an increase in the amount of obsolete inventory quantities on hand. 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 be required to recognize the adjustments in our cost of revenue at the time of the determination. Therefore, although we make every effort to ensure the accuracy of 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.

Investment in Sales-Type Leases

We follow Statement of Financial Accounting Standards, or 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 cost 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. Therefore, if in any period it is determined that a significant number of customers who entered into sales-type leases are underperforming in their respective commitments, it could have a significant impact on our operations.

Warranty

Equipment sold 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 historical experience and an 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,		
	2001	2000	1999
Revenue	100%	100%	100%
Costs and expenses:			
Costs of revenue	35	31	34
Research and development	21	16	18
Sales and marketing	79	61	61
General and administrative	<u>22</u>	<u>18</u>	<u>18</u>
Total costs and expenses	<u>157</u>	<u>126</u>	<u>131</u>
Loss from operations	(57)	(26)	(31)
Interest income, net	<u>7</u>	<u>11</u>	<u>5</u>
Net loss	<u>(50)%</u>	<u>(15)%</u>	<u>(26)%</u>

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 have 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.

For 2002, we believe that our gross margin percentage will remain comparable to the gross margin percentage for the year ended December 31, 2001. We believe that the following factors will contribute to this trend in gross margin percentage: relatively flat unit sales as compared to 2001 of lower gross margin percentage BIS Module Kits, the effect of transitioning our existing installed base to the BIS XP system through the sale of low gross margin percentage upgrade kits and continued depreciation expense on monitors placed under our Equipment Placement program and monitors used by customers for evaluation purposes. We expect that the pressure exerted on our gross margin percentage by these factors will be partially offset by the following: increased sales of our higher gross margin percentage BIS Sensors as the installed base of monitors and BIS Module Kits grows, higher average sensor prices as the installed base continues to transition to the BIS Quatro Sensor which has a higher list price than the BIS Standard Sensor, the introduction of the BIS Extend Sensor in the critical care area as it also has a higher list price than the BIS Standard Sensor, and improved manufacturing efficiencies as a result of the completion in 2001 of the manufacturing 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%. The increase in research and development expenses for the year ended December 31, 2001 as compared to the year ended December 31, 2000, 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 are sponsoring. 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. We expect research and development expenses to increase in 2002 as we continue to invest in the development of product improvements, product extensions and new applications for our technology, including our initiatives into the area of neurodiagnostics.

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%. The increase in sales and marketing expenses in 2001 as compared to 2000 was 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 external consultant 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. We expect sales and marketing expenses in 2002 to be comparable to 2001 as we continue to expand our international operations, continue our sales and marketing efforts in conjunction with group purchasing organizations and begin to see the benefits of

the investments we made in 2001 in our sales and marketing programs, including brand awareness and professional education programs that promote the use of the BIS system by our customers.

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%. The increase in general and administrative expenses in 2001 as compared to 2000 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. We expect general and administrative expenses to increase slightly as we expand the general and administrative function to support our growth while at the same time continue to seek improvements in our administrative infrastructure.

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. We expect interest income to decrease in 2002 as compared to the interest income in 2001 as a result of lower cash and investments balances resulting from continued operating losses and other uses of cash.

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%.

Year Ended December 31, 2000 Compared to Year Ended December 31, 1999

Revenue. Our revenue increased to approximately \$36.0 million in 2000 from approximately \$27.2 million in 1999, an increase of approximately 32%. Revenue from the sale of Equipment increased to approximately \$14.6 million in 2000 from approximately \$14.3 million in 1999, an increase of approximately 2%. The growth in revenue from the sale of Equipment in 2000 as compared to 1999 was primarily attributable to an increase of approximately 10% in the number of monitors sold, partially offset by a decrease in the average selling price of the monitors. There were two primary factors that contributed to the minimal increase in revenue from Equipment sales in 2000 as compared to 1999. First, as a result of the recent FDA approval of a competitive monitoring product, in the second-half of 2000 more customers than we expected elected to delay purchase decisions until they had an opportunity to evaluate the competitive product. Second, during the second and third quarters of 2000 we experienced higher than anticipated turnover in our direct sales force. The development of our domestic distributor channel and the contribution of our international organization offset these factors that negatively affected our monitor revenue.

Revenue from the sale of BIS Sensors increased to approximately \$21.4 million in 2000 from approximately \$12.9 million in 1999, an increase of approximately 67%. The increase in revenue from the sale of BIS Sensors was primarily attributable to an increase in the number of BIS Sensors sold as a result of growth in the installed base of monitors. The number of BIS Sensors sold increased approximately 67% in 2000 as compared to 1999.

Our gross profit was approximately 69% of revenue in 2000 as compared to a gross profit of approximately 66% of revenue in 1999. The increase in the gross profit percentage in 2000 as compared to 1999 was primarily

attributable to an increase in sales of BIS Sensors as a percentage of revenue. BIS sensors have a higher profit margin than Equipment and contributed almost all of the increase in gross profit in 2000 as compared to 1999.

Research and Development. Research and development expenses increased to approximately \$5.7 million in 2000 from approximately \$4.8 million in 1999, an increase of approximately 18%. Research and development expenses decreased as a percentage of revenue to 16% in 2000 as compared to 18% in 1999. The increase in research and development expenses for 2000 as compared to 1999, was primarily attributable to an increase in research and development personnel and related payroll and other expenses of approximately \$818,000. These expenses were incurred in connection with the continued product development efforts related to the A-2000 BIS Monitor, BIS Sensor Plus, BIS Quattro Sensor, BIS Pediatric Sensor and BIS Module Kit and the development of products for use outside the operating room in the intensive care unit and for procedural sedation.

Sales and Marketing. Sales and marketing expenses increased to approximately \$22.0 million in 2000 from approximately \$16.5 million in 1999, an increase of approximately 33%. Sales and marketing expenses remained the same as a percentage of revenue for 2000 as compared to 1999. The increase in sales and marketing expenses in 2000 as compared to 1999 was primarily attributable to an increase in sales and marketing personnel and related payroll and other expenses, which represented approximately 59% of the increase, increased operating expenses associated with our international subsidiaries, which represented approximately 16% of the increase, and fees and commissions related to the agreements with group purchasing organizations, original equipment manufacturers and distributors, which represented approximately 5% of the increase.

General and Administrative. General and administrative expenses increased to approximately \$6.4 million in 2000 from approximately \$4.8 million in 1999, an increase of approximately 32%. General and administrative expenses remained the same as a percentage of revenue for 2000 as compared to 1999. The increase in general and administrative expenses in 2000 as compared to 1999 was primarily attributable to an increase in general and administrative personnel to support our growth and related payroll and other expenses, which represented approximately 58% of the increase. The increase in payroll and other expenses included compensation expense related to stock option grants, which increased approximately 15% in 2000 as compared to 1999. The increase also included incremental expenses related to being a public company, such as expenses related to enhancements of our investor relations capabilities and insurance expenses, which represented approximately 31% of the increase.

Interest Income, Net. Interest income, net, increased to approximately \$4.0 million in 2000 from approximately \$1.3 million in 1999, an increase of approximately 203%. Interest income increased to approximately \$4.7 million in 2000 from approximately \$1.5 million in 1999, an increase of approximately 209%. The increase in interest income was primarily attributable to a higher average balance of cash and investments resulting from our initial public offering of common stock and the proceeds from the sale of a portion of our investment in sales-type leases. Interest expense increased to approximately \$713,000 in 2000 from approximately \$204,000 in 1999, an increase of approximately 250%. The increase in interest expense in 2000 was a result of higher average outstanding debt obligations resulting from borrowings under a term loan we entered into in December 1999 and debt obligations related to the sale of a portion of our investments in sales-type leases in the second half of 1999 and throughout 2000.

Net Loss. As a result of the factors discussed above, in 2000 we had a net loss of approximately \$5.3 million as compared to a net loss of approximately \$7.0 million in 1999, a decrease of approximately 24%.

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, 2001. 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 appearing 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							
	April 1, 2000	July 1, 2000	September 30, 2000	December 31, 2000	March 31, 2001	June 30, 2001	September 29, 2001	December 31, 2001
Revenue	\$9,660	\$11,066	\$ 7,231	\$ 8,067	\$ 8,863	\$ 8,973	\$ 8,528	\$ 9,465
Gross margin	6,576	7,684	5,134	5,351	6,092	6,093	5,477	5,721
Operating expenses	7,336	8,387	8,527	9,831	10,812	11,084	10,823	10,948
Net income (loss)	26	393	(2,419)	(3,344)	(3,797)	(4,267)	(4,837)	(4,818)

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, 2001, we raised approximately \$67.6 million from private equity financings and have received approximately \$3.4 million in equipment financing and approximately \$3.8 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 2002. 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.

We expect to meet our short-term liquidity needs through the use of cash and short-term investments on hand at December 31, 2001.

Working capital at December 31, 2001 was approximately \$41.3 million compared to approximately \$58.5 million at December 31, 2000. The decrease in working capital from December 31, 2000 to December 31, 2001 was primarily attributable to our net loss of approximately \$17.7 million in 2001.

We used approximately \$15.6 million of cash for operations in 2001. Cash used for operations during this period was primarily driven by operating losses, increases in net accounts receivable, inventory and decreases in accounts payable and deferred revenue, offset by decreases in investment in sales-type leases and increases in accrued liabilities and other assets. We used approximately \$29.1 million for operations during the three years ended December 31, 2001. Cash used for operations during this period was also primarily driven by operating losses, increases in net accounts receivable, inventory, investment in sales-type leases and other current assets, offset by increases in accounts payable, accrued liabilities and deferred revenue.

We received approximately \$4.8 million of cash from investing activities in 2001. The cash received from investing activities in 2001 was primarily the result of the sales and maturities of our investments in marketable securities. We received approximately \$12.7 million, net, of proceeds from sales and maturities of marketable securities and invested approximately \$1.8 million primarily in computer equipment and software, manufacturing equipment and furniture and fixtures. Additionally, we invested approximately \$968,000, net, in loans to related parties and increased restricted cash by \$5.1 million. We used approximately \$33.6 million for investing activities during the three years ended December 31, 2001. We invested approximately \$17.9 million, net, in marketable securities, approximately \$9.6 million in manufacturing equipment, leasehold improvements, furniture and fixtures, demonstration and evaluation equipment and new information systems, approximately \$1.1 million, net, in loans to related parties and increased restricted cash by \$5.1 million during the three years ended December 31, 2001.

We received approximately \$1.4 million of cash from financing activities in 2001 primarily as a result of proceeds from our working capital line of credit of \$3.0 million and the issuance of shares of our common stock upon the exercise of stock options, partially offset by payments of principal on debt. We received approximately \$60.0 million of cash from financing activities during the three years ended December 31, 2001. Cash provided by financing activities during this period was primarily the result of the closing of our initial public offering, proceeds from our equipment loan and proceeds from our term loan, the sale of a portion of our investments in sales-type leases and net proceeds from our working capital line of credit in the three year period ended December 31, 2001 offset by payments on our equipment loan, term loan and debt related to our investment in sales-type leases.

In December 1999, we renegotiated our loan agreement with Imperial Bank. 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 2002 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, 2001, the interest rate on the line of credit was 4.75%. 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. The outstanding balance on the line of credit at December 31, 2001 was \$3.0 million. At December 31, 2001, we had standby letters of credit outstanding in the amount of approximately \$404,000. We currently expect that we will extend our revolving line of credit with Fleet National Bank or enter into another line of credit with another commercial bank.

We guarantee certain operating lease obligations of our subsidiaries of approximately \$238,000 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, 2001, we sold approximately \$3.8 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, 2001, approximately \$1.8 million is recorded as debt on our consolidated balance sheet.

We had capital expenditures of approximately \$1.8 million for the year ended December 31, 2001. At December 31, 2001, we did not have any commitments for capital expenditures, however, we anticipate that the level of capital expenditures in 2002 will remain comparable to or increase slightly from to the level of capital expenditures during the year ended December 31, 2001.

We believe that the financial resources available to us, including our current working capital and availability under our revolving line of credit will be sufficient to finance our planned operations and capital expenditures through at least the second quarter of 2003. 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.

We have summarized below our contractual cash obligations as of December 31, 2001.

Contractual Obligations	Payments Due By Period				
	Total	Less Than One Year	One to Three Years	Four to Five Years	After Five Years
Line of credit	\$ 3,000,000	\$3,000,000	\$ —	\$ —	\$—
Operating leases	5,496,068	1,229,594	3,271,278	995,196	—
Sale of investment in sales type leases	<u>1,793,760</u>	<u>829,947</u>	<u>957,289</u>	<u>6,524</u>	<u>—</u>
Total contractual cash obligations	<u>\$10,289,828</u>	<u>\$5,059,541</u>	<u>\$4,228,567</u>	<u>\$1,001,720</u>	<u>\$—</u>

Income Taxes

We have net operating loss and research and development tax credit carryforwards for federal income tax purposes of approximately \$55,200,000 and \$1,550,000, respectively, at December 31, 2001 that will expire commencing in the year 2002 through the year 2020 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

Eleven of the 15 members of the European Union have adopted the Euro as their legal currency. Our current information systems allow us to currently 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 United States dollars. We do not believe the Euro will have a significant effect on our business, financial condition or results of operations.

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 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 agreement. 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 risk exposure.

Recent Accounting Pronouncements

In June 1998, the Financial Accounting Standards Board, or FASB, issued SFAS No. 133, *Accounting for Derivatives and Hedging Activities*, which establishes accounting and reporting standards of derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities. In June 1999, the FASB issued SFAS No. 137, *Accounting for Derivatives and Hedging Activities — Deferral of the Effective Date of FASB Statement No. 133*, which defers the effective date of SFAS No. 133 to be

effective for all fiscal quarters beginning after June 15, 2000. In June 2000, the FASB issued SFAS No. 138, *Accounting for Certain Derivative Instruments and Certain Hedging Activities — An Amendment of FASB Statement No. 133*, which amends the accounting and reporting standards of SFAS No. 133 for certain derivative instruments and certain hedging activities. Effective January 1, 2001, we adopted SFAS No. 133, as amended. The adoption of SFAS No. 133, as amended, did not have a material effect on our financial condition and results of operations as we do not currently hold any derivative instruments or engage in hedging activities.

In December 1999, the SEC issued SAB No. 101, *Revenue Recognition in Financial Statements*, which provides guidance related to revenue recognition in financial statements filed with the SEC. SAB No. 101 requires companies to report any changes in revenue recognition as a cumulative change in accounting principle at the time of implementation in accordance with Accounting Principles Board Opinion No. 20, *Accounting Changes*. Effective January 1, 2000, we adopted SAB No. 101. The adoption of SAB No. 101 did not have a material impact on our results of operations, cash flows or financial position.

In October 2000, the FASB issued SFAS No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities — A replacement of FASB Statement No. 125*. SFAS No. 140 reviews criteria for accounting securitizations, other financial asset transfers and collateral, and introduces new disclosures. The new disclosure requirements must be implemented for fiscal years ending after December 15, 2000. The other provisions of SFAS No. 140 apply prospectively to the transfer of financial assets and extinguishments of liabilities occurring after March 31, 2001. SFAS No. 140 carries forward most of the provisions of SFAS No. 125 without amendment. This pronouncement did not have a material impact on our results of operations, cash flows or financial position.

In August 2001, the FASB issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. This statement supercedes FASB Statement No. 121, *Accounting for the Impairment of Long-Lived Assets to Be Disposed of*, and the accounting and reporting provisions of APB Opinion No. 30, *Reporting the Results of Operations — Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions*. Under this statement it is required that one accounting model be used for long-lived assets to be disposed of by sale, whether previously held and used or newly acquired, and it broadens the presentation of discontinued operations to include more disposal transactions. The provisions of this statement are effective for financial statements issued for fiscal years beginning after December 15, 2001, and interim periods within those fiscal years, with early adoption permitted. We believe the adoption of SFAS No. 144 will not 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 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 2002 and for the year ending December 31, 2002. The following 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.

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. 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 or reliable, they will not buy and use the BIS system in sufficient quantities to enable us to be profitable.

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. Revenue from the sale of Equipment decreased approximately 21% in the year ended December 31, 2001 as compared to the year ended December 31, 2000. To date, we have not achieved widespread market acceptance of the BIS system. 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 second fiscal quarter of 2002 and for the year ending December 31, 2002.

Various factors may adversely affect our quarterly operating results through the second fiscal quarter of 2002 and the year ending December 31, 2002. We are facing increased competition in the domestic level of consciousness monitoring market as a result of the FDA's approval in 2000 of a competitor's monitoring system. Second, during the third fiscal quarter of 2001, we began the reorganization of our sales and clinical organizations. This may adversely impact our revenue through the second fiscal quarter of 2002, depending in part on both the timing of when newly hired sales representatives become fully trained and effective with respect to our products, customer base and sales programs. Third, we have underestimated the amount of clinical education necessary to bring our installed base up to expected sensor utilization levels. Fourth, we have recently transitioned leadership of our international operations. These factors may adversely impact our revenue through the second fiscal quarter of 2002 and the year ending December 31, 2002, depending in part on the timing and effectiveness of our new sales, marketing and clinical education programs. The continuation of difficult worldwide economic conditions, reductions in hospital purchasing programs, placement of monitors under our EP program 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 second fiscal quarter of 2002 and year ending December 31, 2002.

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 line of credit, will be sufficient to finance our planned operations and capital expenditures through the second fiscal quarter of 2003. 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,
- decide to expand faster than currently planned,
- develop new or enhanced services or products ahead of schedule,
- need to respond to competitive pressures, or
- 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 sponsoring three multi-center, multinational studies to assess the incidence of awareness during BIS monitoring. If these studies do not 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 revenue has been adversely affected by commercial introduction of an FDA-approved competitive anesthesia monitoring product. If we do not compete effectively with this new monitoring product, 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 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 2000, we experienced higher than anticipated turnover in our direct sales force and we underestimated the impact that this turnover in our direct sales force would have on our sales efforts. In the third fiscal quarter of 2001, we reorganized our sales force under a new vice president of North American field operations. Until the newly hired sales representatives become experienced with respect to our products, customer base and sales programs, our sales efforts will be adversely affected. If the newly hired sales representatives do not become experienced with respect to our products, customer base and sales programs in a timely and successful manner and we continue to experience high turnover in our direct sales force, we will not be able to sustain and grow our product revenue. In addition, in the second half of 2001 we began the implementation of new marketing programs under a new vice president of marketing. If these new marketing programs are not implemented in a timely and successful manner, we will not be able to achieve the level of market awareness and sales required to expand our 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, we need to hire and train more sales representatives. In the third fiscal quarter of 2001, we reorganized our sales organization and started to implement new sales and marketing programs and clinical education programs to promote the use of our BIS system by our customers. If we do not further develop our direct and indirect sales channels and successfully implement the new sales organization and 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. Revenue from international sales increased to approximately \$7.6 million in 2001 from approximately \$5.9 million in 2000. 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 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 separate sole 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 might 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 purported 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.

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 would 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.

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 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 distribution partners 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 stock would also be likely to 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.

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 a new monitoring system approved by the FDA in 2000. This product is marketed by a well-established medical products company with significant resources. We may not be able to compete effectively with this 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 and clinical specialists who are responsible for customer education and training and post-installation customer support. We continue to experience difficulty in recruiting and retaining skilled personnel because the pool of experienced persons is small and we compete for personnel with other companies, many of which have greater resources than we do. 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 8. Financial Statements and Supplementary Data.

The information required by this item may be found on pages F-1 through F-23 of this Annual Report on Form 10-K.

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

There have been no changes in or disagreements with accountants on accounting or financial disclosure matters.

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 2002 Annual Meeting of Stockholders to be held on May 21, 2002. Information relating to certain filings of Forms 3, 4 and 5 is contained in our 2002 proxy statement under the section entitled "*Section 16(a) Beneficial Ownership Reporting Compliance*."

Item 11. Executive Compensation.

The information required under this item is incorporated by reference to the section entitled "*Compensation of Executive Officers*" in our 2002 proxy statement.

The sections entitled "*Report of the Compensation Committee*" and "*Comparative Stock Performance Graph*" in our 2002 proxy statement are not incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management.

The information required under this item is incorporated by reference to the section entitled "*Stock Ownership Information*" in our 2002 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 2002 proxy statement.

PART IV

Item 14. Exhibits, Financial Statement Schedules, and Reports on Form 8-K.

(a)(1) Consolidated Financial Statements.

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

(a)(2) Financial Statement Schedules.

Schedules not listed above 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.

(a)(3) List of Exhibits.

The following exhibits are filed as part of and incorporated by reference into, this Annual Report on Form 10-K:

<u>Exhibit No.</u>	<u>Description</u>
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).

Exhibit
No.

Description

- 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).
- 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 incorporated herein by reference to Exhibit 10.21 to the 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 warrant holders 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† 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).
- 10.19† 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).

<u>Exhibit No.</u>	<u>Description</u>
10.20	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).
10.21	Promissory Note, dated December 7, 2000, made in favor of the Registrant by Helgert van Raamt is incorporated herein by reference to Exhibit 10.23 to the Registrant's Annual Report on Form 10-K for the year ended December 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).
10.25†	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).
10.26	First Amendment, dated December 21, 2001, to Loan Agreement, dated as of May 16, 2001, by and between the Registrant and Fleet National Bank.
10.27	Agreement dated January 24, 2002, between Helgert van Raamt and the Registrant.
21.1	Subsidiaries of the Registrant.
23.1	Consent of Arthur Andersen LLP.
99.1	Letter from the Registrant regarding Arthur Andersen LLP.

† 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.

(b) Reports on Form 8-K.

There were no reports on Form 8-K filed by the Company for the quarter ended December 31, 2001.

(c) Exhibits.

The Company hereby files as part of this Annual Report on Form 10-K the exhibits listed in Item 14(a)(3) set forth above. 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>".

ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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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. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	December 31, 2001	December 31, 2000
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 14,325,348	\$ 23,776,617
Restricted cash	5,100,000	—
Marketable securities	22,032,628	34,712,325
Accounts receivable, net of allowance of \$522,000 and \$422,000 at December 31, 2001 and 2000, respectively	5,395,096	3,665,572
Current portion of investment in sales-type leases	1,473,260	1,677,312
Inventory	5,108,166	4,764,479
Other current assets	1,182,385	1,334,563
Total current assets	54,616,883	69,930,868
Property and equipment, net	5,695,436	6,807,192
Long-term investment in sales-type leases	1,934,699	2,465,139
Other long-term assets	1,122,026	208,034
Total assets	<u>\$ 63,369,044</u>	<u>\$ 79,411,233</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Working capital line of credit	\$ 3,000,000	\$ —
Current portion of long-term debt	829,947	2,530,707
Accounts payable	1,563,990	1,877,295
Accrued liabilities	7,436,236	6,473,887
Deferred revenue	521,119	802,489
Total current liabilities	13,351,292	11,684,378
Long-term portion of deferred revenue	997,813	1,136,676
Long-term debt	963,813	2,616,657
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred Stock, \$.01 par value; 5,000,000 shares authorized, no shares issued or outstanding at December 31, 2001 and 2000	—	—
Common Stock, \$.01 par value; 60,000,000 shares authorized, 17,791,967 and 17,377,257 shares issued and outstanding at December 31, 2001 and 2000, respectively	177,920	173,773
Additional paid-in capital	126,533,939	124,934,402
Warrants	121,684	121,684
Notes receivable from employees and directors	(335,777)	(510,787)
Deferred compensation	(23,162)	(75,043)
Accumulated other comprehensive income	33,617	63,029
Accumulated deficit	(78,452,095)	(60,733,536)
Total stockholders' equity	48,056,126	63,973,522
Total liabilities and stockholders' equity	<u>\$ 63,369,044</u>	<u>\$ 79,411,233</u>

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

ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	<u>2001</u>	<u>2000</u>	<u>1999</u>
Revenue	\$ 35,828,851	\$36,023,564	\$27,187,650
Costs and expenses:			
Costs of revenue	12,445,938	11,279,031	9,324,111
Research and development	7,466,621	5,712,687	4,847,237
Sales and marketing	28,396,057	21,978,802	16,543,112
General and administrative	<u>7,803,506</u>	<u>6,389,948</u>	<u>4,829,266</u>
Total costs and expenses	<u>56,112,122</u>	<u>45,360,468</u>	<u>35,543,726</u>
Loss from operations	(20,283,271)	(9,336,904)	(8,356,076)
Interest income	2,930,140	4,705,236	1,520,480
Interest expense	<u>(365,428)</u>	<u>(712,666)</u>	<u>(203,709)</u>
Net loss	<u>\$ (17,718,559)</u>	<u>\$ (5,344,334)</u>	<u>\$ (7,039,305)</u>
Net loss per share:			
Basic and diluted	<u>\$ (1.01)</u>	<u>\$ (0.34)</u>	<u>\$ (4.57)</u>
Weighted average shares used in computing net loss per share:			
Basic and diluted	17,614,036	15,754,831	1,538,653

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

ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Comprehensive Income (Loss)	Convertible Preferred Stock Shares	Convertible Preferred Stock Amount	Common Stock Shares	Common Stock Par Value	Additional Paid-in Capital	Warrants	Notes Receivable From Employees and Directors	Deferred Compensation	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
Balance, December 31, 1998	\$ —	11,067,238	\$ 67,560,365	1,778,692	\$ 17,787	\$ 933,467	\$ 146,606	\$ (306,182)	\$ (317,564)	\$ 3,641	\$ (48,349,897)	\$ 19,688,223
Issuance of common stock upon exercise of common stock options	—	—	—	37,148	371	46,924	—	—	—	—	—	47,295
Payments on notes receivable from employees and directors	—	—	—	—	—	—	—	858	—	—	—	858
Deferred compensation related to stock options	—	—	—	—	—	293,334	—	—	(293,334)	—	—	—
Amortization of deferred compensation related to stock options	—	—	—	—	—	—	—	—	385,787	—	—	385,787
Comprehensive loss:												
Net loss	(7,039,305)	—	—	—	—	—	—	—	—	—	(7,039,305)	(7,039,305)
Other comprehensive loss — unrealized loss on marketable securities	(3,641)	—	—	—	—	—	—	—	—	(3,641)	—	(3,641)
Comprehensive loss	(7,042,946)	—	—	—	—	—	—	—	—	—	—	—
Balance, December 31, 1999	—	11,067,238	67,560,365	1,815,840	18,158	1,273,725	146,606	(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	175,862	(24,922)	—	—	—	—	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	\$ 124,934,402	\$ 121,684	\$ (510,787)	\$ (75,043)	\$ 63,029	\$(60,733,536)	\$ 63,973,522

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		Total Stockholders' Equity	
			Shares	Amount	Shares	Par Value										
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	\$126,533,939	\$121,684	\$ (335,777)		\$ (23,162)	\$ 33,617		\$ (78,452,095)		\$ 48,056,126

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

ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2001	2000	1999
Cash flows from operating activities:			
Net loss	\$(17,718,559)	\$ (5,344,334)	\$(7,039,305)
Adjustments to reconcile net loss to net cash used for operating activities —			
Depreciation and amortization	2,942,027	1,767,050	1,296,296
Provision for doubtful accounts	100,000	15,000	212,100
Compensation expense related to stock options	65,371	543,010	385,787
Changes in assets and liabilities —			
(Increase) decrease in accounts receivable	(1,829,524)	619,663	(2,403,392)
Increase in inventory	(343,687)	(3,249,777)	(1,244,513)
Decrease (increase) in other assets	206,202	(418,324)	(696,000)
Decrease (increase) in investment in sales-type leases	734,492	453,581	(2,097,932)
(Decrease) increase in accounts payable	(313,305)	308,202	677,150
Increase in accrued liabilities	962,349	536,333	2,274,147
(Decrease) increase in deferred revenue	(420,233)	(878,569)	760,841
Net cash used for operating activities	<u>(15,614,867)</u>	<u>(5,648,165)</u>	<u>(7,874,821)</u>
Cash flows from investing activities:			
Loans to related parties	(968,016)	(118,250)	6,750
Acquisition of property and equipment	(1,830,271)	(5,124,990)	(2,623,633)
Increase in restricted cash	(5,100,000)	—	—
Purchases of marketable securities	(29,081,621)	(59,899,296)	(1,810,895)
Proceeds from sales and maturities of marketable securities	41,731,907	26,250,000	4,957,593
Net cash provided by (used for) investing activities	<u>4,751,999</u>	<u>(38,892,536)</u>	<u>529,815</u>
Cash flows from financing activities:			
Proceeds from working capital line of credit	3,000,000	—	—
Principal payments on capital lease obligations	—	—	(126,775)
Proceeds from term loan	—	—	2,827,399
Principal payments on equipment loan	(720,670)	(720,672)	(720,672)
Principal payments on term loan	(1,884,933)	(942,462)	—
Proceeds from sale of investment in sales-type leases	341,420	1,614,065	1,852,092
Principal payments on debt related to investment in sales-type leases	(1,089,422)	(801,577)	(122,820)
Proceeds from issuance of common stock	1,590,194	55,603,643	47,295
Payments received on notes receivable from employees and directors	175,010	28,957	858
Net cash provided by financing activities	<u>1,411,599</u>	<u>54,781,954</u>	<u>3,757,377</u>
Net (decrease) increase in cash and cash equivalents	(9,451,269)	10,241,253	(3,587,629)
Cash and cash equivalents, beginning of period	23,776,617	13,535,364	17,122,993
Cash and cash equivalents, end of period	<u>\$ 14,325,348</u>	<u>\$ 23,776,617</u>	<u>\$13,535,364</u>
Supplemental disclosure of cash flow information:			
Interest paid	<u>\$ 403,632</u>	<u>\$ 728,203</u>	<u>\$ 203,709</u>
Supplemental disclosure of non-cash financing activities:			
Conversion of preferred stock into common stock	\$ —	\$ 67,560,365	\$ —
Cashless exercise of warrants	<u>\$ —</u>	<u>\$ 135,075</u>	<u>\$ —</u>

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

ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
NOTES TO 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 about a patient's status 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. 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 \$17,718,559, \$5,344,334 and \$7,039,305 for the years ended December 31, 2001, 2000 and 1999, respectively. At December 31, 2001, the Company had an accumulated deficit of \$78,452,095. 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 are recorded in the consolidated statements of operations for those transactions which occur in a 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 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 as available-for-sale at December 31, 2001 and 2000. The securities are reported at fair value, with any unrealized gains and losses excluded from earnings and reported as other comprehensive income (loss).

ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Revenue Recognition

In December 1999, the Securities and Exchange Commission ("SEC"), issued Staff Accounting Bulletin ("SAB") No. 101, *Revenue Recognition in Financial Statements*, which provides guidance related to revenue recognition in financial statements. SAB No. 101 requires companies to report any changes in revenue recognition as a cumulative change in accounting principle at the time of implementation in accordance with Accounting Principles Board ("APB") Opinion No. 20, *Accounting Changes*. Effective January 1, 2000, the Company adopted SAB No. 101. The adoption of SAB No. 101 did not have a material impact on the Company's results of operations, cash flows or financial position.

The Company recognizes revenue from equipment sales, disposable product sales and sales-type leases at the time of product shipment. 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 11). 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.

Research and Development Costs

The Company charges research and development costs to operations as incurred.

Accounts Receivable

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

Inventory

The Company values inventory at the lower of cost or estimated market, cost being determined on a first-in, first-out basis. The Company regularly reviews inventory quantities on hand and records a provision for excess and obsolete inventory based primarily 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 an increase in the amount of obsolete inventory quantities on hand. 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 be required to recognize the adjustments in its cost 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

ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

leases. The cost of the BIS monitor acquired by the customer is recorded as cost 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 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.

Warranty

Equipment sold 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.

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, 2001, 2000 and 1999 were approximately \$626,000, \$175,000 and \$121,000, 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 equivalents, trade accounts receivable, investment in sales-type lease receivables and marketable securities. To minimize the 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 currently 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.

ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 condition and results of operations.

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. Besides 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.

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.

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.

Reclassifications

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

Recent Accounting Pronouncements

In June 1998, the Financial Accounting Standards Board ("FASB") issued SFAS No. 133, *Accounting for Derivatives and Hedging Activities*, which establishes accounting and reporting standards of derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities. In June 1999, the FASB issued SFAS No. 137, *Accounting for Derivatives and Hedging Activities — Deferral of the Effective Date of FASB Statement No. 133*, which defers the effective date of SFAS No. 133 to be effective for all fiscal quarters beginning after June 15, 2000. In June 2000, the FASB issued SFAS No. 138, *Accounting for Certain Derivative Instruments and Certain Hedging Activities — An Amendment of FASB Statement No. 133*, which amends the accounting and reporting standards of SFAS No. 133 for certain derivative instruments and certain hedging activities. Effective January 1, 2001, the Company adopted SFAS No. 133, as amended. The adoption of SFAS No. 133, as amended, did not have a material effect on the Company's financial condition and results of operations as the Company does not currently hold any derivative instruments or engage in hedging activities.

In October 2000, the FASB issued SFAS No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities — A replacement of FASB Statement No. 125*. SFAS No. 140 reviews criteria for accounting securitizations, other financial asset transfers and collateral, and introduces new disclosures. The new disclosure requirements must be implemented for fiscal years ending after December 15, 2000. The other provisions of SFAS No. 140 apply prospectively to the transfer of financial assets and

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

extinguishments of liabilities occurring after March 31, 2001. SFAS No. 140 carries forward most of the provisions of SFAS No. 125 without amendment. This pronouncement did not have a material impact on the Company's results of operations, cash flows or financial position.

In August 2001, the FASB issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. This statement supercedes FASB Statement No. 121, *Accounting for the Impairment of Long-Lived Assets to Be Disposed of*, and the accounting and reporting provisions of APB Opinion No. 30, *Reporting the Results of Operations — Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions*. Under this statement it is required that one accounting model be used for long-lived assets to be disposed of by sale, whether previously held and used or newly acquired, and it broadens the presentation of discontinued operations to include more disposal transactions. The provisions of this statement are effective for financial statements issued for fiscal years beginning after December 15, 2001, and interim periods within those fiscal years, with early adoption permitted. The Company believes the adoption of SFAS No. 144 will not have a material impact on its results of operations, cash flows or financial position.

(3) Cash Equivalents, Restricted Cash and Marketable Securities

Cash and cash equivalents consist of the following:

	December 31,	
	2001	2000
Cash	\$13,325,776	\$ 8,862,667
Commercial paper	999,572	14,913,950
	<u>\$14,325,348</u>	<u>\$23,776,617</u>

At December 31, 2001, the Company maintained \$5,100,00 of restricted cash as part of its revolving line of credit agreement (see Note 19).

Available-for-sale marketable securities at December 31, 2001 and 2000, consist of the following:

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
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
	<u>\$21,999,011</u>	<u>\$469,507</u>	<u>\$435,890</u>	<u>\$22,032,628</u>
December 31, 2000 —				
U.S. Government debt securities	\$ 1,000,590	\$ —	\$ —	\$ 1,000,590
Corporate obligations	33,648,706	232,516	169,487	33,711,735
	<u>\$34,649,296</u>	<u>\$232,516</u>	<u>\$169,487</u>	<u>\$34,712,325</u>

The amortized cost and estimated fair value of available-for-sale marketable securities at December 31, 2001, by contractual maturity, were as follows:

	Cost	Estimated Fair Value
Maturing in one to two years	<u>\$21,999,011</u>	<u>\$22,032,628</u>

ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 to the Company's financial statements.

(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,	
	2001	2000
Total minimum lease payments receivable	\$4,199,380	\$5,143,738
Less — unearned interest	<u>791,421</u>	<u>1,001,287</u>
Net investment in sales-type leases	3,407,959	4,142,451
Less — current portion	<u>1,473,260</u>	<u>1,677,312</u>
	<u>\$1,934,699</u>	<u>\$2,465,139</u>

Future minimum lease payments due under non-cancelable leases as of December 31, 2001, are as follows:

<u>Year Ending December 31,</u>	
2002	\$1,886,911
2003	1,178,246
2004	668,108
2005	351,983
2006	<u>114,132</u>
	<u>\$4,199,380</u>

(5) Inventory

Inventory consists of the following:

	December 31,	
	2001	2000
Raw materials	\$2,891,400	\$2,200,119
Work-in-progress	90,076	1,742
Finished goods	<u>2,126,690</u>	<u>2,562,618</u>
	<u>\$5,108,166</u>	<u>\$4,764,479</u>

ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

(6) Property and Equipment

Property and equipment consist of the following:

	Useful Life in Years	December 31,	
		2001	2000
Construction in progress	—	\$ 397,022	\$ 1,262,868
Computer equipment	3	4,093,037	3,422,898
Demonstration, evaluation and rental equipment	2	1,074,746	958,542
Machinery and equipment	3 to 5	4,050,004	2,717,802
Furniture and fixtures	3	1,841,667	1,400,788
Leasehold improvements	Shorter of the life of the lease or the estimated remaining useful life	1,629,620	1,629,620
		13,086,096	11,392,518
Accumulated depreciation and amortization		(7,390,660)	(4,585,326)
		<u>\$ 5,695,436</u>	<u>\$ 6,807,192</u>

(7) Income Taxes

Deferred income tax assets consist of the following:

	December 31,	
	2001	2000
Net operating loss carryforwards	\$ 24,061,000	\$ 21,427,000
Tax credit carryforwards	2,600,000	2,005,000
Other	2,882,000	2,553,000
Gross deferred tax assets	29,543,000	25,985,000
Valuation allowance	(29,543,000)	(25,985,000)
Net deferred tax asset	<u>\$ —</u>	<u>\$ —</u>

The Company has provided a full valuation allowance against its gross deferred tax assets at December 31, 2001 and 2000 because the future realizability of such assets is uncertain. 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 \$55,200,000 and \$1,550,000, respectively, at December 31, 2001, that will expire commencing in the year 2002 through the year 2020 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.

ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

(8) Stockholders' Equity

Authorized Capital Stock

As of December 31, 2001 and December 31, 2000, the Company's authorized capital stock consists of 60,000,000 shares of common stock, \$.01 par value, and 5,000,000 shares of preferred stock, \$.01 par value, the terms of which have not been designated. As of December 31, 2001, no shares of preferred stock are outstanding.

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 are fully exercisable with an exercise price of \$12.50 per share and expire on February 2, 2003, the third anniversary of the closing of the Company's initial public offering. However, if the average closing market price per share of common stock over 25 consecutive trading days equals or exceeds \$25.00, the Company has the right to require the exercise of the warrants. The Company has 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. At December 31, 2001, warrants to purchase 160,110 shares of common stock remain outstanding.

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, 2001, the Company has reserved 6,017,212 shares of common stock for issuance under the Company's stock option plans, 252,969 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

At December 31, 2001, 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. At December 31, 2001, 2,607,434 shares of common stock were available for future grant under the Company's stock option plans.

ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

A summary of stock option activity is as follows:

	Number of Shares	Option Price per Share	Weighted Average Option Price per Share
Outstanding, December 31, 1998	1,837,016	\$.20 - 45.83	\$ 2.31
Granted	961,415	6.00 - 11.05	8.84
Exercised	(37,148)	.20 - 6.00	1.27
Canceled	<u>(65,603)</u>	<u>.375 - 11.05</u>	<u>4.66</u>
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	<u>(183,921)</u>	<u>.20 - 28.63</u>	<u>9.36</u>
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	<u>(569,884)</u>	<u>.80 - 47.88</u>	<u>15.49</u>
Outstanding, December 31, 2001	<u>3,409,778</u>	<u>\$.20 - 47.88</u>	<u>\$11.16</u>
Exercisable, December 31, 2001	1,791,303	\$.20 - 47.88	\$ 8.36

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, 2001, no shares remained subject to repurchase.

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, 2001, \$151,445 of this loan remained outstanding.

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.

ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

A summary of outstanding and exercisable options as of December 31, 2001 is as follows:

Exercise Price	Outstanding			Exercisable	
	Number	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number	Weighted Average Exercise Price
\$ 0.20 - \$ 0.80	379,748	5.38	\$ 0.61	379,353	\$ 0.61
2.80	98,333	6.29	2.80	93,617	2.80
4.20	529,652	5.66	4.20	448,709	4.20
6.00 - 8.56	401,269	7.72	7.69	191,190	7.31
9.50 - 10.19	59,275	9.70	9.62	2,594	10.19
10.20	425,130	7.56	10.20	260,588	10.20
11.00 - 12.40	429,390	8.79	11.78	81,210	11.60
12.45 - 12.50	343,000	9.44	12.49	57,771	12.50
12.63 - 15.00	124,117	8.86	13.45	38,008	13.89
23.63 - 47.88	<u>619,864</u>	<u>7.96</u>	<u>26.32</u>	<u>238,263</u>	<u>26.52</u>
\$.20 - \$47.88	3,409,778	7.51	\$11.16	1,791,303	\$ 8.36

In 2001, 2000 and 1999, the Company recorded additional deferred compensation of approximately \$13,500, \$393,000 and \$293,300, respectively, which represents the estimated fair value of stock options granted to non-employees. The remaining unamortized deferred compensation of \$23,162 at December 31, 2001, will be recognized as compensation expense during 2002 over the remaining vesting term of the related options which is approximately 7 months.

In October 1995, the FASB issued SFAS No. 123, *Accounting for Stock-Based Compensation*. SFAS No. 123 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 has determined that it will continue to account for stock-based compensation for employees under APB Opinion No. 25 and elect the disclosure-only alternative under SFAS No. 123. The Company has computed the value of options granted in 2001, 2000 and 1999 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,		
	2001	2000	1999
Risk-free interest rate	5.04%	6.51%	4.34% - 5.91%
Expected dividend yield	—	—	—
Expected life	5 years	5 years	7 years
Expected volatility	75%	75%	60%
Weighted average fair market value of options granted	\$8.84	\$15.14	\$6.29

ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Had compensation cost for these awards been determined 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,		
	2001	2000	1999
Net loss			
As reported	<u>\$(17,718,559)</u>	<u>\$(5,344,334)</u>	<u>\$(7,039,305)</u>
Pro forma	<u>\$(24,719,344)</u>	<u>\$(9,629,145)</u>	<u>\$(7,901,550)</u>
Basic and diluted net loss per common share			
As reported	<u>\$ (1.01)</u>	<u>\$ (0.34)</u>	<u>\$ (4.57)</u>
Pro forma	<u>\$ (1.40)</u>	<u>\$ (0.61)</u>	<u>\$ (5.14)</u>

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.

1991 Amended and Restated Stock Option Plan

The Company's 1991 Amended and Restated Stock Option Plan (the "1991 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 "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 Incentive Plan, including the granting of options to executive officers. At December 31, 2001, the 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 (or less than 110% of the fair market value in the case of incentive stock options granted to optionees holding more than 10% of the voting power of the Company).

1998 Director Stock Option Plan

In February 1998, the Company adopted the 1998 Director Stock Option Plan ("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, 2001, 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

ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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, 2001, 47,031 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 shareholders 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, 2001, 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 (or less than 110% of the fair market value in the case of incentive stock options granted to optionees holding more than 10% of the voting power of the Company).

(10) 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, 2001, 2000, and 1999 the Company has excluded from the calculation of the Company's diluted earnings per share approximately 1,049,000, 3,162,000 and 12,671,000 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. The Company evaluated the requirements of the SEC's SAB No. 98, *Computation of Earnings per Share*, and concluded that there are no nominal issuances of common stock or common stock equivalents which would be required to be shown as outstanding for all periods as outlined in SAB No. 98.

(11) Distribution and Licensing Agreements

The Company has entered into various distribution, licensing and royalty agreements relating to its products with distributors and original equipment manufacturer partners covering both the domestic and the international markets. These agreements have terms ranging from two to ten years. In connection with these agreements, approximately \$1,519,000 and \$1,939,000 in revenue was deferred as of December 31, 2001 and

ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

2000, respectively. The deferred revenue relates to prepayments for monitoring systems under minimum purchase obligations and also includes prepaid license and royalty fees. The deferred revenue will be 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.

(12) 401(k) Savings Plan

The Company has a 401(k) savings plan in which substantially all 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, 2001, 2000 and 1999.

(13) Commitments and Contingencies

Leases

The Company leases approximately 61,000 square feet of development, production and administrative space under an operating lease that expires in December 2006. Prior to April 2000, the Company also leased office space under an operating lease that was terminated in May 2000. Rent expense was approximately \$967,000, \$1,130,000 and \$440,000 in 2001, 2000 and 1999, respectively. Future gross minimum lease commitments for all non-cancelable operating leases as of December 31, 2001 are as follows:

<u>Year Ending December 31,</u>	
2002	\$1,229,594
2003	1,175,463
2004	1,104,873
2005	990,942
2006	<u>995,196</u>
Total minimum lease payments	<u>\$5,496,068</u>

(14) Other Related Party Transactions

In addition to the related party transactions discussed in Note 9, the Company has made loans to certain employees and a consultant of the Company. Through December 31, 2000, the Company loaned, on a full recourse basis, certain employees of the Company a total of \$285,000. During the first quarter of 2001, the Company loaned, on a full recourse basis, certain employees of the Company \$75,000. In April 2001, the Company loaned, on a full recourse basis, an aggregate of \$1,081,000, to an officer, certain employees and a consultant of the Company. The loans are evidenced by promissory notes bearing interest with rates ranging from 5.07% to 8.00% per annum. The loans, included in other assets in the accompanying consolidated balance sheet are payable over periods ranging from two to five years and are in each case secured by assets of the borrower, including shares of the Company's common stock owned by the borrower. The outstanding balance on these loans at December 31, 2001 and 2000 was approximately \$1,209,000 and \$242,000, respectively.

ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

(15) Accrued Liabilities

Accrued liabilities consist of the following:

	December 31,	
	2001	2000
Payroll and payroll-related	\$3,467,479	\$2,759,230
Clinical studies	253,000	389,000
Warranty	1,090,120	1,475,000
Other	2,625,637	1,850,657
	<u>\$7,436,236</u>	<u>\$6,473,887</u>

(16) Summarized Quarterly Financial Data (Unaudited)

The tables that follow summarize unaudited quarterly financial data for the years ended December 31, 2001 and December 31, 2000:

	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)

	For the Quarter Ended			
	April 1, 2000	July 1, 2000	September 30, 2000	December 31, 2000
Revenue	\$9,659,377	\$11,066,167	\$ 7,231,033	\$ 8,066,987
Gross margin	6,576,240	7,683,869	5,133,317	5,351,107
Operating expenses	7,336,485	8,387,406	8,526,876	9,830,670
Net income (loss)	\$ 25,800	\$ 393,006	\$(2,418,558)	\$(3,344,582)
Basic and diluted net income (loss) per share	\$ 0.00	\$ 0.02	\$ (0.14)	\$ (0.19)

(17) Segment Information and Enterprise Reporting

The Company has adopted SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*, effective for fiscal years beginning after December 31, 1997. 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.

ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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

	Year Ended December 31,		
	2001	2000	1999
Geographic Area by Destination			
Domestic	\$28,164,957	\$30,085,477	\$24,629,484
International	<u>7,663,894</u>	<u>5,938,087</u>	<u>2,558,166</u>
	<u>\$35,828,851</u>	<u>\$36,023,564</u>	<u>\$27,187,650</u>

	Year Ended December 31,		
	2001	2000	1999
Geographic Area by Destination			
Domestic	79%	84%	91%
International	<u>21</u>	<u>16</u>	<u>9</u>
	<u>100%</u>	<u>100%</u>	<u>100%</u>

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, 2001, 2000 and 1999.

(18) Valuation and Qualifying Accounts

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

Year Ended —	Balance at Beginning of Period	Charges to Expenses	Deductions	Balance at End of Period
December 31, 1999	\$200,000	\$212,100	\$5,100	\$407,000
December 31, 2000	407,000	15,000	—	422,000
December 31, 2001	422,000	100,000	—	522,000

(19) Loan Agreements

At December 31, 2000, the Company had approximately \$721,000 and approximately \$1,885,000 outstanding under the equipment portion and term loan portion, respectively, of its December 1999 loan agreement with a commercial bank. The equipment portion of the loan agreement was payable in monthly installments of approximately \$60,000 plus interest through December 2001. The term loan portion was payable in 36 monthly installments of approximately \$79,000 plus interest through December 2002. In May 2001, the Company paid the outstanding principal on both the equipment portion and term loan portion of its loan agreement 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 revolving line of credit is for \$5,000,000 and expires in May 2002 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.

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 sheet. The Company is required to maintain

ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

restricted cash and securities with a net equity value equal to 102% of the \$5,000,000 commitment. At December 31, 2001, \$3,000,000 of the revolving line of credit was outstanding, and the Company was in compliance with all covenants contained in the revolving line of credit agreement. At December 31, 2001, the interest rate on the revolving line of credit was 4.75%.

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, 2001, the Company sold approximately \$3.8 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 11.5% 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 debt agreements are as follows:

<u>Year Ending December 31,</u>	
2002	\$3,829,947
2003	593,659
2004	292,036
2005	71,594
2006	<u>6,524</u>
Total principal payments	<u>\$4,793,760</u>

STOCKHOLDERS

All stockholders are welcome to attend our annual meeting, which will be held at 9:00 am on Tuesday, May 21, 2002, at the office of Hale and Don, LLP, 60 State Street, Boston, Massachusetts. We look forward to meeting stockholders and answering any questions you may have at the meeting.

FORWARD-LOOKING STATEMENTS

Certain statements made in this Annual Report to stockholders are forward-looking statements that are subject to risks and uncertainties. There are a number of factors that could cause the Company's future performance and results of operations to differ materially from such statements, including without limitation those set forth under the heading, "Factors Affecting Future Operating Results" in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2001, which is filed with the Securities and Exchange Commission. These statements should not be relied upon as representing the Company's expectations or beliefs as of any date subsequent to the date of the Annual Report.

Nassib C. Chamoun
Chief Executive Officer,
President and Founder

J. Breckenridge Eagle
Chairman of the Board of Directors

Boudewijn Bollen
President of International Operations

Stephen E. Coit
Independent Consultant

Edwin M. Kania, Jr.
Senior Managing Director and Chairman
Flagship Ventures

Lester John Lloyd

Richard J. Meelja
President and Chief Executive Officer
Tyco Healthcare Group

Donald R. Stankis, M.D.
Professor of Anesthesia
Stanford University

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President and Founder

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Chairman of the Board of Directors

J. Neal Armstrong
Vice President
Chief Financial Officer and Secretary

Jeffrey L. Barnett
Vice President of
Corporate Operations

Boudewijn Bollen
President of International Operations

F. Iot Daley
Vice President of Corporate Strategy

Philip H. Deym
Vice President of Technology and
General Manager of Neurodiagnostics

William Floyd
Vice President of Marketing

Scott D. Kelley, M.D.
Vice President and Medical Director

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FORM 10-K

The Company's Annual Report on Form 10-K has been filed with the Securities and Exchange Commission for the year ended December 31, 2001, is available free of charge upon written request to Aspect Medical Systems, Inc., Investor Relations Department, 141 Needham Street, Newton, Massachusetts 02464.



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