

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 10-Q**

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

**For the quarterly period ended March 30, 2002**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

Commission file number: 0-24663

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**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

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 ☐

The Registrant had 17,857,192 shares of Common Stock, \$0.01 par value per share, outstanding as of May 8, 2002.

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# PART I — FINANCIAL INFORMATION

## Item 1. Financial Statements.

### ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

#### CONSOLIDATED BALANCE SHEETS

	March 30, 2002	December 31, 2001
	(Unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 22,499,341	\$ 14,325,348
Restricted cash	5,100,000	5,100,000
Marketable securities	9,337,917	22,032,628
Accounts receivable, net of allowance of \$521,000 at March 30, 2002 and \$522,000 at December 31, 2001	4,744,408	5,395,096
Current portion of investment in sales-type leases	1,495,441	1,473,260
Inventory	4,065,307	5,108,166
Other current assets	1,446,600	1,182,385
	<hr/>	<hr/>
Total current assets	48,689,014	54,616,883
Property and equipment, net	5,344,466	5,695,436
Long-term investment in sales-type leases	2,023,481	1,934,699
Other long-term assets	1,118,693	1,122,026
	<hr/>	<hr/>
Total assets	\$ 57,175,654	\$ 63,369,044
	<hr/>	<hr/>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Working capital line of credit	\$ 3,000,000	\$ 3,000,000
Current portion of long-term debt	812,762	829,947
Accounts payable	1,590,221	1,563,990
Accrued liabilities	5,900,383	7,436,236
Deferred revenue	557,305	521,119
	<hr/>	<hr/>
Total current liabilities	11,860,671	13,351,292
Long-term portion of deferred revenue	940,625	997,813
Long-term debt	910,373	963,813
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, \$.01 par value; 5,000,000 shares authorized, no shares issued or outstanding	—	—
Common Stock, \$.01 par value; 60,000,000 shares authorized, 17,840,206 and 17,791,967 shares issued and outstanding at March 30, 2002 and December 31, 2001, respectively	178,402	177,920
Additional paid-in capital	126,677,605	126,533,939
Warrants	121,684	121,684
Notes receivable from employees and directors	(335,777)	(335,777)
Deferred compensation	(10,481)	(23,162)
Accumulated other comprehensive (loss) income	(15,835)	33,617
Accumulated deficit	(83,151,613)	(78,452,095)
	<hr/>	<hr/>
Total stockholders' equity	43,463,985	48,056,126
	<hr/>	<hr/>
Total liabilities and stockholders' equity	\$ 57,175,654	\$ 63,369,044
	<hr/>	<hr/>

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

# ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended	
	March 30, 2002	March 31, 2001
	(Unaudited)	(Unaudited)
Revenue	\$ 9,686,566	\$ 8,862,820
Costs and expenses:		
Costs of revenue	3,517,536	2,770,612
Research and development	1,936,544	1,796,123
Sales and marketing	7,356,505	6,960,919
General and administrative	1,850,064	2,054,597
Total costs and expenses	14,660,649	13,582,251
Loss from operations	(4,974,083)	(4,719,431)
Interest income	344,611	1,040,675
Interest expense	(70,046)	(118,451)
Net loss	\$ (4,699,518)	\$ (3,797,207)
Net loss per share:		
Basic and diluted	\$ (0.26)	\$ (0.22)
Weighted average shares used in computing net loss per share:		
Basic and diluted	17,815,859	17,458,433

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

**ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Three Months Ended	
	March 30, 2002	March 31, 2001
	(Unaudited)	(Unaudited)
Cash flows from operating activities:		
Net loss	\$ (4,699,518)	\$ (3,797,207)
Adjustments to reconcile net loss to net cash used for operating activities –		
Depreciation and amortization	661,104	583,923
Compensation expense related to stock options	12,824	16,544
Changes in assets and liabilities –		
Decrease (increase) in accounts receivable	650,688	(780,286)
Decrease (increase) in inventory	1,042,859	(383,178)
(Increase) decrease in other assets	(267,340)	37,429
(Increase) decrease in investment in sales-type leases	(110,963)	413,980
Increase in accounts payable	26,231	18,797
Decrease in accrued liabilities	(1,535,853)	(528,012)
Decrease in deferred revenue	(21,002)	(184,000)
Net cash used for operating activities	(4,240,970)	(4,602,010)
Cash flows from investing activities:		
Loans to related parties	6,458	(75,000)
Acquisition of property and equipment	(310,134)	(474,887)
Purchases of marketable securities	(763,674)	—
Proceeds from sales and maturities of marketable securities	13,408,934	7,502,764
Net cash provided by investing activities	12,341,584	6,952,877
Cash flows from financing activities:		
Principal payments on equipment loan	—	(180,167)
Principal payments on term loan	—	(235,617)
Proceeds from sale of investment in sales-type leases	184,905	283,528
Principal payments on debt related to investment in sales-type leases	(255,530)	(320,134)
Proceeds from issuance of common stock	144,004	190,684
Net cash provided by (used for) financing activities	73,379	(261,706)
Net increase in cash and cash equivalents	8,173,993	2,089,161
Cash and cash equivalents, beginning of period	14,325,348	23,776,617
Cash and cash equivalents, end of period	\$22,499,341	\$25,865,778
Supplemental disclosure of cash flow information:		
Interest paid	\$ 69,850	\$ 144,941

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

## ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

#### (1) Basis of Presentation

The accompanying unaudited consolidated financial statements of Aspect Medical Systems, Inc. and subsidiaries (the "Company") have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all normal, recurring adjustments considered necessary for a fair presentation have been included. The consolidated financial statements and notes included herein should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2001 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC"). Interim results of operations are not necessarily indicative of the results to be expected for the full year or any other interim period.

#### (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. Foreign currency transaction gains and losses have not been material.

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

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

The Company accounts for its investments in marketable securities in accordance with Statement of Financial Accounting Standards ("SFAS") No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. In accordance with SFAS No. 115, the Company has classified all of its investments in marketable securities as available-for-sale at March 30, 2002 and December 31, 2001. The securities are reported at fair value, with any unrealized gains and losses excluded from earnings and reported as other comprehensive income (loss).

##### *Revenue Recognition*

In December 1999, the 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.



## ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

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. 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 costs of revenue at the time of the determination.

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

The Company follows SFAS No. 13, *Accounting For Leases*, for its investment in sales-type leases. Under the Company's sales-type leases, customers purchase BIS Sensors and the BIS monitor for the purchase price of the BIS Sensors plus an additional charge per BIS Sensor to pay for the purchase price of the BIS monitor and related financing costs over the term of the agreement. In accordance with SFAS No. 13, the minimum lease payment, consisting of the additional charge per BIS Sensor, less the unearned interest income, which is computed at the interest rate implicit in the lease, is recorded as net investment in sales-type leases. The cost of the BIS monitor acquired by the customer is recorded as 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.

## ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

#### *Advertising Costs*

Advertising costs are expensed as incurred. These costs are included in sales and marketing expense in the consolidated statements of operations.

#### *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. The Company has experienced shortages and delays in obtaining certain components of its products in the past. There can be no assurance that the Company will not experience similar delays or shortages in the future. The disruption or termination of the supply of components or a significant increase in the costs of these components from these sources could have a material adverse effect on the Company's business, financial position and results of operations.

#### *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 periods 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.

## ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

#### *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 year's 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 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 adoption of SFAS No. 144 did not have a material effect on the Company's results of operations, cash flows or financial position.

# ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

### (3) Computation of Net Loss Per Share

In accordance with SFAS No. 128, *Earnings Per Share*, basic and diluted net loss per share amounts for the three months ended March 30, 2002 and March 31, 2001, were computed by dividing the net loss by the weighted average number of common shares outstanding during the periods presented. The computation of basic and diluted net loss per share amounts is as follows:

	Three Months Ended	
	March 30, 2002	March 31, 2001
	(Unaudited)	(Unaudited)
<b>BASIC AND DILUTED NET LOSS PER SHARE COMPUTATION</b>		
Numerator:		
Net loss available to common stockholders	\$ (4,699,518)	\$ (3,797,207)
Denominator:		
Weighted average common shares outstanding	17,815,859	17,458,433
Basic and diluted net loss per share	\$ (0.26)	\$ (0.22)

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. For the three months ended March 30, 2002 and March 31, 2001, the Company has excluded from the calculation of the Company's diluted earnings per share approximately 832,000 and 1,110,000 shares, respectively, related to restricted common stock subject to repurchase and common stock issuable pursuant to the exercise of stock options and warrants because the inclusion of these shares would have been antidilutive as a result of the Company's net loss position for each of the periods above.

### (4) Comprehensive Income (Loss)

The Company's total comprehensive income (loss) is as follows:

	Three Months Ended	
	March 30, 2002	March 31, 2001
	(Unaudited)	(Unaudited)
Net loss	\$ (4,699,518)	\$ (3,797,207)
Other comprehensive income (loss):		
Unrealized loss on marketable securities	(49,452)	(3,178)
Comprehensive loss	\$ (4,748,970)	\$ (3,800,385)

# ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

### (5) Investment in Sales-Type Leases

The components of the Company's net investment in sales-type leases are as follows:

	March 30, 2002	December 31, 2001
	(Unaudited)	
Total minimum lease payments receivable	\$4,318,715	\$4,199,380
Less — unearned interest	799,793	791,421
Net investment in sales-type leases	3,518,922	3,407,959
Less — current portion	1,495,441	1,473,260
	<u>\$2,023,481</u>	<u>\$1,934,699</u>

### (6) Inventory

Inventory consists of the following:

	March 30, 2002	December 31, 2001
	(Unaudited)	
Raw materials	\$2,286,436	\$2,891,400
Work-in-progress	63,059	90,076
Finished goods	1,715,812	2,126,690
	<u>\$4,065,307</u>	<u>\$5,108,166</u>

### (7) Segment Information and Enterprise Reporting

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

# ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

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

	Three Months Ended	
	March 30, 2002	March 31, 2001
	(Unaudited)	(Unaudited)
Geographic Area by Destination		
Domestic	\$7,849,723	\$6,795,320
International	1,836,843	2,067,500
	<u>\$9,686,566</u>	<u>\$8,862,820</u>

  

	Three Months Ended	
	March 30, 2002	March 31, 2001
	(Unaudited)	(Unaudited)
Geographic Area by Destination		
Domestic	81%	77%
International	19	23
	<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 three months ended March 30, 2002. For the three months ended March 31, 2001, approximately 13% of the Company's revenue was derived from sales to Germany.

### (8) Related Party Transactions

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 sheets, 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 March 30, 2002 and December 31, 2001 was approximately \$1,203,000 and \$1,209,000, respectively.

In January 2002, the Company entered into a consulting agreement with one of its directors to provide consulting, advisory and neurodiagnostics business planning services to the Company. As of March 30, 2002, no payments had been made to this director under this consulting agreement.

### (9) Loan Agreements

In May 2001, the Company paid the outstanding principal on both the equipment portion and term loan portion of its December 1999 loan agreement with a commercial bank and terminated the agreement. Following the termination of this loan agreement, the Company entered into an agreement with another commercial bank for a revolving line of credit. The revolving line of credit is for \$5,000,000 and expires on May 14, 2003 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.

**ASPECT MEDICAL SYSTEMS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**(Unaudited)**

The revolving line of credit agreement contains restrictive covenants that require the Company to maintain liquidity and net worth ratios and is secured by certain investments of the Company which are shown as restricted cash in the accompanying consolidated balance sheets. The Company is required to maintain restricted cash and securities with a net equity value equal to 102% of the \$5,000,000 commitment. At March 30, 2002, \$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 March 30, 2002, the interest rate on the revolving line of credit was 4.75%.

## **Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

*This Quarterly Report on Form 10-Q 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 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 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 our group of disposable sensors, including 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. 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% and 2% of total revenue in the three months ended March 30, 2002 and March 31, 2001, 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 the three months ended March 30, 2002 and March 31, 2001, revenue from the sale of Equipment represented approximately 36% and 32%, respectively, of our revenue, and revenue from the sale of BIS Sensors represented approximately 64% and 68%, respectively, of our revenue. In the second fiscal quarter of 2002 we believe that revenue from the sale of BIS Sensors and Equipment will increase slightly compared to the first quarter of 2002 as a result of our growing installed base, the introduction of the BIS Pediatric Sensor, BIS Quatro Sensor and BIS Extend Sensor, 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 the free placement of monitors in the medical community and the shipments of BIS Module Kits to our original equipment manufacturers.



Revenue from domestic sales in the three months ended March 30, 2002 and March 31, 2001 was approximately \$7.8 million and \$6.8 million, respectively, which represented approximately 81% and 77%, respectively, of our revenue. Revenue from international sales in the three months ended March 30, 2002 and March 31, 2001 was approximately \$1.8 million and \$2.1 million, respectively, which represented approximately 19% and 23%, 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. 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. Sales to Nihon Kohden represented approximately 33% of international revenue in the three months ended March 30, 2002. In the three months ended March 31, 2001, there was no revenue from the sale of BIS monitors and BIS Sensors to Nihon Kohden as we believe Nihon Kohden postponed new purchases until it received marketing approval of our A-2000 BIS Monitor in May 2001.

Various factors may adversely affect our quarterly operating results through the second fiscal quarter of 2002. First, we recently completed the reorganization of our sales and clinical organizations, and we are continuing to evaluate the effects of the reorganization. Second, we have underestimated the amount of clinical education necessary to bring our installed base up to expected sensor utilization levels. Third, we have recently transitioned leadership of our international operations. Fourth, in Japan, Nihon Kohden is waiting for approval of both the BIS XP system and its BIS module which in the interim may cause customers in Japan to delay their purchasing decisions. 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 costs 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 from our consolidated statements of operations expressed as a percentage of revenue. This information has been derived from our consolidated statements of operations included elsewhere in this Quarterly Report on Form 10-Q. You should not draw any conclusions about our future results from the results of operations for any period.

	Three Months Ended	
	March 30, 2002	March 31, 2001
Revenue	100%	100%
Costs and expenses:		
Costs of revenue	36	31
Research and development	20	20
Sales and marketing	76	79
General and administrative	19	23
Total costs and expenses	151	153
Loss from operations	(51)	(53)
Interest income, net	3	10
Net loss	(48)%	(43)%



### *Three Months Ended March 30, 2002 Compared to Three Months Ended March 31, 2001*

**Revenue.** Our revenue increased to approximately \$9.7 million in the three months ended March 30, 2002 from approximately \$8.9 million in the three months ended March 31, 2001, an increase of approximately 9%. Revenue from the sale of Equipment increased to approximately \$3.4 million in the three months ended March 30, 2002 from approximately \$2.8 million in the three months ended March 31, 2001, an increase of approximately 23%. We believe there were four primary factors that contributed to the increase in revenue from the sale of Equipment in the three months ended March 30, 2002 as compared to the three months ended March 31, 2001. First, during the first quarter of 2001, many of our customers received the right to use our monitors under our Equipment Placement program, or EP program, which was introduced in the second half of 2000. Under the EP program, monitors are placed free of charge for customers that agree to purchase BIS Sensors for a premium price. We have significantly reduced our emphasis on this program and the number of monitors that we provided under this program was significantly less than that in the first quarter of 2001. Second, the increase in revenue from the sale of Equipment was attributable to an increase of approximately 29% in the number of monitors sold during the first quarter of 2002 as compared to the first quarter of 2001. Third, revenue from the sale of Equipment in Japan for the three months ended March 30, 2002 was approximately \$535,000. During the three months ended March 31, 2001, there was no revenue from the sale of Equipment in Japan because we believe our Japanese distributor delayed purchases 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. Finally, revenue from the sale of accessories, particularly sales of the XP system upgrade kits, which was introduced in September 2001, increased approximately 259% in the three months ended March 30, 2002 as compared to the three months ended March 31, 2001. This increase in revenue from the sale of accessories more than offset the 43% decrease in revenue from the sale of BIS Module Kits in the first quarter of 2002 as compared to the first quarter of 2001.

Revenue from the sale of BIS Sensors increased slightly to approximately \$6.2 million in the three months ended March 30, 2002 from approximately \$6.1 million in the three months ended March 31, 2001, an increase of approximately 3%. The increase in revenue from the sale of BIS Sensors in the three months ended March 30, 2002 compared to the three months ended March 31, 2001 was primarily attributable to a 3% increase in the number of BIS Sensors sold as a result of growth in the installed base of monitors and modules. Our installed base of monitors and modules increased approximately 26% at March 30, 2002 compared to March 31, 2001, to more than 14,000.

Our gross profit margin was approximately 64% of revenue in the three months ended March 30, 2002 as compared to a gross profit margin of approximately 69% of revenue in the three months ended March 31, 2001. We believe that the decrease in the gross profit margin for the three months ended March 30, 2002 compared to the three months ended March 31, 2001 was primarily the result of two factors. First, during the first quarter of 2002, we had a 24% increase in revenue from the sale of monitors and a 21% increase in revenue from the sale of other Equipment as compared to only a 3% increase in revenue from the sale of BIS Sensors. Equipment has a lower gross profit margin than our BIS Sensors. Second, the gross profit margin on BIS Module Kits and XP system upgrades is less than that on monitors. In the second fiscal quarter of 2002, we believe that our gross margin percentage will increase slightly compared to the first fiscal quarter of 2002 because we expect 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, and the introduction of the BIS Extend Sensor in the critical care area which also has a higher list price than the BIS Standard Sensor. We believe that the following factors may, to some extent, limit the increase in gross margin percentage in the second fiscal quarter of 2002: sales of lower gross margin BIS Module Kits, which are expected to be at levels comparable to the first quarter of 2002, 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 EP program and monitors used by customers for evaluation purposes.

**Research and Development.** Research and development expenses increased to approximately \$1.9 million in the three months ended March 30, 2002 from approximately \$1.8 million in the three months ended March 31, 2001, an increase of approximately 8%. The increase in research and development expenses for the three months ended March 30, 2002 as compared to the three months ended March 31, 2001, was primarily attributable to an increase in research and development personnel and related payroll and other expenses of approximately \$265,000, offset by decreases of approximately \$63,000 in new product development expense, approximately \$52,000 in consulting expenses, and approximately \$29,000 in clinical studies expense. We expect research and development expenses to increase in the second fiscal quarter of 2002 as we continue to invest in the development of product improvements, product extensions, clinical studies and new applications for our technology, including our initiatives into the area of neurodiagnostics.

*Sales and Marketing.* Sales and marketing expenses increased to approximately \$7.4 million in the three months ended March 30, 2002 from approximately \$7.0 million in the three months ended March 31, 2001, an increase of approximately 6%. The increase in sales and marketing expenses in the three months ended March 30, 2002 as compared to the three months ended March 31, 2001 was primarily attributable to an increase in expenses associated with increasing name and brand awareness through advertising, public relations, tradeshow and the Internet of approximately \$286,000, an increase in operating expenses associated with our international subsidiaries of approximately \$468,000, and an increase in clinical education initiatives of approximately \$33,000. These increases were offset by decreases in consulting expenses of approximately \$313,000, and a decrease in sales and marketing personnel and related payroll and other expenses of approximately \$84,000. We expect sales and marketing expenses in the second fiscal quarter of 2002 to decrease slightly as we have completed the reorganization of both our domestic sales and clinical organizations and our international sales organization, and the initial investment in certain of our sales and marketing programs that we commenced in 2001, 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 decreased to approximately \$1.9 million in the three months ended March 30, 2002 from approximately \$2.1 million in the three months ended March 31, 2001, a decrease of approximately 10%. The decrease in general and administrative expenses in the three months ended March 30, 2002 as compared to the three months ended March 31, 2001 was attributable to a decrease in general and administrative personnel and related payroll and other expenses, which was equal to approximately \$112,000. The reduction in general and administrative expenses also included a decrease in expenses incurred in connection with our investor relations and the preparation of our annual report of approximately \$126,000. These decreases were offset by increases in professional and consulting expenses of approximately \$114,000. We expect general and administrative expenses in the second fiscal quarter of 2002 to be comparable to the first fiscal quarter of 2002.

*Interest Income, Net.* Net interest income decreased to approximately \$275,000 in the three months ended March 30, 2002 from approximately \$922,000 in the three months ended March 31, 2001, a decrease of approximately 70%. Interest income decreased to approximately \$345,000 in the three months ended March 30, 2002 from approximately \$1.0 million in the three months ended March 31, 2001, a decrease of approximately 67%. 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 \$70,000 in the three months ended March 30, 2002 from approximately \$118,000 in the three months ended March 31, 2001, a decrease of approximately 41%. The decrease in interest expense in the three months ended March 30, 2002 was a result of the repayment of our equipment and term loans in May 2001, lower average outstanding debt obligations resulting from payments under our other debt obligations, and lower interest rates on our working capital line of credit as compared to the equipment and term loans. We expect interest income to decrease in the second fiscal quarter of 2002 as compared to the interest income in the second fiscal quarter of 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, for the three months ended March 30, 2002 we had a net loss of approximately \$4.7 million as compared to a net loss of approximately \$3.8 million for the three months ended March 31, 2001, an increase of approximately 24%.

## **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 March 30, 2002, we raised approximately \$67.6 million from private equity financings and have received approximately \$3.4 million in equipment financing and approximately \$4.0 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 on May 14, 2003. The revolving line of credit agreement contains restrictive covenants that require us to maintain liquidity and net worth ratios and is secured by certain of our investments which are shown as restricted cash on our consolidated balance sheets. We are required to maintain restricted cash and securities with a net equity value equal to 102% of the \$5.0 million commitment.

We expect to meet our short-term liquidity needs through the use of cash and short-term investments on hand at March 30, 2002.

Working capital at March 30, 2002 was approximately \$36.8 million compared to approximately \$41.3 million at December 31, 2001. The decrease in working capital from December 31, 2001 to March 30, 2002 was primarily attributable to our continued net loss of approximately \$4.7 million.

We used approximately \$4.2 million of cash for operations in the three months ended March 30, 2002 as compared to approximately \$4.6 million in the three months ended March 31, 2001. Cash used for operations in the three months ended March 30, 2002 was primarily driven by operating losses, a decrease in accrued liabilities of approximately \$1.5 million, an increase in other assets of approximately \$267,000 and an increase in our investment in sales-type leases of approximately \$111,000, offset by decreases in accounts receivable of approximately \$651,000 and inventory of approximately \$1.0 million.

We received approximately \$12.3 million of cash from investing activities in the three months ended March 30, 2002 as compared to approximately \$7.0 million in the three months ended March 31, 2001. The cash received from investing activities in the three months ended March 30, 2002 was primarily the result of the sales and maturities of our investments in marketable securities. We received approximately \$12.6 million, net, of proceeds from sales and maturities of marketable securities and invested approximately \$310,000 primarily in information systems and machinery and equipment in the three months ended March 30, 2002. In the three months ended March 31, 2001, we received approximately \$7.5 million, net, of proceeds from sales and maturities of marketable securities and invested approximately \$475,000 primarily for improvements to our information systems and additions to demonstration equipment and approximately \$75,000 in loans to related parties.

We received approximately \$73,000 of cash from financing activities in the three months ended March 30, 2002 primarily as a result of proceeds from the sale of our investment in sales type leases and the issuance of shares of our common stock upon the exercise of stock options, partially offset by payments of principal on debt. In the three months ended March 31, 2001, we used approximately \$262,000 of cash from financing activities primarily from making payments on our debt obligations.

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 on May 14, 2003 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 March 30, 2002, 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 March 30, 2002 was \$3.0 million. At March 30, 2002, we had standby letters of credit outstanding in the amount of approximately \$404,000.

We guarantee approximately \$238,000 of operating lease obligations of our subsidiaries 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 March 30, 2002, we sold approximately \$4.0 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 March 30, 2002, approximately \$1.7 million is recorded as debt on our consolidated balance sheet.

We had capital expenditures of approximately \$310,000 for the three months ended March 30, 2002. At March 30, 2002, we did not have any commitments for capital expenditures, however, we anticipate that the level of capital expenditures in the second fiscal quarter of 2002 will remain comparable to the level of capital expenditures during the first fiscal quarter of 2002.

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 March 30, 2002:

**Payments Due By Period**

Contractual Obligations	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	5,117,364	1,184,651	2,214,223	1,718,490	
Sale of investment in sales type leases	1,723,135	812,762	885,627	24,746	—
Total contractual cash obligations	<u>\$9,840,499</u>	<u>\$4,997,413</u>	<u>\$3,099,850</u>	<u>\$1,743,236</u>	<u>\$ —</u>

## Income Taxes

We have net operating loss and research and development tax credit carryforwards for federal income tax purposes that will expire commencing in the year 2002 through the year 2022 if not utilized.

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

## Effects of Inflation

We believe that inflation and changing prices over the past year 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.

## 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. Effective January 1, 2002, we adopted SFAS No. 144. The adoption of SFAS No. 144 did not have a material effect on our results of operations, cash flows or financial position.

## **FACTORS AFFECTING FUTURE OPERATING RESULTS**

This Quarterly Report on Form 10-Q 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 the fiscal quarter ending June 29, 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. 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. First, we recently completed 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. Second, we have underestimated the amount of clinical education necessary to bring our installed base up to expected sensor utilization levels. Third, 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, possible delays in purchasing decisions by customers in Japan 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,
- we decide to expand faster than currently planned,
- we develop new or enhanced services or products ahead of schedule,
- we decide to undertake new sales and/or marketing initiatives,
- sales of our products do not meet our expectations in the United States or internationally,
- we need to respond to competitive pressures, or
- we decide to acquire complementary products, businesses or technologies.

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

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

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

We are currently 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 two risks:

- we may not successfully adapt the BIS system to function properly for procedural sedation, when used with anesthetics we have not tested or with patient populations we have not studied, such as infants, and
- our technology is complex, and we may not be able to develop it further for applications outside anesthesia monitoring, such as the diagnosis and tracking of neurological diseases.

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

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

We recently completed the reorganization of our domestic sales force. 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 the second half of 2001 we began the implementation of new marketing programs. 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. In addition, we recently completed the transition to new management in our international operations, including the combination of our international commercial and clinical groups. If this international reorganization is not successful, we will not be able to expand our international business. We have only limited sales and marketing experience both in the United States and internationally and may not be successful in developing and implementing our strategy. We need to:

- provide or assure that distributors and original equipment manufacturers provide the technical and educational support customers need to use the BIS system successfully,
- promote frequent use of the BIS system so that sales of our disposable BIS Sensors increase,
- establish and implement successful marketing and sales programs that encourage our customers to purchase our products or the products that are made by original equipment manufacturers incorporating our technology,
- manage geographically dispersed operations, and
- modify our products and marketing and sales programs for foreign markets.

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

In order to increase our sales, we need to continue to strengthen our relationships with our domestic and international distributors and continue to add international distributors. We need to also continue to strengthen our relationships with our original equipment manufacturers and other sales channels and increase sales through these channels. In addition, we need to hire and train more sales representatives. We recently completed the reorganization of our sales organization and, in the second half of 2001, started to implement new sales and marketing programs and clinical education programs to promote the use of the BIS system by our customers. If we do not further develop our direct and indirect sales channels and successfully implement the new sales 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. 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 may not cover the costs of any product liability claims made against us. Furthermore, we may not be able to obtain insurance in the future at satisfactory rates or in adequate amounts. In addition, publicity pertaining to the misuse or malfunction of, or design flaws in, our products could impair our ability to successfully market and sell our products.

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

The underwriters of our initial public offering are named as defendants in several class action complaints which have been filed allegedly on behalf of certain persons who purchased shares of our common stock between January 28, 2000 and December 6, 2000. These complaints allege violations of the Securities Act of 1933 and the Securities Exchange Act of 1934. Primarily they allege that there was undisclosed compensation received by our underwriters in connection with our initial public offering. While we and our officers and directors have not been named as defendants in these suits, based on comparable lawsuits filed against other companies, there can be no assurance that we and our officers and directors will not be named in similar complaints in the future.

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 distributors and original equipment manufacturers and the timing and amount of our expenses. Because of these fluctuations, it is likely that in some future quarter or quarters our operating results could again fall below the expectations of securities analysts or investors. If our quarterly operating results are below expectations in the future, the market price of our 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 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 3. 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.



## **PART II — OTHER INFORMATION**

### **Item 1. Legal Proceedings.**

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

### **Item 2. Changes in Securities and Use of Proceeds.**

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 March 30, 2002, we used approximately \$7.3 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 March 30, 2002, we used approximately \$29.5 million of the net proceeds for general corporate purposes, including working capital, product development, increasing our sales and marketing capabilities and expanding our international operations. As of March 30, 2002, we had approximately \$17.8 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.

### **Item 3. Defaults Upon Senior Securities.**

None.

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

None.

### **Item 5. Other Information.**

None.

### **Item 6. Exhibits and Reports on Form 8-K.**

#### **(a) Exhibits**

- |       |   |
|-------|---|
| 10.1† | Addendum No. 1, effective January 1, 2002, to OEM Development and Purchase Agreement, dated December 22, 1999, by and between the Registrant and GE Medical Systems, Inc. |
| 10.2  | Advisory Board Agreement, dated as of January 23, 2002, by and between Stephen E. Coit and the Registrant.  |

† 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**

We did not file any reports on Form 8-K during the quarter ended March 30, 2002.

## **SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ASPECT MEDICAL SYSTEMS, INC.

Date: May 13, 2002

By: /s/ J. Neal Armstrong

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J. Neal Armstrong  
Vice President and Chief Financial Officer  
(Principal Financial and  
Accounting Officer)

## EXHIBIT INDEX

EXHIBIT NUMBER	EXHIBIT
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