SONOSITE INC
Form 10-K
March 31, 2003

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON D.C. 20549

FORM 10-K

**FOR ANNUAL AND TRANSITION REPORTS
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934**

|X| **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2002**

|_| **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

for the transition period from _____ to _____.

Commission file no. 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**

(425) 951-1200

(Address and telephone number of registrant s principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of exchange on which registered**
None	Not applicable

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

Common stock, $0.01 par value

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

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

The aggregate market value of the voting stock held by nonaffiliates of the registrant, based on the closing sale price of the registrant s Common Stock on June 28, 2002, as reported on the Nasdaq National Market, was $169,485,083.

As of March 21, 2003, there were 14,216,446 shares of the registrant s Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this report, to the extent not set forth herein, is incorporated by reference from the registrant s definitive proxy statement relating to the annual meeting of shareholders to be held in 2003, which definitive proxy statement shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

SONOSITE, INC.

ANNUAL REPORT ON FORM 10-K
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Trademarks

SonoSite® is the registered trademark of SonoSite, Inc. The stylized SonoSite logo, iLook , SonoHeart ELITE , SonoSite 180PLUS , SiteStand , SiteLink , S.I.T.E. , OnSite and SonoKnowledge are trademarks of SonoSite, Inc. All other brand names, trademarks or service marks referred to in this report are the property of their owners.

PART I

Our disclosure and analysis in this report and in our 2002 Annual Report to shareholders, of which this report is a part, contain 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 revenues, and about the expected composition of our revenues;
- 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.

ITEM 1. BUSINESS

Overview

We are a leading provider of point-of-care, high performance, all-digital ultrasound imaging systems for use in a variety of clinical applications and settings. Our proprietary technologies have enabled us to design point-of-care 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 portability, high quality 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 the point of care such as the patient s bedside or the physician s examining table.

The size and complexity of traditional ultrasound systems typically compel physicians to refer patients to a highly trained sonographer employed by an imaging center, 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.

We currently focus on six key market segments: radiology, obstetrics and gynecology, emergency medicine, surgery, cardiology and vascular medicine. Our current products include the SonoSite 180PLUS, for general ultrasound imaging, the SonoHeart ELITE, specifically configured for cardiovascular applications, and our newest products, the iLook 15, intended for quick look diagnostics in areas such as emergency medicine, radiology, surgery or intensive care, and the iLook 25, designed to provide visual imaging for physicians and nurses while performing vascular access procedures. Our SonoSite 180PLUS and SonoHeart ELITE products are used together with any of our seven interchangeable handheld components, or transducers, that are designed for specific clinical applications. Our iLook products each have a single transducer for specific clinical applications.

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 point-of-care, high performance, all-digital 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 have 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 has 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 becomes nonexclusive and, except for the patented technology of each party, extends to all ultrasound systems regardless of weight. We sold our first products in September 1999.

Industry Background

Ultrasound emerged as a safe and noninvasive method to provide real-time, dynamic images for medical, soft-tissue imaging purposes in the late 1950s. Ultrasound uses low power, high frequency sound waves to provide noninvasive, real-time images of the body s soft tissue, organs and blood flow. Ultrasound can be cost effective by eliminating the need for more invasive and expensive procedures and allowing for earlier diagnosis of diseases and conditions. To generate an ultrasound image, a clinician places the transducer on the skin or in a body cavity near the targeted area. Tissues and bodily fluids reflect the sound waves emitted by the transducer, which also receives these reflections. Based on these reflections, the ultrasound system s beamformer measures and organizes the sound waves and produces an image for visual examination, using digital or analog signal processing or a combination of the two. Digital signal processing technology, such as that used by our products, allows an ultrasound system to process greater amounts of information. Accordingly, digital ultrasound systems produce higher resolution images than analog and hybrid analog/digital ultrasound machines.

Standard ultrasound imaging produces a two-dimensional image that physicians use to diagnose and monitor disease states and conditions by analyzing the relative shading of tissues or organs. This is known as grayscale imaging or two-dimensional imaging. Colorization technology expands standard ultrasound imaging by generating an image showing the direction and extent of the relative velocity of blood flow through the body, including the chambers and valves of the heart.

Initially, ultrasound was used to assess the general shape, size and structure of internal soft tissues and organs. As ultrasound technology evolved, leading to improved functionality and image quality, ultrasound imaging expanded as a diagnostic tool in radiology, obstetrics and gynecology and cardiology. In recent years, technological advances have greatly improved the image quality of ultrasound systems and substantially increased their diagnostic utility, encouraging growth in ultrasound procedure volume. Our products enable high performance ultrasound imaging by traditional users at the point-of-care and expand point-of-care ultrasound to emergency medicine, surgery, anesthesiology and vascular medicine. Prior to our products availability, however, high quality images could be produced only by highly trained sonographers using heavier and more expensive traditional cart-based ultrasound imaging systems.

Our Strategy

Our goal is to lead in the design, development and commercialization of point-of-care, high performance, all-digital ultrasound imaging systems. Our strategy to reach that goal consists of the following key elements:

Maximize the productivity of our direct sales force in the U.S. and key European markets. As of December 31, 2002, we employed 50 direct sales representatives in the United States. We established direct sales operations in the United Kingdom and France in 2001, and in Germany and Spain in 2002. As of December 31, 2002, we had 19 direct sales representatives in Europe, and we expect to grow this team over the next 24 months. We also employ clinical application specialists who, by assuming responsibility for product demonstrations and customer support, have enabled our sales representatives to improve

their efficiency. To further enhance the productivity of our direct sales force, we will continue to:

invest in training, educating and mentoring our sales force;

expand our clinical application specialist staff;

expand our corporate account relationships; and

organize our sales force by clinical markets and geographic regions.

Raise market awareness of the SonoSite platform and brand name. We believe the opportunity exists to build the SonoSite name into a global brand synonymous with point-of-care, high performance, all-digital ultrasound imaging. Although we have sold over 10,000 units to date, our products are relative newcomers to the ultrasound market, the first having been introduced in September 1999. To raise market awareness of our brand and our technology, we intend to:

focus marketing efforts by clinical segment;

implement targeted local marketing efforts;

market to potential new users by promoting innovative uses and clinical applications of ultrasound; and

utilize education to market our products.

Maintain product and technology leadership. We believe our products represent the most advanced technology in point-of-care, high performance, all-digital ultrasound systems. We are committed to maintaining this technological advantage by continuing to enhance our existing products and to create new ones. As of December 31, 2002, we employed over 50 people in research and development dedicated to creating the next generation of SonoSite products.

Improve and expand our sales distribution channels. Outside of our core markets, we have also sold products to many other clinical segments and countries. We believe that these other markets offer opportunity for growth but will require enhancements to our sales distribution channels. Specifically, we intend to improve our distribution channel in Japan, establish a tele-sales capability, enter into new third party distributor arrangements and explore strategic partnerships to develop new markets within ultrasound or with ultrasound-dependent technologies.

Expand into new ultrasound markets. We believe that the portability, high quality and cost effectiveness of our products will result in the creation of new markets for us. We are bringing ultrasound out of the imaging center directly to the patient at the primary point of care, such as the emergency room, vascular access procedures, the physician s office and other nontraditional ultrasound settings. We anticipate the development of an imaging physical the use of ultrasound imaging in routine physical examinations. We believe that these new users and new applications of ultrasound offer us a significant potential for growth.

Our Products

We offer four types of point-of-care ultrasound imaging systems: the SonoSite 180PLUS, the SonoHeart ELITE, the iLook 15 and the iLook 25. The 180PLUS and Elite imaging systems each consist of an integrated color display, control panel, including navigational trackball, and alphanumeric keyboard. Both systems are built on the same hardware platform, which provides internal storage for over 100 images, clinical analysis packages, measurement tools and direct personal computer connectivity. The SonoSite 180PLUS and the SonoHeart Elite imaging systems weigh less than six pounds with a single transducer attached. The following is a summary of our four ultrasound imaging products and their major features:

SonoSite 180PLUS. The SonoSite 180PLUS is a point-of-care ultrasound system for general diagnostic imaging and offers the following major features:

two dimensional, or B-mode, imaging, allowing real-time two-dimensional visualization of anatomic structures within the body;

M-mode imaging, providing a display of motion versus time. M-mode is particularly useful for evaluation of fast-moving structures, such as valves within the heart;

pulsed wave, or PW, Doppler technology. PW Doppler imaging uses short, pulsing bursts of ultrasound waves to provide a quantitative assessment of the velocity of blood flow. The name of the technology refers to the Doppler effect, which is an apparent change in the frequency of the reflected ultrasound wave due to the relative motion between the reflector and transducer;

color power Doppler and directional color power Doppler, allowing two-dimensional visualization of blood flow patterns;

tissue harmonic imaging, or THI, a signal processing technique providing enhanced image quality by using high frequency information to enhance image resolution; and

basic echocardiogram, or ECG, capability. When visualizing the heart, it is often useful to visualize basic relationships between cardiac motion and cardiac electrical activity. ECG provides this capability.

SonoHeart ELITE. The SonoHeart ELITE is a point-of-care ultrasound system intended for use by cardiologists and other healthcare providers in the cardiology market. The SonoHeart ELITE has all the product features of the SonoSite 180PLUS, as well as the following:

continuous wave, or CW, Doppler technology. CW Doppler imaging uses continuous, reflected ultrasound waves to provide a quantitative assessment of the velocity of blood flow. CW Doppler, because it relies on a continuous stream of information, enables assessments of blood flow moving at speeds higher than PW Doppler is capable of assessing.

ILook 15. The iLook 15, with its fixed curved array transducer, provides imaging at the patient s bedside for focused abdominal and cardiac applications.

ILook 25. The iLook 25, with its fixed linear transducer, provides superb image quality of a patient s vessels to aid in vascular access applications.

Both of these iLook products, which each weigh approximately three pounds, offer the following:

a touch screen for data input;

a single point-to-point measurement tool;

ability to store over 70 images for off-line printing and review;

cine loop retains images for frame-by-frame review;

connectivity to a PC for image download through a docking station;

2D and color power Doppler; and

The iLook 15 offers directional color power Doppler and harmonic imaging.

We offer seven types of transducers. Each of our transducers may be used with either the SonoSite 180PLUS or SonoHeart Elite Systems. This interchangeability allows our customers to purchase a single point-of-care ultrasound system that can be used in a variety of clinical applications.

Transducers. Our seven transducers are designed for use in the following clinical applications:

general abdominal and obstetrics imaging;

intracavitary and gynecological ultrasound imaging;

neonatal, vascular and pediatric imaging;

cardiac, thoracic and abdominal imaging, and trauma assessment;

breast, musculoskeletal, vascular, interventional and small-parts imaging;

intraoperative and superficial vascular imaging; and

musculoskeletal, obstetric and urological imaging for veterinarian applications.

We also offer the following related accessories and educational programs:

Accessories. We sell the *SiteStand* mobile docking station and the *SiteLink* imaging software, both of which enable communication between our products and third-party output devices, such as printers, storage devices and networks. We also offer a high resolution, 12.1-inch flat panel monitor that may be physically connected with our SiteStand to increase the image size and allow easy consultation among healthcare providers.

Specialized training and education. We promote educational courses for physicians and other healthcare providers who currently do not use ultrasound imaging in order to educate them in the general use of ultrasound and the fundamental operation of our products. We offer an internal program, *OnSite,* as well as accredited programs developed by third-party providers. In addition, as we develop new and emerging markets, we continue to develop new accredited and market specific training materials, produced by leaders in ultrasound education.

Sales and Marketing

Initially, we sold and marketed our products through third-party medical product distributors worldwide. Currently, we have moved to a direct sales model in the United States, the United Kingdom, France, Germany and Spain. We rely on third-party distributors in those markets where we do not have a direct sales staff.

At December 31, 2002, we had 50 direct sales representatives in the United States along with 27 clinical application specialists, who provide product demonstration and support to our sales representatives. In addition, we focused our sales representatives on specific clinical markets in addition to geographic regions.

In the United States, we have complemented our direct sales efforts by entering into group purchasing agreements with major healthcare group purchasing organizations, or GPOs. Typically, a GPO negotiates with medical suppliers, such as us, on behalf of the GPO s member healthcare facilities, providing such members with uniform pricing and terms and conditions. In exchange, the GPO identifies us as a preferred supplier for its members. Member facilities participating in the GPO s purchasing program can consist of hospitals, medical group practices, nursing homes, surgery centers, managed care organizations, long term care facilities, clinics and integrated delivery networks. Currently, we have GPO supply agreements with AmeriNet, Inc., Kaiser Permanente, Novation, LLC, Premier, Inc., Broadlane, Inc., Consorta, Inc. and Aurora Health Care.

Elsewhere outside the United States, we continue to sell to other potential markets through third-party foreign distributors, such as Olympus Optical, our exclusive distributor in Japan. In the first half of 2003, Olympus will modify its distribution network to improve its sales of our products. They plan to add direct resources and redirect their dealer network in order to focus their efforts on the clinical segments with the greatest sales opportunities. In the United Kingdom, we have a supply agreement with the Purchasing and Supply Agency of the National Health Service, or NHS, which contracts on a national basis for products and services purchased by the NHS.

We derived approximately $42.6 million, or 58%, of our revenue from domestic sales in 2002. This compares to approximately $23.8 million, or 52%, and approximately $15.2 million, or 47%, in 2001 and 2000.

We derived approximately $30.4 million, or 42%, of our revenue from international sales in 2002. This compares to approximately $21.9 million, or 48%, and approximately $16.9 million, or 53%, in 2001 and 2000. Japan accounted for approximately $7.5 million, or 10%, of our revenue in 2002. This compares to approximately $7.8 million, or 17%, and approximately $8.3 million, or 26%, in 2001 and 2000. Other than Olympus, no other single customer or distributor accounts for more than 10% of our revenue. We attribute revenue to a foreign country based on the location to which we ship our products. However, products sold to the U.S. government but deployed in a foreign country are attributed to domestic revenue.

Our revenues from international sales may be adversely affected by a number of risks, including competition, currency rate fluctuations, reduced protection for intellectual property rights and longer receivables collection periods. Our revenues from international sales may also be adversely affected by the cost or difficulty of localizing products for foreign markets and complying with export laws, including license requirements, trade restrictions and tariff increases.

Patents and Intellectual Property Rights

We rely on a combination of patent, copyright, trademark and trade secret laws and other agreements with employees and third parties to establish and protect our proprietary rights. We require our officers, employees and consultants to enter into standard agreements containing provisions requiring confidentiality of proprietary information and assignment to us of all inventions made during the course of their employment or consulting relationship. We also seek to enter into nondisclosure agreements with our commercial counterparties and limit access to, and distribution of, our proprietary information.

We are committed to developing and protecting our intellectual property and, where appropriate, file patent applications to protect our technology. We hold eleven U.S. patents relating to various aspects of our products, including the weight of digital beamformers, beamforming capabilities, digital conversion circuitry, transceiver circuitry and circuit integration. We hold two foreign patents relating to our products, and we currently have numerous patent applications pending both in the U.S. and abroad. We consider all of our patents to be significant to our business.

We license ultrasound technology from our former parent, ATL, under a Technology Transfer and License Agreement executed at the time of our spin-off as a public company. Under that agreement, 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 have 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 has 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 becomes nonexclusive and, except for the patented technology of each party, extends to all ultrasound systems regardless of weight.

Additionally, under the terms of our spin-off from ATL, the point-of-care ultrasound technology assigned to us by ATL remains subject to rights reserved or acquired by the U.S. government in connection with the original research funding provided to ATL by the U.S. Office of Naval Research to develop that technology. Specifically, under the standard patent rights afforded the U.S. government in connection with government-funded scientific research and included in ATL s original development agreement with the Office of Naval Research, the U.S. government holds what are commonly known as march-in rights a nonexclusive, nontransferrable, irrevocable, fully paid worldwide license to manufacture or have manufactured for use by the U.S. government any inventions conceived or first reduced to practice by ATL during the course of its government-funded research. As we expect to be able to fulfill anticipated purchases of our products by the U.S. government, we do not currently expect any exercise by the U.S. government of its march-in rights.

We hold a number of registered and unregistered trademarks, service names and domain names that are used in our business in the United States and overseas. Generally, federally registered trademarks offer protection for renewable terms of 10 years so long as the mark continues to be used in commerce.

On July 24, 2001, Neutrino Development Corporation filed a complaint against us, which alleged that our sale and manufacture of our point-of-care ultrasound systems infringed upon a patent held by Neutrino. We responded to the claim, asserting alternative defenses of noninfringement and patent invalidity. In addition, we filed a counterclaim seeking a declaratory judgment of noninfringement and invalidity regarding Neutrino s patent. We defeated Neutrino s request for a preliminary injunction preventing 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. The court has not yet ruled on the issues presented in that hearing. On October 10, 2002, the court granted our motion to stay the proceedings until it issues its Markman order and rules on our summary judgment motion. Although we continue to vigorously defend ourselves against this claim, this litigation may result in an adverse judgment against us. Sales of the allegedly infringing products represented virtually all of our revenue for the years ended December 31, 2002, 2001 and 2000. We have been forced to incur substantial expenses in defense of this claim, and we may incur additional substantial litigation expenses until the claim is resolved.

Competition

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 acquired two other competitors, Agilent Healthcare Solutions Group and ATL, our former parent company. In addition, as the market for point-of-care, high performance 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 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.).

Research and Development and Technology

We currently employ over 50 individuals in product development dedicated to the enhancement of existing products and development of new products. In 2002, 2001 and 2000, expenses attributable to research and development for our business totaled $12.1 million, $12.7 million and $11.8 million. We believe our products represent the most advanced technology in point-of-care, high performance, all-digital ultrasound imaging systems. We believe our technology gives us a competitive advantage, and we are committed to maintaining this advantage by continuing to enhance our existing products and create new ones. Accordingly, we intend to maintain our research and development expenses at levels we believe necessary to maintain this competitive advantage.

Manufacturing

We manufacture our products in our facility in Bothell, Washington. 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 maintain inventories of components to meet near term production requirements. While our suppliers have generally produced our components with acceptable quality, quantity and cost in the past, they have experienced periodic problems that have caused us delays in production. To date, these problems have not resulted in lost sales or lower demand.

Governmental Regulation

The manufacture and sale of our products are subject to extensive regulation by numerous governmental authorities, principally the U.S. Food and Drug Administration, or FDA, as well as several other state and foreign agencies. The FDA requires that all medical devices introduced to the market be preceded either by pre-market notification clearance under Section 510(k) of the Federal Food, Drug & Cosmetic Act, or an approved pre-market approval application, or PMA. 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. A PMA is filed when the FDA has determined the company must submit clinical trial data and manufacturing quality assurance information to prove it is safe and effective for its labeled indications. The process of obtaining 510(k) clearance typically takes approximately two to three months, while the PMA process typically takes more than a year. To date, all our products have received 510(k) clearance and we have not been required to file any PMAs. We believe that our future generation point-of-care ultrasound systems will also require only 510(k) clearance. Foreign regulatory agencies also require similar pre-market clearance or registration before our products can be marketed or offered for sale in their countries. Any delays, or failures, in obtaining such clearances may result in lost sales and revenue.

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. We appealed the FDA s classification and have received verbal confirmation from the FDA that we satisfied their requirements to complete the field action. We are seeking final written closure of this matter from the FDA.

Our products and our product components are also subject to various domestic and foreign manufacturing standards and electrical safety and emission standards, such as those of Underwriters Laboratories and the ISO 9001 standards, described below. We and our suppliers are subject to FDA regulations governing registration of manufacturing facilities and compliance with the FDA s Quality System Regulations, or QSR. The FDA performs periodic unannounced on-site inspections to determine compliance with such regulations. The FDA inspected our manufacturing facility in August 2001. In addition, the British Standards Institution (BSI) performed a management systems assessment of our manufacturing processes in May 2000, February 2001, June 2001, November 2001, January 2002 and July 2002.

SonoSite also complied with the new Canadian Medical Device Regulation requirements for an independent audit in December 2002. We met the requirements defined in the Canadian Medical Device Conformity Assessment Scheme (CMDCAS) and BSI will be issuing a certification to these requirements. These inspections resulted in our submitting and implementing corrective action responses, and we believe those responses have been accepted by those agencies. We believe that we are currently in compliance with applicable QSR.

Our regulatory compliance programs encompass verification of our compliance with international standards for medical device design, manufacture, installation and servicing, known as ISO 9001:1994, ISO 13485:1996 and EN 46001:1996 standards. On September 13, 1999, we received Conformite Europeenne, or CE, Marking approval, signifying European Certification to the international quality system standards and to the European Medical Device Directive, which encompass ISO 9001 standards. The Certification allows us to distribute the SonoSite 180, 180PLUS, SonoHeart, SonoHeart PLUS and SonoHeart ELITE systems to the 19 countries of the European Union and the European Free Trade Association. The FDA harmonized in June 1998 its QSR for the United States with ISO 9001 and EN 46001 standards.

Our current products do not require any U.S. export control licenses in order to be sold overseas.

Service and Warranty

Our typical warranty period is one year and is included with the original purchase of our ultrasound imaging systems. However, the customer can purchase a service contract from us to extend the original warranty period or enhance its coverage. All returned products are diagnosed for cause of failure and for possible design improvements to incorporate in future products.

Employees

As of December 31, 2002, we had approximately 350 full-time employees, of which approximately 14% were engaged in research and product development, 33% in manufacturing, 43% in sales and marketing activities and the remaining 10% in administrative capacities, including executive, finance, legal, human resources, regulatory and information services and technology. Of these, approximately 320 are U.S. employees. There has never been a work stoppage and no employees are covered by collective bargaining agreements. We believe our employee relations are good.

Website Access to Reports

We make available, free of charge, on our website copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, or Exchange Act, as soon as reasonably practicable after filing or furnishing the information to the Securities and Exchange Commission. The Internet address for the information is http://investor.sonosite.com/edgar.cfm.

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

If our products do not gain market acceptance, we will fail to generate sufficient revenue to maintain our business.

The market for point-of-care, high performance ultrasound systems is new and largely undeveloped. Our products represent a new technological alternative to traditional ultrasound examinations. 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, and our success will depend on the acceptance of our products by the medical community, patients and third-party payors as medically useful, safe and cost-effective. Competing point-of-care or traditional

cart-based ultrasound systems may be more cost-effective than our products. Physicians and other healthcare providers may adopt our products at a slow rate, if at all. If the market fails to accept our products, we will be unable 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:

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 point-of-care, high performance 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 or our products. Our current competitors in the point-of-care market include 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 new entrants to the point-of-care, high performance ultrasound market, we will be unable to generate sufficient revenue to maintain our business.

If our competitors develop and market medical imaging systems 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.

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 will receive reimbursement for the use of our products from governmental authorities such as Medicare, private health insurers and other third-party payors. 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 governmental authorities, private health insurers and other third-party payors to contain or reduce the costs of healthcare through various means may, however, limit market acceptance of our products and, therefore, may affect our ability to market our current products, commercialize our potential products and become profitable. Reimbursement coverage, to the extent available, may not be adequate to enable us to achieve market acceptance of our products. In addition, we believe that third-party payors will attempt to reduce healthcare costs by limiting both coverage and level of reimbursement for new products cleared by the FDA or comparable foreign agencies. Our products enable new kinds of medical procedures involving novel ultrasound applications for which there is no reimbursement history. The efforts of government and third-party payors to contain or reduce the cost of healthcare could restrict physicians and other healthcare providers willingness to select our products and implement new ultrasound procedures, which could delay or reduce market acceptance of our products.

We have recently become aware of notices issued by three state Medicare carriers to their clients in fifteen states that limits reimbursement under various Part B Medicare ultrasound CPT codes for certain ultrasound procedures conducted with hand-carried ultrasound systems. We are seeking clarification from these carriers of the meaning of these policy changes in an effort to determine the extent to which they may potentially impact our business. If such reimbursement practices continue in force or are adopted by additional health insurance providers, market acceptance of our products may be limited.

Additionally, there has been and will likely continue to be a number of federal and state proposals to implement government controls on pricing. The existence and adoption of these proposals could affect our ability to successfully market our current products and commercialize new products.

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

Trends toward managed care, health care 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:

- major third-party payers of hospital and pre-hospital services, including Medicare, Medicaid and private health care 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. health care system that could have an adverse effect on our business;
- there has been a consolidation among health care 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 health care 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 health care industry.

Both the pressure to reduce prices for our products in response to these trends and the decrease in the size of the market as a result of these trends could adversely affect our levels of revenues and profitability of sales, which could have a material adverse effect on our business.

Our single technological platform renders us less able to withstand adverse changes in the ultrasound market.

Although we market our products for use in a variety of clinical applications and settings, we have only a single technological platform upon which all our ultrasound systems are based. Any attempt to design a new platform for ultrasound imaging will require substantial amounts of time and money, and may not be successful.

If our platform becomes obsolete, unmarketable or unaccepted by the ultrasound market for any reason, and we are unable or slow to develop a new platform to replace it, we will be unable to generate sufficient revenue to maintain our business.

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

In traditional ultrasound practice, physicians and other healthcare providers typically refer patients to centralized locations where radiologists and other specialized personnel provide ultrasound examinations. 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 practice. 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 discourage new users from adopting our products, we could experience limited 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 (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. Prior to the discontinuance, we expect to obtain supplies of 0.35-micron chips from Philips in an amount sufficient to supply us with enough components for our anticipated manufacturing needs until new chips have been incorporated in all of our products. 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, a deterioration in gross margin or lower revenue.

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 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 all medical devices introduced to the market be preceded either by pre-market notification clearance under Section 510(k) of the Federal Food, Drug & Cosmetic Act, or an approved pre-market approval application, or PMA. 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, we have not been required to file any PMAs and 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. Any delays, or failures, in obtaining such clearances may result in lost sales and revenue.

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 August 2001. In addition, the British Standards Institution 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. We appealed the FDA s classification and have received verbal confirmation that we satisfied the requirements to complete the field action. We are seeking final written closure of this matter from the FDA.

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.

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 quarter ending December 31, 2002, we have incurred net losses in each quarter since we commenced operations. As of December 31, 2002, we had an accumulated deficit of approximately $86 million. Although we expect to continue to incur additional losses in the fiscal quarter ending March 31, 2003, we expect to achieve profitability on an annual basis in 2003. Even if we do achieve one or more profitable periods, 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. With the exception of the fiscal quarter ending December 31, 2002, our revenue from product sales has been insufficient to cover our expenses. We expect that our operating expenses will substantially increase in the foreseeable future as we expand our sales and marketing infrastructure, our administrative support and possibly 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 $32.0 million in 2000 to $45.7 million in 2001 and $73.0 million in 2002. During 2002, we added over 100 new employees, primarily in manufacturing and sales and marketing. During 2002, we introduced five new products and continued our expansion into Europe. 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. For example, sales to our distributor in Japan, Olympus, represented 10% of our revenue in 2002 and 17% of our revenue in 2001. 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 Japan, we have not achieved revenue growth the past two fiscal years. In late 2002, we examined the market for our product and confirmed a significant market opportunity that was not being realized by Olympus and their dealer network. In an effort to develop this market opportunity, Olympus will add direct resources and redirect the efforts of its dealers in the first half of 2003. We expect that this transition will result in reduced revenues in Japan in the first half of fiscal 2003 compared with the same period in 2002.

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 revenues, higher expenses and reduced margins.

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 revenues;
- 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 revenues, and reduced margins.

Our creation, maintenance and expansion of direct sales and distribution operations in Europe and Asia 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 2002, we began the process of terminating a joint venture that distributed our products in China, which we expect to have completed in 2003 along with the formation of a joint venture with a new partner that has greater financial and marketing resources. We expect our foreign direct sales operations to grow. 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 Europe and Asia 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. Despite our expenditures and efforts, we may not generate a substantial increase in European or Asian 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 42% in 2002 and 48% in 2001. Of this foreign revenue, approximately 25% originated in Japan in 2002 and 35% in 2001. Total sales for the year ended December 31, 2002 denominated in a currency other than USDs were approximately $9.8 million, or 13% of total consolidated revenues. Our revenue from international sales may be adversely affected by any of the following risks:

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 December 31, 2002, 51% of our outstanding accounts receivable balance was from international customers. Our distributor in Japan was indebted to us for approximately $2.5 million, representing 12% of our outstanding accounts receivable balance. We regularly review our receivable positions in foreign countries for any indication that collection may be at risk. For example, due to recent economic events in Argentina, including the decision to allow the Argentine peso to float against the U.S. dollar, we wrote off $400,000 of our Argentine receivables in 2002, for which we had already established an allowance.

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.

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. 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.

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 eleven 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 is exclusive through April 5, 2003, and nonexclusive after that date. We also enter into confidentiality or license 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:

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, which alleged that our sale and manufacture of our point-of-care ultrasound systems infringed upon a patent held by Neutrino. We responded to the claim, asserting alternative defenses of noninfringement and patent invalidity. In addition, we filed a counterclaim seeking a declaratory judgment of noninfringement and invalidity regarding Neutrino s patent. We defeated Neutrino s request for a preliminary injunction preventing us from manufacturing and selling our products for the duration 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. The court has not yet ruled on the issues presented in that hearing, and may issue a ruling at any time. On October 10, 2002, the court granted our motion to stay the proceedings until it issues its Markman order and rules on our summary judgment motion. Although we continue to vigorously defend ourselves against this claim, this litigation may result in an adverse judgment against us. Sales of the allegedly infringing products represented virtually all of our revenue for the years ended December 31, 2002, 2001 and 2000. We have been forced to incur substantial expenses in defense of this claim, and we may incur additional substantial litigation expenses until the claim is resolved.

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.

Compliance with governmental regulation of our business could be costly and time-consuming, and could prevent us from introducing new products in a timely manner.

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 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.

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. We may be subject to fines, sanctions, including the temporary or permanent suspension of operations, product field actions, criminal prosecution and marketing restrictions, if we fail to comply with the laws and regulations pertaining to our business. Our third-party medical device manufacturers may also be subject to the same sanctions and, as a result, may fail to supply us with components required to manufacture our products.

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:

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.

If we incur 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.

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 February 28, 2003, our executive officers, directors and affiliated entities together beneficially owned approximately 4.4% of the outstanding shares of our common stock. Seven other shareholders owned in the aggregate approximately 50.5% of the outstanding shares of our common stock. Among these shareholders, the State of Wisconsin Investment Board, or SWIB, owned approximately 16.1% of the outstanding shares of our common stock and WM Advisors 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. 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.

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:

$150 million if, prior to April 6, 2003, any single person or entity obtains, directly or indirectly, voting control of a majority of our common stock or the power to elect our entire board of directors; or

$75 million if, at any time between April 6, 2003 and 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, 15% 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 15% 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. Our rights plan excludes SWIB s ownership of our common stock so long as such ownership does not reach 20% of our outstanding common stock.

ITEM 2. PROPERTIES

Our principal offices are located in Bothell, Washington, where we lease approximately 65,000 square feet. The facility includes approximately 30,000 square feet of office space, 30,000 square feet of manufacturing space and 5,000 square feet for other uses, such as reception and meeting rooms. The lease runs through 2007. Our warehouse is located in a nearby 18,000 square foot building. The lease on this building runs through 2006. We believe that these facilities will be adequate to meet our needs for the foreseeable future. Additionally, we lease smaller office facilities at each subsidiary location.

ITEM 3. 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 as a result of our use, sale and manufacture of the SonoSite 180, SonoSite 180PLUS, SonoHeart and SonoHeart PLUS systems. 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 alternative defenses of noninfringement and patent invalidity, and included a counterclaim seeking a declaratory judgment of noninfringement 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. The court has not yet ruled on the issues presented in that hearing. On October 10, 2002, the court granted our motion to stay the proceedings until it issues its Markman order and rules on our summary judgment motion. We believe we have good and sufficient defenses to the claims of patent infringement asserted against us by Neutrino and we are vigorously defending ourselves in this matter, however this litigation may result in an adverse judgment.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of our shareholders during the fourth quarter of the year ended December 31, 2002.

PART II

ITEM 5. MARKET FOR REGISTRANT S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock is traded on the Nasdaq National Market under the symbol SONO. As of February 28, 2003, there were 3,534 holders of record of the common stock. This figure does not include the number of shareholders whose shares are held of record by a broker or clearing agency, but does include each such brokerage house or clearing agency as a single holder of record.

The high and low sales prices for our common stock for each quarter are listed below. These prices reflect interdealer prices, without retail mark-up, mark-down or commission, and may not necessarily represent actual transactions.

Year	High	Low
2002		
Fourth quarter	$ 16.17	$ 9.76
Third quarter	$ 15.65	$ 10.25
Second quarter	$ 19.68	$ 11.71
First quarter	$ 28.01	$ 18.20
2001		
Fourth quarter	$ 27.50	$ 17.99
Third quarter	$ 27.85	$ 14.65
Second quarter	$ 20.00	$ 10.50
First quarter	$ 17.38	$ 8.38

We have not declared or paid cash dividends on our common stock. We currently intend to retain all earnings, if any, for future growth and, therefore, do not intend to pay cash dividends on our common stock in the foreseeable future.

ITEM 6. SELECTED FINANCIAL DATA

The selected financial data should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and the Consolidated Financial Statements and Notes thereto included elsewhere in this Form 10-K.

	For the Years Ended December 31,				
	2002	2001	2000	1999	1998
	(in thousands, except per share data)				
Statement of Operations Data					
Sales revenues	$ 73,035	$ 45,695	$ 32,037	$ 10,185	$
Cost of sales revenue	29,800	21,861	18,649	6,498	
Gross margin	43,235	23,834	13,388	3,687	
Grant revenue				125	973
Operating expenses:					
Research and development	12,126	12,715	11,835	14,533	9,474
Sales and marketing	33,555	22,312	17,371	9,767	3,120
General and administrative	5,824	5,198	4,647	2,637	1,904
Total operating expenses	51,505	40,225	33,853	26,937	14,498
Other income (loss):					
Interest income	958	1,123	2,478	1,600	541
Interest expense	(195)	(175)	(155)	(117)	(41)
Equity in (losses) earnings of affiliates	(188)	(675)	(830)	30	
Other loss	(36)	(291)			
Total other income (loss)	539	(18)	1,493	1,513	500
Net loss	$ (7,731)	$ (16,409)	$ (18,972)	$ (21,612)	$ (13,025)
Basic and diluted net loss per share (1)	$ (0.59)	$ (1.59)	$ (2.01)	$ (3.08)	$ (2.72)
Weighted average common and potential common shares used in computing basic and diluted net loss per share (1)	13,075	10,300	9,418	7,025	4,796

	As of December 31,				
	2002	2001	2000	1999	1998
	(in thousands)				
Balance Sheet Data					
Cash and cash equivalents	$ 26,381	$ 33,116	$ 11,067	$ 33,252	$ 7,526
Working capital	56,705	49,326	40,534	54,923	16,934
Total assets	105,877	63,076	58,024	69,726	23,290
Long-term obligations, less current portion	88	185	316	135	481
Total shareholders equity	92,614	55,683	47,808	63,709	19,833

(1) Net loss per share amounts are computed on the basis described in Note 2 of Notes to the Consolidated Financial Statements for periods subsequent to the April 6, 1998 Distribution Date. For the periods prior to the Distribution Date, weighted average shares outstanding represent ATL weighted average shares as adjusted for the exchange ratio established on the Distribution Date of one of our shares for every three shares of ATL.

ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

We are a leading provider of point-of-care, high performance, all-digital ultrasound imaging systems for use in a variety of clinical applications and settings. Our proprietary technologies have enabled us to design point-of-care 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 portability, high quality 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 the point of care such as the patient s bedside or the physician s examining table.

The size and complexity of traditional ultrasound systems typically compel physicians to refer patients to a highly trained sonographer employed by an imaging center, 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.

We currently focus on six key market segments: radiology, obstetrics and gynecology, emergency medicine, surgery, cardiology and vascular medicine. Our current products include the SonoSite 180PLUS, for general ultrasound imaging, the SonoHeart ELITE, specifically configured for cardiovascular applications, and our newest products, the iLook 15, intended for quick look diagnostics in areas such as emergency medicine, radiology, surgery or intensive care, and the iLook 25, designed to provide visual imaging for physicians and nurses while performing vascular access procedures. Our SonoSite 180PLUS and SonoHeart ELITE products are used together with any of our seven interchangeable handheld components, or transducers, that are designed for specific clinical applications. Our iLook products each have a single transducer for specific clinical applications.

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 point-of-care, high performance, all-digital 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 have 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 has 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 becomes nonexclusive and, except for the patented technology of each party, extends to all ultrasound systems regardless of weight.

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, revenues 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.

We believe the following critical accounting policies require our more significant judgments and estimates used in the preparation of our consolidated financial statements:

Accounts receivable. We provide an allowance for doubtful accounts based upon specific customer risks and a general provision based upon historical trends. Losses can be difficult to anticipate. For example, in 2002, we wrote off approximately $400,000 of our Argentine receivables due to adverse economic conditions in Argentina. An increase in losses beyond those expected by management would reduce earnings when they become known.

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. 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. Additionally, in cases of nonstandard delivery and acceptance criteria, we do not recognize revenue at shipment, but rather when the delivery and acceptance criteria have been satisfied.

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. Cost adjustments are recorded for obsolete material, earlier generation products and used product held either as saleable inventory or as demonstration product, if necessary to reduce their carrying values to amounts not lower than that which will result in approximately normal profit margins upon sale. 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 inventory 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 inventory.

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 our products. Any unexpected increase in defects would result in an increase in warranty expense and a reduction in earnings.

Results of Operations

Revenue

Revenue increased to $73.0 million in 2002, compared to $45.7 million in 2001 and $32.0 million in 2000. Approximately 69% of the 2002 increase was in the United States. The increase in revenue in 2002 compared to 2001 was primarily due to an increase in sales in the United States resulting from having a fully staffed direct sales force for an entire year, our new product introductions and our increased average selling price. Sales representatives increased productivity as they became more experienced and were assisted by 27 clinical application specialists. These specialists performed product demonstrations and customer support, enabling sales representatives to focus on sales calls. Additionally, the average selling price per system increased due to an increase in sales of higher priced features. Approximately 21% of the increase was in Europe, where we opened two new sales offices in Germany and Spain in 2002 and had a full year of operation in the United Kingdom and France compared to the prior year.

The increase in revenue in 2001 compared to 2000 was primarily due to an increase in sales in the United States resulting from an increase in the number of direct sales representatives to 51 at the end of 2001, compared to 26 at the end of 2000. The increase was also due to an increased average selling price.

U.S. revenues increased to $42.6 million in 2002, compared to $23.8 million in 2001, due to the increase in U.S. direct sales representatives, our new product introductions and our increased average selling prices. U.S. revenues increased to $23.8 million in 2001, compared to $15.2 million in 2000, due to the increase in U.S. direct sales representatives and increased average selling prices.

Revenue from Japan decreased to $7.5 million in 2002 from $7.8 million in 2001 primarily due to the timing of orders received from our distributor in Japan and the delay in approval of our new products. The decrease of revenue in Japan to $7.8 million in 2001 from $8.3 million in 2000 was due to initial distributor orders received in the prior year.

Revenue from Europe, Africa and the Middle East increased to $14.8 million in 2002 from $9.1 million in 2001 primarily due to an increase in direct sales in the United Kingdom and France along with sales from our recently established direct sales operations in Germany and Spain. The increase to $9.1 million in 2001 from $3.8 million in 2000 was primarily due to an increase in direct sales in the United Kingdom and a large multi-order system sale in the first quarter of 2001.

Revenue from Canada, Australia, South and Latin America and other Asia increased to $8.1 million in 2002 from $5.0 million in 2001 primarily due to an increase in orders from our distributors in China and Mexico. Revenue from Canada, Australia, South and Latin America and other Asia increased slightly to $5.0 million in 2001 from $4.8 million in 2000.

We anticipate that revenue will increase in 2003 compared to prior years due to continued expansion of our direct selling efforts in the United States and Europe, introduction of new products and 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 are introducing highly portable and point-of-care ultrasound products. In 2003, we do not anticipate any increase in our revenue from Japan due to the changes in the distribution network of our partner, Olympus, in the first half of the year. Additionally, regulatory approval of our new products in Japan may experience delays, which could impact our anticipated revenue.

Gross margin

Gross margin increased to 59% in 2002, compared to 52% in 2001 and 42% in 2000. The increase in gross margin was primarily due to an increase in the percentage of direct sales compared with distributor sales, increased average selling prices due to the sale of higher priced features, and improved manufacturing efficiencies.

The increase in gross margin in 2001 from 2000 was primarily due to a combination of increased selling prices and improved manufacturing efficiencies. The increased average selling prices resulted from an increase in the number of transducers and accessories sold with each system and an increase in the percentage of our direct sales compared with distributor sales. Costs as a percentage of sales decreased in 2001 because costs on a per unit basis decreased as our production volumes increased.

We expect gross margin in 2003 to increase slightly from gross margin achieved in 2002. 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. Included in our inventories are demonstration products, refurbished products and products held by our customers, which are valued by us at amounts expected to result in a normal margin upon sale. 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 goods sold and a decrease in our gross margin.

Operating expenses

Research and development expenses were $12.1 million in 2002, compared to $12.7 million in 2001 and $11.8 million in 2000. Research and development expenses decreased in 2002 compared to 2001 primarily due to a reduction in product development costs after the completion and introduction of the SonoHeart ELITE and iLook products during the first nine months of 2002.

The increase in 2001 research and development expenses compared to 2000 was primarily due to increased activities surrounding the final design, verification and validation of the PLUS platforms and related transducers and continued engineering design and development of new products, including the SonoHeart ELITE system and its features which was released in March 2002.

We anticipate that research and development expenses will be level in 2003 as compared to 2002. 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 increased to $33.6 million in 2002, compared to $22.3 million in 2001 and $17.4 million in 2000. Of the $11.3 million increase in expenses in 2002 compared to 2001, approximately 22% was related to our direct sales activities in the United States, where for the first time we had a fully operational sales force for an entire year. Approximately 22% of the increase was related to the addition of clinical application specialists in the United States, who assisted sales representatives with product demonstrations and customer support. Approximately 38% of the increase was related to our direct sales activities in Europe where we opened two new sales office and increased headcount in our two existing offices.

The increase in sales and marketing expenses in 2001 compared to 2000 was primarily due to an increase in direct selling expenses in the United States and Europe. U.S. direct selling expenses increased by $3.2 million to $10.3 million, compared to $7.1 million in 2000. This increase was primarily due to costs associated with the increase in the number of sales representatives and sales management. Our expansion into Europe in 2001 resulted in additional expenses due to the addition of our direct selling operation. Offsetting these increases was a decrease in marketing expenses due to market research expenses incurred at the end of 2000 that were not incurred in 2001.

We anticipate that sales and marketing expenses in 2003 will increase primarily due to increased expenses in Europe resulting from the expansion of our European direct sales offices.

General and administrative expenses were $5.8 million in 2002, compared to $5.2 million in 2001 and $4.6 million in 2000. The increases in general and administrative expenses in 2002 and 2001 were related primarily to supporting our business growth and to legal expenses incurred to defend our intellectual property rights.

We anticipate that general and administrative expenses will increase in 2003 due to increased insurance, accounting and legal expenses in addition to general expenses to support the growth of our infrastructure. We may incur additional substantial legal expenses as we continue to defend our patent rights in the existing patent litigation. In addition, we may incur unanticipated legal expenses if we become involved in any new litigation.

Other income (loss)

For other income and loss, we reported income of $539,000 in 2002 compared to a