SONOSITE INC
Form 10-K
March 15, 2004

UNITED STATES
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, 2003

o 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 S.E.
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 o

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. o

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

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 30, 2003 as reported on the Nasdaq National Market, was $247,535,054.

As of March 5, 2004, there were 14,668,784 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 2004, 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®, the stylized SonoSite logo, iLook®, SonoHeart®, SonoKnowledge®, SiteStand®, SitePack® and SiteCharge® are all registered trademarks of SonoSite, Inc. TITAN , SonoSite 180PLUS , OnSite and The Imaging Physical 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 2003 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 worldwide developer of high-performance, hand-carried ultrasound imaging systems for use in a variety of clinical applications and settings. Our proprietary technologies have enabled us to design hand-carried diagnostic ultrasound systems that combine all-digital, high-resolution imaging with advanced features and capabilities traditionally found on cart-based ultrasound systems. We believe that the mobility, high clinical utility, durability, ease of use and cost-effectiveness of our products are expanding existing markets and will create new markets for ultrasound imaging by bringing ultrasound out of the imaging center to other clinical settings and to the point-of-care such as the patient s bedside or the physician s examining table.

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

Our products are used for imaging in a variety of medical specialties, such as radiology, obstetrics and gynecology, emergency medicine, surgery, cardiology, internal medicine and vascular medicine. Our current products include the SonoSite TITAN system, for general imaging and cardiology applications, the SonoSite 180PLUS system, for general ultrasound imaging, and the SonoHeart ELITE, specifically configured for cardiovascular applications. The iLook 25 imaging tool is designed to provide visual guidance for physicians and nurses while performing vascular access procedures and the iLook 15 imaging tool is designed to provide visual imaging of the chest and abdomen for physicians and nurses while performing other procedures and examinations. Our TITAN, SonoSite 180PLUS and SonoHeart ELITE products are used together with any of our transducers that are designed for specific clinical applications. Our iLook

products each have a single transducer for specific clinical applications. We first shipped our newest product, the SonoSite TITAN, in June 2003.

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

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. 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 in the clinic and at the point-of-care and expand hand-carried ultrasound to emergency medicine, surgery and vascular medicine. Prior to our products availability, however, high quality images could be produced only by physicians or highly trained clinicians using heavier and more expensive traditional cart-based ultrasound imaging systems.

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 obtain and 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 and texture of tissues and organs. This is known as grayscale imaging or two-dimensional imaging. Color Doppler technology expands standard ultrasound imaging by generating a colorized image showing the presence, direction and velocity of blood flow through the body, including the chambers and valves of the heart.

Our Markets

According to a study published by Klein Biomedical Consultants, Inc. for 2003, the worldwide ultrasound market is approximately $3.5 billion. Radiology or general imaging is the largest clinical segment and accounts for approximately 40% of this market. Cardiology and obstetrics/gynecology account for approximately 25% and 20%, respectively. Vascular medicine and other applications account for the remaining 15%. The U.S. market represents approximately 35% of the total $3.5 billion worldwide market. Another important clinical segment identified as shared services exists within the international market. This market is comprised of systems configured to perform both radiology and cardiology examinations and accounts for approximately 20% of the international market, or an estimated $460 million. We believe that lower cost, high-performance hand-carried systems, such as ours, will increasingly be used to replace higher-priced cart-based ultrasound systems for existing users as well as to accelerate the proliferation of ultrasound to new users.

In 2003, for the first time, industry analysts began to separately track the market for hand-carried ultrasound (HCU). According to 2003 estimates from Klein Biomedical Consultants, Inc. and Frost & Sullivan, SonoSite is recognized as the leader of this new HCU market that is considered to be the fastest growing segment of the worldwide market. HCU products are defined as approximately laptop size weighing 10 pounds or less. Worldwide sales of HCU products have

grown from approximately $10 million in 1999, when SonoSite began shipping the first HCU products to estimated sales of $160 million in 2003. In 2003, the United States accounted for over half of these sales, Europe for approximately 20%, and Japan for 15%. Assuming the growth rate for the HCU market internationally is similar to that estimated by Frost & Sullivan for the U.S. in their 2003 published study, we expect the HCU worldwide market to reach $550 million by 2010. Although some of this growth may come at the expense of cart-based systems, we believe the majority of the growth will come from new clinical applications and new users of ultrasound due to the mobility and ease-of-use of HCU products. HCU is making possible new clinical uses of ultrasound in settings such as the physician s office, the emergency room and the surgical suite where the size, weight and complexity of cart-based systems made them difficult to use.

We see our clinical market opportunities in three major sectors mobile diagnostic, visual procedure assist and the Imaging Physical . The mobile diagnostic market accounted for approximately 80% of the HCU market in 2003 and includes the use of HCU for diagnostic examinations in radiology, cardiology, obstetrics/gynecology and vascular applications. It also includes emerging applications such as emergency medicine and surgery. Visual procedures accounted for approximately 20% of this market and consist of using ultrasound to guide medical interventions such as biopsies or line insertions in the operating room, critical care unit or physician s office. The third category, the Imaging Physical, is a market that is beginning to evolve. The Imaging Physical involves the use of ultrasound in the routine physical examination to screen for the early detection of disease. With an estimated 225,000 primary care physicians in the U.S., we believe that the imaging physical sector represents a significant additional market opportunity for SonoSite.

Our Strategy

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

Build upon and maintain product and technology leadership. We believe our products represent the most advanced technology in high-performance, hand-carried ultrasound systems. We are committed to continuing to build upon this technological advantage by continuing to enhance our existing products and to create new ones. As of December 31, 2003, we employed over 50 people in research and development. Since our inception, we have introduced two generations of ASIC, or application specific integrated circuit, technology, which have improved performance and expanded diagnostic capabilities. We are working on our third generation of ASIC technology, which will allow us to provide products customized for specific clinical applications.

Maximize the productivity of our direct sales force in the U.S. and key international markets. As of December 31, 2003, we employed approximately 60 direct sales representatives in the United States, United Kingdom, France, Germany and Spain. We expect to grow this team over the next 12 months and recently announced plans to open subsidiaries in Japan, Australia and Canada. 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 and educating our sales force;
expand our direct sales and clinical application specialist staff; and
expand our corporate account relationships.

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 expand our 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. We will also explore establishing sales offices in other key international markets.

Expand into new clinical markets. We believe that the mobility, high quality and cost effectiveness of our products will result in the creation of new clinical 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, 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.

Raise market awareness of the SonoSite platform and brand name. We will continue to invest to build the SonoSite name into a global brand synonymous with high-performance, hand-carried ultrasound imaging. 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
expand training and education offerings.

Our Products

We offer five types of hand-carried ultrasound imaging systems: the SonoSite TITAN, the 180PLUS, the SonoHeart ELITE, the iLook 15 and the iLook 25. All SonoSite ultrasound systems consist of a digital beamformer, integrated color display, control panel, including navigational trackpad (TITAN), trackball (180PLUS and ELITE) or D-controller (iLook), alphanumeric keyboard and measurements. Each of the five SonoSite systems supports image storage, image documentation to video printer or VCR and direct personal computer connectivity. The following is a summary of our five ultrasound imaging products and their major features:

SonoSite TITAN: The TITAN system, first shipped in June 2003, is our newest product and represents our second generation of digital technology. The TITAN system combines the high performance of cart-based systems with the speed, flexibility and durability of mobile ultrasound devices. The TITAN can be used for stationary applications in its Mobile Docking Station (MDS), which supports connectivity to hospital PACS and HIS systems, multiple transducer connections and on-board documentation devices, yet the modular design of the TITAN system enables it to be taken out of the MDS to rapidly deliver imaging at the point-of-care. The modularity of the TITAN system

enables the user to easily and economically expand or upgrade to new features through a standard flashcard or interchangeable hardware. The following features are offered:

- 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 depth versus time. M-mode is particularly useful for evaluation of fast-moving structures, such as valves within the heart;
- pulsed wave, or PW, Doppler imaging. 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;
- continuous wave, or CW, Doppler imaging. 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; *(planned released is June 2004)*
- velocity based color Doppler. Color Doppler is traditionally used to allow the user to visualize blood flow within blood vessels or chambers of the heart; *(planned released is June 2004)*
- basic electrocardiogram, 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; *(planned released is June 2004)*
- 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;
- split screen capabilities for side imaging or duplex Doppler;
- image documentation capabilities, including connection to video printers or VCRs, and DICOM compliance for use with PACS print and storage capabilities; and
- measurement tools and clinical analysis packages

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 depth versus time. M-mode is particularly useful for evaluation of fast-moving structures, such as valves within the heart;
- pulsed wave, or PW, Doppler imaging. 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;
- ability to store up to 119 images for off-line printing and review;
- image documentation capabilities, including connection to printers or VCRs and downloading to personal computers;
- tissue harmonic imaging, or THI, a signal processing technique providing enhanced image quality by using high frequency information to enhance image resolution; and
- basic electrocardiogram, 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 imaging. 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 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 or video printer for image download through a docking station;
- 2D and color power Doppler; and
- The iLook 15 offers directional color power Doppler and harmonic imaging.

The TITAN, 180PLUS and SonoHeart ELITE utilize seven transducers which are designed for use in the following clinical applications:

- general abdominal and obstetrics imaging;
- intracavitary (gynecologic, urologic) ultrasound imaging;
- neonatal, vascular and pediatric imaging;
- cardiac, thoracic and abdominal imaging, including trauma assessment;
- breast, musculoskeletal, vascular, interventional and small-parts imaging;
- intraoperative and superficial vascular imaging; and
- veterinarian applications (musculosketetal, obstetric, gynecologic, cardiovascular and general imaging).

We also offer the following related accessories and educational programs:

Accessories. We offer a wide selection of accessories for our products. These include mobile docking stations, multiple transducer connections, image transfer and management software, printers, VCRs, auxiliary monitors, storage devices, carrying cases and disposable supplies.

Specialized training and education. SonoSite has partnered with numerous medical societies and other recognized experts in ultrasound education to provide courses for SonoSite customers. These educational offerings include traditional educational courses, including *Imported Courses* which are CME events held at the customer s location, traditional enduring materials, including books and CDs, and *Site Visits*, which allow SonoSite customers to visit with renowned experts. SonoSite also pioneered the development of *OnSite* skill transfer workshops, which use registered sonographers to help customers improve their scanning techniques in the customer s location. In addition, as we develop new and emerging markets, we plan to continue to support the development of 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. In 2004, we plan to establish direct sales operations in Japan, Canada, and Australia. We rely on third-party distributors in those markets where we do not have a direct sales staff.

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., Novation, LLC, Premier, Inc., Broadlane, Inc. (includes Kaiser Permanente, Tenet Healthcare and others) and Consorta, Inc.

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 $52.4 million, or 62%, of our revenue from domestic sales in 2003. This compares to approximately $42.6 million, or 58%, and approximately $23.8 million, or 52%, in 2002 and 2001.

We derived approximately $32.4 million, or 38%, of our revenue from international sales in 2003. This compares to approximately $30.4 million, or 42%, and approximately $21.9 million, or 48%, in 2002 and 2001. Japan accounted for approximately $1.6 million, or 1.9%, of our revenue in 2003. This compares to approximately $7.5 million, or 10%, and approximately $7.8 million, or 17%, in 2002 and 2001. No single customer or distributor accounted for more than 10% of our revenue in 2003. 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. For information regarding revenues and long-lived assets by geography, please refer to note 13 to our consolidated financial statements.

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.

We have one reporting segment. For information regarding revenues from external customers, profits and total assets for each of our last three fiscal years, please refer to our consolidated financial statements.

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 17 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 had the exclusive right to use certain ATL technology existing on April 6, 1998 or developed by ATL during the three-year period following April 6, 1998 in ultrasound systems weighing 15 pounds or less, and ATL had the exclusive right to use our technology existing on April 6, 1998 or developed by us during the same three-year period in ultrasound systems weighing more than 15 pounds. On April 6, 2003, this cross-license became nonexclusive and, except for the patented technology of each party, now extends to all ultrasound systems regardless of weight.

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

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

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

We also have asked the Texas court to stay proceedings in Neutrino s suit filed in the Middle District of Florida on August 19, 2003 against a former SonoSite distributor alleging that the sale of SonoSite s products by such distributor infringes the 021 patent, and to enjoin Neutrino from filing similar suits against other sellers of SonoSite products. Neutrino had previously filed such a suit in the Middle District of Tennessee against another medical device distributor for selling a SonoSite product. That Tennessee case has been dismissed based on a final judgment and permanent injunction filed a month after the case was filed. The Tennessee judgment has no effect on the Texas proceedings. In the Florida action, we have filed a motion to stay the proceedings in the Florida court pending a final resolution of the patent suit in Texas. We have also filed a motion to strike certain counts of Neutrino s complaint.

We believe that we have good and sufficient defenses to the claims of patent infringement asserted against us by Neutrino and we are vigorously defending ourselves in these matters. If we are not successful in our defense of these claims, we could be forced to modify or discontinue selling our products or may enter into royalty or licensing agreements, which may not be available on terms acceptable to us, if at all, and which could adversely affect our financial condition, results of operations and cash flow. Sales of the allegedly infringing products represented the majority of our revenue for the years ended December 31, 2003, 2002 and 2001.

We do not consider a negative litigation outcome to be probable and have not accrued any amounts for potential losses related to these proceedings. Because of uncertainties related to both the amount and range of loss on the pending litigation, management is unable to make a reasonable estimate of the liability that could result from an unfavorable outcome. As additional information becomes available, we will assess the potential liability related to its pending

litigation. We will record accruals for losses if and when we determine the negative outcome of such matters to be probable and reasonably estimable. Our estimates regarding such losses could differ from actual results. Revisions in our estimates of the potential liability could materially impact our results of operations, financial position and cash flow.

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 high-performance, hand-carried ultrasound systems develops, we expect competition to increase as potential and existing competitors enter the hand-carried 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 people in research and development. In 2003, 2002 and 2001, expenses attributable to research and development for our business totaled $11.2 million, $12.1 million and $12.7 million. We believe our products represent the most advanced technology in high-performance, hand-carried 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 we obtain a pre-market notification clearance under Section 510(k) of the Federal Food, Drug & Cosmetic Act prior to introducing our products to the market. By granting 510(k) clearance, the FDA indicates agreement with an applicant s determination that the product for which clearance has been sought is substantially equivalent to medical devices that were on the market prior to 1976 or have subsequently received clearance. The process of obtaining 510(k) clearance typically takes approximately two to three months. To date, all of our products have received 510(k) clearance. We believe that our future generation hand-carried 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. Such foreign regulatory approvals may take up to 6-9 months to obtain. Any delays, or failures, in obtaining such clearances may result in lost sales 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. In September 2000, we provided purchasers of our products with a software upgrade to correct this error, and at the FDA s request, we recently sent two additional letters to these purchasers to provide them with a final opportunity to upgrade the software at no charge. We expect that when this action is completed, we will receive final written closure from the FDA on this matter.

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 on-site inspections to determine compliance with such regulations. The FDA inspected our manufacturing facility in September 2003. In

addition, the British Standards Institution (BSI) performs periodic management systems assessments of our manufacturing processes. 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 has issued 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, SonoHeart ELITE, iLook 15, iLook 25 and TITAN 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.

Compliance with the regulations of 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. 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 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. The warranty liability is summarized as follows (in thousands):

	Balance at beginning of year	Charged to cost of revenue	Applied to liability	Balance at end of year
Year ended December 31, 2003	$ 331	$ 351	$ (301)	$ 381
Year ended December 31, 2002	$ 281	$ 300	$ (250)	$ 331

Employees

As of December 31, 2003, we had approximately 340 employees, of which approximately 16% were engaged in research and product development, 23% in manufacturing, 49% in sales and marketing activities and the remaining 12% in administrative capacities, including executive, finance, legal, human resources, regulatory and information services and technology. Of these, approximately 290 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.

Available Information

We were incorporated in the state of Washington in July 1986 and were spun off from ATL as an independent, publicly owned company in April 1998. 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. Our Code of Conduct, which is our written Code of Ethics under Section 406 of the Sarbanes-Oxley Act of 2002, is also available on our website.

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

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

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

In June 2003, we began shipping to customers our newest product, the SonoSite TITAN ultrasound system. Sales of TITAN accounted for approximately 28% of our revenue for the year ended December 31, 2003. The TITAN system has a modular design allowing both stationary and mobile usage and is based on the next generation of our proprietary ASIC, or application specific integrated circuit, technology. Along with the point-of-care market, we have positioned the TITAN system to compete in the traditional stationary ultrasound cart market.

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

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

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

- greater financial and infrastructure resources;

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

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

In addition, as the market for high-performance, hand-carried ultrasound systems develops, we expect competition to increase as potential and existing competitors enter the point-of-care market or modify their existing products to more closely approximate the combined portability, quality, performance and cost of our products. Our current competitors in the point-of-care market include 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 high-performance, hand-carried ultrasound market, we will be unable to generate sufficient revenue to maintain our business.

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

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

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

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

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

Trends toward managed care, 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.

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

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

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

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

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

Alternatively, specific types of ultrasound products could be targeted for exclusion from coverage under the existing ultrasound codes. As an example, in the first half of 2003, six Medicare carriers adopted policies that precluded Part B Medicare reimbursement for ultrasound procedures conducted with hand-carried ultrasound units described as lightweight ultrasound machines with Doppler capability. The notices restricted coverage for devices that allow only a

limited view of structures. These policies applied to Medicare reimbursement of health care providers in 22 states, including California and upstate New York.

In all states, these policies have been revised to allow payment for studies performed with hand-carried ultrasound units. The new policies, recognizing that many hand-carried ultrasound systems have functionality equal to that of cart-based ultrasound systems, define the requirements of medical necessity, completeness and documentation required of all ultrasound services, regardless of the equipment that is used to supply the service. In all states, there are no longer any billing restrictions in place for hand-carried ultrasound that do not also exist for cart-based ultrasound and that were not in place prior to the adoption of these original policies.

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

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

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

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

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

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

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

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

In March 2003, one of our component suppliers, Philips Semiconductor, or Philips, informed us that, commencing in September 2003, it would discontinue production of our integrated circuit chips using 0.35-micron technology. We have designed and implemented a new chip using 0.2-micron technology that will continue to be produced by Philips to replace all but one of the discontinued chips. We expect to design and implement an additional new chip to replace the remaining 0.35-micron chip by early 2005. In the second quarter of 2003, we entered into a purchase commitment totaling approximately $3.6 million for supplies of 0.35-micron chips from Philips for our anticipated manufacturing needs until new chips have been incorporated in all of our products. We pay for these chips at the time deliveries are made to us. As of December 31, 2003, our remaining purchase commitment was approximately $3.4 million. On December 31, 2004, we are required to take possession of, and pay for, the balance of the undelivered chips. Demand for our products, however, may exceed our forecasts, in which case we would require additional 0.35-micron chips to manufacture additional products. Conversely, if demand for our products falls short of our forecasts, we may experience excess inventory of 0.35-micron chips. If our actual demand for these chips varies significantly from our forecasted demand, we may experience delays in manufacturing, lost sales, a write-down of inventory or a deterioration in gross margin.

In addition, we have transferred the production of our main circuit board to one of the world s largest electronic manufacturing services suppliers who will produce the board in their Thailand manufacturing facility. We expect this transfer to be completed by the end of the first quarter of 2004 with production deliveries beginning in the following quarter. If, as a result of this transfer, we experience delays in the receipt of this component, a deterioration in product yields or an increase in costs, we may experience delays in manufacturing, lost sales or a deterioration in gross margin.

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

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

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

The manufacture and sale of our products are subject to extensive regulation by numerous governmental authorities, principally the FDA, as well as several other state and foreign agencies. The FDA requires that we obtain a pre-market notification clearance under Section 510(k) of the Federal Food, Drug & Cosmetic Act prior to introducing our products to the market. By granting 510(k) clearance, the FDA indicates agreement with an applicant s determination that the product for which clearance has been sought is substantially equivalent to medical devices that were on the market prior to 1976 or have subsequently received clearance. The process of obtaining 510(k) clearance typically takes approximately two to three months. To date, all of our products have received 510(k) clearance. In addition, foreign regulatory agencies also

require similar pre-market clearance or registration before our products can be marketed or offered for sale in their countries. Such foreign regulatory approvals may take up to 6-9 months to obtain. Any delays, or failures, in obtaining such clearances may result in lost sales.

In addition, the FDA requires us and our key medical device suppliers to demonstrate and maintain compliance with the FDA s Quality System Regulation, or QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, shipping and servicing of our products. The FDA enforces the QSR through periodic inspections; the FDA inspected our manufacturing facility in September 2003. In addition, the British Standards 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. In September 2000, we provided purchasers of our products with a software upgrade to correct this error, and at the FDA s request, we recently sent two additional letters to these purchasers to provide them with a final opportunity to upgrade the software at no charge. We expect that when this action is completed, we will receive final written closure from the FDA on this matter.

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

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