SONOSITE INC
Form 10-Q
August 09, 2004

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SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

X **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**

For the quarterly period ended June 30, 2004

OR

Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.
For the transition period from to _____ to _____

Commission file number 0-23791

SONOSITE, INC.

(Exact name of registrant as specified in its charter)

Washington	**91-1405022**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**
21919 30th Drive SE, Bothell, WA	**98021-3904**
(Address of Principal Executive Offices)	**(Zip Code)**

(425) 951-1200
(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 X No

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Common Stock, $0.01 par value	**14,821,364**
(Class)	**(Outstanding as of August 6, 2004)**

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SonoSite, Inc.

Quarterly Report on Form 10-Q
For the Quarter Ended June 30, 2004
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PART I: FINANCIAL INFORMATION
Item 1. Financial Statements

SonoSite, Inc.

Condensed Consolidated Balance Sheets
(unaudited)

(In thousands, except share data) Assets	June 30, 2004	December 31, 2003
Current assets:		
Cash and cash equivalents	$ 14,139	$ 13,683
Short-term investment securities	5,334	13,094
Accounts receivable, less allowance for doubtful accounts of $972 and $933	23,421	25,849
Inventories	13,510	14,148
Prepaid expenses and other current assets	2,030	1,520

Total current assets	58,434	68,294
Property and equipment, net	6,362	5,564
Investment securities	42,271	34,239
Goodwill	266	--
Identifiable intangible assets, net	1,983	--
Other assets	1,715	993
Total assets	$ 111,031	$ 109,090
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 3,431	$ 3,054
Accrued expenses	7,534	6,503
Current portion of long-term obligations	--	88
Deferred revenue	3,854	3,840
Total current liabilities	14,819	13,485
Deferred rent	252	275
Total liabilities	15,071	13,760
Commitments and contingencies		
Shareholders' equity:		
Preferred stock, $1.00 par value		
Authorized shares--6,000,000		
Issued and outstanding shares--none	--	--
Common stock, $.01 par value		
Authorized shares--50,000,000		
Issued and outstanding shares:		
As of June 30, 2004--14,813,050		
As of December 31, 2003--14,572,524	148	146
Additional paid-in-capital	183,626	180,839
Accumulated deficit	(88,880)	(87,416)
Accumulated other comprehensive income	1,066	1,761
Total shareholders' equity	95,960	95,330
Total liabilities and shareholders' equity	$ 111,031	$ 109,090

See accompanying notes to condensed consolidated financial statements.

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SonoSite, Inc.

Condensed Consolidated Statements of Operations

(unaudited)

(In thousands, except loss per share)	**Three Months Ended**	**Six Months Ended**

	June 30,		June 30,	
	2004	2003	2004	2003
Revenue	$ 26,076	$ 20,120	$ 49,590	$ 37,278
Cost of revenue	8,746	7,494	17,031	13,861
Gross margin	17,330	12,626	32,559	23,417
Operating expenses:				
Research and development	3,047	2,875	6,120	5,708
Sales and marketing	12,163	9,618	23,748	18,508
General and administrative	2,147	1,739	4,379	3,744
Total operating expenses	17,357	14,232	34,247	27,960
Other income (expense):				
Interest income	221	250	439	520
Interest expense	(1)	(7)	(2)	(14)
Other income (expense)	(257)	66	(213)	176
Total other income (expense)	(37)	309	224	682
Net loss	$ (64)	$ (1,297)	$ (1,464)	$ (3,861)
Basic and diluted net loss per share	$ (0.00)	$ (0.09)	$ (0.10)	$ (0.27)
Weighted average common shares used in computing net loss per share	14,757	14,268	14,694	14,237

See accompanying notes to condensed consolidated financial statements.

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SonoSite, Inc.

Condensed Consolidated Statements of Cash Flows
(unaudited)

(In thousands)	Six Months Ended June 30, 2004	2003
Operating activities:		
Net loss	$ (1,464)	$ (3,861)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,416	1,227
Equity in losses of affiliates	5	--
Net gain on investments	(42)	(17)
Amortization of premiums on investment securities	351	346
Stock-based compensation to non-employees	51	--
Changes in operating assets and liabilities:		
Accounts receivable	2,322	3,391

Inventories	638	(1,730)
Prepaid expenses and other assets	(1,522)	(396)
Accounts payable	383	(2,280)
Accrued expenses	1,057	610
Deferred liabilities	(11)	261
Net cash provided by (used in) operating activities	3,184	(2,449)
Investing activities:		
Purchase of investment securities	(20,470)	(18,626)
Proceeds from sales/maturities of investment securities	19,554	6,895
Purchase of SonoMetric Health, Inc.	(2,036)	--
Purchase of property and equipment	(2,174)	(733)
Net cash used in investing activities	(5,126)	(12,464)
Financing activities:		
Exercise of stock options	2,738	1,492
Repayment of long-term obligations	(88)	(66)
Net cash provided by financing activities	2,650	1,426
Effect of exchange rate changes on cash and cash equivalents	(252)	452
Net change in cash and cash equivalents	456	(13,035)
Cash and cash equivalents at beginning of period	13,683	26,381
Cash and cash equivalents at end of period	$ 14,139	$ 13,346
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 2	$ 14

See accompanying notes to condensed consolidated financial statements.

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SonoSite, Inc.

Notes to Condensed Consolidated Financial Statements
(unaudited)

Interim Financial Information

Basis of Presentation

The information contained herein has been prepared in accordance with instructions for Form 10-Q and Article 10 of Regulation S-X. The information furnished reflects, in the opinion of SonoSite, Inc. management, all adjustments necessary (which are of a normal and recurring nature) for a fair presentation of the results for the interim periods presented. The results of operations for the three and six months ended June 30, 2004 are not necessarily indicative of our expected results for the entire year ending December 31, 2004 or for any other fiscal period. These financial statements do not include all disclosures required by generally accepted accounting principles. For a presentation including all disclosures required by generally accepted accounting principles, these financial statements should be read in conjunction with the audited

financial statements for the year ended December 31, 2003, included in our Annual Report on Form 10-K.

Stock-based compensation

At June 30, 2004, we had five stock-based employee compensation plans. We account for those plans under the intrinsic value method in accordance with the provisions of Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees." Accordingly, compensation cost related to stock option grants to employees has been recognized only to the extent that the fair market value of the stock exceeds the exercise price of the stock option at the date of the grant. There was no compensation expense related to stock option grants to employees for the three and six month periods ended June 30, 2004 or 2003. The following table illustrates the effect on net loss and net loss per share if we had applied the fair value recognition provisions of SFAS No. 123, "Accounting for Stock-Based Compensation," to stock-based employee compensation (in thousands, except per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Net loss, as reported	$ (64)	$ (1,297)	$ (1,464)	$ (3,861)
Less: Stock-based employee compensation expense determined under fair value based method	(1,358)	(1,267)	(2,491)	(2,667)
Pro forma net loss	$ (1,422)	$ (2,564)	$ (3,955)	$ (6,528)
Basic and diluted net loss per share:				
As reported	$ (0.00)	$ (0.09)	$ (0.10)	$ (0.27)
Pro forma	$ (0.10)	$ (0.18)	$ (0.27)	$ (0.46)

We account for non-employee stock-based compensation in accordance with SFAS No. 123 and FASB Emerging Issues Task Force, or EITF, Issue No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services."

Cash and cash equivalents

Cash and cash equivalents consist of money market accounts with major U.S. banks and highly liquid debt instruments with original or remaining maturities at purchase of three months or less.

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Investment securities

Investment securities consist of high-grade U.S. government or corporate debt and high-grade asset-backed securities. While our intent is to hold our securities until maturity, we classify all securities as available-for-sale, as the sale of such securities may be required prior to maturity to implement management strategies. These securities are carried at fair value, with the unrealized gains and losses reported as a component of other comprehensive income (loss) until realized. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis.

A decline in market value of any available-for-sale security below cost that is determined to be other than temporary results in a revaluation of its carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the effective interest method. Interest income is recognized when earned.

Accounts receivable

In the ordinary course of business, we grant credit to a broad customer base. Of the accounts receivable balance at June 30, 2004, 43% and 57% were receivable from domestic and international parties, prior to any allowance for doubtful accounts. The same percentages as of December 31, 2003 were 48% and 52% prior to any allowance for doubtful accounts.

For the three months ended June 30, 2004, revenue was 53% domestic and 47% international, compared to 66% domestic and 34% international for the three months ended June 30, 2003. For the six months ended June 30, 2004, revenue was 52% domestic and 48% international, compared to 62% domestic and 38% international for the six months ended June 30, 2003.

We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. When we determine that amounts owed from customers are uncollectible, such amounts are charged off against the allowances for doubtful accounts. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.

Fair value of financial instruments

The carrying value of our financial instruments, including cash and cash equivalents, accounts receivable, accounts payable and certain long-term other assets, approximates fair value. Cash and cash equivalents, accounts receivable and accounts payable approximate fair value due to their short-term nature. Other long-term assets approximate fair value as interest rates on these items approximate market. Investment securities are carried at fair value.

We utilize foreign currency forward contracts to reduce our exposure to foreign currency risk due to fluctuations in exchange rates underlying the value of intercompany accounts receivable denominated in foreign currencies. We recognize all derivative financial instruments (foreign currency forward contracts) in accordance with Statement of Financial Accounting Standards, or SFAS, No. 133 "Accounting for Derivative Instruments and Hedging Activities," as amended. Changes in the fair value of derivative instruments are recorded in earnings unless hedge accounting criteria are met. For derivative instruments designated as fair value hedges, the changes in fair value of both the derivative instrument and the hedged item are recorded in earnings. For derivative instruments designed as cash flow and net investment hedges, the effective portions of changes in the fair value of the derivative are recorded in other comprehensive income. The ineffective portions are recognized in earnings.

Inventories

Inventories are stated at the lower of cost or market, on a first-in, first-out method. Included in our inventories balance are demonstration products used by our sales representatives and marketing department, and items that have been shipped to customers for which revenue recognition requirements have not been met, including products whose title and custody have passed to the customer. Adjustments to reduce carrying costs are recorded for obsolete material, earlier generation products and refurbished products held either as saleable inventory or as demonstration product. Inventory items for which title has passed to customers are evaluated for recoverability based on the same process we use to evaluate collection of accounts receivable. If market conditions are less favorable than those projected by management, additional downward inventory cost adjustments may be required.

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Inventories consisted of the following (in thousands):

	As of	
	June 30, 2004	December 31, 2003
Raw material	$ 4,202	$ 4,479
Work-in-process	70	48
Demonstration inventory	3,557	2,578
Finished goods	5,681	7,043

Total	$ 13,510	$ 14,148

At June 30, 2004 and December 31, 2003 finished goods included $0.1 million and $0.2 million of inventory whose title had passed to the customer and for which revenue has not yet been recognized.

Property and equipment

Property and equipment are stated at historical cost, less accumulated depreciation and amortization. Maintenance and repair costs are expensed as incurred, with additions and improvements to property and equipment capitalized.

Depreciation and amortization are calculated using the straight-line method over estimated useful lives as follows:

Asset	**Estimated Useful Lives**
Equipment and computers	3-5 years
Software	3 years
Furniture and fixtures	5 years
Leasehold improvements	Lesser of estimated useful life or expected remaining lease term

Direct internal and external costs for computer software developed for internal use are capitalized in accordance with SOP 98-1, "Accounting for Costs of Computer Software Developed or Obtained for Internal Use." Capitalized costs are amortized using the straight-line method over the estimated useful lives beginning when each module is complete and ready for use. Such costs are insignificant for all periods presented.

The carrying value of long-lived assets is evaluated for impairment when events or changes in circumstances occur, which may indicate the carrying amount of the asset may not be recoverable. We evaluate the carrying value of the assets by comparing the estimated future undiscounted cash flows generated from the use of the asset and its eventual disposition with the asset's reported net book value.

Warranty liability

Our typical warranty period is one year and is included with the original purchase of our ultrasound imaging systems. The warranty liability is summarized as follows (in thousands):

	Balance at beginning of period	**Charged to cost of revenue**	**Applied to liability**	**Balance at end of period**
Six months ended June 30, 2004	$ 381	297	(247)	$ 431
Six months ended June 30, 2003	$ 331	190	(140)	$ 381

Concentration of credit and supply risk

Financial instruments that potentially subject us to concentrations of credit risk consist principally of cash equivalents, investments and accounts receivable.

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We depend on some single-source suppliers to provide highly specialized parts and other components, and may experience an interruption of supply if a supplier is unable or unwilling to meet our time, quantity and quality requirements. There are relatively few alternative sources of supply for some of these items. A change in demand for some parts by other companies in our industry could also interrupt our supply of components. For example, in March 2003, one of our component suppliers, Philips Semiconductor, or Philips, informed us that, commencing in September 2003, it would discontinue production of our integrated circuit chips using 0.35-micron technology. We have designed and implemented a new chip using 0.2-micron technology that will continue to be produced by Philips to replace all but one of the discontinued chips. We expect to design and implement an additional new chip to replace the remaining 0.35-micron chip by early 2005. In the second quarter of 2003, we entered into a purchase commitment totaling approximately $3.6 million for supplies of 0.35-micron chips from Philips for our anticipated manufacturing needs until new chips have been incorporated in all of our products. We pay for these chips at the time deliveries

are made to us. As of June 30, 2004, our remaining purchase commitment was approximately $2.5 million. On December 31, 2004, we are required to take possession of, and pay for, the balance of the undelivered chips. Demand for our products, however, may exceed our forecasts, in which case we would require additional 0.35-micron chips to manufacture additional products. Conversely, if demand for our products falls short of our forecasts, we may experience excess inventory of 0.35-micron chips. If our actual demand for these chips varies significantly from our forecasted demand, we may experience delays in manufacturing, lost sales, a write-down of inventory or a deterioration in gross margin. In addition, we have transferred the production of our circuit boards to one of the world's largest electronic manufacturing services suppliers who produces the boards in their Thailand manufacturing facility. If, as a result of this transfer, we experience delays in the receipt or a deterioration in product yields of these components, we may experience delays in manufacturing or an increase in costs resulting in lost sales or a deterioration in gross margin.

Accumulated other comprehensive income (loss)

Unrealized gains or losses on our available-for-sale securities and foreign currency translation adjustments are included in accumulated other comprehensive income.

The following presents the components of accumulated comprehensive loss (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	**2003**	**2004**	**2003**
Net loss	$ (64)	$ (1,297)	$ (1,464)	$ (3,861)
Other comprehensive income (loss):				
Foreign currency translation adjustment	(195)	458	(360)	778
Unrealized holding losses arising during the period	(360)	(34)	(293)	(38)
Less reclassification adjustment for losses (gains) included in net loss	10	--	(42)	(17)
Comprehensive loss	$ (609)	$ (873)	$ (2,159)	$ (3,138)

Net loss per share

Basic and diluted net loss per share was computed by dividing the net loss by the weighted average common shares outstanding. Outstanding options to purchase our shares were not included in the computations of diluted net loss per share because to do so would be antidilutive. For the three and six month periods ended June 30, 2004, our outstanding options totaled 2,764,499. For the three and six month periods ended June 30, 2003, our outstanding options totaled 3,161,390.

Foreign currency translation

The functional currencies of our international subsidiaries are the local currency of the country in which the subsidiary is located. Assets and liabilities denominated in foreign currencies are translated at the exchange rate on the balance sheet date. Revenues, costs and expenses of international operations are translated at average rates of exchange prevailing during the period. Net realized and unrealized losses on currency transactions were $302,000 and $186,000 for the three and six months ended June 30, 2004. Net realized and unrealized gains on currency transactions were $70,000 and $163,000 for the three and six months ended June 30, 2003.

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Litigation

On July 24, 2001, Neutrino Development Corporation filed a complaint against us in U.S. District Court, Southern District of Texas, Houston Division, alleging infringement of U.S. Patent 6,221,021, or the '021 patent, by SonoSite as a result of our use, sale and manufacture of the SonoSite 180, SonoSite 180PLUS, SonoHeart and SonoHeart ELITE devices. The complaint asserts claims for preliminary and permanent injunctive relief enjoining all alleged acts of infringement, compensatory and enhanced damages, attorney's fees and costs, and pre- and post-judgment interest. On August 14, 2001, we filed an answer asserting affirmative defenses of non-infringement and patent invalidity, and

included a counterclaim seeking a declaratory judgment of non-infringement and invalidity regarding Neutrino's patent. On October 4, 2001, the court denied a request by Neutrino for preliminary injunctive relief to prevent us from manufacturing and selling our products pending the ultimate disposition of the litigation. On February 20, 2002, in what is known as a "Markman" hearing, the parties presented their arguments regarding the proper construction of Neutrino's patent claims.

On August 20, 2003, the U.S. District Court in the Southern District of Texas issued a decision interpreting certain terms used in the '021 patent. This decision does not discuss whether the patent is valid or whether the patent would apply to any of our products. In the order, the court, in resolving disputed terms in the Markman hearing, adopted our construction of the term "a portable body designed to be hand held", and adopted Neutrino's construction of the terms "the moveably connected transducer mounting assembly" and "ultrasound emitter". The court denied our motion for summary judgment. We subsequently filed a new summary judgment motion using the court's construction of the claim language that the '021 patent is invalid based on prior art. Neutrino has filed a summary judgment motion based on its allegations of infringement.

We also have asked the Texas court to stay proceedings in Neutrino's suit filed in the Middle District of Florida on August 19, 2003 against a former SonoSite distributor alleging that the sale of our products by such distributor infringes the '021 patent, and to enjoin Neutrino from filing similar suits against other sellers of SonoSite products. Neutrino had previously filed such a suit in the Middle District of Tennessee against another medical device distributor for selling a SonoSite product. That Tennessee case has been dismissed based on a final judgment and permanent injunction filed a month after the case was filed. The Tennessee judgment has no effect on the Texas proceedings. In the Florida action, we assumed defense of the case and have filed a motion to stay the proceedings in the Florida court pending a final resolution of the patent suit in Texas. We have also filed a motion to strike certain counts of Neutrino's complaint. In June 2004, the Florida court stayed the Florida action for six months, pending resolution of the Texas case, granted Neutrino's request to add SonoSite as a party to the Florida case, and denied our motion to strike certain counts, suggesting instead that we file our arguments contained in the motion to strike as a motion to dismiss.

We believe that we have good and sufficient defenses to the claims of patent infringement asserted against us by Neutrino and we are vigorously defending ourselves in these matters. If we are not successful in our defense of these claims, we could be forced to pay damages related to past product sales, modify or discontinue selling our products or may enter into royalty or licensing agreements for future product sales, which may not be available on terms acceptable to us, if at all, and which could adversely affect our financial condition, results of operations and cash flow. Sales of the allegedly infringing products represented the majority of our revenue for six month periods ended June 30, 2004 and 2003.

We have not accrued any amounts for potential losses related to these proceedings. Because of uncertainties related to both the amount and range of loss on the pending litigation, management is unable to make a reasonable estimate of the liability that could result from an unfavorable outcome. As additional information becomes available, we will assess the potential liability related to pending litigation. We will record accruals for losses if and when we determine the negative outcome of such matters to be probable and reasonably estimable. Our estimates regarding such losses could differ from actual results. Revisions in our estimates of the potential liability could materially impact our results of operations, financial position and cash flow.

Acquisition of SonoMetric Health, Inc.

On May 20, 2004, we acquired 100% of the outstanding common shares of SonoMetric Health, Inc., or SonoMetric. The results of SonoMetric's operations have been included in our consolidated financial statements since that date. SonoMetric is a medical software company whose primary product is designed to be used with ultrasound technology to measure the intima media thickness, or IMT, of the carotid artery. Increased thickness of the IMT in the carotid artery is associated with an increased risk of developing atherosclerosis, which is a leading cause of heart disease. We plan to incorporate SonoMetric's software into our products.

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We purchased all of SonoMetric's outstanding common shares for an immediate cash payment of $1.5 million, plus future cash payments of up to $4.5 million contingent upon the amount of revenue recognized from the sale of SonoMetric's software over the five-year period following the closing date of the acquisition. In addition to the immediate cash payment, we also incurred $354,000 in acquisition-related expenses, bringing the initial aggregate purchase price to $1,854,000.

The following table summarizes the estimated fair value of the assets acquired and liabilities assumed at the date of acquisition. As part of the consideration paid to SonoMetric, the company paid off the assumed liabilities upon closing.

(unaudited)(in thousands)	At May 20, 2004
Intangible assets	$ 1,770
Goodwill	266
Total assets acquired	2,036
Current liabilities	(182)
Net assets acquired	$ 1,854

Of the $1.77 million of acquired intangible assets, $1.3 million was assigned to existing software technology that will be amortized over seven years and $470,000 was assigned to non-compete agreements with former shareholders of SonoMetric that will be amortized over three years. Any future contingent payments that are made will be recorded as additional goodwill. Amortization expense of approximately $29,000 related to these intangible assets was recorded for both the three and six month periods ended June 30, 2004.

Segment reporting

We currently have one reportable segment. We market our products in the United States and internationally through our direct sales force and our indirect distribution channels. Our chief operating decision maker evaluates resource allocation decisions and our performance based upon revenue recorded in geographic regions and does not receive financial information about expense allocation on a disaggregated basis. Geographic regions are determined by the shipping destination. Revenue by geographic location is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
United States	$ 13,886	$ 13,372	$ 25,670	$ 23,206
Europe, Africa and the Middle East	7,940	4,121	16,744	9,193
Japan	1,958	189	3,223	326
Canada, Australia, South and Latin America	1,274	1,306	2,040	2,303
Other Asia (a)	1,018	1,132	1,913	2,250
Total revenue	$ 26,076	$ 20,120	$ 49,590	$ 37,278

(a) Other Asia includes primarily China, Taiwan, Korea and India.

Recent accounting pronouncements

In November 2002, the Emerging Issues Task Force, or EITF, reached a consensus on EITF 00-21, "Revenue Arrangements with Multiple Deliverables," with respect to determining when and how to allocate revenue from sales with multiple deliverables. The EITF 00-21 consensus provides a framework for determining when and how to allocate revenue from sales with multiple deliverables based on a determination of whether the multiple deliverables qualify to be accounted for as separate units of accounting. The consensus is effective prospectively for arrangements entered into in fiscal periods beginning after June 15, 2003 and we adopted this consensus on July 1, 2003. The adoption of this consensus did not have a material impact on our consolidated financial statements.

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In January 2003, the FASB issued Interpretation No. 46, or FIN 46, "Consolidation of Variable Interest Entities". Variable interest entities often are created for a single specified purpose, for example, to facilitate securitization, leasing, hedging, research and development, or other transactions or arrangements. This interpretation of Accounting Research Bulletin No. 51, "Consolidated Financial Statements," defines what these variable interest entities are and provides guidelines on how to identity them and also on how an enterprise should assess its interests in a

variable interest entity to decide whether to consolidate that entity. On October 8, 2003, the FASB deferred the implementation date for the consolidation requirements of FIN 46 as it relates to variable interest entities that existed before February 1, 2003. FIN 46 also requires companies that expect to consolidate a variable interest entity they acquired before February 1, 2003 to disclose the entity's nature, size, activities, and the company's maximum exposure to loss in financial statements issued after January 31, 2003. In December 2003, the FASB issued FIN 46R with respect to variable interest entities created before January 31, 2003, which, among other things, revised the implementation date to the fiscal year or interim period ending after March 15, 2004 except for Special Purpose Entities. The adoption of this interpretation did not have an impact on our consolidated financial statements.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This quarterly report on Form 10-Q contains forward-looking statements. Forward-looking statements provide our current expectations or forecasts of future events. Forward-looking statements in this report include, without limitation:

- information concerning possible or assumed future results of operations, trends in financial results and business plans, including those relating to earnings growth and revenue growth;
- statements about the level of our costs and operating expenses relative to our revenue, and about the expected composition of our revenue;
- statements about our future capital requirements and the sufficiency of our cash, cash equivalents, investments and available bank borrowings to meet these requirements;
- other statements about our plans, objectives, expectations and intentions; and
- other statements that are not historical facts.

Words such as "believe," "anticipate," "expect" and "intend" may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements are subject to known and unknown risks and uncertainties, and are based on potentially inaccurate assumptions that could cause actual results to differ materially from those expected or implied by the forward-looking statements. You should not unduly rely on these forward-looking statements, which speak only as of the date of this report.

We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosures we make on related subjects in our future Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and Annual Reports on Form 10-K. Also note that we provide a cautionary discussion of risks, uncertainties and possibly inaccurate assumptions relevant to our business under the caption "Important Factors That May Affect Our Business, Our Results of Operations and Our Stock Price" in this report. These are risks that could cause our actual results to differ materially from those anticipated in our forward-looking statements or from our expected or historical results. Other factors besides the risks, uncertainties and possibly inaccurate assumptions described in this report could also affect actual results.

Overview

We are a leading worldwide developer, manufacturer and seller of high-performance, hand-carried ultrasound imaging systems for use in a variety of clinical applications and settings. Our proprietary technologies have enabled us to design hand-carried diagnostic ultrasound systems that combine all-digital, high-resolution imaging with advanced features and capabilities traditionally found on cart-based ultrasound systems. We believe that the mobility, high clinical utility, durability, ease of use and cost-effectiveness of our products are expanding existing markets and will create new markets for ultrasound imaging by bringing ultrasound out of the imaging center to other clinical settings and to the point-of-care such as the patient's bedside or the physician's examining table.

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The size and complexity of traditional cart-based ultrasound systems typically require a physician or highly trained clinician to perform the examination in a centralized imaging department, such as a hospital's radiology department. By providing ultrasound at the primary point-of-care, our easy-to-use systems can eliminate delays associated with the referral process and enable physicians to use ultrasound more frequently and in a wider variety of clinical settings. This increased accessibility creates the potential for enhanced patient care through earlier diagnosis of diseases and conditions.

Our products are used for imaging in a variety of medical specialties, such as radiology, obstetrics and gynecology, emergency medicine, surgery, cardiology, internal medicine and vascular medicine. Our current products include the SonoSite TITAN system, for general imaging

and cardiology applications, the SonoSite 180PLUS system, for general ultrasound imaging, and the SonoHeart ELITE, specifically configured for cardiovascular applications. The iLook 25 imaging tool is designed to provide visual guidance for physicians and nurses while performing vascular access procedures and the iLook 15 imaging tool is designed to provide visual imaging of the chest and abdomen for physicians and nurses while performing other procedures and examinations. Our TITAN, SonoSite 180PLUS and SonoHeart ELITE products are used together with any of our transducers that are designed for specific clinical applications. Our iLook products each have a single transducer for specific clinical applications. We first shipped our newest product, the SonoSite TITAN, in June 2003.

We were formerly a division of ATL Ultrasound, Inc., or ATL. On April 6, 1998, we were spun-off as an independent, publicly owned Washington corporation to further the development and commercialization of high-performance, hand-carried ultrasound imaging systems. ATL retained no ownership in us following the spin-off. We entered into a technology transfer and license agreement with ATL pursuant to which we took ownership of certain ultrasound technology developed as part of a government grant and also patent rights, which had been established or were being pursued for that technology. As part of this agreement, we also entered into a cross-license whereby we had the exclusive right to use certain ATL technology existing on April 6, 1998 or developed by ATL during the three-year period following April 6, 1998 in ultrasound systems weighing 15 pounds or less, and ATL had the exclusive right to use our technology existing on April 6, 1998 or developed by us during the same three-year period in ultrasound systems weighing more than 15 pounds. On April 6, 2003, this cross-license became nonexclusive and, except for the patented technology of each party, now extends to all ultrasound systems regardless of weight. We sold our first products in September 1999.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to product returns, bad debts, inventories, investments, warranty obligations, service contracts, contingencies and litigation. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances. The results form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our critical accounting policies and estimates include accounts receivable, revenue recognition, valuation of inventories and treatment of warranty expense.

Accounts receivable. We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. We determine the adequacy of these allowances by regularly reviewing the agings of our accounts receivable and evaluating individual customer receivables, considering customers' financial condition, historical experience, credit history and current economic condition. Losses can be difficult to anticipate. An increase in losses beyond those expected by management would reduce earnings when they become known or as the estimated loss increases.

Revenue recognition. We recognize revenue on products and accessories when goods are shipped under an agreement with a customer, risk of loss and title have passed to the customer and collection of any resulting receivable is reasonably assured. For service contracts, revenue is recognized over the term of the contract. Revenue is recorded net of estimated returns. Sales discounts are recorded as a reduction in revenue.

In connection with sales to certain specific international customers, we sometimes conclude that full collection of the related accounts receivable is not reasonably assured due to extended payment terms or the financial condition of our customer and, consequently, we do not recognize revenue or cost of revenue at the time of title transfer. In instances where collection is not reasonably assured, revenue and cost of revenue are recorded when cash is received.

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Our sales arrangements may contain multiple elements, which include hardware and software products. Revenue from the sale of software in these arrangements is recognized in accordance with the American Institute of Certified Public Accountants Statement of Position 97-2, "Software Revenue Recognition," as amended. We have vendor specific objective evidence, or VSOE, of fair value for our products. Accordingly, for transactions that have undelivered elements for which we have VSOE of the elements, revenue equal to the total fair value of the undelivered elements is deferred and is not recognized until the element is delivered to the customer.

Valuation of inventories. Inventories are stated at the lower of cost or market on a first-in, first-out method. Included in our inventories balance are demonstration products used by our sales representatives and marketing department and items that have been shipped to customers for which revenue recognition requirements have not been met. Adjustments to reduce carrying costs are recorded for obsolete material, earlier generation products and used or refurbished products held either as saleable inventory or as demonstration product. Inventory items for which title has passed to customers are evaluated for recoverability based on the same process we use to evaluate collection of accounts receivable.

We make judgments regarding the carrying value of our inventories based on current market conditions. Market conditions may change depending upon competitive product introductions, consumer demand and reimbursement criteria in the medical community. If market conditions change or if the introduction of new products by us impacts the market for our previously released products, we may be required to write down the cost of our inventories.

Warranty expense. We accrue estimated warranty expenses at the time of sale for costs expected to be incurred under our product warranties. This provision for warranty expenses is made based upon our historical experience and management's judgment. We have limited history with some of our products. Any unexpected increase in defects would result in an increase in warranty expense and a reduction in earnings.

Results of Operations for the Three Months and Six Months Ended June 30, 2004 and June 30, 2003

Revenue

Overview

Revenue increased to $26.1 million for the three months ended June 30, 2004 from $20.1 million for the three months ended June 30, 2003, primarily due to an increase in sales in Europe and Japan. Revenue increased to $49.6 million for the six months ended June 30, 2004 from $37.3 million for the six months ended June 30, 2003, due to an increase in sales in Europe, Japan and the United States. The increase in revenue in both periods was primarily due to increased sales of our TITAN system. The first shipments of the TITAN system occurred in June 2003 and accounted for approximately 64% of our worldwide revenue for the three months ended June 30, 2004, compared to 24% of our worldwide revenue for the three months ended June 30, 2003. Sales of the TITAN system accounted for approximately 56% of our worldwide revenue for the six months ended June 30, 2004, compared to 13% of our worldwide revenue for the six months ended June 30, 2003.

United States

U.S. revenue increased to $13.9 million for the three months ended June 30, 2004, compared to $13.4 million for the three months ended June 30, 2003. U.S. revenue increased to $25.7 million for the six months ended June 30, 2004, compared to $23.2 million for the six months ended June 30, 2003. The year-over-year increase in both periods was due to an increase in direct sales offset by a decrease in government and military sales. Sales of the TITAN system accounted for approximately 67% and 58% of U.S. revenue for the three months and six months ended June 30, 2004, compared to 25% and 14% of U.S. revenue for the three months and six months ended June 30, 2003.

Rest of the world

Revenue from Europe, Africa and the Middle East increased to $7.9 million for the three months ended June 30, 2004 from $4.1 million for the comparable period in 2003. Changes in exchange rates accounted for approximately $0.3 million of the increase in revenue for the three months ended June 30, 2004. Revenue from Europe, Africa and the Middle East increased to $16.7 million for the six months ended June 30, 2004, from $9.2 million for the comparable period in 2003. Changes in exchange rates accounted for approximately $1.2 million of the increase in revenue for the six months ended June 30, 2004. The increase in both periods is primarily due to increased direct sales in the United Kingdom, France, Germany and Spain. Sales of the TITAN system accounted for approximately 67% and 60% of such revenue for the three and six months ended June 30, 2004, compared to 19% and 9% of revenue for the three months and six months ended June 30, 2003.

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Revenue from Canada, South and Latin America and Asia (excluding Japan) decreased to $2.3 million for the three months ended June 30, 2004, from $2.4 million for the three months ended June 30, 2003. Revenue decreased to $4.0 million for the six months ended June 30, 2004, from $4.6 million for the six months ended June 30, 2003. Both the three and six month decreases from the prior year periods were due to timing of distributor orders in China and changes in our distributor relationships in Australia, Canada and Mexico. Sales of the TITAN system accounted for approximately 55% of such revenue for the three and six months ended June 30, 2004, compared to 47% and 27% of revenue for the three months and six months ended June 30, 2003.

Revenue from Japan increased to $2.0 million for the three months ended June 30, 2004 from $0.2 million for the three months ended June 30, 2003. The increase was primarily due to initial sales during the quarter ended June 30, 2004 under our exclusive TITAN distribution arrangement with our distributor, Aloka Co., Ltd. and direct sales by our new subsidiary. Revenue from Japan increased to $3.2 million for the six months ended June 30, 2004 from $0.3 million for the six months ended June 30, 2003. The increase was primarily due to initial sales to Aloka Co. Ltd., direct sales, and to final sales under our exclusive distribution arrangement with our former distributor, Olympus, to fill their existing backlog. During 2003, our previous distributor, Olympus, underwent significant organizational changes, which affected its ability to provide sufficient sales and marketing focus on our products. As a result, our exclusive distribution arrangement with Olympus was ended by mutual agreement. We established a wholly-owned subsidiary in Japan with both a direct and a contract sales force and finalized in the second quarter of 2004 a new exclusive distribution relationships in Japan with Aloka Co. Ltd. for the TITAN system. In July 2004, we finalized a distribution relationship with Nippon Sherwood Medical Industries Ltd. for the iLook system. Our Japanese subsidiary has taken over the customer accounts formerly managed by Olympus. The year-over-year revenue increase was also due to ongoing sales under an OEM and Technology Agreement with Olympus. Sales under this agreement are expected to continue. Sales of the TITAN system accounted for approximately 35% and 21% of Japanese revenue for the three and six months ended June 30, 2004, compared to none in 2003.

We anticipate that revenue will increase in 2004 compared to prior years due to continued expansion of our direct selling efforts in the United States and Europe, the establishment of direct sales operations in Japan, Canada and Australia, introduction of new product features, and the overall expansion of market awareness and acceptance of our products. However, increased competition may impact the extent of the increase in our anticipated growth in revenue. We currently face competition from larger companies that manufacture cart-based and portable ultrasound systems and have greater financial and other resources. Some of these competitors have introduced hand-carried ultrasound products. In 2004, we anticipate continued improvement in our revenue from Japan due to the establishment of a direct sales operation there and the establishment of additional distributor relationships. Our newly created wholly-owned subsidiary in Japan has received licenses in its name to sell the 180 series, TITAN systems and iLook systems in Japan. However, regulatory approval of our new product introductions in Japan could be delayed, which could impact our anticipated revenue.

Gross margin

Gross margin increased to 66% for the three and six months ended June 30, 2004, compared to 63% for the three and six months ended June 30, 2003. The increase in gross margin was primarily due to increased average selling prices resulting primarily from sales of the TITAN system and improved manufacturing efficiencies.

We expect our gross margin percentage in 2004 to increase from our gross margin percentage in 2003. Nevertheless, increased competition from existing and new competitors in the highly portable ultrasound system market could result in lower average realized prices and could lower our gross margin. Our gross margin can be expected to fluctuate in future periods based on the mix of business between direct and distributor sales and our product and accessories sales mixes. Changes in our cost of inventory also may impact our gross margin. Adjustments to reduce carrying costs are recorded for obsolete material, earlier generation products and used or refurbished products held either as saleable inventory or as demonstration product. If market conditions change or the introduction of new products by us impacts the market for our previously released products, we may be required to write down the cost of our inventory, resulting in a negative impact on gross margins. Additionally, we rely on our sales forecasts by product to determine production volume. To the extent our sales forecasts or product mix estimates are inaccurate, we may produce excess inventory or experience inventory shortages, which may result in an increase in our costs of revenue, a decrease in our gross margin or lost sales.

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Operating expenses

Research and development expenses were $3.0 million for the three months ended June 30, 2004, compared to $2.9 million for the three months ended June 30, 2003. Research and development expenses were $6.1 million for the six months ended June 30, 2004, compared to $5.7 million for the six months ended June 30, 2003. Research and development expenses increased in both periods primarily due to expenses associated with the development of advanced features for the TITAN system and the development of our next generation chip-set.

We anticipate that research and development expenses will increase in 2004 due to increased development of new products using newly-designed integrated circuit chips, costs associated to comply with new HIPPA regulations, and integration activities associated with the recently acquired SonoMetric software. However, should our competitors develop products with features that equal or exceed the features that exist in our products, we may incur higher than anticipated research and development costs in order to accelerate existing programs and compete more effectively.

Sales and marketing expenses were $12.2 million for the three months ended June 30, 2004, compared to $9.6 million for the three months ended June 30, 2003. Changes in exchange rates accounted for approximately $0.3 million of the increase in these expenses. Sales and marketing expenses were $23.7 million for the six months ended June 30, 2004, compared to $18.5 million for the six months ended June 30, 2003. Changes in exchange rates accounted for approximately $0.7 million of the increase in these expenses. The increase in both periods was primarily due to expansion of our international operations, increased compensation for commissions related to the increase in revenue and costs related to improving our sales processes.

We anticipate that sales and marketing expenses in 2004 will increase primarily due to sales force expansion in the U.S., the establishment of direct sales operations in Japan, Canada and Australia, and growth in our European subsidiaries.

General and administrative expenses were $2.1 million for the three months ended June 30, 2004, compared to $1.7 million for the three months ended June 30, 2003. General and administrative expenses were $4.4 million for the six months ended June 30, 2004, compared to $3.7 million for the six months ended June 30, 2003. The increase in general and administrative expenses in both periods was related primarily to supporting our business growth and to meeting requirements of Section 404 of the Sarbanes-Oxley Act.

We anticipate that general and administrative expenses will increase in 2004 in order to support our increased business activity and also to comply with various requirements of the Sarbanes-Oxley Act. We may incur additional substantial legal expenses as we continue to defend our patent rights in the existing Neutrino patent infringement litigation. In addition, we may incur unanticipated legal expenses if we become involved in any new litigation.

Other income (expense)

Other expense was $37,000 for the three months ended June 30, 2004, compared to other income of $309,000 for the three months ended June 30, 2003. Other income decreased to $224,000 for the six months ended June 30, 2004, compared to $682,000 for the six months ended June 30, 2003. Decreases in both periods were primarily due to foreign currency transaction losses.

Liquidity and Capital Resources

Our cash and cash equivalents balance was $14.1 million as of June 30, 2004, compared to $13.7 million as of December 31, 2003. Cash and cash equivalents were primarily invested in money market accounts. Our short-term and long-term investment securities totaled $47.6 million as of June 30, 2004, compared to $47.3 million as of December 31, 2003. Investment securities consist of high-grade U.S. government or corporate debt and high-grade asset-backed securities. While our intent is to hold our securities until maturity, we classify all securities as available-for-sale, as the sale of such securities may be required prior to maturity to implement management strategies.

Operating activities provided cash of $3.2 million for the six months ended June 30, 2004, compared to cash used of $2.4 million for the six months ended June 30, 2003. The increase in cash provided in 2004 compared with 2003 was primarily due to a reduction in our net loss, a decrease in inventory in 2004 due to a higher than planned sales volume and an increase in accounts payable due to timing differences. These were partially offset by an increase in prepaid expenses and other assets due to an increased cash deposit for a value-added tax guarantee by our U.K subsidiary.

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We anticipate that cash provided by operations will increase in 2004 compared to 2003 primarily due to anticipated decreases in our net loss. This decrease will depend on our ability to successfully sell our products, collect our receivables, control our inventories and manage our expenses.

Investing activities used cash of $5.1 million for the six months ended June 30, 2004, compared to cash used of $12.5 million for the six months ended June 30, 2003. The decrease in cash used in 2004 compared with 2003 was primarily due to a decrease in net purchases of investment securities, partially offset by the acquisition of SonoMetric Health, Inc. and an increase in purchases of property and equipment.

We anticipate using cash to invest in high quality investment instruments in 2004, the extent of which will depend on the interest rate environment during the period and the timing of cash flows from our operations during the period.

Financing activities provided cash of $2.7 million for the six months ended June 30, 2004, compared to $1.4 million for the six months ended June 30, 2003. The main source of cash provided by financing activities in 2004 was the exercise of employee stock options totaling $2.7 million, compared to $1.5 million in 2003.

We believe that our existing cash and cash generated from operations will be sufficient to fund our operations and planned capital expenditures in 2004. Nevertheless, we may experience an increased need for additional cash due to:

- any significant decline in our revenue or gross margin;
- any delay or inability to collect accounts receivable;
- any acquisition or strategic investment in another business;
- any significant increase in expenditures as a result of expansion of our sales and marketing infrastructure, our manufacturing capability, or our product development activities;
- any significant increase in our sales and marketing expenditures as a result of our introduction of new products; and
- any significant increase in expenditures related to the Neutrino patent infringement litigation.

Important Factors That May Affect Our Business, Our Results of Operations and Our Stock Price

If our products, including our new TITAN™ modular ultrasound system, do not gain market acceptance, we will fail to generate sufficient revenue to maintain our business.

The market for high-performance, hand-carried ultrasound systems is relatively new and largely undeveloped. We seek to sell our products to current users of ultrasound, as well as to physicians and other healthcare providers who do not currently use ultrasound. The success of our products depends on their acceptance by the medical community, patients and third-party payers as medically useful, safe and cost-effective.

In June 2003, we began shipping to customers our newest product, the SonoSite TITAN ultrasound system. Sales of TITAN accounted for approximately 56% of our revenue for the six months ended June 30, 2004. The TITAN system has a modular design allowing both stationary and mobile usage and is based on the next generation of our proprietary ASIC, or application specific integrated circuit, technology. Along with the point-of-care market, we have positioned the TITAN system to compete in the traditional stationary ultrasound cart market.

Users of stationary ultrasound carts may not accept the TITAN system, which could discourage widespread new users and uses for the TITAN. Our new or existing customers may not accept the TITAN due to pricing and functionality differences. If demand for the TITAN differs from our projections, we may experience excess inventory levels or inventory shortages and may be unable to generate sufficient revenue to grow our business. If we are unable to gain market acceptance for our products generally, we will fail to generate sufficient revenue to maintain our business.

If we are unable to compete effectively, we will fail to generate sufficient revenue to maintain our business.

We currently face competition from companies that manufacture cart-based and portable ultrasound systems. The dominant competitors in this industry are GE Medical Systems, a unit of General Electric Company, Siemens AG and Philips Medical Systems, a unit of Koninklijke Philips Electronics, N.V. that owns two other competitors, Agilent Healthcare Solutions Group and ATL, our former parent company. These competitors are very large, global organizations and have the following advantages over us:

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- greater financial and infrastructure resources;
- larger research and development staffs;
- greater experience in product manufacturing, marketing and distribution;
- greater brand name recognition; and
- long-standing relationships with many of our potential customers.

These manufacturers of cart-based and portable ultrasound systems could use their greater resources to increase and withstand competition through various means, including price and payment terms, product quality, market penetration, employee compensation, hospital systems integration and complementary services such as warranty protection, maintenance and product training. Existing product supply relationships between these companies and our potential customers could discourage widespread adoption of our products due to brand loyalty or preferred customer discounts. Competition from these companies for employees with experience in the primary point-of-care market could result in higher turnover of our employees. If we are unable to respond to competitive pressures from the cart-based and portable ultrasound markets, we could experience delayed or reduced market acceptance of our products, higher expenses and lower revenue.

In addition, as the market for high-performance, hand-carried ultrasound systems develops, we expect competition to increase as potential and existing competitors enter the point-of-care market or modify their existing products to more closely approximate the combined portability, quality, performance and cost of our products. Our current competitors in the point-of-care market include Siemens, GE Medical Systems, Agilent/Philips Medical Systems, Biosound Esaote, Inc., Medison America Inc., a subsidiary of Medison Company, Ltd., and Terason, a division of TeraTech Corporation. Other potential entrants to the point-of-care market include ZONARE Medical Systems, Inc. (formerly Novasonics, Inc.). These competitors may develop highly portable or point-of-care ultrasound systems that offer the same or greater reliability and quality, perform greater or more useful functions, or are more cost-effective than our products. Some of these competitors may also be able to use their marketing resources to gain a competitive advantage by more effectively building brand awareness of their products. If we are unable to compete effectively with current or new entrants to the high-performance, hand-carried ultrasound market, we will be unable to generate sufficient revenue to maintain our business.

If our competitors develop and market medical imaging devices that render our products obsolete or noncompetitive, we will be unable to compete.

The life cycles of our products are difficult to estimate. Our products could become obsolete or unmarketable if:

- our competitors introduce ultrasound systems that are superior to ours;
- other products using new technologies emerge; or
- industry standards exceed our products' capabilities.

If we fail to enhance our existing products or develop and market new products, our products will become obsolete and we will be unable to compete.

Changes in the healthcare industry could result in a reduction in the size of the market for our products or may require us to decrease the selling price for our products, each of which could have a negative impact on our financial performance.

Trends toward managed care, healthcare cost containment, and other changes in government and private sector initiatives in the United States and other countries in which we do business are placing increased emphasis on the delivery of more cost-effective medical therapies, which could adversely affect the sale and/or the prices of our products. For example:

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- Major third-party payers of hospital and pre-hospital services, including Medicare, Medicaid and private healthcare insurers, have substantially revised their payment methodologies during the last few years which has resulted in stricter standards for reimbursement of hospital and pre-hospital charges for certain medical procedures;
- Numerous legislative proposals have been considered that would result in major reforms in the U.S. healthcare system that could have an adverse effect on our business;
- There has been a consolidation among healthcare facilities and purchasers of medical devices in the United States who prefer to limit the number of suppliers from whom they purchase medical products, and these entities may decide to stop purchasing our products or demand discounts on our prices;
- There is economic pressure to contain healthcare costs in international markets; and
- There are proposed and existing laws and regulations in domestic and international markets regulating pricing and profitability of companies in the healthcare industry.

These trends could lead to pressure to reduce prices for our products and could cause a decrease in the size of the market or a potential increase in competition that could adversely affect our levels of revenue and profitability of sales, which could have a material adverse effect on our business.

If healthcare reimbursement practices or reform restricts coverage available to our customers for the use of our products, we may experience limited market acceptance of our products.

Market acceptance of our products depends in part on the extent to which our customers receive reimbursement for the use of our products from third party payers such as Medicare, Medicaid and private health insurers. Our customers generally have received reimbursement for ultrasound procedures performed using our products consistent with reimbursement criteria applicable to ultrasound procedures generally. The continuing efforts of third party payers to contain or reduce the costs of healthcare through various means may, however, result in unfavorable reimbursement policies or payments that would limit market acceptance of our products.

Reimbursement policy has the potential to influence the adoption of our products in several ways. Payment for specific ultrasound procedures could be greatly reduced or eliminated all together. If that procedure was critical to the acceptance of our products in a given market segment, such a policy change could reduce the demand for our products in that particular market.

Payment for ultrasound procedures when performed by specific types of healthcare providers could be restricted. This too could depress demand in a particular market segment. Such a policy change as well as the one previously mentioned would affect all ultrasound manufacturers attempting to do business in an affected market segment.

Alternatively, specific types of ultrasound products could be targeted for exclusion from coverage under the existing ultrasound codes. As an example, in the first half of 2003, six Medicare carriers adopted policies that precluded Part B Medicare reimbursement for ultrasound procedures conducted with hand-carried ultrasound units described as "lightweight ultrasound machines with Doppler capability." The notices restricted coverage for devices that "allow only a limited view of structures." These policies applied to Medicare reimbursement of healthcare providers in 22 states, including California and upstate New York. In all states, these policies have been revised to allow payment for studies performed with hand-carried ultrasound units. The new policies, recognizing that many hand-carried ultrasound systems have functionality equal to that of cart-based ultrasound systems, define the requirements of medical necessity, completeness and documentation required of all ultrasound services, regardless of the equipment that is used to supply the service. In all states, there are no longer any billing restrictions in place for hand-carried ultrasound that do not also exist for cart-based ultrasound and that were not in place prior to the adoption of these original policies.

Additionally, to the extent that the use of future products that SonoSite may develop is not described by existing CPT codes, there is a risk that reimbursement for studies performed with such products could not be attained at all or within a reasonable timeframe.

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International markets too are in the process of responding to increases in healthcare spending by adjusting their reimbursement policies. These responses, like those in the United States, could similarly affect reimbursement for our products and thereby reduce demand for our products. As an example, in Germany, healthcare reform in 2003 introduced a Diagnosis Related Group system that changes healthcare reimbursements from a "per day" reimbursement to a "per case" reimbursement. This change caused hospital administrators to delay capital equipment purchases as they evaluate the impact of the new healthcare system. Although revenue from Germany increased in 2003 compared to 2002, this delay negatively impacted our actual results against our sales expectations in Germany in 2003. If similar changes in healthcare reimbursement are adopted in other countries, they could affect our ability to successfully market our products.

If traditional providers of ultrasound examinations discourage potential new users from adopting our products, we could experience limited demand for our products.

The size and complexity of traditional cart-based ultrasound systems typically require a physician or highly trained clinician to perform the examination in a centralized imaging department, such as a hospital's radiology department. Although our products are currently used by radiologists, our products also enable the delivery of ultrasound examinations at the primary point of care by the examining physician or healthcare provider. Radiologists and other ultrasound specialists have a professional and financial interest in maintaining traditional ultrasound practices. If these traditional providers of ultrasound examinations discourage other healthcare providers from adopting our products, we could experience limited demand for our products.

If the training and education necessary to conduct ultrasound examinations is not adequate or not readily available, this could discourage new users from adopting our products, which could affect demand for our products.

We seek to sell our products to customers already experienced in ultrasound procedures, as well as to physicians and other healthcare providers who do not currently use ultrasound imaging systems or administer ultrasound examinations. Although customers who are experienced in ultrasound procedures will need little, if any, specialized training to use our products, any new users of ultrasound will require training and education to properly administer ultrasound examinations. If these potential customers are unable or unwilling to be trained due to cost, time constraints, unavailability of courses or other reasons, we could experience limited demand for our products.

If our suppliers, including our single-source suppliers, fail to supply us with the components that we need to manufacture our products on a timely basis, we could experience production delays, cost increases and lost sales.

We depend on suppliers, including some single-source suppliers, to provide highly specialized parts, such as custom-designed integrated circuits, cable assemblies and transducer components. We also depend on single-source suppliers to provide other components, such as image displays, batteries, capacitors and cables. We do not maintain significant inventories of components, and may experience an interruption of supply if a supplier is unable or unwilling to meet our time, quantity and quality requirements. There are relatively few alternative sources of supply for some of these components. An increase in demand for some parts by other companies could also interrupt our supply of components. We have in the past experienced supply problems in timeliness and quality, but to date these problems have not resulted in lost sales or lower demand. Nevertheless, if we experience an interruption of supply or are required to switch suppliers, the manufacture and delivery of our products could be interrupted, our manufacturing costs could substantially increase and we could lose substantial amounts of product sales.

In March 2003, one of our component suppliers, Philips Semiconductor, or Philips, informed us that, commencing in September 2003, it would discontinue production of our integrated circuit chips using 0.35-micron technology. We have designed and implemented a new chip using 0.2-micron technology that will continue to be produced by Philips to replace all but one of the discontinued chips. We expect to design and implement an additional new chip to replace the remaining 0.35-micron chip by early 2005. In the second quarter of 2003, we entered into a purchase commitment totaling approximately $3.6 million for supplies of 0.35-micron chips from Philips for our anticipated manufacturing needs until new chips have been incorporated in all of our products. We pay for these chips at the time deliveries are made to us. As of June 30, 2004, our remaining purchase commitment was approximately $2.5 million. On December 31, 2004, we are required to take possession of, and pay for, the balance of the undelivered chips. Demand for our products, however, may exceed our forecasts, in which case we would require additional 0.35-micron chips to manufacture additional products. Conversely, if demand for our products falls short of our forecasts, we may experience excess inventory of 0.35-micron chips. If our actual demand for these chips varies significantly from our forecasted demand, we may experience delays in manufacturing, lost sales, a write-down of inventory or a deterioration in gross margin.

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In addition, we transferred the production of our circuit boards to one of the world's largest electronic manufacturing services suppliers who produces the boards in their Thailand manufacturing facility. If, as a result of this transfer, we experience delays in the receipt or a deterioration in product yields of these components, we may experience delays in manufacturing or an increase in costs resulting in lost sales or a deterioration in gross margin.

If our suppliers or we fail to comply with U.S. and foreign governmental regulations applicable to our products and manufacturing practices, we could experience product introduction delays, production delays, cost increases and lost sales.

Our products, our manufacturing activities and the manufacturing activities of our third-party medical device manufacturers are subject to extensive regulation by a number of governmental agencies, including the U.S. Food and Drug Administration, or FDA, and comparable international agencies. Our third-party manufacturers and we are or will be required to:

- obtain prior clearance or approval from these agencies before we can market and sell our products;
- undergo rigorous inspections by domestic and international agencies; and
- satisfy content requirements for all of our sales and promotional materials.

The manufacture and sale of our products are subject to extensive regulation by numerous governmental authorities, principally the FDA, as well as several other state and foreign agencies. The FDA requires that we obtain a pre-market notification clearance under Section 510(k) of the Federal Food, Drug & Cosmetic Act prior to introducing our products to the market. By granting 510(k) clearance, the FDA indicates agreement with an applicant's determination that the product for which clearance has been sought is substantially equivalent to medical devices that were on the market prior to 1976 or have subsequently received clearance. The process of obtaining 510(k) clearance typically takes approximately two to three months. To date, all of our products have received 510(k) clearance. In addition, foreign regulatory agencies also require similar pre-market clearance or registration before our products can be marketed or offered for sale in their countries. Such foreign regulatory approvals may take up to 6-9 months to obtain. Any delays, or failures, in obtaining such clearances may result in lost sales.

In addition, the FDA requires us and our key medical device suppliers to demonstrate and maintain compliance with the FDA's Quality System Regulation, or QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, shipping and servicing of our products. The FDA enforces the QSR through periodic inspections. The FDA inspected our manufacturing facility in September 2003. In addition, the British Standards Institute has performed several management systems assessments of our manufacturing processes. These inspections resulted in observations to which we submitted responses, and we believe these responses have been accepted by those agencies. Any failure to take corrective action in response to a QSR inspection could force a shutdown of our manufacturing operations, and a recall of, or field action relating to, our products. Also, in August 2001, the FDA classified as a class II field action a May 2000 software upgrade we issued to correct an error in an algorithm contained in one of our products. In September 2000, we provided purchasers of our products with a software upgrade to correct this error, and at the FDA's request, we recently sent two additional

letters to these purchasers to provide them with a final opportunity to upgrade the software at no charge. We expect that when this action is completed, we will receive final written closure from the FDA on this matter.

Compliance with the regulations of these agencies, including the Environmental Protection Agency and the Occupational Safety and Health Administration, may require us to incur substantial costs and may delay or prevent the introduction of new or improved products. Although to date these actions by regulatory bodies have not required us to incur substantial costs or delay product shipments, we expect to experience further inspections and incur additional costs as a result of governmental regulation. If we fail to comply with the laws and regulations pertaining to our business, we may be subject to fines, sanctions, including the temporary or permanent suspension of operations, product field actions, criminal prosecution and marketing restrictions. Our third-party medical device manufacturers may also be subject to the same sanctions if they fail to comply with the laws and regulations, and, as a result, may fail to supply us with components required to manufacture our products.

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Our reliance on a single manufacturing facility may impair our ability to respond to natural disasters or other unforeseen catastrophic events.

Our sole manufacturing facility is located in a single building in Bothell, Washington. Despite precautions taken by us, a natural disaster such as an earthquake or other unanticipated catastrophic events at this building could significantly impair our ability to manufacture our products and operate our business. Our facility and certain manufacturing equipment would be difficult to replace and could require substantial replacement lead-time. Such catastrophic events may also destroy any inventory of product or components. While we carry insurance for natural disasters and business interruption, the occurrence of such an event could result in losses that exceed the amount of our insurance coverage, which would impair our financial results.

We have a history of losses, we expect future losses and we may never achieve sustained profitability.

With the exception of the fiscal quarters ended December 31, 2002 and December 31, 2003, we have incurred net losses in each quarter since we commenced operations. As of June 30, 2004, we had an accumulated deficit of approximately $88.9 million. We achieved a profitable fiscal quarter ended December 31, 2003 and expect to achieve one or more profitable quarters within the next several quarters. Even if we do achieve one or more profitable quarters, however, we may be unable to sustain or increase future profitability on a quarterly or annual basis. Additionally, our losses may increase if we cannot increase or sustain our revenue. We expect that our operating expenses will increase in the foreseeable future as we expand our sales and marketing infrastructure, our administrative support and our product development activities. Our expansion efforts, to be successful, may require more funding than we currently anticipate. Accordingly, we will need to generate significant additional revenue in the future before we will be able to sustain or increase profitability. If we cannot generate such revenue, we may never be profitable. If we fail to achieve sustained profitability, the market price for our common stock will likely fall.

A failure to manage our growth could impair our ability to achieve our business objectives.

We have experienced rapid growth since our inception as a stand-alone company. Our revenue increased from $45.7 million in 2001 to $73.0 million in 2002 and $84.8 million in 2003. We expect continued significant growth as we continue to develop, manufacture, market and sell our products. Our growth could strain our existing management, operational and financial resources. In order to manage our growth effectively, we will need to expand our manufacturing and quality assurance staff, our sales staff and our manufacturing capabilities. In addition, we will need to improve the productivity and efficiency of our existing operational, financial and management resources and information systems. We may be unable to hire and retain the personnel necessary to operate and expand our business. We also may be unable to increase the productivity and efficiency of our existing resources. If we fail to timely improve or augment our existing resources in response to our growth, we may be unable to effectively manage our business and achieve our objectives.

Our foreign distributors may be unwilling or unable to devote sufficient resources to market and sell our products, which could delay or reduce market acceptance and sales of our products outside the United States.

We currently depend on foreign distributors to help promote market acceptance and demand for our products in countries in which we do not have a direct sales force. Foreign distributors that are in the business of distributing other medical products may not devote the resources and support required within these countries to generate awareness of our products and grow or maintain product sales. If these distributors are unwilling or unable to market and sell our products, we could experience delayed or reduced market acceptance and sales of our products outside the United States. In addition, if our foreign distributors fail to pay us, or fail to pay us in a timely manner, for the products they have purchased, it may be difficult to recover such monies in a foreign court or proceeding, thereby resulting in the write-off of amounts owed to us.

Revenue from Japan increased to $3.2 million for the six months ended June 30, 2004, from $326,000 for the six months ended June 30, 2003. The increase was primarily due to initial sales under our exclusive TITAN distribution arrangement with our new distributor, Aloka, and to final sales under our exclusive distribution arrangement with our former distributor, Olympus, to fill their existing backlog. During 2003, the Olympus organization underwent significant organizational changes, which affected its ability to provide sufficient sales and marketing focus on our products. As a result, sales to Olympus decreased from 10% of our revenue in 2002 to 2% of our revenue in 2003 and, consequently, our exclusive distribution arrangement with Olympus has ended, by mutual agreement. We have established a wholly-owned subsidiary in Japan with both a direct and a contract sales force and have developed new distribution relationships in Japan. Our Japanese subsidiary will take over the customer accounts formerly managed by Olympus. This new subsidiary has received licenses in its name to sell the 180 series, TITAN systems and iLook systems in Japan.

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Our lack of customer purchase commitments and our limited order backlog make it difficult to predict sales and plan manufacturing requirements, which can lead to lower revenue, higher expense and reduced gross margin.

We do not generally have volume purchase commitments with our customers, who typically order products on a purchase order basis. In limited circumstances, customer orders may be cancelled, changed or delayed on short notice. Lack of significant order backlog makes it difficult for us to forecast future sales with certainty. Varying sales cycles with our customers make it difficult to accurately forecast component and product requirements. These factors expose us to a number of risks:

- If we overestimate our requirements, we may be obligated to purchase more components or third-party products than is required;
- If we underestimate our requirements, our third-party manufacturers and suppliers may have an inadequate product or product component inventory, which could interrupt manufacturing of our products and result in delays in shipments and lower revenue;
- We may also experience shortages of product components from time to time, which also could delay the manufacturing of our products; and
- Over or under production can lead to higher expense, lower than anticipated revenue, and reduced gross margin.

Our establishment, maintenance and expansion of direct sales and distribution operations will require a significant investment of our financial and management resources and may fail to generate a substantial increase in sales.

We have historically relied on third-party distributors to sell our products in Europe and Asia. In 2001, we commenced operations in the United Kingdom and France, and in 2002, we commenced operations in Germany and Spain to sell our products directly in each of those countries. In 2003, we entered into a joint venture with a partner in China to sell our products there. We also hired a vice president for international sales in 2003 and, as a result, our foreign direct sales operations have grown. In the first quarter of 2004, we established wholly-owned sales subsidiaries in Japan, Canada, and Australia and hired experienced ultrasound sales personnel to manage them. Establishing, maintaining and expanding these operations will require us to:

- substantially increase our costs of operations;
- temporarily divert existing management resources;
- establish an efficient and self-reliant local infrastructure;
- attract, hire and train qualified local sales and administrative personnel;
- comply with additional local regulatory requirements; and
- expand our information, financial, distribution and control systems to manage expanded global operations.

Our movement into international markets has required, and will continue to require, substantial financial and management resources. The costs of this expansion are unpredictable, difficult to control and may exceed budgeted amounts. In 2003, we experienced some operational challenges within our European subsidiaries. In Germany, healthcare reform in the first half of 2003 caused hospital administrators to delay capital equipment purchases as they evaluated the impact of the new healthcare system. Although revenue from Germany increased in 2003 compared to 2002, this delay negatively impacted our actual results against our sales expectations in Germany in 2003. In France and Spain, we experienced challenges related to sales management and execution. Despite our expenditures and efforts, we may not generate a substantial increase in international revenue, which would impair our operating results.

Our foreign revenue is subject to currency fluctuation and other risks associated with doing business outside the United States.

The percentage of our revenue originating outside the United States equaled 38% for the year 2003 and 48% for the six months ended June 30, 2004. Total sales for the six months ended June 30, 2004 denominated in a currency other than USDs were approximately $14.1 million, or 29% of total consolidated revenues. Our revenue from international sales may be adversely affected by any of the following risks:

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- currency rate fluctuations;
- adverse political or economic conditions;
- reduced protection for intellectual property rights;
- longer receivables collection periods and greater difficulty in receivables collection;
- localizing products for foreign markets; and
- compliance with export laws, including license requirements, trade restrictions and tariff increases.

As of June 30, 2004, 57% of our outstanding accounts receivable balance was from international customers. We regularly review our receivable positions in foreign countries for any indication that collection may be at risk.

We have used and may continue to use forward foreign exchange contracts and other instruments to reduce our exposure to exchange rate fluctuations from intercompany balances denominated in foreign currencies, and we may not be able to reduce this exposure successfully. Accordingly, we may experience economic loss and a negative impact on our results of operations and equity as a result of foreign currency exchange rate fluctuations.

Our efforts to integrate the business and technology of any future acquisition, even if successful, may result in significant costs or create significant disruptions that outweigh the benefits of any such acquisition.

As part of our business strategy, we may acquire other companies, products or technologies. We may fail in our attempt to successfully integrate into our business the operations, technology, products, customers, suppliers and personnel of any such acquired business or technology. Even if integration is successful, any such acquisition may include costs for:

- integration of operations, including combining teams and processes in various functional areas;
- integration of new technology into our products;
- fees and expenses of professionals involved in completing the integration process; and
- potential existing liabilities of any future acquisition target.

Additionally, our efforts to consummate an acquisition or to successfully integrate any such acquisition could place a significant burden on our management and internal resources, disrupting our business. If we fail in our attempts to integrate any acquired business or technology, or if the costs and burdens of such acquisition or integration outweigh the benefits of such acquisition, our financial resources or financial results could be impaired.

On May 20, 2004, we acquired 100% of the outstanding common shares of SonoMetric Health, Inc., or SonoMetric. The results of SonoMetric's operations have been included in our consolidated financial statements since that date. SonoMetric is a medical software company whose primary product is designed to be used with ultrasound technology to measure the intima media thickness, or IMT, of the carotid artery. Increased thickness of the IMT in the carotid artery is associated with an increased risk of developing atherosclerosis, which is a leading cause of heart disease. We plan to incorporate SonoMetric's software into our products.

The loss of any principal member of our management team or product development staff, on whom we rely heavily, could impair our ability to compete.

Our success depends heavily on our ability to retain the services of the principal members of our management team and product development staff. Competition among medical device companies for qualified employees is intense. We may fail to retain these key employees, and we may fail to attract qualified replacements if they do leave. In particular, our limited ability to offer stock options to new and current employees due to the limited availability of options in our employee stock option pool may adversely affect our ability to attract and retain employees. We do not maintain key-person insurance on any of our employees. We do not have employment agreements with any of our employees, except in certain countries outside the United States. The loss of any of our key employees could significantly delay or prevent the achievement of our product development or business objectives.

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If we are unable to protect and enforce our intellectual property rights, we may be unable to compete effectively.

Much of our value arises out of our proprietary technology and intellectual property for the design, manufacture and use of point-of-care ultrasound imaging systems. Our success and ability to compete effectively depend on our ability to protect our proprietary information. We rely on patent, copyright, trade secret and trademark laws to protect our proprietary technology and limit the ability of others to compete with us using the same or similar technology.

We currently hold 19 patents relating to our technology. A number of other patents are pending in the United States and in foreign jurisdictions. Additionally, we have a license from our former parent, ATL, to use certain ATL technology and ATL technological developments in our point-of-care products. This license was exclusive through April 5, 2003, and became nonexclusive after that date. We also enter into confidentiality and invention ownership agreements with our employees, consultants and corporate partners, and generally control access to, and the distribution of, our product designs, documentation and other proprietary information, as well as the designs, documentation and other information that we license from others.

Our efforts afford only limited protection and may not adequately protect our rights to the extent necessary to sustain any competitive advantage we may have. Despite our efforts to protect our intellectual property, we may experience:

- unauthorized use of our technology by competitors;
- independent development of the same or similar technology by a competitor, coupled with a lack of enforceable patents on our part;
- failure of our pending patent applications to result in issued patents;
- successful interference actions to our patents, successful patent infringement lawsuits or successful oppositions to our patents and patent applications;
- unauthorized disclosure or use of our proprietary information by former employees or affiliates; and
- failure by our commercial partners to comply with their obligations to share technology or use our technology in a limited manner.

Policing unauthorized use of our intellectual property will be difficult and may be cost-prohibitive. We may fail to prevent misappropriation of our technology, particularly in countries where the laws may not protect our proprietary rights to the same extent as do the laws of the United States. If we cannot prevent other companies from using our proprietary technology or if our patents are found invalid or otherwise unenforceable, we may be unable to compete effectively against other manufacturers of ultrasound systems, which could decrease our market share.

Existing or potential intellectual property claims and litigation may divert our resources and subject us to significant liability for damages, substantial litigation expense and the loss of our proprietary rights.

In order to protect or enforce our patent rights, we may initiate patent litigation. In addition, others may initiate patent litigation against us. We may become subject to interference proceedings conducted in patent and trademark offices to determine the priority of inventions. There are numerous issued and pending patents in the ultrasound field. The validity and breadth of medical technology patents may involve complex legal and factual questions for which important legal principles may remain unresolved. In addition, because patent applications can take many years to result in issued patents and are maintained in confidence by the U.S. Patent and Trademark Office while pending, there may be currently pending applications of which we are unaware, which may later result in issued patents that our products may infringe. There could also be existing patents of which we are not aware that one or more of our products may infringe. Litigation may be necessary to:

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- assert or defend against claims of infringement;
- enforce our issued and licensed patents;
- protect our trade secrets or know-how; or
- determine the enforceability, scope and validity of the proprietary rights of others.

We may become involved in the defense and prosecution, if necessary, of intellectual property suits, patent interferences, opposition proceedings and other administrative proceedings. For example, on July 24, 2001, Neutrino Development Corporation filed a complaint against us in U.S. District Court, Southern District of Texas, Houston Division, alleging infringement of U.S. Patent 6,221,021, or the '021 patent, by SonoSite as a result of our use, sale and manufacture of the SonoSite 180, SonoSite 180PLUS, SonoHeart and SonoHeart ELITE devices. The complaint asserts claims for preliminary and permanent injunctive relief enjoining all alleged acts of infringement, compensatory and enhanced damages, attorney's fees and costs, and pre- and post-judgment interest. On August 14, 2001, we filed an answer asserting affirmative defenses of non-infringement and patent invalidity, and included a counterclaim seeking a declaratory judgment of non-infringement and invalidity regarding Neutrino's patent. On October 4, 2001, the court denied a request by Neutrino for preliminary injunctive relief to prevent us from manufacturing and selling our products pending the ultimate disposition of the litigation. On February 20, 2002, in what is known as a

"Markman" hearing, the parties presented their arguments regarding the proper construction of Neutrino's patent claims.

On August 20, 2003, the U.S. District Court in the Southern District of Texas issued a decision interpreting certain terms used in the '021 patent. This decision does not discuss whether the patent is valid or whether the patent would apply to any of our products. In the order, the court, in resolving disputed terms in the Markman hearing, adopted our construction of the term "a portable body designed to be hand held", and adopted Neutrino's construction of the terms "the moveably connected transducer mounting assembly" and "ultrasound emitter". The court denied our motion for summary judgment. We subsequently filed a new summary judgment motion using the court's construction of the claim language that the '021 patent is invalid based on prior art. Neutrino has filed a summary judgment motion based on its allegations of infringement.

We also have asked the Texas court to stay proceedings in Neutrino's suit filed in the Middle District of Florida on August 19, 2003 against a former SonoSite distributor alleging that the sale of our products by such distributor infringes the '021 patent, and to enjoin Neutrino from filing similar suits against other sellers of SonoSite products. Neutrino had previously filed such a suit in the Middle District of Tennessee against another medical device distributor for selling a SonoSite product. That Tennessee case has been dismissed based on a final judgment and permanent injunction filed a month after the case was filed. The Tennessee judgment has no effect on the Texas proceedings. In the Florida action, we assumed defense of the case and have filed a motion to stay the proceedings in the Florida court pending a final resolution of the patent suit in Texas. We have also filed a motion to strike certain counts of Neutrino's complaint. In June 2004, the Florida court stayed the Florida action for six months, pending resolution of the Texas case, granted Neutrino's request to add SonoSite as a party to the Florida case, and denied our motion to strike certain counts, suggesting instead that we file our arguments contained in the motion to strike as a motion to dismiss.

We believe that we have good and sufficient defenses to the claims of patent infringement asserted against us by Neutrino and we are vigorously defending ourselves in these matters. If we are not successful in our defense of these claims, we could be forced to pay damages related to past product sales, modify or discontinue selling our products or may enter into royalty or licensing agreements for future product sales, which may not be available on terms acceptable to us, if at all, and which could adversely affect our financial condition, results of operations and cash flow. Sales of the allegedly infringing products represented the majority of our revenue for the six month periods ended June 30, 2004 and 2003.

We have not accrued any amounts for potential losses related to these proceedings. Because of uncertainties related to both the amount and range of loss on the pending litigation, management is unable to make a reasonable estimate of the liability that could result from an unfavorable outcome. As additional information becomes available, we will assess the potential liability related to pending litigation. We will record accruals for losses if and when we determine the negative outcome of such matters to be probable and reasonably estimable. Our estimates regarding such losses could differ from actual results. Revisions in our estimates of the potential liability could materially impact our results of operations, financial position and cash flow.

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Our involvement in intellectual property claims and litigation could:

- divert existing management, scientific and financial resources;
- subject us to significant liabilities;
- allow our competitors to market competitive products without obtaining a license from us;
- cause product shipment delays and lost sales;
- require us to enter into royalty or licensing agreements, which may not be available on terms acceptable to us, if at all; or
- force us to modify or discontinue selling our products, or to develop new products.

The termination or other loss of our license to use certain ATL technology would significantly impair our ability to manufacture, market and sell our products.

We license certain technology from ATL that is incorporated into our single technology platform, and we use this ATL technology in all of our point-of-care ultrasound imaging systems. Virtually all of our revenue is attributable to products incorporating this ATL technology.

ATL may terminate our license in the event of an uncured material default by us in our obligations under the license agreement. Although many key aspects of our technology platform--including the high level of miniaturization that allows us to manufacture our systems--are independently owned by us under the terms of our spin-off from ATL, the termination or other loss of our license to use ATL technology would significantly impair our ability to manufacture, market and sell our products. If this happens, we may be unable to generate sufficient revenue to

maintain our business.

Product liability and other claims and product field actions could increase our costs, delay or reduce our sales and damage our reputation, which could significantly impair our financial condition.

Our business exposes us to the risk of product liability, malpractice or warranty claims inherent in the sale and support of medical device products, including those based on claims that the use or failure of one of our products resulted in a misdiagnosis or harm to a patient. Such claims may damage our reputation by raising questions about our products' safety and efficacy, and could interfere with our efforts to market our products. Although to date we have not been involved in any medical malpractice or product liability litigation, we may incur significant liability if such litigation were to occur. We may also face adverse publicity resulting from product field actions or regulatory proceedings brought against us. Although we currently maintain liability insurance in amounts we believe are commercially reasonable, any product liability we incur may exceed our insurance coverage. Liability insurance is expensive and may cease to be available on acceptable terms, if at all. A product liability or other claim or product field action not covered by our insurance or exceeding our coverage could significantly impair our financial condition. In addition, a product field action or a liability claim against us could significantly harm our reputation and make it more difficult to obtain the funding and commercial relationships necessary to maintain our business.

If our stock price continues to be volatile, your shares may decline in value.

The market price for our common stock, as well as for securities of emerging growth companies generally, has been volatile in the past and is likely to continue to be volatile. You may be unable to resell your shares at or above the price you paid due to a number of factors, many of which are beyond our control, including:

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- the difference between quarterly operating results and those expected by investors or securities analysts;
- changes in earnings estimates by analysts;
- the loss of significant orders;
- announcements of technological innovations or new products by our competitors;
- changes in the structure of healthcare financing and payment systems;
- general conditions in the medical industry or global economy;
- a lack of liquidity in the market for our stock; and
- a significant sale or sales of our common stock by one or more of our shareholders.

Our future capital-raising activities or acquisition of businesses or assets could involve the issuance of equity securities, which would dilute your investment and could result in a decline in the trading price of our common stock.

To meet our long-term funding requirements, we may sell securities in the public or private equity markets if and when conditions are favorable, even if we do not have an immediate need for additional capital at that time. For example, in May 2002, we raised net proceeds of $42.6 million through the sale of 2,700,000 shares of our common stock. Furthermore, we may enter into financing transactions at prices that represent a substantial discount to market price. In addition, we may issue a significant amount of our securities in connection with our purchase of, or strategic investment in, other businesses or assets. Raising funds or paying for acquisitions through the issuance of equity securities will dilute the ownership of our existing shareholders. A negative reaction by investors and securities analysts to any sale or issuance of our equity securities could result in a decline in the trading price of our common stock.

The concentrated ownership of our common stock could delay or prevent a change of control, which could cause a decline in the market price of our common stock.

As of June 30, 2004, our executive officers, directors and affiliated entities together beneficially owned approximately 6.4% of the outstanding shares of our common stock. Based on currently available information, seven other shareholders owned in the aggregate approximately 51.6% of the outstanding shares of our common stock. Among these shareholders, the State of Wisconsin Investment Board, or SWIB, owned approximately 12.7% of the outstanding shares of our common stock and Kopp Investment Advisors, Inc. owned approximately 10.2%. As a result, these shareholders or any other concentrated owner may be able to exert significant influence over all matters requiring shareholder approval, including the election of directors, matters relating to the attraction and retention of employees, such as stock option plans, and approval of significant corporate transactions that could include certain matters relating to future financing arrangements and unsolicited tender offers. In addition, many of our institutional shareholders have indicated that they will follow the recommendations on proxy voting issued by Institutional Shareholder Services. This concentration of ownership may delay, deter or prevent a third party from acquiring control

over us at a premium over the then-current market price of our common stock, which could result in a decline in our stock price.

Our restated articles of incorporation, our bylaws, Washington law and some of our agreements contain provisions that could discourage a takeover and prevent shareholders from receiving a premium for their shares.

There are provisions in our restated articles of incorporation, our bylaws and Washington law that make it more difficult for a third party to obtain control of us, even if doing so would be beneficial to our shareholders.

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Additionally, our acquisition may be made more difficult or expensive by the following:

- change of control provisions in our license agreement with ATL, which require us to pay ATL $75 million if, at any time through April 6, 2006, any single person or entity engaged in the medical diagnostic imaging business, other than through the sale or manufacture of our products, obtains, directly or indirectly, voting control of a majority of our common stock or the power to elect our entire board of directors;
- acceleration provisions in benefit plans and change-in-control agreements with our employees; and
- our shareholder rights plan, which is designed to dilute a hostile acquiror's interest so that the acquisition becomes prohibitively expensive. Under our rights plan, each of our shareholders has one share purchase right for each share of common stock held, with each right having an exercise price approximating our board of directors' estimate of the long-term value of one share of our common stock. The rights are triggered if an acquiror acquires, or successfully makes a tender offer for, 20% or more of our outstanding common stock. In such event, each shareholder other than the acquiror would have the right to purchase, at the exercise price, a number of newly issued shares of our capital stock at a 50% discount. If the acquiror were to acquire 50% or more of our assets or earning power, each shareholder would have the right to purchase, at the exercise price, a number of shares of acquiror's stock at a 50% discount. Our board of directors may redeem the rights at a nominal cost at any time before a person acquires 20% or more of our outstanding common stock, which allows board-approved transactions to proceed. In addition, our board of directors may exchange all or part of the rights (other than rights held by the acquiror) for such number of shares of our common stock equal in value to the exercise price. Such an exchange produces the desired dilution without actually requiring our shareholders to purchase shares.

If we incur a tax liability in connection with our spin-off from ATL, we would be required to pay a potentially significant expense, which would diminish our financial resources.

Our spin-off was treated by ATL as a tax-free spin-off under Section 355 of the Internal Revenue Code of 1986. If ATL were to recognize taxable gain from the spin-off, the Internal Revenue Service, or IRS, could impose that liability on any member of the ATL consolidated group as constituted prior to the spin-off, including us. Generally, the IRS may assert that our spin-off from ATL is a taxable transaction until the expiration of the statute of limitations applicable to ATL with respect to the spin-off transaction. The expiration of the statute of limitations with respect to the spin-off transaction depends upon the actions and tax filings of ATL and the special rules applicable to spin-offs in general, which special rules could result in the extension of the general statute of limitations for an indefinite period of time. In the event of a tax liability, ATL has agreed to cover 85% of any such liability, unless the tax is imposed due to our actions solely or by ATL solely, in which case, we have agreed with ATL that the party who is solely at fault shall bear all of the tax liability. We are unaware of any actions that would result in a tax liability to us under the indemnity agreement regarding the spin-off transaction. We are aware that ATL was acquired in a transaction subsequent to the spin-off transaction, which could potentially result in the spin-off being treated as a taxable transaction, but which resulting tax liability in our view would be the sole responsibility of ATL pursuant to our agreement with ATL. ATL may refuse, however, to indemnify us for a tax liability arising out of the spin-off transaction or may argue that it did not cause the tax liability to be imposed. In such event, we may incur a significant expense for all or a portion of the taxes related to the spin-off.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest rate risk

We are exposed to market risk relating to changes in interest rates, which could adversely affect the value of our investments in marketable securities.

As of June 30, 2004, our portfolio consisted of $5.3 million of interest-bearing debt securities with maturities of less than one year and $42.3 million of interest-bearing debt securities with maturities of more than one year. Our intent is to hold these securities until maturity, but we have classified them as available-for-sale in the event of unanticipated cash needs. The interest bearing securities are subject to interest rate risk and

will fall in value if market interest rates increase. We believe that the impact on the fair market value of our securities and related earnings for the remainder of 2004 from a hypothetical 10% increase in market interest rates would not have a material impact on the investment portfolio.

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Foreign currency risk

Except for sales transacted by our wholly-owned subsidiaries, we transact all our sales in U.S. dollars, or USDs; therefore, the obligations of many of our international customers are in USDs. Our exposure to risk from fluctuations in foreign currencies relates primarily to the strengthening of the USD against the local currency of both our international subsidiaries, which may result in foreign exchange losses on transactions with them, and our international customers, which may impact our ability to collect amounts owed by them.

As of June 30, 2004, 57% of our outstanding accounts receivable balance was from international customers, of which 63%, or approximately $8.8 million was denominated in a currency other than USDs. Total sales for the six months ended June 30, 2004 denominated in a currency other than USDs were approximately $14.1 million, or 29% of total consolidated revenues. The British pound, the euro and the Japanese yen represented the majority of financial transactions executed in a currency not denominated in USDs. We regularly review our receivable positions in foreign countries for any indication that collection may be at risk. In addition, we utilize letters of credit where they are warranted in order to mitigate our collection risk.

We periodically enter into foreign currency forward contracts to reduce the impact of adverse fluctuations on earnings associated with foreign currency exchange rate changes. As of June 30, 2004, we did not have any foreign currency hedging contracts.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures

The term "disclosure controls and procedures" is defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. These rules refer to the controls and other procedures of a company that are designed to ensure that the information required to be disclosed by a company in the reports that it files under the Exchange Act is recorded, processed, summarized and reported within required time periods. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our Exchange Act reports is accumulated and communicated to management, including our principal executive officer and our chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

Our chief executive officer and our chief financial officer have evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2004, and they have concluded that our disclosure controls and procedures were effective.

Changes in internal controls

There were no significant changes in SonoSite's internal controls over financial reporting or, to the knowledge of SonoSite's management, in other factors that could significantly affect SonoSite's disclosure controls and procedures during the quarter ended June 30, 2004.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

On July 24, 2001, Neutrino Development Corporation filed a complaint against us in U.S. District Court, Southern District of Texas, Houston Division, alleging infringement of U.S. Patent 6,221,021, or the '021 patent, by SonoSite as a result of our use, sale and manufacture of the SonoSite 180, SonoSite 180PLUS, SonoHeart and SonoHeart ELITE devices. The complaint asserts claims for preliminary and permanent injunctive relief enjoining all alleged acts of infringement, compensatory and enhanced damages, attorney's fees and costs, and pre- and post-judgment interest. On August 14, 2001, we filed an answer asserting affirmative defenses of non-infringement and patent invalidity, and included a counterclaim seeking a declaratory judgment of non-infringement and invalidity regarding Neutrino's patent. On October 4, 2001, the court denied a request by Neutrino for preliminary injunctive relief to prevent us from manufacturing and selling our products pending the ultimate disposition of the litigation. On February 20, 2002, in what is known as a "Markman" hearing, the parties presented their arguments regarding the proper construction of Neutrino's patent claims.

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On August 20, 2003, the U.S. District Court in the Southern District of Texas issued a decision interpreting certain terms used in the '021 patent. This decision does not discuss whether the patent is valid or whether the patent would apply to any of our products. In the order, the court, in resolving disputed terms in the Markman hearing, adopted our construction of the term "a portable body designed to be hand held", and adopted Neutrino's construction of the terms "the moveably connected transducer mounting assembly" and "ultrasound emitter". The court denied our motion for summary judgment. We subsequently filed a new summary judgment motion using the court's construction of the claim language that the '021 patent is invalid based on prior art. Neutrino has filed a summary judgment motion based on its allegations of infringement.

We also have asked the Texas court to stay proceedings in Neutrino's suit filed in the Middle District of Florida on August 19, 2003 against a former SonoSite distributor alleging that the sale of our products by such distributor infringes the '021 patent, and to enjoin Neutrino from filing similar suits against other sellers of SonoSite products. Neutrino had previously filed such a suit in the Middle District of Tennessee against another medical device distributor for selling a SonoSite product. That Tennessee case has been dismissed based on a final judgment and permanent injunction filed a month after the case was filed. The Tennessee judgment has no effect on the Texas proceedings. In the Florida action, we assumed defense of the case and have filed a motion to stay the proceedings in the Florida court pending a final resolution of the patent suit in Texas. We have also filed a motion to strike certain counts of Neutrino's complaint. In June 2004, the Florida court stayed the Florida action for six months, pending resolution of the Texas case, granted Neutrino's request to add SonoSite as a party to the Florida case, and denied our motion to strike certain counts, suggesting instead that we file our arguments contained in the motion to strike as a motion to dismiss.

We believe that we have good and sufficient defenses to the claims of patent infringement asserted against us by Neutrino and we are vigorously defending ourselves in these matters. If we are not successful in our defense of these claims, we could be forced to pay damages related to past product sales, modify or discontinue selling our products or may enter into royalty or licensing agreements for future product sales, which may not be available on terms acceptable to us, if at all, and which could adversely affect our financial condition, results of operations and cash flow. Sales of the allegedly infringing products represented the majority of our revenue for six month periods ended June 30, 2004 and 2003.

We have not accrued any amounts for potential losses related to these proceedings. Because of uncertainties related to both the amount and range of loss on the pending litigation, management is unable to make a reasonable estimate of the liability that could result from an unfavorable outcome. As additional information becomes available, we will assess the potential liability related to pending litigation. We will record accruals for losses if and when we determine the negative outcome of such matters to be probable and reasonably estimable. Our estimates regarding such losses could differ from actual results. Revisions in our estimates of the potential liability could materially impact our results of operations, financial position and cash flow.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

Exhibit No.	Description
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002)
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002)

(b) Reports on Form 8-K

On April 29, 2004, we filed a Current Report on Form 8-K, dated April 29, 2004, (a) furnishing under Item 12 thereof our financial results for the first quarter ended March 31, 2004 and (b) filing as exhibits under Item 7 thereof the related press release dated April 29, 2004.

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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.

SONOSITE, INC.

(Registrant)

Dated: August 9, 2004

By: /s/ MICHAEL J. SCHUH

Michael J. Schuh
Vice President-Finance, Chief Financial Officer and Treasurer
(Authorized Officer and Principal Financial Officer)

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