SONOSITE INC
Form 10-K
March 12, 2009
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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, 2008

OR

¨ 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:

None

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

Common stock, $0.01 par value

Indicate by check mark if the registrant is a well-known seasoned issuer (as defined in Rule 405 of the Securities Act). Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

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. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2). Yes ¨ No x

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, 2008 as reported on the Nasdaq National Market, was $472,586,905.

As of February 19, 2009, there were 17,071,582 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 2009, 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.

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SONOSITE, INC.

ANNUAL REPORT ON FORM 10-K

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Trademarks

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PART I

Our disclosure and analysis in this report and in our 2008 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, future 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 Risk Factors 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 the world leader in hand-carried ultrasound, or HCU, systems. We specialize in the development of HCU systems for use in a variety of medical specialties in a range of clinical settings at the point-of-care. Our proprietary technologies have enabled us to design HCU systems that combine high resolution, all-digital, broadband imaging with advanced features and capabilities typically found on cart-based ultrasound systems. We believe that the performance, size, durability, ease of use and cost-effectiveness of our products are expanding existing ultrasound markets, and are opening new markets by bringing ultrasound visualization out of the imaging lab to the point-of-care such as the patient s bedside or the physician s examining table for diagnosis and procedural guidance.

The large size, weight 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. Our strategic intent is to enable clinicians to use ultrasound in a variety of clinical settings by developing each potential market based on three fundamental tenets: (i) the design of high performance system hardware, software and transducers with application-specific settings and capabilities; (ii) the provision of educational training that ensures appropriate use of the equipment in the clinical setting; and (iii) the support of professional institutions and ultrasound thought leaders in the completion of use protocols and clinical research that accelerates the adoption of HCU to improve patient

outcomes. By providing ultrasound at

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the primary point-of-care, our systems expedite diagnosis and treatment in acute and critical care settings and provide visual guidance for interventional procedures. In outpatient settings, our systems can eliminate delays associated with the outpatient referral process. This increased accessibility is changing clinical practice, improving patient care and safety and has the potential to reduce healthcare costs through earlier diagnosis of diseases and conditions.

We design our products for applications where ultrasound has not typically been used such as emergency medicine, surgery, critical care, internal medicine and vascular access procedures as well as for imaging in traditional applications, such as radiology, cardiology, vascular medicine and obstetrics and gynecology (OB/Gyn). In addition, the U.S. military has successfully deployed our systems in traditional hospital settings, field hospitals and forward surgical teams in war zones and areas of conflict. We began shipping our first products in September 1999 and today have an installed base of approximately 50,000 systems worldwide.

Our fourth generation product platform is the basis of two product lines, the M-Turbo® system and the S Series ultrasound tools, which we introduced in October 2007. These products together with the MicroMaxx® system, our third generation of hand-carried technology and introduced in 2005, offer a broad-based product portfolio for hospital and physician office markets. Based on our proprietary Application Specific Integrated Circuit (ASIC) technology for high-resolution ultrasound imaging these systems offer image resolution comparable to costly, conventional cart-based ultrasound systems weighing over 200 pounds. A five-year warranty covering the system and SonoSite-manufactured transducers, comes standard with these products. In 2008, we introduced major upgrades for both the M-Turbo and S Series product lines which increased performance and expanded clinical capabilities. Additionally we introduced a specialized configuration of the M-Turbo product for the OB/Gyn market, and expanded the S Series product line by introducing customized configurations to address the musculoskeletal, gynecology, veterinary, and vascular access markets.

Our second generation product, the TITAN® system, began shipping in 2003. This system addresses point-of-care and traditional ultrasound markets. Our first generation of products includes the 180 and iLook® series. The SonoSite 180PLUS system is designed for general ultrasound imaging and the SonoHeart® ELITE is 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 imaging of the chest and abdomen.

We commenced operations as a division of ATL Ultrasound, Inc., or ATL (now a part of Philips Medical Systems). On April 6, 1998, we became an independent, publicly owned company through a distribution of one new share of our stock for every three shares of ATL stock held as of that date. ATL retained no ownership in SonoSite following the spin-off.

Medical Ultrasound Imaging

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 time intensive, invasive and expensive procedures and allowing for earlier diagnosis of diseases and conditions. Further, it does not expose the patient to ionizing radiation that is present in X-ray and computed tomography technology. To generate an ultrasound image, a clinician places the transducer on the skin or in a body cavity near or by the targeted area of interest. Tissues and bodily fluids reflect the sound waves emitted by the transducer, which then 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. Broadband 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.

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Standard ultrasound imaging produces a two-dimensional image, known as grayscale or 2D imaging, which physicians use to diagnose, stage and monitor disease states and conditions. Color Doppler technology expands standard ultrasound imaging by generating a colorized image showing the presence and direction of blood flow. Through the use of software algorithms in the ultrasound system, clinicians can provide a quantitative assessment of anatomical structures and physiological functions such as blood flow velocity and cardiac ejection fraction.

Our Markets

According to a report by InMedica, a market research company that focuses on the medical device industry, the worldwide ultrasound market for HCU was $615.7 million in 2008, excluding upgrades and services. In the report, InMedica projected that the HCU market would grow to $1.2 billion in 2012, representing a compounded annual growth rate of approximately 18.4%. According to the report, HCU is the fastest growing sector of the ultrasound market and is being driven by the identification of new clinical applications and expansion into new geographic regions.

Our markets can be classified by location and clinical application. From a location perspective, we see our growth continuing to come from further penetration into the hospital market, the major source of our revenue today. Additionally, we see strong future growth opportunities from sales into the clinic or physician s office, as well as into alternate care sites. On a clinical application basis, within the hospital, we see accelerating growth in non-traditional or point-of-care ultrasound markets such as anesthesia and critical care. In the clinic or private practice office setting, despite the current economic condition we believe that slower growth in the more competitive markets, such as radiology, cardiology and OB/Gyn, will be balanced by accelerating growth trends and interest in outpatient physician office settings. We consider the use of HCU in the military and disaster settings as promising opportunities, as well as expanded use in mobile screening services and other non-clinical sites.

Our Strategy

Our goal is to lead in the design, development and commercialization of high-performance, innovative ultrasound technology and HCU systems. We plan to increase our share in markets that we currently serve and also seek growth by entering new markets with significant opportunities. Our strategy to achieve our objectives consists of the following key elements:

Continue to lead the HCU market by building upon and expanding product and technology leadership. We believe our products represent the most advanced and innovative technology available in HCU systems. We are committed to continuing to expand this technological advantage by further enhancing our existing products and creating new ones. As of December 31, 2008, we employed approximately 120 people in research and development. Since our inception in 1998, we have introduced four generations of our hand-carried technology, which have improved performance and expanded clinical capabilities of our systems. The M-Turbo system and S Series ultrasound tools, our fourth generation products based on ASIC technology, provide scalable technology platforms that will enable us to deliver products to specific clinical applications that vary by size, cost and performance.

Maximize the productivity of our direct sales force. As of December 31, 2008, we employed over 100 direct sales representatives in the U.S., Australia, Canada, France, Germany, Italy, Japan, Spain and the United Kingdom. To further enhance the productivity of our direct sales force, we will continue to:

- invest in training and educating our sales force;
- maximize sales to our installed base;
- provide education to increase market awareness and generate new customer leads; and
- expand our strategic alliances.

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Expand our strategic alliances. We believe that other markets offer opportunity for growth, but will require enhancements to our sales distribution channels. We intend to enter into new strategic alliances to develop markets within ultrasound or with ultrasound-dependent technologies. We believe that strategic alliances can accelerate market penetration to customers not currently served by our direct sales force.

Drive our technology across the point-of-care spectrum. We believe that the performance, mobility, durability and cost effectiveness of our products are resulting in the creation of new clinical markets for us. We are expanding the use of ultrasound beyond the imaging center to the patient point-of-care, such as the emergency room, the physician s office and other non-traditional ultrasound settings. With our SonoCalc® IMT software, which allows physicians to measure the wall thickness (known as the IMT) of the carotid artery, we have taken initial steps to enter the market for cardiovascular disease management. We believe that new markets like these will offer us significant potential for additional growth.

Acquisition of complimentary companies, products or technology. We believe that the acquisition of one or more medical device companies, products or technologies could expand our product portfolio and sales channels, create international operating leverage, improve marketing and other efficiencies and leverage manufacturing and supply chain economics.

Our Products

Our product portfolio consists of the M-Turbo system, the S Series ultrasound tools, the MicroMaxx system, the TITAN system, the 180 series and the iLook series. All SonoSite ultrasound systems offer a digital beamformer, broadband imaging, an integrated color display, a control panel, an alphanumeric keyboard and multiple caliper measurement tools. With the exception of the iLook series (which supports color power Doppler only), each of the systems provides 2/D velocity color Doppler, color power Doppler, M-mode, pulse wave and continuous wave Doppler imaging. All systems (except for the iLook) can be used with certain transducers that are capable of providing Tissue Harmonic Imaging, which uses high frequency imaging to optimize gray scale differentiation and optimize overall image quality. All systems (except for iLook) support basic ECG (electrocardiogram) synchronization to image gathering, essential for understanding cardiac cycle and anatomical variations. Image storage, image documentation to video printer or video recorder and direct personal computer connectivity are available on all SonoSite platforms. All systems are capable of operating on battery power when needed and are designed for the rigors of mobile use. We make and sell a broad array of transducers to use with our systems to address a full range of clinical applications.

In addition to the above, the M-Turbo, MicroMaxx and TITAN systems support dual screen imaging for comparative imaging. These systems can be used for stationary applications in a Mobile Docking Station (MDS), which supports connectivity to hospital information systems, multiple transducer connections and on-board documentation devices. The systems can be easily removed from the docking station to be hand-carried to the point-of-care. Unlike recently introduced convertible ultrasound products, the MDS does not contain any system electronics. All SonoSite systems are fully functional in all portable exam environments, whether or not connected to a docking station.

The following is a summary of our ultrasound product platforms:

M-Turbo System and S Series Ultrasound Tools. The M-Turbo and S Series products, first shipped in December 2007, deliver an exponential increase in processing power for superior image clarity across all exam types, plus seamless connectivity for digital image export in a rugged, easy to use form factor. Clinicians can export images easily to a USB storage device in standard PC formats for review or storage on a Windows® PC or Mac® computers.

The M-Turbo system, at 7.5 pounds and a complement of 14 transducers, can be configured for the full range of clinical and procedural guidance applications at the point-of-care including abdominal, nerve, vascular, cardiac, venous access, small part and superficial imaging.

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The S Series are the first ultrasound tools customized to specific clinical applications and designed to be wall or ceiling mounted or can be used from a stand. With the S Series products, clinicians need only to manipulate two controls depth and gain to get the image they need. Transducers, exam settings, software and algorithms are all specialized for the specific clinical application. Weighing 9.4 pounds, the S Series ultrasound tools S-FAST for emergency medicine, S-Nerve for regional anesthesia, S-ICU for critical care and S-Cath for interventional radiology and cardiac cath labs. In 2008, SonoSite introduced the S-MSK for musculoskeletal applications, the S-GYN and S-Women s Health.

Transducers are interchangeable between the M-Turbo and S Series product lines. A 5-year warranty comes standard on the system and most of the transducers. These systems may be upgraded with purchased software features that can be added through a USB drive.

MicroMaxx System. The MicroMaxx system, first shipped in June 2005, weighs 7.6 pounds (with battery). It has 14 transducers and can be configured for use in anesthesia, cardiology, critical and acute care, emergency medicine, OB/Gyn, preventive cardiology, radiology, surgery and vascular applications. A 5-year warranty comes standard on the system and most of the transducers.

SonoSite TITAN. The TITAN system, first shipped in June 2003, weighs 7.5 pounds. Like the MicroMaxx system, the TITAN system features a larger display screen than the 180 or iLook products and has removable memory flashcards for enhanced image or study storage.

SonoSite 180 Series. The 180 Series consists of the 180PLUS and SonoHeart Elite, each weighing approximately 5.4 pounds. The SonoSite 180PLUS system is a point-of-care ultrasound system for general diagnostic and procedural assistance imaging. It was our initial product that created the hand-carried ultrasound category. The SonoHeart ELITE system is a point-of-care ultrasound system with expanded measurement tools and clinical analysis packages intended for use by cardiologists and other healthcare providers in the cardiology or bedside assessment market. The SonoHeart ELITE has all the product features of the SonoSite 180PLUS.

iLook Series. The iLook series consists of the iLook 15 and 25, each weighing approximately 3 pounds. The iLook 15 tool, with its fixed curved array transducer, provides imaging for focused abdominal and cardiac applications. The iLook 25 tool, with its fixed linear transducer, enables the clinician to visualize a patient s vessels to aid in vascular access applications.

We also offer accessories and clinical education programs including:

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, video recorders, auxiliary monitors, storage devices, carrying cases and disposable supplies.

Specialized training and education. We develop education programs independently and in partnership with numerous medical societies and other recognized experts in ultrasound education to provide courses for our customers through the SonoSite Institute for Training and Education. We have pioneered a unique online education site, which has been developed for the benefit of existing customers in the traditional and emerging markets that are new to the routine use of ultrasound. Additionally, with the introduction of the M-Turbo and S Series we developed the Education Key program a USB thumb drive that contains a combination of system operation video tutorials, application-specific video refresher programs that provide peer-to-peer instruction on how to perform specific exams and procedures and an image reference library of application specific sonographic anatomy for comparison purposes. As we develop new and emerging markets, we plan to continue to support the development of accredited and market-specific training materials, and expand the use of workshops in conjunction with recognized leaders in ultrasound.

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Sales and Marketing

We currently sell our products through sales channels comprised of direct sales force, independent third-party distributors, and strategic alliances. As of December 31, 2008, we employed over 100 direct sales representatives in the U.S. and in our wholly-owned subsidiaries located in Australia, Canada, France, Germany, India, Italy, Japan, Spain, and the United Kingdom. In addition to our direct sales, we sell products in over 100 countries through a network of independent third-party distributors. In addition, we employ regional distribution managers responsible for Africa, Asia, China, Europe, Middle East, and Latin America.

In the U.S., we have complemented our direct sales efforts by entering into group purchasing agreements with major healthcare group purchasing organizations (GPO). Currently, we have GPO supply agreements with various groups including Amerinet, Inc., Broadlane, Inc. (includes Kaiser Permanente, Tenet Healthcare and others), HealthTrust Purchasing Group, MedAssets HSCA, Inc., Novation LLC, and Premier, Inc. We also have two supply agreements with the U.S. government, specifically with the Defense Supply Center of Philadelphia and the Veteran s Administration. In the United Kingdom, we have a supply agreement with the Purchasing and Supply Agency of the National Health Service, which contracts on a national basis for the purchase of products and services.

We derived 48% of our revenue from domestic sales in 2008 compared to 51% in 2007 and 52% in 2006. We attribute revenue to a foreign country based on the location to which we ship our products. Products sold to the U.S. government but deployed in a foreign country are attributed to domestic revenue. Our quarterly revenue is affected by seasonality from year to year with the fourth quarter having the highest revenue, and first quarter being typically the lowest. Quarterly revenue patterns may be affected somewhat by large government orders or shipment of product inventory to new distributors. We currently have one reporting segment. For information regarding revenues and long-lived assets by geography, refer to Note 16 of 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 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, filing patent applications to protect our technology. We hold 27 U.S. patents relating to various aspects of our products, including digital beamformers, beamforming capabilities, digital conversion circuitry, transceiver circuitry, designs and circuit integration. We hold 32 foreign patents relating to our products, and we currently have 42 patent applications pending in the U.S. and 46 pending registrations abroad.

We license ultrasound technology from ATL under a Technology Transfer and License Agreement executed at the time of our spin-off as a public company in 1998. 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 U.S. 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.

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In order to protect or enforce our patent rights, we may initiate patent litigation. Additionally, others may initiate patent litigation against us. For further description of our litigation and the status of these proceedings, see Item 3, Legal Proceedings.

Competition

We currently face competition from companies that manufacture cart-based and portable ultrasound systems. Many of our competitors are larger and have greater resources than we do and offer a range of products broader than our products. The dominant competitors in this industry are GE Healthcare, a unit of General Electric Company (GE Healthcare), Siemens Medical Solutions (Siemens) and Philips Medical Systems, a division of Koninklijke Philips Electronics, N.V. (Philips). In addition, as the market for high-performance, HCU systems develops, we expect competition to increase as potential and existing competitors enter the portable 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 portable market include Siemens, GE Healthcare, Mindray Medical International Limited, Philips, Biosound Esaote, Inc., Terason, a division of TeraTech Corporation (Terason), Ultrasonix Medical Corporation, and Zonare.

Research and Development and Technology

We currently employ approximately 120 people in research and development. In 2008, 2007 and 2006, expenses attributable to research and development for our business totaled $28.7 million, $25.9 million and $20.2 million. We believe our products represent the most advanced and innovative technology in high-performance, HCU 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.

Manufacturing

Final assembly and testing of all products is done in our facility in Bothell, Washington. We depend on suppliers, including some single-source suppliers, to provide highly specialized parts and subassemblies, such as custom-designed integrated circuits, circuit boards, 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, (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, but it can take significantly longer. To date, all of our products have received 510(k) clearance.

Many of the regulations applicable to our products in foreign countries are similar to those of the FDA. Some foreign regulatory agencies 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 be longer or shorter than that required for FDA clearance and the requirements may differ significantly. The national health or social security organizations of certain countries may additionally require our products to be qualified before they can be marketed in those countries. We cannot be assured that such clearances will be obtained.

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We are subject to regulations in each of the foreign countries in which we sell products. Currently, our products bear a CE Mark, which indicates that our products comply with the requirements of the applicable European Union Medical Device Directive. Medical devices properly bearing the CE marking may be commercially distributed throughout the European Union. We have received certification from the British Standards Institute (BSI) for conformity with certain quality system standards allowing us to place the CE mark on our product lines. The quality system has been developed by the International Organization for Standardization to ensure that companies are aware of the standards of quality to which their products will be held worldwide. While no additional pre-market approvals in individual European Union countries are required prior to marketing a device bearing the CE marking, practical complications with respect to marketing introduction may occur. For example, differences among countries have arisen with regard to labeling requirements. We may not be successful in maintaining certification requirements necessary for distribution of our products in the European Union and failure to maintain the CE marking will preclude us from selling our products there.

To ensure that manufacturers adhere to good manufacturing practices, medical device manufacturers are routinely subject to periodic inspections by the FDA and may be inspected by foreign regulatory agencies from countries in which we do business. In addition, the BSI performs periodic assessments of our manufacturing processes.

Reimbursement

In the U.S., the Center for Medicare and Medicaid Services (CMS), has established rules governing the reimbursement for ultrasound and other healthcare services to healthcare providers treating Medicare patients. Under current CMS rules, payment amounts and conditions of coverage for ultrasound are generous enough to allow physicians to incorporate the use of ultrasound into their practice when clinically appropriate. Private insurance policies, based largely on Medicare policies, also currently support the continued use and adoption of ultrasound. The use of our products outside the U.S. is similarly affected by reimbursement policies adopted by foreign regulatory agencies and insurance carriers. For additional consideration of risks associated with Reimbursement, see Item 1A, Risk Factors.

Service and Warranty

Our warranty period is five years for the M-Turbo, S Series, and MicroMaxx systems. Our warranty period for our other products is one year. The warranty is included with the original purchase. In addition to our standard warranty, we offer extended warranty agreements for maintenance beyond the standard warranty period or for coverage above what is provided under the standard warranty. We repair equipment that is out of warranty on a time and materials basis. The warranty liability is summarized as follows (in thousands):

	Beginning of year	Charged to cost of revenue	Applied to liability	End of year
Year ended December 31, 2008	$ 4,045	$ 4,773	$ (1,724)	$ 7,094
Year ended December 31, 2007	$ 2,318	$ 3,160	$ (1,433)	$ 4,045
Year ended December 31, 2006	$ 995	$ 2,397	$ (1,074)	$ 2,318

Employees

As of December 31, 2008, we had approximately 640 employees, of which approximately 19% were engaged in product research and development, 22% in manufacturing, 45% in sales and marketing activities and the remaining 14% in administrative capacities, including executive, finance, legal, human resources, regulatory and information services and technology. Of these, approximately 470 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.

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Available Information

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://www.sonosite.com and then click on About SonoSite then For Investors . 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.

ITEM 1A. RISK FACTORS.

Our operations and cash flows are subject to various risks and uncertainties, including those described below, which could adversely affect our business, financial condition, and the trading price of our common stock.

Current economic conditions have had and may continue to have an adverse impact on our business.

Global economic conditions directly influence our operating results. Current and future economic conditions that affect consumer healthcare spending as well as physician and hospital spending, including the level of unemployment, inflation, availability of credit, and the financial condition and growth prospects of our customers may adversely affect our business and results of operations. Additionally, if our suppliers face challenges in obtaining credit, in selling their products or otherwise in operating their businesses, they may become unable to continue to offer the materials we use to manufacture our products, which may adversely affect our business and results of operations.

We may face significant challenges if global economic conditions do not improve or continue to worsen, including reduced demand for our products and services, increased order cancellations and longer sales cycles and slower adoption of new technologies; increased difficulty in collecting accounts receivable and risk of excess and obsolete inventories; increased price competition in our served markets; supply chain interruptions, which could disrupt our ability to produce our products; and increased risk of impairment of investments, goodwill and intangible and long-lived assets.

Currency exchange rate fluctuations in various currencies in which we do business and longer receivables collection periods outside of the United States could adversely affect our business.

Total sales denominated in a currency other than USD were $78.2 million, or 32% of our total consolidated revenues for the year ended December 31, 2008. As a result, our results of operations could be adversely affected by certain movements in exchange rates. Although we take steps to hedge a substantial portion of our foreign currency exposures, there is no assurance that our hedging strategy will be successful or that the hedging markets will have sufficient liquidity or depth for us to implement our strategy in a cost effective manner.

Additionally, as of December 31, 2008, 66% of our accounts receivable balance was from international customers, of which 56%, or $24.1 million, was denominated in a currency other than USD. Although we regularly review our receivable positions in foreign countries for any indication that collection may be at risk, our revenue from international sales may be adversely affected by longer receivables collection periods and greater difficulty in receivables collection.

We may be unable to expand the market for our products to new applications and new users, which could limit our ability to grow our business.

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. Our market focus, and we believe our greatest growth opportunities, will come from new point-of-care clinical applications and new users of ultrasound. Any new users of ultrasound will not only require training and education to properly administer ultrasound examinations but

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also must develop an appreciation of the treatment value of our products so that our products will become successfully integrated into their day-to-day practices. Although we have spent, and will continue to spend, considerable marketing resources educating potential customers about the value of HCU products in new applications, our efforts may be unsuccessful. If these potential customers are unable or unwilling to be trained due to cost, time constraints, unavailability of courses or other reasons, or if they consider our products nonessential to their medical practices, our ability to expand the market for our products and to increase our revenues could be limited.

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

In October 2008, we ended negotiations with an acquisition candidate. However, we intend to continue exploring the possible acquisition of one or more medical device companies or medical device products or technologies in an effort to expand our product portfolio, expand our sales channels, create international operating leverage, improve marketing and other efficiencies and leverage manufacturing and supply chain economics. If we are unable to identify suitable acquisition candidates or to successfully consummate and integrate acquisitions into our business, our ability to grow our business may be affected.

Any acquisition we do complete may be costly and difficult and we may experience:

- difficulty in integrating operations, including combining teams and processes in various functional areas;
- delays in realizing the benefits of the acquired company or technology;
- limited market acceptance of acquired products or technology;
- diversion of our management s time and attention from other business concerns;
- lack of or limited direct experience in new markets we may enter;
- difficulties in obtaining regulatory approvals or reimbursement codes for acquired technologies;
- increased risk of product liability actions from acquired products or technologies;
- additional costs, including fees and expenses of professionals involved in completing the integration process; and
- unexpected costs associated with existing liabilities of any acquired business.

In addition, an acquisition could materially impair our operating results by causing us to incur additional debt or requiring us to incur one-time charges. 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.

If healthcare reimbursement policies place limits on which providers may receive payment for imaging services or substantially reduce reimbursement amounts or coverage for specific procedures, market acceptance of our products may be reduced.

Continued demand for our products depends in part on the extent to which our customers continue to receive reimbursement for the use of our products from third-party payers such as Medicare, Medicaid and private health insurers (and equivalent third-party payers in foreign countries).

Presently, reimbursement policies for physician-performed diagnostic imaging services are fairly unrestricted in the United States and payment levels are sufficient to enable providers to recoup the costs of purchasing ultrasound systems in a reasonable timeframe. The continuing efforts of governmental authorities, private health insurers and other third-party payers to contain or reduce the costs of healthcare could, however, result in reduced payment for imaging services or more restrictive payment policies for diagnostic imaging. Some private insurers have implemented imaging privileging

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programs as a means of controlling utilization of imaging services. Finally, both governmental and private third-party payers are calling for increasing amounts of clinical evidence of beneficial patient outcomes in addition to proof of clinical efficacy as a prerequisite to granting new or continued coverage for technologies and devices.

We may be unable to compete effectively and could fail to generate sufficient revenue to maintain our business.

Competition in the cart-based and portable ultrasound systems market is very significant. Our main competitors in this industry are GE Healthcare, Siemens, and Philips. These companies are very large global organizations that have the following competitive advantages over us:

- significantly 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 existing and potential customers.

These manufacturers of cart-based and portable ultrasound systems could use their greater resources to further increase the level of competition in the market through various means, including:

- price and payment terms that we are unable to match;
- marketing strategies that bundle the sale of portable systems with other medical products that we do not sell;
- technological innovation;
- market penetration and hospital systems integration that we cannot match;
- employee compensation that we cannot match; and
- complementary services such as warranty protection, maintenance and product training that are outside of the scope of our product offerings.

Existing product supply relationships between these competitors and our potential customers could adversely impact the level or rate of adoption of our products due to brand loyalty or preferred customer discounts. Competing portable or traditional cart-based ultrasound devices may be more accepted or cost-effective than our products. 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 within the cart-based and HCU markets, we could experience delayed or reduced market acceptance of our products, higher expenses and lower revenue.

We expect the market for high-performance HCU products and the competition in the HCU market will continue to increase as new and existing competitors enter the portable ultrasound market or modify their existing products to more closely approximate the combined portability, quality, performance and cost of our products. If we are unable to compete effectively with current or new entrants to the high-performance HCU market, we will be unable to generate sufficient revenue to maintain our business.

If our relationships with our distributors are unsuccessful, our ability to sell our products could be limited.

We currently depend on distributors to help promote market acceptance and demand for our products in countries in which we do not have a direct sales force. Distributors that are in the business of selling other medical products may not devote a sufficient level of resources and support required to generate awareness of our products and grow or maintain product sales. If our distributors are unwilling or unable to market and sell our products, or if they do not perform to our expectations, we could experience delayed or reduced market acceptance and sales of our products.

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In addition, disagreements with our distributors or non-performance by these third parties could lead to costly and time-consuming litigation or arbitration and disrupt distribution channels for a period of time and require us to re-establish a distribution channel.

We may be unable to effectively develop new and innovative products and product features that achieve market acceptance, which could result in our products becoming technologically obsolete in the ultrasound market.

Because substantially all of our revenue comes from the sales of our existing HCU systems and related products, in order to remain competitive, our future financial success will depend in large part upon our ability to successfully invent, deliver and market new and innovative products and product features. In 2008 and 2007, we released several new products, including the M-Turbo system and the S Series ultrasound tools which are customized for different clinical applications. The development of new, technologically advanced products and product features is a complex and uncertain process requiring great innovation and the ability to anticipate technological and market trends and needs. We may be unable to achieve or maintain market acceptance of any new products we develop, and we may be required to expend more costs than anticipated to successfully introduce these products. Without successful product innovation and market introduction of new offerings and improvements, our products will become technologically obsolete and we will be unable to compete effectively in the ultrasound market. Even with successful innovation and development, we cannot assure you that revenues from the sales of our HCU systems will continue to remain at or above current levels or that we will continue to be financially profitable.

Because technology innovation is complex, it can require long development and testing periods. If the launch of new products or product improvements is delayed for any reason, our business may be adversely affected. Factors which could cause delays in our product development or release schedules or cancellation of our product development projects include:

- research and development challenges;
- defects or errors in newly developed products or software for those products;
- third-party intellectual property rights that preclude us from pursuing a new product design; and
- the availability, cost and performance of supplies and components needed for new products.

We may experience delays in our innovation cycle, and in the scheduled introduction of future new products. Any such delays could adversely affect our ability to compete effectively in the ultrasound market and could adversely affect our operating results.

Existing or potential intellectual property claims and litigation either initiated by or against us 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. For example, in 2009, we initiated a lawsuit against Zonare Inc. for patent infringement, a case which settled in 2008.

Others may initiate patent litigation against us. For example, in 2007 and again in 2008, GE Healthcare initiated patent litigation against us, alleging that we infringed several of their patents, and attempting to invalidate one of our key patents (for a discussion of these matters, see Item 3, Legal Proceedings). If we fail to successfully defend claims against us, we may be required to pay monetary damages (including treble damages) and, unless we are able to redesign our products to avoid infringing the asserted patents or to license proprietary rights from them, we may be prevented from continuing to market and sell certain of our products, sales of which represent a substantial portion of our total revenue. If this outcome were to occur, we may be unable to redesign our products in a timely and cost effective manner, and licensing proprietary rights may not be possible on commercially reasonable terms, if at all. Even if we are successful in defending these actions and in proving infringement, we will incur substantial costs that could adversely affect our financial condition and the actions will be distracting to management.

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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.

We may be liable for infringing the intellectual property of others as there could be existing patents of which we are unaware, or pending applications of which we are unaware which may later result in issued patents, that one or more of our products may infringe.

We may also become involved in the defense and prosecution, if necessary, of intellectual property suits, patent interferences, opposition proceedings and other administrative proceedings.

Involvement in intellectual property claims and litigation, including those described above, could have significant adverse consequences, including:

- diversion of management, scientific and financial resources;
- exposure to significant adverse judgments and financial liabilities;
- substantial litigation costs;
- product shipment delays and lost sales;
- inability to design around third party patents;
- modification of our products; or
- discontinuation of product sales.

If we are unable to protect our patents and proprietary rights, we may be unable to compete effectively and we may lose sources of revenue.

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. 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. Third parties may infringe or misappropriate our intellectual property, which could harm our business.

We currently hold 59 U.S and foreign patents relating to our technology. A number of other patents are pending in the United States and in foreign jurisdictions. Although we enter into confidentiality agreements with our employees, consultants and strategic partners, and generally control access to and distribution of our proprietary information, the steps we have taken to protect our intellectual property may not prevent misappropriation. In addition, we do not know whether we will be able to defend our proprietary rights since the validity, enforceability and scope of protection of proprietary rights is still evolving.

Policing unauthorized use of our intellectual property is difficult, costly and time-intensive. 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.

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

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

- major third-party payers of hospital and non-hospital based healthcare services, including Medicare, Medicaid and private healthcare insurers, are considering revising their payment methodologies which may result in stricter standards for reimbursement of imaging charges and/or a lower or more bundled payment;
- numerous legislative proposals have been considered that would result in major reforms in the U.S. and foreign healthcare systems that could harm our business;
- there has been a consolidation among healthcare facilities and purchasers of medical devices in the United States and foreign countries who prefer to limit the number of suppliers from whom they purchase medical products, and these entities may decide to stop purchasing our products or demand discounts on our prices;
- there is economic pressure to contain healthcare costs in worldwide markets; and
- there are proposed and existing laws and regulations in domestic and international markets regulating pricing and profitability of companies in the healthcare industry.

These trends could lead to pressure to reduce prices for our products and could cause a decrease in the size of the market that could adversely affect our revenue and profitability, which could harm our business.

We may be unable to predict our sales and plan manufacturing requirements with accuracy, which may adversely affect our operating results.

Our customers typically order products on a purchase order basis. In some 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 and could result in over or under production, which could lead to higher expense, lower than anticipa