ENDOCARDIAL
SOLUTIONS

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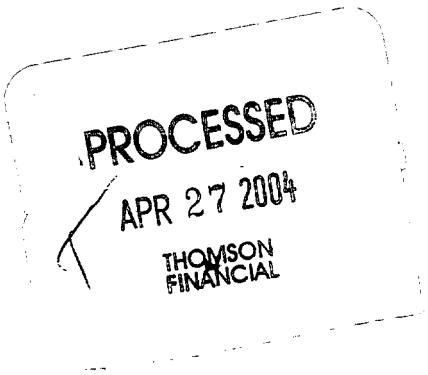
GUIDING THE DIRECTION OF CARDIAC THERAPIES ANNUAL REPORT 2003



One System, Any Arrhythmia

One of Endocardial Solutions' most significant milestones was the introduction of our EnSite NavX advanced navigation and visualization platform in the second quarter of 2003. EnSite NavX surface electrode patches are applied at several locations on the body. Electrical signals are transmitted between the patches; catheters sense the signals to compute their location within the heart. The physician then sweeps a catheter across the heart chamber to create a geometry of the cardiac structures and generate a 3-D computer model of the heart chamber.

EnSite NavX enables physicians to visualize and navigate a myriad of intracardiac catheters in any chamber of the heart. It also simultaneously displays more electrodes and catheters than any other 3-D mapping system currently available.

The EnSite NavX capabilities complement the EnSite Array multielectrode catheter, which acts like a miniature radio antenna. The catheter's "balloon," covered by a wire mesh with 64 electrodes, collects more than 3,000 points of the heart chamber's electrical activity in a single beat and relays them to the EnSite workstation. The EnSite System then displays the electrical activation pattern of the arrhythmia in 3-D, allowing the physician to diagnose, and then guide an ablation catheter, to treat the arrhythmia.

Endocardial Solutions remains committed to advancing its "one system solution" in future product developments.

Navigating the AF Revolution

With the introduction of EnSite NavX, Endocardial Solutions is poised to lead the way in facilitating ablation treatments for atrial fibrillation (AF). Atrial fibrillation is the most common and perhaps the most complex of all heart rhythm disturbances, affecting more than five million people worldwide. Described as a "quivering" of the heart that can be associated with dizziness, tiredness, and a lack of energy, AF can lead to serious consequences for patients, including lost work time and stroke.

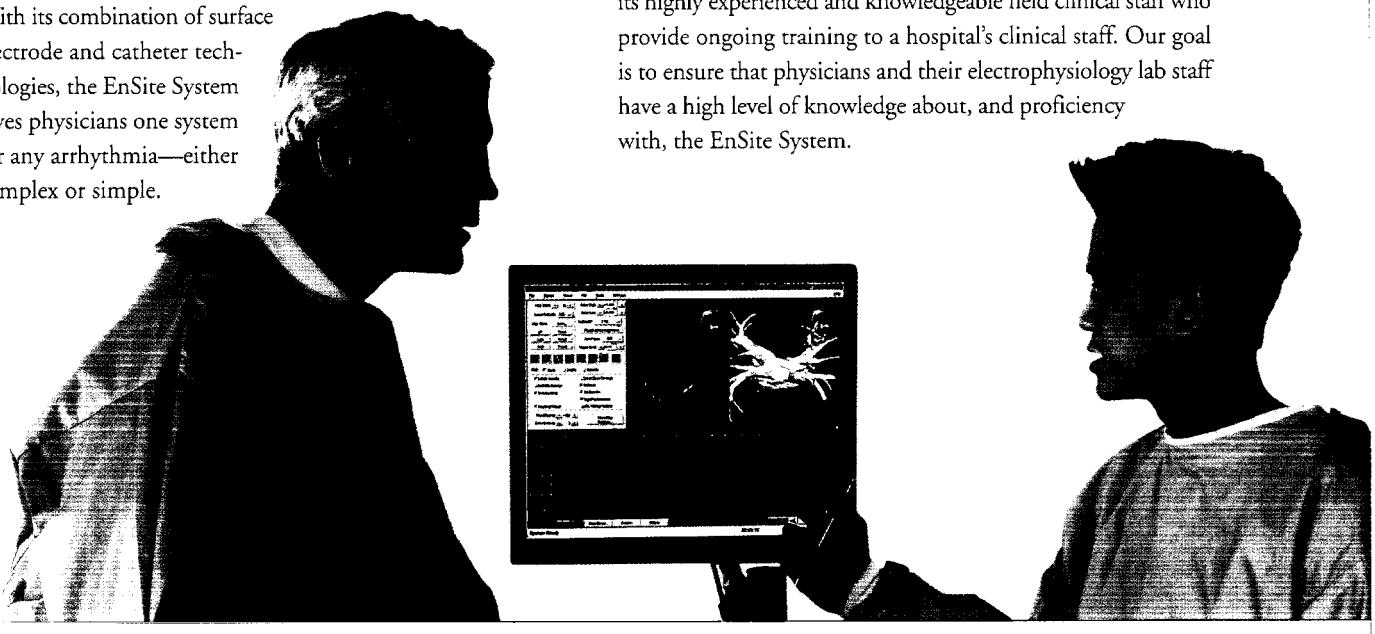
EnSite NavX provides physicians with accurate 3-D renderings of the cardiac structure and allows physicians to facilitate the AF ablation strategy of their choice.

Industry estimates show that the number of therapeutic ablations performed on AF patients is expected to grow significantly in the next few years as the result of high procedure success rates and the availability of advanced mapping systems such as the EnSite System.

Unsurpassed Clinical Competency

A key component of Endocardial Solutions' product offering is its highly experienced and knowledgeable field clinical staff who provide ongoing training to a hospital's clinical staff. Our goal is to ensure that physicians and their electrophysiology lab staff have a high level of knowledge about, and proficiency with, the EnSite System.

With its combination of surface electrode and catheter technologies, the EnSite System gives physicians one system for any arrhythmia—either complex or simple.



1998 1999 2000 2001 2003

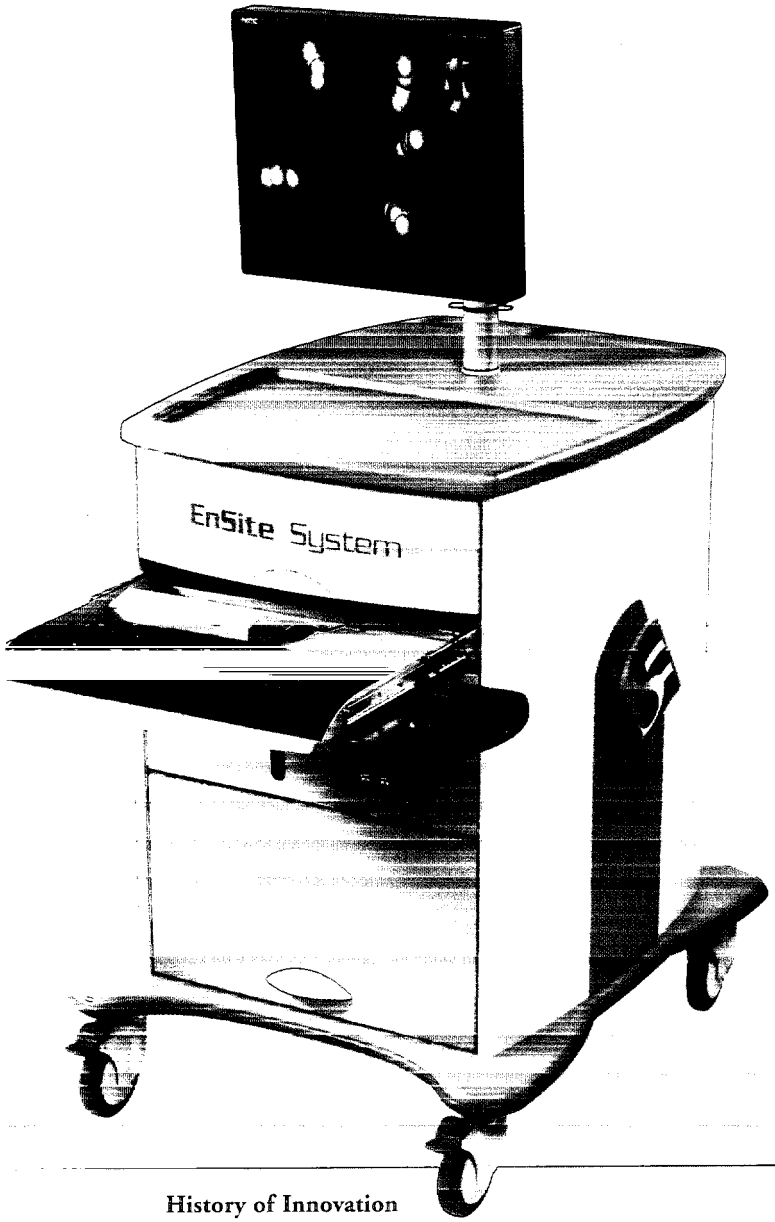
200 Systems Sold

EnSite DIF First Generation

Next Generation Display Workstation, Intel Xeon

300 Systems Sold

"The speed of the EnSite System workstation allows me to view catheter movement in real time, and EnSite NavX is crucial to creating accurate geometries of the heart and performing AF ablations. The combination of technologies allows me to reduce the time it takes to perform procedures and improve outcomes for patients with AF."
Carlo Pappone, MD, Milan, Italy



Foundation for Growth

The EnSite® System next generation display workstation, launched in the fourth quarter of 2003, combines a faster and more powerful computing platform and advanced software to enhance the treatment of people with arrhythmias.

Powered by dual Intel® Xeon™ processors and equipped with a 120 GB hard drive for patient data storage, the robust capabilities of the new EnSite System workstation support current clinical applications and future system developments. The system's advanced software features the first-of-its-kind simultaneous display of computed tomography (CT) or magnetic resonance (MRI) images of a specific heart chamber next to EnSite NavX cardiac geometries.

The simultaneous display of segmented CT or MRI images and EnSite geometries is Endocardial Solutions' first generation of EnSite DIF™ (Digital Image Fusion)—which, in the future, will combine or "register" the two images to provide unsurpassed anatomic detail.

The clarity and detail of the EnSite System's 3-D images facilitates viewing cardiac structures and accurately delivering the appropriate treatment. The EnSite System provides physicians with an advanced mapping and navigation platform that has the potential to streamline difficult cardiac ablation procedures and improve outcomes for patients.

History of Innovation

1992 **1993** **1995** **1996** **1997**

Letter to Shareholders

Last year was a turning point in the history of Endocardial Solutions. I had the privilege of announcing our first quarter of profitability in the fourth quarter. Compared to Q4 2002, revenues increased by more than $4 million, and gross margins increased four percent to 70.8 percent. We saw a year-over-year growth in revenue of more than $10 million or 40 percent, with year-end gross margins of 66.5 percent.

Several activities led to our 2003 success, including the introduction of our EnSite NavX™ cardiac navigation and visualization platform. EnSite NavX enables the precise creation of cardiac chambers to assist in guiding and displaying electrophysiology catheters in any chamber of the heart. It provides physicians with advanced 3-D navigation and mapping to meet the needs of the growing ablation market for patients with atrial fibrillation, a common heart rhythm disturbance. EnSite NavX complements our EnSite Array™ catheter, giving our customers a comprehensive three-dimensional cardiac mapping and navigation system *for any arrhythmia.*

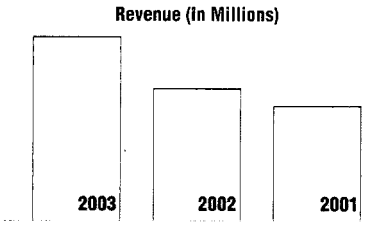
In 2003, we also launched the EnSite® System next generation display workstation, a powerful computer platform with advanced software and a new mobile cart. This new computing platform allows physicians to navigate and map cardiac structures with greater speed, accuracy and confidence. The platform's robust performance supports future capabilities and system enhancements.

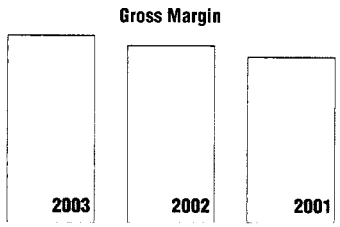
With the new platform, we introduced EnSite DIF™ (Digital Image Fusion), the first-of-its-kind simultaneous display of segmented cardiac computed tomography (CT) and magnetic resonance (MRI) images with EnSite NavX cardiac geometries. This first generation of EnSite DIF™ helps physicians view and validate complex cardiac anatomy, streamline procedures and reduce exposure to fluoroscopy.

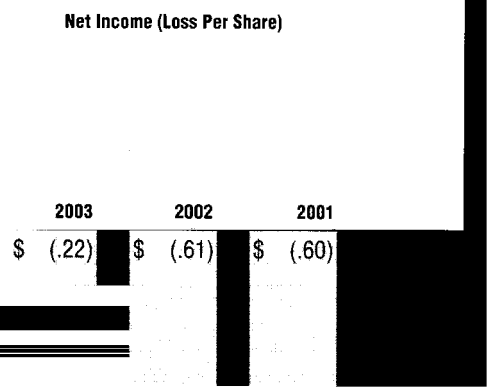
After realigning our field organization into regional teams in 2002, we dramatically improved productivity, reduced overall travel expenses and built stronger relationships with customers. The realignment also allowed our field clinical engineers to increase training to customers for improved proficiency with the EnSite System. We will continue these efforts in 2004, helping our customers achieve even greater efficiencies and improve patient outcomes.

In the coming year, we expect to further increase utilization of our disposable products and expand the number of labs with our EnSite Systems. I continue to be optimistic about the growth of Endocardial Solutions, and I am confident in our ability to offer our physician customers unrivaled cardiac mapping and navigation products and clinical support.

James W. Bullock
President and Chief Executive Officer







Financial Highlights

(Thousands, except per share amounts)

As of December 31	2003	2002	2001
Statements of Operations			
Total Sales	$ 36,557	$ 26,265	$ 22,893
Net Income (Loss)	$ (4,454)	$ (9,961)	$ (8,479)
Net Income (Loss Per Share)-Basic and Diluted	$ (0.22)	$ (0.61)	$ (0.60)
Diluted Average Shares Outstanding	20,322,481	16,324,066	14,211,318

As of December 31	2003	2002	2001
Balance Sheet			
Cash and Cash Equivalents	$ 10,216	$ 1,348	$ 4,550
Total Assets	$ 30,276	$ 17,721	$ 15,797
Total Liabilities	$ 9,963	$ 8,906	$ 7,081
Stockholder's Equity	$ 20,313	$ 8,815	$ 8,716

In Q4 of 2003, Endocardial Solutions achieved its first quarter of profitability with a growth in sales of 68 percent over Q4 of 2002.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2003

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 Number 0-22233

ENDOCARDIAL SOLUTIONS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**41-1724963**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1350 Energy Lane, Suite 110, St. Paul, MN	**55108**
(Address of principal executive offices)	(Zip Code)

(651) 523-6900

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: **None**

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

Common Stock, par value $.01 per share

Preferred Share Purchase Rights

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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 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 an accelerated filer (as defined in Rule 12b-2 of the Act). Yes ☒ No ☐

The aggregate market value of voting stock held by non-affiliates of the registrant as of June 30, 2003 (the last business day of the registrant's most recently completed second fiscal quarter) was approximately $117,812,058 (based on the last sale price of such stock as quoted on The Nasdaq National Market ($5.98) on such date).

As of March 5, 2004 the number of shares outstanding of the registrant's common stock, par value $.01 per share, was 21,805,642.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2004 Annual Meeting of Stockholders to be held on May 18, 2004 are incorporated by reference into Part III of this Annual Report on Form 10-K (the "Form 10-K Report").

ENDOCARDIAL SOLUTIONS, INC.
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PART I

ITEM 1. BUSINESS

The Company

Endocardial Solutions, Inc. ("ESI" or the "Company") designs, develops and manufactures a minimally invasive diagnostic system that maps and diagnoses, within the span of a few heartbeats, potentially fatal abnormal heart rhythms known as arrhythmias. This minimally invasive system also enables three-dimensional ("3D") non-fluoroscopic navigation and positioning of conventional linear electrophysiology catheters used to diagnose and treat cardiac arrhythmias. When defects in or injuries to the heart tissue interfere with the heart's normal electrical activity, cardiac arrhythmias develop, disrupting the heart's normal pumping action.

Cardiac arrhythmias are characterized by an abnormally fast heart rate (more than 100 beats per minute) are known as tachycardias, which can appear in various forms. Ventricular tachycardia, or VT, for example, occurs in the lower two chambers of the heart, or ventricles, and can prevent the heart from pumping adequate blood through the body. VTs frequently lead to serious complications, including sudden cardiac death. VT is estimated to afflict more than one million Americans. Additionally, approximately three to four million Americans have some form of supraventricular tachycardia, or SVT, which originates in the upper two chambers of the heart, or atria. Principal types of SVT include atrial tachycardia, atrial fibrillation and atrial flutter. Atrial fibrillation is the most common type of sustained arrhythmia and is characterized by contractions in an uneven and disorganized manner, causing the heart's upper chambers to quiver (fibrillate)—sometimes as fast as 600 to 1,000 beats per minute. While generally not life-threatening, SVTs cause the heart to overwork, often resulting in chest pain, fatigue and dizziness, and are a leading cause of stroke in the United States.

The EnSite System consists of the EnSite® clinical workstation, the EnSite Array™ catheter (the EnSite clinical workstation together with the EnSite Array catheter is referred to in this report as the "EnSite Array"), and the EnSite NavX™ surface electrode kit (the EnSite clinical workstation together with the EnSite NavX surface electrode kit is referred to in this report as "EnSite NavX") (collectively, the EnSite Array together with EnSite NavX is hereinafter referred to as the "EnSite System"). Historically, electrophysiologists have had difficulty in adequately diagnosing complex cardiac arrhythmias due to the limited capabilities of diagnostic technologies. The EnSite System is a powerful diagnostic and navigation tool that enables electrophysiologists to rapidly and precisely locate the multiple, unpredictable points of origin of complex cardiac arrhythmias, provides electrophysiologists with important information designed to improve the selection of patient treatment options, and enables the 3D non-fluoroscopic navigation and positioning of conventional linear electrophysiology catheters used to diagnose and treat cardiac arrhythmias. The EnSite Array allows electrophysiologists to map both ventricular and atrial arrhythmias, and applies mathematical algorithms that we developed to compute more than 3,000 points of electrical activity within a heart chamber, producing a high resolution, real-time, 3D color display of the electrical activity in the heart chamber. The "virtual electrogram" function of the EnSite Array allows electrophysiologists to instantly view the electrical activity at any of the more than 3,000 points, and is also capable of tracking and displaying the location and movements of catheters introduced into the heart chamber. EnSite NavX allows electrophysiologists to visualize, display, navigate and track up to 64 electrodes on up to 8 linear catheters in any chamber of the heart.

In 1998, the Company received the necessary approval to market the EnSite Array in the European Community ("EC") for use in the right atrium and left ventricle of the heart. Distribution of the EnSite Array in Europe began in the second quarter of 1998. In 1999, the Company received clearance from the U.S. Food and Drug Administration (the "FDA") to market the EnSite Array in the U.S. for diagnosis of complex arrhythmias in the right atrium of the heart. The Company received

general approval to market the EnSite Array for cardiac mapping in Australia, Korea, Thailand, Malaysia, China and Hong Kong in 2000, and in Taiwan in 2001, as well as various countries in the Middle East. An exclusive distribution arrangement with Nihon Kohden, one of Japan's leading manufacturers, developers and distributors of medical electronic products, was established in 2001, and distribution of the EnSite Array will commence pending receipt of Japan regulatory approval.

In April of 2003, the Company received clearance from the FDA to market EnSite NavX™ in the U.S., at which time EnSite NavX also was approved for commercial sale in Europe as well as all other geographies in which the EnSite Array is currently sold and distributed. EnSite NavX is a navigation and localization application designed to enable three-dimensional non-fluoroscopic navigation and positioning of conventional linear mapping or ablation catheters. EnSite NavX was developed, in part, using certain three-dimensional intracardiac positioning and navigation technology that the Company licensed from Medtronic, Inc. ("Medtronic") in January of 1998. Pursuant to the terms of this license agreement with Medtronic, the Company has the right to use the licensed technology for intracardiac mapping applications in the treatment of arrhythmias, and the term of the license extends until the expiration of the last of the patents on the technology, which patents begin to expire in 2015, unless extended. The EnSite workstation with EnSite NavX also is approved for use in Europe and in all other geographies where the EnSite System is currently sold or distributed. The Company commercially released EnSite NavX worldwide during the second quarter of 2003. By the end of calendar 2003, the Company had more than 235 EnSite Systems worldwide that had been upgraded with EnSite NavX technology.

The Company was incorporated in Minnesota in 1992, and was reincorporated in Delaware in 1995. The Company's common stock began trading on The Nasdaq National Market under the symbol "ECSI" on March 19, 1997. The Company's world corporate headquarters are located at 1350 Energy Lane, Suite 110, St. Paul, Minnesota 55108, and its telephone number is (651) 523-6900. The address of the Company's web site is *www.endocardial.com*. The Company's European subsidiary office is located at Lambroekstraat 5, 1831 Diegem, Belgium, and its telephone number is 32 2 719 02 27. The address of the Company's European subsidiary web site is *www.endocardial.com/europe*. The Company's annual report on Form 10-K and quarterly reports on Form 10-Q, and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, are available to the public free of charge through the Company's website (www.endocardial.com) as soon as reasonably practical after the Company electronically files or furnishes the material with the Securities and Exchange Commission. Copies of any other reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 that are not posted on the Company's website will be furnished free of charge.

Company Strategy

Endocardial Solutions, Inc. develops, manufactures and markets the EnSite clinical workstation and the EnSite Array catheter for use by electrophysiologists in diagnosing and mapping abnormal heart rhythms known as tachycardias, and EnSite NavX surface electrodes for use by electrophysiologists in visualizing and navigating the precise placement of conventional linear catheters used during diagnostic and therapeutic electrophysiology procedures. The Company's strategy is to establish the EnSite System as the leading tool for diagnosing arrhythmias and guiding the treatment of cardiac arrhythmias in the more than 2,200 electrophysiology laboratories worldwide. The Company believes patients who suffer from complex cardiac arrhythmias that are difficult to diagnose, together with the availability of a cost-effective system that enables the precise three-dimensional, non-fluoroscopic visualization and navigation of a variety of linear electrophysiology catheters, provide

significant market opportunities for the EnSite System. The key elements of the Company's strategy are as follows:

- *Increase Clinical Utilization of the EnSite System by Electrophysiologists.* The Company's ability to increase revenues and derive future profitability from this business depends, in part, on the Company's ability to effectively market and sell the EnSite System to the more than 2,200 electrophysiology laboratories worldwide in which these electrophysiology procedures are performed. Through a combination of the continued development and introduction of new EnSite products and technologies, the implementation of improved clinical training and education programs, and introduction of new "ease-of-use" features for the EnSite System, the Company is striving to increase the clinical adoption and utilization of the EnSite System for a variety of cardiac arrhythmias. The Company has realigned its direct field sales and clinical support organizations in both the U.S. and Europe with the objective, in part, to improve the education, training and clinical support of electrophysiologists and staff to use the EnSite System. The objective of these efforts is to drive increased clinical utilization at individual accounts. The Company also has restructured the scope, content and focus of its training and education organization, programs and materials to further drive this increased EnSite clinical adoption and utilization strategy.

- *Increase Clinical Awareness with Electrophysiologists.* The Company had established relationships with leading electrophysiologists who practice and promote the clinical acceptance of the EnSite System. In addition to the training and education efforts described above, the Company has ongoing clinical research and educational relationships with several leading medical institutions in the United States, Europe and Asia Pacific to improve current and develop future clinical applications for the EnSite System. The Company also continues to demonstrate the clinical efficacy and expanded clinical application of the EnSite System through the publication of the results of these research efforts, and the presentation of the results of these clinical studies, as well as the presentation of the results of post-market clinical studies done at a number of different clinical sites. These presentations typically are given at variety of international, national, and regional medical and scientific conferences, including those sponsored by the North American Society of Pacing and Electrophysiology, the American Heart Association, and the American College of Cardiology.

- *Expand Technology and Clinical Applications.* The Company believes applications of the EnSite Array and EnSite NavX can be extended to a variety of cardiac arrhythmias, including use of the EnSite Array for mapping atrial tachycardias in the right atrium (as currently cleared for marketing by the FDA) and mapping complex ventricular tachycardias in the left atrium (as currently cleared for marketing in Europe). EnSite NavX currently is cleared for use in all four chambers of the heart, and is being used for atrial fibrillation and atrial flutter, which share similar complex characteristics such as multiple sites of origin in unpredictable locations, but which also tend to be more challenging from a mapping, navigation, and treatment perspective. Medical research has shown that atrial fibrillation, the most common form of sustained arrhythmia, although possible to originate in the right atrium, most often originates in the left atrium. In addition, EnSite NavX currently is being used in a variety of other clinical applications, including atrioventricular nodal re-entrant tachycardia, and "Wolff-Parkinson-White" syndrome.

  The Company is required to seek FDA approval to market the EnSite Array for applications in the left ventricle. The Company has received approval to market the EnSite System in Europe and Canada for left ventricular use. In December 1998, the Company filed a pre-market notification application with the FDA under Section 510(k) detailing the results of a left ventricular multi-center clinical trial, but the FDA did not find substantial equivalence with other devices used in the ventricles based on initial clinical data. Following discussions with the FDA,

in March 1999, the Company announced that an application for left ventricular use of the EnSite System would be submitted as a pre-market approval application. Portions of the application have been submitted and approved, but the Company has not yet undertaken another clinical study for left ventricular use. The Company is still in discussions with the FDA regarding the best approach to obtain market approval for left ventricular use, which may include a revised 510(k) application.

In January of 2001, the Company received approval from the FDA for the use of the EnSite Array in the left atrium in a multi-center clinical study for diagnosing arrhythmias, including atrial fibrillation. The Company began this study in the second quarter of 2001. Following the Company's receipt of FDA clearance to market EnSite NavX in April of 2003, the Company saw clinical adoption of EnSite NavX for atrial fibrillation increase at a rapid rate. Concurrently, enrollment in the Company's multi-center clinical study using the EnSite Array for diagnosing and treating atrial fibrillation declined significantly. As a result of seeing this market adoption of EnSite NavX, in November of 2003, the Company discontinued its multi-center clinical study of the EnSite Array in the left atrium.

- *New Products and Technologies*. The Company continues to focus on developing new products and technologies to drive increased use of its EnSite System platform for a variety of current and future clinical applications. Each of these new products and technologies are designed to improve the speed, accuracy, and cost-effective mapping of various arrhythmias, as well as improving the navigation and positioning of linear catheters used in diagnosing and delivering therapy for these arrhythmias. The Company received clearance from the FDA in October of 2003 to market its EnSite Digital Image Fusion software application ("EnSite DIF™"), which, in its initial version, allows physicians to display, side-by-side with an EnSite NavX geometry of the heart chamber in which the procedure is being performed, a segmental digital computed tomography ("CT") or MRI image of the patient's actual cardiac anatomy. The Company expects future generations of the EnSite DIF product will allow physicians to register these "patient-specific digital images" with the intra-operative EnSite NavX geometries, thereby enabling the real-time visualization and navigation of linear catheters in the registered images. The Company also continues to invest in the development of additional new advanced mapping, navigation, and electrophysiology information display products and technologies designed to benefit electrophysiologists and their patients in performing diagnostic and therapeutic procedures for an expanded patient population suffering from cardiac arrhythmias.

Recent Developments

In October of 2003, the Company introduced its first version of EnSite DIF. The initial version of EnSite DIF allows clinicians to display on the EnSite workstation CT images of a patient's cardiac anatomy that have been "segmented" using third-party software to isolate the cardiac chamber of interest. These segmented patient images are displayed side-by-side with the cardiac geometry created with the use of the EnSite NavX application. In November of 2003, the Company also introduced a new state-of-the-art high-performance Intel® Xeon™ using a LINUX operating system. This new high performance workstation, with NVIDIA Quadro®4 graphics technology significantly improved the graphics processing and display capability of the EnSite System, and resulted in improved margins on EnSite System sales.

In January of 2003, the Company received gross proceeds of $8,516,750 in a private placement of 3,097,000 shares of its common stock to accredited investors. In August of 2003, the Company received gross proceeds of $7,361,123 in a private placement of 1,732,029 shares of its common stock to accredited investors. Proceeds from these sales of shares were used for general working capital including expenses associated with new product development, clinical studies, and the commercial introduction of EnSite NavX following the Company's receipt of regulatory approval.

Background

The heart consists of four chambers: the ventricles are the lower two chambers; the atria are the upper two chambers. A normal heartbeat is the result of electrical impulses generated at the sinoatrial node, the heart's natural pacemaker located near the top of the right atrium. These impulses form a wave of electrical activation that travels down the atria, causing them to contract and fill the ventricles, the heart's primary pumping chambers, with blood. After a brief delay in the atrioventricular node, located between the ventricles, the electrical activation wave enters the ventricles and produces a coordinated contraction of the ventricles that pumps blood throughout the body's circulatory system.

When defects in the heart tissue interfere with the normal formation or conduction of the heart's electrical activity, abnormal heart rhythms, known as cardiac arrhythmias, develop. Cardiac arrhythmias have numerous causes, including congenital defects, tissue damage from heart attacks or arteriosclerosis (the deposit of fatty substances in the inner layer of the arteries), and other diseases that accelerate, delay or redirect the transmission of the heart's electrical activity, thereby disrupting the normal coordinated contractions of the chambers. Cardiac arrhythmias characterized by an abnormally fast heart rate (more than 100 beats per minute) are known as tachycardias, which can appear in various forms.

Ventricular Tachycardia

Characteristics of Ventricular Tachycardias. Ventricular tachycardia, which afflicts approximately one million Americans, is a potentially life-threatening condition caused either by abnormally rapid impulse formation or by slow ventricular conduction which interferes with the heart's normal electrical activity and causes abnormally frequent contractions of the ventricles. Rapid ventricular contractions often result in significantly reduced cardiac output due to inefficient blood pumping. As a result, the body receives an inadequate supply of oxygen, which can cause dizziness, unconsciousness, cardiac arrest and death. VT conditions tend to become more serious over time, and individuals with VT are at risk of imminent death due to its unpredictable nature.

Many VT conditions are the result of heart attacks caused by coronary artery disease. When a heart attack occurs due to a blockage in one or more coronary arteries, a portion of the heart muscle (most often in the left ventricle) dies. As a result, irregular borders, consisting of intermixed healthy and scar tissue, are formed in the heart tissue and VT typically originates at these sites. As the average age of the U.S. population increases, the number of people who suffer heart attacks and are at risk of VT also is expected to increase.

VT is a highly complex and transient form of cardiac arrhythmia that varies significantly from patient to patient. A small percentage of VT patients have simple forms of the disease, which tend to focus on a single anatomic site within the ventricle. The Company estimates, however, that of the one million patients who suffer from VT, the majority suffer from complex VTs that (i) have multiple sites of aberrant electrical activity, (ii) prevent sufficient cardiac output, making them dangerous to induce in the patient (which is required for diagnosis), and (iii) are non-sustained and, consequently, are only periodically detectable during a limited number of heartbeats.

Diagnosing Ventricular Tachycardia. Patients suspected of suffering from VT typically are initially screened by a cardiologist by means of external cardiac monitoring over a 24-hour period, usually in the form of an electrocardiogram or Holter recording, which captures electrical activity from surface leads placed on the patient's chest. If further testing is warranted, the patient is referred to a cardiac electrophysiologist for a cardiac electrophysiology ("EP") study.

An EP study evaluates the electrical integrity of the heart by stimulating multiple intra-cardiac sites and recording the electrical response. During an EP study, a patient's clinical tachycardia is induced in a controlled setting in order to diagnose the tachycardia and select an appropriate treatment or

combination of treatments. EP studies using currently available technology are lengthy and tedious procedures which consist of probing the interior of the left ventricle with single-point contact catheters, often causing significant discomfort for the patient. In order to analyze the information generated by single-point contact catheters for the purpose of prescribing treatment, electrophysiologists review the signals measured by these catheters as multiple rows of waveforms displayed on a computer screen. Two or more catheters are often used to provide more information to the electrophysiologist and thereby aid in identifying the sites of origin of tachycardia. The electrophysiologist generally constructs a mental image of the sites of the VT within the heart's chamber by calculating the relative timing of electrical activation among the waveforms displayed on the computer screen. The electrophysiologist then estimates the site or sites of origin (which correspond to the physical positions of the catheters) using two-dimensional fluoroscopic (x-ray) images. As the tachycardia becomes more complex, the electrophysiologist's reconstruction of the heart's electrical activity and location of the sites of origin becomes more difficult.

The use of single-point contact catheter technology to perform diagnostic EP procedures can be extremely time-consuming, tedious and invasive. While the relatively small number of patients who suffer from simple forms of VT can be effectively diagnosed using existing single-point catheter technology, single-point contact catheters have limited utility in diagnosing complex ventricular tachycardias, including those that are dangerous to induce or are short in duration. The limited data produced in point-by-point mapping often does not provide the electrophysiologist with sufficient diagnostic information for a complete understanding of complex ventricular tachycardias. Moreover, the use of single-point contact catheters to diagnose complex ventricular tachycardias can take six-to-twelve hours, and require the extended use of fluoroscopy to guide the catheters, which exposes both the patient and attending medical staff to increased levels of radiation.

In an effort to address the diagnostic shortcomings of single-point contact catheters, several "basket" contact catheters measuring multiple points of electrical activity simultaneously currently have been commercialized and/or are under development by other manufacturers. These basket catheters require contact with the heart's surface in order to record and measure electrical activity, and the Company believes the use of these basket catheters are and will be subject to many of the same shortcomings of single-point contact catheters discussed above.

Treatments Following Diagnosis of Ventricular Tachycardia. The Company's EnSite Array catheter is designed for mapping and diagnosing both simple and complex VT. While the Company does not currently design therapeutic products for the treatment of this disease, the Company believes the EnSite Array provides electrophysiologists with a powerful diagnostic tool that improves their ability to more effectively select among available tachycardia treatment options.

Currently available options to treat VT include non-curative treatments such as antiarrhythmic drugs and implantable defibrillators, both of which attempt to ameliorate the patient's condition and reduce the risks associated with the VT, but do not eliminate the underlying cause of the tachycardia. Historically, the only curative treatment available for VT was open heart surgery, but the procedure was rarely used due to its high morbidity and mortality risk.

While antiarrhythmic drugs, which chemically suppress the arrhythmic activity, are commonly prescribed to treat VT, they are not curative and can result in considerable side effects, which limit the effectiveness of the drugs as well as the ability of patients to use these drugs over long periods of time. Automatic implantable cardioverter defibrillators ("ICDs"), which detect and stop a tachycardia once it has started by pacing or by applying high energy pulses, have also become a common treatment for VT. The useful life of an ICD is approximately five-to-seven years, at the end of which time the ICD is generally replaced in another surgical procedure. Many ICD patients also receive antiarrhythmic drug therapy in an attempt to minimize the frequency of VT episodes.

More recently, catheter ablation, a potentially curative treatment, has been used in an increasing number of cases for treating complex VT. In a catheter ablation procedure, a specially-designed catheter is guided to a patient's heart through a vein in the neck or groin. A high radiofrequency current is emitted through the ablation catheter (an "RF catheter") to selectively destroy the heart tissue responsible for the abnormal electrical activity, and in many cases, resulting in a cure of the underlying VT. One of the limitations on the use of catheter ablation to treat VT has been the inability to consistently and effectively map the abnormal electrical activity caused by complex VT cases with single-point contact catheters. The difficulty in mapping these arrhythmias is due, in part, to the fact that it is very difficult for patients to tolerate a sustained hemodynamically unstable VT event required to map this type of arrhythmia with a single-point catheter. By contrast, the EnSite Array can map these types of complex arrhythmias in a single beat. The development of ablation catheters continues to be the subject of increasing technological research and development by several manufacturers, and the Company believes the number of catheter ablation procedures to treat VT will continue to increase with further advances in diagnostic technology such as the Company's EnSite System.

Supraventricular Tachycardia

Approximately three million of the four million people in the United States who suffer from tachycardia have some form of Supraventricular tachycardia ("SVT"). Supraventricular tachycardia is an abnormally rapid beating of the atria which may reduce the amount of blood pumped into the ventricles, and, consequently, from the ventricles to the rest of the body. Although SVT can be debilitating, causing chest palpitations, fatigue and dizziness, it is generally not life-threatening. The principal types of SVT are Wolff-Parkinson-White syndrome ("WPW"), atrioventricular nodal re-entrant tachycardia ("AVNRT"), atrial fibrillation, atrial flutter, and atrial tachycardia.

Approximately one million people in the United States suffer from WPW or AVNRT. The tachycardias associated with WPW and AVNRT generally are relatively easy to diagnose and locate due to their more simple, single-site nature, and predictable location within the atria. Tachycardias associated with WPW and AVNRT usually can be effectively treated by catheter ablation with currently available contact catheters. EnSite NavX enables the three-dimensional non-fluoroscopic navigation and positioning of conventional linear mapping or ablation catheters used as part of these procedures, with or without the use of heart chamber geometries.

Approximately two million people in the United States suffer from atrial fibrillation or atrial flutter. Atrial fibrillation is the most common type of sustained atrial arrhythmia and is characterized by a disorganized and chaotic conduction of electrical activation, causing the heart's upper chambers to quiver (sometimes as fast as 600 to 1,000 beats per minute), which results in ineffective pumping of the atria. Under these conditions, blood in the atria tends to pool and clot, increasing the risk of stroke. The American Heart Association estimates that approximately fifteen percent of all strokes in the United States are caused by atrial fibrillation. The incidence of atrial fibrillation is linked to aging and thus is expected to increase as the average age of the United States population increases.

Typically, diagnosis of atrial fibrillation is easily discerned through an electrocardiogram recording. Beyond initial detection, electrophysiologists have had limited success in mapping the origin point of atrial fibrillation using current single-point catheter technology due to its highly complex and chaotic nature. The inability to effectively map and understand the origins of atrial fibrillation has hindered the development of treatments for this disease.

While antiarrhythmic drugs and anticoagulation therapy are the most commonly prescribed treatments for atrial fibrillation, these drugs are not curative and often have undesirable side effects. Prior to the emergence of ablation therapy, the only known curative treatment for atrial fibrillation was a costly and rarely performed open-heart surgical procedure known as the surgical maze procedure. The incisions made in this surgery electrically isolate the atria into regions that can no longer maintain

fibrillation. While an implantable atrial defibrillator has been developed for detecting and controlling atrial fibrillation with low energy shocks, this therapy has not been widely adopted.

RF catheters have been approved for delivering ablation therapy in the atria. Until recently, the clinical adoption of RF ablation for the treatment of atrial fibrillation has been somewhat limited due, in part, to the incomplete clinical understanding of the inter-relationship between the morphology and electrophysiology of atrial fibrillation. As a result, the clinical success of ablation therapy for this disease was inconsistent. However, clinical study results reported in academic publications in 2003 demonstrated significant improvement in outcomes from ablation therapy delivered utilizing innovative new ablation techniques. As a result, there has been an increase in the clinical adoption of ablation therapy for the treatment of atrial fibrillation. Several manufacturers have developed, and are continuing to develop, specialized RF generator features (higher power) and RF catheters for atrial fibrillation ablation therapy. These new and emerging methods of ablation therapy include both anatomically based procedures, as well as procedures that utilize more precise electrophysiological measurements of electrical activity in the atria. Both approaches result in a more localized ablation treatment based on the assumption that atrial fibrillation is maintained in an electrically localized region of the chamber. Both approaches require detailed three-dimensional mapping and navigation technology.

The complexity of atrial fibrillation and the search for effective and curative treatments, including RF catheter ablation, requires the use of diagnostic three-dimensional mapping and navigation technology with greater resolution and diagnostic capabilities than traditional EP recording technology. The EnSite System is currently being used by clinicians in connection with both anatomical procedures and electrical activation measurement procedures for the ablation treatment of atrial fibrillation.

The EnSite System

The EnSite System consists of the EnSite clinical workstation, the EnSite Array catheter, and the EnSite NavX surface electrode kit. The Company has developed and continues to enhance its proprietary EnSite System to address the need for more rapid, comprehensive and cost-effective diagnosis of complex forms of cardiac arrhythmias. The high resolution, three-dimensional, color display generated by the EnSite System of the heart chamber geometries, electrical activation information, and the diagnostic and ablation catheters used during these procedures is designed to provide electrophysiologists with greater diagnostic capabilities and information than that which is available from "traditional" single-point contact catheter mapping devices and electrophysiology recording systems.

Using the EnSite Array, the EnSite System provides electrophysiologists with a real time, virtual image of the electrical activity of the heart without contacting the endocardial wall of the heart chamber. The EnSite System displays more than 3,000 points of electrical activity collected by the EnSite Array using the Company's proprietary algorithms. Diagnosis is enhanced by the "Virtual Electrogram" function of the EnSite workstation which allows electrophysiologists to instantaneously view the electrical activity at any of the more than 3,000 points displayed by selecting a specific point, or multiple points, on the three-dimensional color map of the heart that generated and displayed on the EnSite System workstation. In addition, the locator function of the EnSite System workstation also enhances diagnosis and treatment by providing electrophysiologists with real-time feedback as to the precise location of auxiliary and therapy catheters introduced into the heart.

Using EnSite NavX, the EnSite System allows electrophysiologists to visualize, navigate and position, non-fluoroscopically, in real-time and in three dimensions, the conventional linear mapping and ablation catheters of any manufacturer used to diagnose and treat a variety of cardiac arrhythmias. EnSite NavX enables electrophysiologists to visualize, navigate and position up to 64 electrodes on up to 8 catheters in any chamber of the heart, with or without geometry.

The EnSite Array Catheter

The EnSite Array is a percutaneous, non-contact, single-use, multi-electrode catheter designed for use exclusively with the EnSite clinical workstation. The EnSite Array catheter contains 64 electrodes that sense and measure the electrical activity generated from the endocardial wall of the heart chamber in which the catheter is positioned. The EnSite Array catheter consists of 64 braided wires, each of which contains a "laser etched" electrode, and the array of braided wire surrounds an inflatable polyurethane balloon. A handle and cable connector are located at the proximal end of the EnSite Array catheter allowing the electrophysiologist to position the distal end of the catheter in a heart chamber, deploy the multi-electrode array of braided wire, and make electrical connection from the EnSite Array to the patient interface unit of the EnSite System.

The EnSite Array catheter is inserted percutaneously over a standard guide wire into a selected chamber of the heart. When positioned, the balloon residing underneath the array of braided wire is inflated with a radiopaque solution, and the wire braid is mechanically expanded, thereby creating an ellipsoidal, multi-electrode array. When deployed, the multi-electrode array is small enough to permit the normal functioning of the heart. Following deployment of the EnSite Array, the electrophysiologist will insert a standard single-point diagnostic catheter into the heart chamber to facilitate establishing the spatial boundaries of the heart chamber for the EnSite System. The deployed EnSite Array then collects more than 3,000 points of electrical conduction data from the entire chamber, transmits this information through the EnSite Array to the EnSite System clinical workstation, and the workstation creates a three-dimensional isochronal color map of the heart chamber's electrical activity in the span of a few heartbeats.

The EnSite NavX Surface Electrodes

EnSite NavX is a navigation and localization technology designed to enable three-dimensional non-fluoroscopic navigation and positioning of conventional linear mapping or ablation catheters. EnSite NavX consists of three pairs of surface electrodes which are placed on a patient's body in orthogonal directions (neck-leg, front-back, and left-right on the patient's thorax). An alternating low voltage electrical current is applied across each pair of surface electrodes, and the EnSite System alternatively creates and measures a voltage gradient on each of the three axes to create a three-dimensional navigation field. Electrophysiologists percutaneously insert intracardiac diagnostic and ablation catheters from any manufacturer and guide them into the heart chamber of interest to diagnose and ablate the cardiac arrhythmia. The electrodes on each such catheter are identified by the EnSite NavX low voltage navigation field, and are measured and displayed in three dimensions on the EnSite workstation. EnSite NavX allows the electrophysiologist to visualize, navigate, and guide up to 64 electrodes on 8 different intracardiac catheters in any chamber of the heart, with or without geometry, to diagnose and treat a variety of cardiac arrhythmias.

EnSite NavX was developed, in part, using certain three-dimensional intracardiac positioning and navigation technology that the Company licensed from Medtronic, Inc. in January of 1998. Pursuant to the terms of this license agreement with Medtronic, the Company has the right to use the licensed technology for intracardiac mapping applications in the treatment of arrhythmias, and the term of the license extends until the expiration of the last of the patents on the technology, which patents begin to expire in 2015, unless extended. The Company received clearance from the FDA to market EnSite NavX surface electrodes in April of 2003, and EnSite NavX is approved for use in Europe and in all other geographies where the EnSite System is currently sold or distributed. The Company commercially released EnSite NavX worldwide during the second quarter of 2003.

EnSite Digital Image Fusion

In October of 2003, the Company received clearance from the FDA to market the initial version of the Company's new "digital image fusion" ("EnSite DIF™") software. This initial commercial version of EnSite DIF technology enables physicians to display on the EnSite workstation, side-by-side with the heart chamber geometry created with EnSite NavX, a three-dimensional digital computed tomography ("CT") image of a patient's heart chamber. The initial version of EnSite DIF is compatible with gated CT images from GE Medical Systems LightSpeed® CT scanner running GE's CardEP™ electrophysiology advanced software application, as well as the "open platform" image segmentation software, AnalyzeMD™, developed and sold by the Mayo Foundation for Medical Education and Research through its Biomedical Image Resource Group.

The EnSite System Clinical Workstation

The clinical workstation component of the EnSite System consists of the Company's proprietary patient interface unit, a high-speed computer workstation, and other third-party peripherals, such as a color monitor, a printer and an optical disk drive. The EnSite System patient interface unit amplifies and digitizes the electrical information transmitted by the EnSite Array catheter. The patient interface unit also accepts information generated by other auxiliary sensors, including data from as many as 32 standard contact catheter electrodes, which allows the electrophysiologist to monitor clinical events or capture additional data for simultaneous display on the EnSite workstation. The electrical information transmitted by the EnSite Array or EnSite NavX is processed by the workstation using the Company's proprietary algorithms. These algorithms reconstruct and display the geometric layout of the heart chamber, the electrical activity within the heart chamber, and the visual display and navigation of the diagnostic or therapeutic catheters being used by the electrophysiologist in conjunction with the EnSite System. The geometries and electrical activity of the heart chambers are displayed on the EnSite workstation as high resolution, three-dimensional isopotential or isochronal color maps. The maps can be viewed as a snapshot in time, or as an animated playback at adjustable rates of speed. The maps can also be viewed from any perspective in space and may be zoomed in and out to facilitate rapid diagnosis and treatment of the tachycardia, including identifying the optimal site or sites for the delivery of ablation therapy. The EnSite Array, together with any diagnostic or ablation catheters, are displayed in three-dimensions, and the colors can be set to coordinate with the display of the "Virtual Electrograms" (as described below) being generated by each such catheter.

The electrical activity displayed on the EnSite workstation's three-dimensional isopotential map from use of the EnSite Array also can be displayed as time-waveforms (e.g., "Virtual Electrograms") at multiple selected sites on the endocardium. These Virtual Electrograms are computed by the Company's proprietary algorithms, and the electrophysiologist then has the ability to select for display any of the more than 3,000 sites and waveforms by simply pointing and clicking with the workstation's mouse pointer at the desired location on the map of the heart. The Virtual Electrogram function provides the equivalent data as that which would result from positioning a standard single-point contact catheter at the same site on the endocardium, but without the need for actual physical contact with the endocardial wall to collect each data point.

Another feature of the EnSite System clinical workstation using the EnSite Array is the EnGuide™ locator signal that can be emitted from selected electrodes on standard electrophysiology catheters introduced into the heart chamber along with the EnSite Array. The EnGuide locator signal provides electrophysiologists with an interactive method for locating and positioning auxiliary or therapy catheters used during an EnSite Array procedure. The EnGuide locator function is designed to allow electrophysiologists to reduce the amount of fluoroscopy used to diagnose and treat complex tachycardias than that which is required when using conventional single-point contact catheters. The EnGuide locator signal is detected and displayed on the workstation's isopotential three-dimensional map to provide electrophysiologists with real-time feedback on the precise location of the auxiliary or

therapy catheter, and to assist in guiding the catheter (or catheters) to specific sites on the endocardium. When using EnSite NavX, the EnSite workstation can non-fluoroscopically display, navigate and precisely locate the electrophysiology catheters used during the procedure in three-dimensions, with or without geometries of the heart chamber.

The EnSite System is designed to function as a complete, integrated electrophysiology laboratory system with a wide range of accurate and versatile diagnostic tools. In addition to displaying high resolution, graphical, three-dimensional maps of the heart chamber, the EnSite System provides multi-channel recording from standard EP electrode catheters and standard waveform displays. The Company intends to continue to develop and market new clinical applications for the EnSite System, some of which will require periodic software and hardware upgrades.

In the second quarter of 2000, the Company released Clarity™, an upgraded version of the Company's EnSite software that provided a simplified user interface, together with increased automation of arrhythmia analysis. In October 2001, the Company released EnSite Precision™, a further upgrade to the EnSite software that improved the displayed heart chamber geometry, together with new catheter positioning techniques designed to improve orientation, decrease overall procedure times, and reduce the use of fluoroscopy. In November of 2003, the Company discontinued use of the Silicon Graphics computing platform in new models of its EnSite workstation, and introduced new Intel® Xeon™ high performance computing platform using a LINUX operating system. This new Intel® Xeon™ high performance workstation, with NVIDIA Quadro®4 graphics technology, significantly improves the graphics processing and display capability of the EnSite System, and results in improved margins on EnSite System sales. The Company is offering its current customers an opportunity to purchase this hardware and software upgrade to their EnSite clinical workstations.

Research and Development

The Company's research and development activity is primarily performed internally by the Company's team of scientists, engineers and technicians, in consultation with the Company's outside clinical consultants. The Company's research and development team is divided into five groups: software engineering, applied research, hardware engineering, verification and validation, and catheter engineering. In addition, various members of the research and development team support the design and development of the manufacturing processes used in fabricating the Company's products.

Among its research and development projects, the Company is developing future versions of EnSite DIF that will utilize segmentation software compatible with the CT or MRI images of any manufacturer. Future versions of EnSite DIF will allow physicians to register heart chamber geometries created with the EnSite System with the patient-specific CT or MRI heart chamber images. Physicians then will have the ability to visualize, navigate, and precisely locate the electrophysiology catheters used during a procedure in the registered digital CT or MRI image. In addition, the Company will continue to pursue software and hardware upgrades that improve and optimize the EnSite System functionality of both the EnSite Array and EnSite NavX, as well as incorporating EnSite location technology for use in conventional EP studies. The Company continues to evaluate new catheter technologies that may reduce the size and cost, and improve the clinical functionality, of the EnSite Array. Future research and development objectives also include developing new clinical applications for the EnSite System, and improving the current mapping and display functions, the clinical capabilities together with the ease-of-use features of the EnSite System. In addition, the research and development team will continue to support the Company's manufacturing personnel in refining manufacturing processes, and improving the efficiency, and reducing the cost of, manufacturing the Company's products.

The Company incurred research and development expenses of $5.6 million, $5.5 million, and $5.3 million for the fiscal years ended December 31, 2003, 2002 and 2001, respectively. The Company anticipates that it will continue to make significant investments in research and development.

Manufacturing

The Company manufactures its EnSite Array catheters in a 4,600 square foot clean-room facility at its world corporate headquarters in St. Paul, Minnesota. The Company also performs final assembly and system level testing of all hardware and software components for the EnSite System at this facility.

The manufacturing process for the EnSite Array catheter involves a number of steps and component parts. The Company assembles and individually tests each EnSite Array catheter prior to packaging and sterilization, which it conducts in accordance with the FDA and European Economic Union requirements. The Company has designed its manufacturing processes to automate, to the extent appropriate, production of its EnSite Array catheters to increase volume, improve efficiencies and reduce costs.

Manufacturing the EnSite System workstation, including the patient interface unit, involves the assembly, integration and testing of components purchased from third parties. The Company purchases the computer workstation for its EnSite System from a third-party vendor, and the Company's software engineers program the workstation with its proprietary software, which includes advanced proprietary mathematical algorithms.

The Company purchases the raw materials and various component parts for the EnSite System from a number of suppliers. The Company has adopted rigorous quality control measures to ensure that component parts purchased from third-party vendors meet its specifications and standards. Certain of these component parts are purchased from sole-source suppliers, including the computing platform of the EnSite System workstation and the EnSite NavX surface electrode kits. There are relatively few alternative sources of supply for these components, and it may be difficult for the Company to locate additional suppliers for these components.

The Company has implemented a manufacturing quality program designed to meet all domestic and international standards for manufacturing medical devices. The Company is required to meet the requirements of the FDA's good manufacturing practices ("GMP") in order to distribute its products in the United States, the requirements for ISO 9001 and ISO 9002 and CE Mark certification in order to distribute its products in Europe, as well as the requirements of various other countries in the Asia Pacific region. During the fourth quarter of 2001, the Company passed an FDA inspection of the facility and the manufacturing processes. During the fourth quarter of 2003, the Company passed an ISO inspection of its facilities and quality systems. The Company first received ISO 9001 certification for its catheter and quality system in August 1997, and ISO 9002 certification for the EnSite workstation and a CE Mark for each of the EnSite Array catheter and the EnSite System workstation in the first quarter of 1998. The Company subsequently received ISO 9001 certification for the EnSite workstation in November 1998. The EnSite NavX surface electrode kits are manufactured by a third-party vendor who also operates with all applicable ISO certifications. As part of standard medical device regulatory requirements, the Company's facilities and manufacturing processes are subject to periodic inspections and audits by representatives of the various regulatory authorities. In the event the Company fails to satisfy GMP requirements, it may be required to alter its manufacturing processes. Moreover, any such failure could have a material adverse effect on the Company's ability to market its products, which could adversely affect its business and results of operations. The Company's suppliers also are required to satisfy GMP standards.

Sales and Marketing

In the first quarter of 1998, the Company received a CE Mark for each of the EnSite catheter and the EnSite workstation for use in the right atrium and left ventricle. The Company began marketing and selling the EnSite System and EnSite Array catheter in Europe during the second quarter of 1998 through a distribution partnership with Medtronic. In the second quarter of 1999, the Company received clearance from the FDA to market the EnSite Array catheter and EnSite workstation in the

United States for use in the right atrium. In 2000, the Company received regulatory approval to market the EnSite Array for cardiac mapping in Australia, Korea, Thailand, Malaysia, China and Hong Kong, and in Taiwan in 2001, as well as in various countries in the Middle East. The Company has filed and is awaiting approval from the regulatory authorities in Japan to begin marketing the EnSite System in Japan.

In April of 2003, the Company received clearance from the FDA to market EnSite NavX in the U.S., at which time EnSite NavX also was approved for commercial sale in Europe as well as all other geographies in which the EnSite Array is currently sold and distributed. The Company commercially released EnSite NavX worldwide during the second quarter of 2003. In October of 2003, the Company received clearance from the FDA to market EnSite DIF in the U.S., and EnSite DIF also is approved for commercial sale in Europe as well as all other geographies in which the EnSite Array is currently sold and distributed. The Company commercially released EnSite DIF worldwide during the fourth quarter of 2003.

The Company employs a direct sales force in the United States and Europe, and uses distributors for certain other international markets. In 2001, the Company ended an exclusive distribution arrangement in Europe and Japan with Medtronic, Inc., and established an exclusive distribution arrangement in Japan with Nihon Kohden, one of Japan's leading manufacturers, developers and distributors of medical electronic products. The Company intends to appoint additional distributors in various emerging markets throughout the world.

The Company's initial distribution strategy focused on prominent electrophysiology labs in major medical centers that generally were more likely to keep abreast of and utilize new technologies such as the EnSite System for diagnosing and treating tachycardias. With more than 350 EnSite Systems now installed globally, the Company has broadened its sales and marketing efforts to include a growing number of smaller, regional and community-based electrophysiology labs who are seeking to acquire and utilize advanced EP mapping and navigation technologies such as the EnSite System. As part of its strategy to increase the awareness of and acceptance by electrophysiologists of the clinical utilization of the EnSite System, the Company has and will continue to focus on developing peer-reviewed journal articles authored by leading experts in electrophysiology, entering into consulting and clinical study agreements with selected experts and "key opinion leaders" in the field of electrophysiology, sponsoring clinical studies focused on use of the EnSite System in a variety of clinical applications, sponsoring the publication and presentation of papers based on research covering the performance and benefits of the EnSite System, and conducting periodic informational seminars on the clinical application of the EnSite System. In addition, as part of its marketing programs, the Company conducts introductory and advanced technical seminars, and training and education sessions with physicians, its sales and field clinical organizations, and its distributors in the use and clinical application of the EnSite System.

Patents and Proprietary Intellectual Property Rights

The Company's success will depend, in part, on its ability to (i) obtain and continue protection on patents for its products and processes; (ii) obtain and continue protection on its trademarks and trade names; (iii) preserve its trade secrets; and (iv) operate without infringing or violating the proprietary rights of third parties. The Company actively pursues patent and trademark protection in the United States and foreign jurisdictions for each of the areas of invention embodied in the EnSite System, and will actively pursue patent protection for proprietary aspects of its technology in the future. The Company has numerous issued and pending U.S. patent applications protecting various aspects of the technology underlying the EnSite System, including, without limitation, proprietary algorithms, the EnSite Array, EnSite NavX, catheter localization techniques, and user interface elements. The Company also has several patents which have been allowed, in whole or in part, with issuance expected within the year.

In January 1998, the Company signed a license agreement with Medtronic, Inc. which gave the Company the right to develop, use and commercialize certain three-dimensional intracardiac location technology for its EnSite System. This technology license, as currently in use by the Company, grants the Company the non-exclusive right to commercialize the licensed technology. The Company issued Medtronic certain stock warrant rights as consideration for this technology license. The Company's right to use the technology for intracardiac mapping applications in the treatment of arrhythmias is effective until the expiration of the last of the patents on the licensed technology, which patents begin to expire in 2015, unless otherwise extended. EnSite NavX was developed, in part, utilizing this licensed technology from Medtronic.

The Company, like other firms that engage in the development and marketing of medical devices, must address issues and risks relating to patents, trademarks and trade secrets. The coverage sought in a patent application can be denied or significantly reduced before or after a patent is issued. Consequently there can be no assurance that any of the Company's pending or future U.S. or foreign patent applications will result in issued patents, that the scope of any patent protection will exclude competitors or provide competitive advantages to the Company, that any of the Company's current or future U.S. or foreign patents will not be challenged, circumvented by competitors or others or that such patents will be found to be valid or sufficiently broad to protect the Company's technology. Since patent applications are confidential until patents are issued in the United States, or corresponding applications are published in other countries, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, the Company cannot be certain that it was the first to make the inventions covered by each of its pending patent applications, or that it was the first to file patent applications for such inventions. In addition, there can be no assurance that competitors, many of which have substantial resources and have made substantial investments in competing technologies, will not seek to apply for and obtain patents that will prevent, limit or interfere with the Company's ability to make, use or sell its products either in the United States or in international markets. Furthermore, the laws of certain foreign countries may not protect the Company's intellectual property rights to the same extent as do the laws of the United States.

Similarly, the Company markets and sells it EnSite products under a variety of trademarks and trade names. As is the case with other firms that engage in the development and marketing of medical devices, the Company must address issues and risks relating to trademarks and trade names. The coverage sought in a trademark registration application can be denied or amended before or after a trademark registration is issued. Consequently there can be no assurance that any of the Company's pending or future U.S. or foreign trademark applications will result in issued trademark registration, or that any of the Company's current or future U.S. or foreign trademarks will not be challenged, circumvented by competitors or others. Since trademark applications are confidential until registered trademarks are issued in the United States, or corresponding applications are published in other countries, and since publication of registered trademarks often lags behind actual use, the Company

cannot be certain that it was the first to register or use any particular trademark covered by each of its pending trademark registration applications, or that it was the first to file any particular trademark registration application. In addition, there can be no assurance that competitors, many of which have substantial resources and have made substantial investments in competing products, will not seek to apply for and obtain trademarks that could prevent, limit, or interfere with the Company's ability to use, market or sell its EnSite products using the Company's trademarks in either in the United States or in international markets. Furthermore, the laws of certain foreign countries may not protect the Company's intellectual property rights to the same extent as do the laws of the United States.

In addition to patents and trademarks, the Company relies on trade secrets and proprietary knowledge, which it seeks to protect, in part, through appropriate confidentiality and proprietary information agreements. In particular, the Company relies upon such means to protect the proprietary software used in the EnSite System. The confidentiality and proprietary information agreements generally provide that all confidential information developed or made known to individuals by the Company during the course of the relationship with the Company is to be kept confidential and not disclosed to third parties, except in specific circumstances. The agreements also generally provide that all inventions conceived by the individual in the course of rendering services to the Company shall be the exclusive property of the Company. There can be no assurance that proprietary information or confidentiality agreements with employees, consultants and others will not be breached, that the Company will have adequate remedies for any breach, or that the Company's trade secrets will not otherwise become known to or independently developed by competitors.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry, and companies in the medical device industry have employed intellectual property litigation to gain a competitive advantage. There can be no assurance that the Company will not become subject to patent infringement claims or litigation in a court of law, or interference proceedings declared by the United States Patent and Trademark Office ("USPTO") to determine the priority of inventions or an opposition to a patent grant in a foreign jurisdiction. The defense and prosecution of intellectual property suits, USPTO interference or opposition proceedings, and related legal and administrative proceedings, are both costly and time-consuming and could result in substantial uncertainty to the Company. Litigation or regulatory proceedings may also be necessary to enforce patent or other intellectual property rights of the Company or to determine the scope and validity of other parties' proprietary rights. Any litigation, opposition or interference proceedings will result in substantial expense to the Company and significant diversion of effort by the Company's technical and management personnel. There can be no assurance that the Company will have the financial resources to defend its patents from infringement or claims of invalidity. An adverse determination in any litigation could subject the Company to significant liabilities to third parties, require the Company to seek licenses from or pay royalties to third parties or prevent the Company from manufacturing, selling or using its proposed products, any of which could have a material adverse effect on the Company's business and prospects. The Company is not currently a party to any patent or other litigation.

Competition

The Company believes its competitive success will depend primarily upon its ability to continue to drive increased clinical efficacy of the EnSite System, which will continue to increase market awareness and clinical acceptance and utilization of the EnSite System, while maintaining the proprietary nature of current and future product applications. The markets for the diagnostic mapping of tachycardias and the mapping and ablation of atrial fibrillation has attracted a great deal of interest from various companies in the medical device industry, including both those with an established presence in the field of electrophysiology, as well as from more recently formed companies. The Company's competitors include companies that offer standard, single-point contact diagnostic catheters, and companies that offer multi-point, basket contact catheters that use multiple electrodes to provide more data points for

the measurement of the heart's electrical activity. The Company also is aware of other medical device companies that are developing alternatives to single-point contact catheter mapping technology.

The Company believes that participants in these markets compete on several different levels, including clinical effectiveness, ease-of-use, price, and clinical acceptance and utilization by health care professionals. Competition also is affected by the length of time and resources required for the development of products, clinical trials and regulatory approval. The medical device industry is characterized by rapid and significant technological change. As a result, the Company's success will depend in part on its ability to respond quickly to medical and technological changes through the development and introduction of new technologies or products.

Many of the Company's competitors and potential competitors have substantially greater capital and organizational resources, including larger and more experienced research and development staffs, larger field sales and clinical support organizations, and larger facilities. In addition, most of the Company's competitors and potential competitors have substantially greater experience than the Company in researching and developing new products, testing products in clinical trials, obtaining regulatory approvals, and manufacturing, marketing and selling medical devices. There can be no assurance that the Company will be successful in its efforts to continue to develop, manufacture, market, and sell technologies and products that are clinically more efficacious and cost-effective than more established products or new approaches and products developed and marketed by its competitors. Moreover, there can be no assurance that the Company will succeed in developing new technologies and products that are available prior to those offered by competitors. The Company's failure to demonstrate the clinical efficacy and cost-effective advantages of its products over those of its competitors could have a material adverse effect on the Company's business and results of operations.

Third-Party Reimbursement for the Company's Products

In the United States, health care providers, including hospitals and physicians, that purchase medical products for treatment of their patients generally rely on third-party payers, principally federal Medicare, state Medicaid, and private health insurance plans, to reimburse all or a part of the costs and fees associated with the medical procedures performed using these medical products. The Company's success will depend on, among other things, the ability of health care providers to obtain satisfactory reimbursement from third-party payers for medical procedures in which the Company's products are used. Third-party reimbursement will depend upon decisions by the federal Center for Medicare and Medicaid Services, as well as by individual health maintenance organizations and private insurers and other payers. Third-party payers determine whether to reimburse for a particular procedure and, if so, will reimburse health care providers for medical treatment based on a variety of methods, including a lump sum prospective payment system based on a diagnosis related group or per diem, a blend between the health care provider's reported costs and a fee schedule, a payment for all or a portion of charges deemed reasonable and customary, or a negotiated per capita fixed payment. Specific to Medicare, the EnSite Array catheter and EnSite NavX surface electrode kit is currently reimbursable under both inpatient and outpatient procedure scenarios. Third-party payers are increasingly challenging the pricing of medical products and procedures. Even if a procedure is eligible for reimbursement, the level of reimbursement may not be adequate. Additionally, payers may deny reimbursement if they determine the device used in the treatment was unnecessary, inappropriate, not cost-effective, experimental, or used for a non-approved indication.

The Company's EnSite Array and EnSite NavX surface electrodes are sold at a premium in comparison to existing single-point catheters used in conventional diagnostic or mapping procedures, and require an initial capital outlay for the companion EnSite clinical workstation. In addition to establishing the safety and efficacy of the EnSite System, and assuming no increase in the level of reimbursement for electrophysiological procedures expected to utilize the Company's products, the Company may be required to economically justify the relative increased cost of utilizing the EnSite

System by satisfactorily demonstrating the benefits of the EnSite System to health care providers and payers in terms of such factors as enhanced patient procedural efficiencies, reduced radiation exposure (resulting from the use of less fluoroscopy), improved patient outcomes, and lower overall costs with respect to competitive mapping and navigation systems.

Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. Many international markets have government managed health care systems that control reimbursement for new products and procedures. In most markets, there are private insurance systems as well as government managed systems. Market acceptance of the Company's products will depend on the availability and level of reimbursement in international markets targeted by the Company. There can be no assurance that the Company will obtain reimbursement in any country within a particular time, for a particular time, for a particular amount, or at all.

The Company believes less-invasive electrophysiology procedures generally provide a more cost-effective overall treatment when compared to conventional drug, surgical, and other treatments. Many hospital administrators and physicians justify the use of the Company's products by the attendant cost savings and clinical benefits that they believe will be derived from the use of the Company's products. However, the Company cannot provide assurance that these cost-savings and clinical benefit assumptions will, in fact, be realized. Reimbursement for the Company's products is not assured in some international markets under either government or private reimbursement systems, and health care providers may not advocate reimbursement for procedures using the Company's products. Failure by hospitals in the United States or in international markets and other users of the Company's products to obtain reimbursement from third-party payers, or changes in government and private third-party payers' policies toward reimbursement for procedures employing the Company's products, would have a material adverse effect on the Company's business, financial condition and results of operations. Moreover, the Company is unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future, or what effect such legislation or regulation would have on the Company.

Political, economic and regulatory influences are subjecting the health care industry in the United States to increased scrutiny. The Company anticipates that Congress, state legislatures and the private sector will continue to review and assess alternative health care delivery and payment systems. Potential approaches that have been considered include mandated basic health care benefits, controls on health care spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, greater reliance on prospective payment systems, the creation of large insurance purchasing groups, price controls and other fundamental changes to the health care delivery system. Legislative debate is expected to continue in the future, and market forces are expected to demand reduced costs. The Company cannot predict what impact the adoption of any federal or state health care reform measures, future private sector reform or market forces may have on its business.

Government Regulation

United States

The Company's EnSite System is regulated in the United States as a medical device by the FDA under the federal Food, Drug and Cosmetic Act ("FDC Act") and future products or technologies developed by the Company as part of its EnSite System will require pre-market approval by the FDA prior to commercialization. In addition, certain material changes or modifications to medical devices also are subject to FDA review and approval. Pursuant to the FDC Act, the FDA regulates the research, testing, manufacture, safety, labeling, storage, record keeping, advertising, distribution and production of medical devices in the United States. Noncompliance with applicable requirements can result in warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial

suspension of production, a decision by the government not to grant pre-market approval for medical devices under review, and criminal prosecution.

Medical devices are classified into one of three classes, Class I, II or III, on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices are subject to general controls (e.g., labeling and adherence to good manufacturing practices ("GMPs")). Class II devices are subject to general controls and to special controls (e.g., performance standards, and pre-market notification). Generally, Class III devices are those which must receive pre-market approval by the FDA to ensure their safety and effectiveness (e.g., life-sustaining, life-supporting and implantable devices, or new devices which have not been found substantially equivalent to legally marketed devices), and require clinical testing to ensure safety and effectiveness and FDA approval prior to marketing and distribution. The FDA also has the authority to require clinical testing of Class II devices.

If human clinical trials of a device are required and if the device presents a "significant risk," the manufacturer or the distributor of the device is required to file an investigational device exemption ("IDE") application with the FDA prior to commencing human clinical trials. The IDE application must be supported by data, typically including the results of animal and, possibly, mechanical and safety tests. If the IDE application is approved by the FDA, human clinical trials may begin at a specified number of investigational sites with a maximum number of patients, as approved by the FDA. Sponsors of clinical trials are permitted to sell those devices distributed in the course of the study, provided such costs do not exceed recovery of the costs of manufacture, research, development and handling. The clinical trials must be conducted under the auspices of each hospital's independent institutional review board ("IRB") established pursuant to FDA regulations.

The FDC Act provides two basic review procedures for medical devices. Certain products may qualify for a submission authorized by Section 510(k) of the FDC Act, pursuant to which the manufacturer provides the FDA with a pre-market notification of the manufacturer's intention to commence marketing the product. The manufacturer must, among other things, establish that the product to be marketed is substantially equivalent to another product that has previously been approved by the FDA and is currently being marketed. Marketing of this type of new medical device can commence when the FDA issues a letter finding "substantial equivalence." If a medical device does not qualify for the 510(k) procedure, the manufacturer must file a pre-market approval ("PMA") application with the FDA. The PMA procedure typically requires more extensive validation and clinical testing prior to filing than that required for devices using the 510(k) procedure, and involves a significantly longer FDA review process.

A PMA application must include extensive supporting data, including preclinical and clinical trial data, as well as credible scientific and/or medical literature to substantiate the safety and effectiveness of the device. Following receipt of a PMA application, if the FDA determines that the application is sufficiently complete to permit a substantive review, the FDA will "file" the application. Under the FDC Act, the FDA has 180 days to review a PMA application, although the review of such an application more often occurs over a protracted time period, and generally takes approximately two years or more from the date of filing to completion.

The PMA application approval process can be expensive, uncertain and lengthy. A number of devices for which pre-market approval has been sought have never been approved for marketing. The review time is often significantly extended by the FDA, which may require more information or clarification of information already provided in the filing. During the review period, an advisory committee likely will be convened to review and evaluate the application and provide recommendations to the FDA as to whether the device should be approved. In addition, the FDA will inspect the manufacturing facility to ensure compliance with the FDA's GMP requirements prior to approval of an

application. If granted, the approval of the PMA application may include significant limitations on the indicated uses for which a product may be marketed.

The Company conducted clinical trials of its EnSite System on patients with VT at medical centers in the United Kingdom in 1995, 1996 and 1997 under an authorization of the Medical Devices Agency of the British government. The Company submitted its IDE application to the FDA in May 1996 based on the results of the initial four-patient trial, plus extensive pre-clinical testing. Based on consultation with the FDA, and to further support its IDE submission, the Company conducted nine additional ventricular patient trials and submitted this data in November 1996 in an amendment to the original IDE application. In December 1996, the FDA granted the Company an IDE to conduct a limited clinical trial of the EnSite System in the United States for left ventricular tachycardia mapping in five patients at one institution. The Company conducted a limited five patient clinical study under an IDE in early 1997. Based on the results of those trials, the FDA approved testing of the EnSite System on an additional ten patients. The Company had completed 13 of the 15 clinical trials in June 1997 when the FDA authorized full-scale clinical testing of the EnSite System in 73 patients at up to five institutions in the United States. In December 1998, the Company filed a pre-market notification application with the FDA under Section 510(k) of the FDC Act containing the results of its left ventricular multi-center clinical trials and indicating the Company's intention to commence marketing in the U.S., but the FDA did not find substantial equivalence with other devices used in the ventricles based on initial clinical data. Following further discussions with the FDA, in March 1999, the Company announced that its FDA application for left ventricular use of the EnSite System would be submitted as a PMA application. Portions of the application were submitted and approved, but the Company has not yet undertaken another clinical study for use of the EnSite System and EnSite Array catheter in the left ventricle. The Company is still in discussions with the FDA regarding the best approach to obtain market approval for left ventricular use, which may include a revised 510(k) application.

The Company conducted an initial study of its technology for mapping atrial tachycardia in seven patients in the United Kingdom during the second half of 1996. The Company submitted an IDE application to the FDA in June 1997 for use of the EnSite System in the right atrium, and received approval for the IDE in August 1997. In September 1998, the Company filed a 510(k) application with the FDA containing the results of its right atrial multi-center clinical trials. In April 1999, the Company received FDA approval to market the EnSite System for use in the right atrium. In January 2001, the FDA approved an IDE for a multi-center clinical study of the EnSite System in the left atrium for diagnosing arrhythmias, including atrial fibrillation. The Company began this study in the second quarter of 2001. In January of 2003, the Company filed a 510(k) application with the FDA seeking approval to begin marketing EnSite NavX for use in all four chambers of the heart. The Company received clearance from the FDA to market EnSite NavX in April of 2003. In October of 2003, the Company filed an expedited 510(k) application with the FDA seeking approval to begin marketing the initial version of EnSite DIF, and received clearance from the FDA in October of 2003.

The Company is required to register as a medical device manufacturer with the FDA and various state agencies, and to list its products with the FDA. As part of such medical device manufacturer registrations, the Company is periodically inspected by the FDA both for compliance with the FDA's GMP, and with other applicable regulations. These regulations require the Company to manufacture its products and maintain its documents in a prescribed manner with respect to manufacturing, testing and quality control activities. Furthermore, the Company is required to comply with various FDA requirements for design, safety, advertising and labeling.

The Company is required to provide information to the FDA on death or serious injuries alleged to have been associated with the use of its medical devices, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur. In addition, the FDA prohibits an approved device from being marketed for unapproved applications. If the FDA believes that a company is not in compliance with the law, it can institute proceedings to detain or

seize products, issue a recall, enjoin future violations, and assess civil and criminal penalties against the Company, its officers and its employees. Failure to comply with applicable FDA regulatory requirements could have a material adverse effect on the Company's business, financial condition and results of operations.

The advertising of most FDA-regulated products is subject to both FDA and Federal Trade Commission jurisdiction. The Company also is subject to regulation by the Occupational Safety and Health Administration and by other governmental entities.

Regulations regarding the manufacture and sale of the Company's products are subject to change. The Company cannot predict what impact, if any, such changes might have on its business, financial condition or results of operations.

International

International sales of the Company's products are subject to the respective regulatory agency and product registration requirements of each country. The regulatory review process varies from country to country, and the Company cannot provide assurance that such approvals will be obtained on a timely basis or at all.

The Company received ISO 9001 certification for its catheter manufacturing and quality systems in August 1997, and ISO 9001 certification for the clinical workstation manufacturing in November 1998. The ISO 9000 series of standards for quality operations were developed to ensure that companies know the standards of quality to which they must adhere to receive certification. The European Union promulgated rules which required that medical products receive the right to affix the CE Mark, an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. ISO 9000 certification was one of the CE Mark certification requirements. The Company has obtained CE Mark certification for the EnSite Array, the EnSite clinical workstation and EnSite NavX.

Product Liability and Insurance

The development, manufacture and sale of medical products entails significant risk of product liability and product failure claims. The Company faces an inherent business risk of financial exposure to product liability claims in the event the use of its products results in personal injury or death. The Company also faces the possibility that defects in the design or manufacture of the Company's products might necessitate a product recall. There can be no assurance that the Company will not experience losses due to product liability claims or recalls in the future. The Company currently maintains product liability insurance with coverage limits of $5 million per occurrence and $5 million annually, in the aggregate, and there can be no assurance that the coverage limits of the Company's insurance policies will be adequate. Product liability insurance is expensive, may be difficult to obtain and may not be available in the future on acceptable terms, or at all. Any claims against the Company, regardless of their merit or eventual outcome, could have a material adverse effect upon the Company's business, financial condition and results of operations.

Employees

The Company and its European subsidiary had a total of 193 full-time employees as of December 31, 2003. No employee of the Company is covered by a collective bargaining agreement. The Company expects to add new employees as needed for future expansion of the business.

Executive Officers

The executive officers of the Company, their ages and positions and a brief biography of each individual are as follows:

Name	Age	Position
James W. Bullock	47	President and Chief Executive Officer and Director
J. Robert Paulson, Jr.	47	Chief Financial Officer
Frank J. Callaghan	50	Vice President, Research and Development
Richard J. Omilanowicz	51	Vice President, Manufacturing and Operations
Patrick J. Wethington	35	Vice President, North American Sales
Graydon E. Beatty	47	Chief Technical Officer and Director

James W. Bullock has been President, Chief Executive Officer and a Director of the Company since May 1994. In addition, Mr. Bullock served as the Chief Financial Officer of the Company from May 1994 until May 1996. From April 1992 until joining the Company, Mr. Bullock served as President and Chief Operating Officer of Stuart Medical, Inc., a cardiac monitoring start-up company. From April 1990 to April 1992, Mr. Bullock served as Vice President of Sales and Marketing of the Stackhouse Division of Bird Medical Technologies, a medical device company. From 1978 to 1990, Mr. Bullock served in a variety of marketing and sales management positions, most recently as Vice President of Sales, for the Pharmaseal Division of Baxter International Inc., a medical products company.

J. Robert Paulson, Jr. has been Chief Financial Officer of the Company since August 2002, and also leads the Company's marketing organization. From 2001 until joining the Company, Mr. Paulson served as Sr. Vice President and General Manager of the auditory products division of Advanced Bionics Corporation, a maker of cochlear implant systems. From 1995 to 2001, Mr. Paulson served in variety of positions within Medtronic, Inc., a medical device company. Among his Medtronic positions were Vice President and General Manager of Surgical Navigation Technologies; Vice President of Corporate Strategy and Planning; and Director of Corporate Development. From 1988 to 1995, Mr. Paulson held various marketing, business development and legal positions at General Mills, Inc., and prior to that practiced law at the Minneapolis firm of Lindquist & Vennum.

Frank J. Callaghan has been Vice President of Research and Development of the Company since November 1995. From 1987 until joining the Company, Mr. Callaghan served as a Director of Research and Development at Telectronics Pacing Systems, Inc., a manufacturer of cardiac rhythm management devices. From 1983 to 1987, Mr. Callaghan served in several capacities, including Manager, Systems Technology, at Cordis Corporation, a manufacturer of angiographic and implantable devices.

Richard J. Omilanowicz has been Vice President of Manufacturing and Operations of the Company since November 1994, and Vice President of Operations since January 2001. From May 1993 until joining the Company, Mr. Omilanowicz served as General Manager of McKechnie Plastic Components, a custom injection molding company. From 1980 to May 1993, Mr. Omilanowicz served in several capacities at the Pharmaseal Division of Baxter International Inc., most recently as Director of Research, Development and Engineering.

Patrick J. Wethington has been Vice President of North American Sales of the Company since February 2003. From March 2000 to February 2003, Mr. Wethington served as the Company's Territory Manager for the Upper Midwest. Mr. Wethington also served as Director of Marketing of the Company from November 1996 to March 2000. From 1989 until joining the Company, Mr. Wethington served in various marketing and sales positions with Cardiac Pacemakers division of Guidant Corporation.

Graydon E. Beatty is a founder of the Company, has been the Company's Chief Technical Officer since May 1995, and served as a Director of the Company since August 1992. Prior to assuming the role of the Company's Chief Technical officer in 1995, Mr. Beatty served in several technical and management positions at the Company. From May 1992 until December 1993, Mr. Beatty served as a consultant with GMN Consulting, an engineering consulting firm, and from February 1992 to September 1992, Mr. Beatty served as a consulting engineer to the AngeMed division of Angeion Corp., a cardiovascular device company. Mr. Beatty was Senior Development Engineer of Bio-Medical Design Group, Inc., an electrophysiology system developer, from December 1991 to May 1992. From 1989 to December 1991, Mr. Beatty served as Principal Research Engineer at Cardiac Pacemakers, Inc., a cardiovascular device company.

Forward-Looking Statements

This Annual Report on Form 10-K and the Company's financial statements, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 of this report and other documents incorporated by reference contain certain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements represent the Company's expectations, beliefs, intentions or strategies concerning future events, including, but not limited to, any statements regarding its current assumptions about future financial performance; the continuation of historical trends; the sufficiency of its cash balances and cash generated from operating activities for future liquidity and capital resource needs; the expected impact of changes in accounting policies on the Company's results of operations, financial condition or cash flows; anticipated problems and its plans for future operations; and the economy in general or the future of the medical device industry, all of which are subject to various risks and uncertainties.

When used in this Form 10-K and in other filings by the Company with the Securities and Exchange Commission, in its press releases, presentations to securities analysts or investors, or in oral statements made by or with the approval of an executive officer of the Company, the words or phrases "believes," "may," "will," "expects," "should," "continue," "anticipates," "intends," "will likely result," "estimates," "projects" or similar expressions and variations thereof are intended to identify such forward-looking statements. However, any statements contained in this Form 10-K that are not statements of historical fact may be deemed to be forward-looking statements.

The Company cautions that these statements by their nature involve risks and uncertainties, certain of which are beyond its control, and actual results may differ materially depending on a variety of important factors, including, but not limited to such factors as market demand and pressures on the pricing for its products; changing market conditions; medical device reimbursement; competition and procedure growth rates within the medical device industry; changes in accounting policies; risks associated with operations outside of the U.S.; changing economic conditions such as general economic slowdown, decreased consumer confidence and the impact of war on the economy; and other risks and uncertainties, including those described in Exhibit 99.1 to this Form 10-K.

ITEM 2. PROPERTIES

The Company leases approximately 33,660 square feet in St. Paul, Minnesota as its world corporate headquarters and production facilities. These facilities are leased through March 2006, with an option to extend the lease through March 2008. The Company believes that these facilities will be adequate to meet its needs through the full commercial introduction of its currently planned products. The Company's European subsidiary, Endocardial Solutions N.V./S.A., leases office space in Diegem, Belgium as its European headquarters. This Belgium office space is leased on a month-to-month basis.

ITEM 3. LEGAL PROCEEDINGS

The Company is not currently subject to any pending or threatened litigation.

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

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year ended December 31, 2003.

PART II

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

The Company's common stock began trading on the Nasdaq National Market under the symbol "ECSI" on March 19, 1997. On March 24, 1997, the Company received net proceeds of approximately $18,833,000 from an initial public offering of 2,250,000 shares of its common stock and approximately $6,278,000 from a concurrent private placement to Medtronic, Inc. of 750,000 shares of its common stock. Since its initial public offering, the Company has raised capital through several separate private placements of common stock to accredited investors. In July 1999, the Company received proceeds of $10,000,000 from a private placement of 1,111,111 shares of its common stock to accredited investors. In June 2000, the Company received proceeds of $12,687,500 from a private placement of 2,030,000 shares of its common stock to accredited investors. In March 2001, the Company received proceeds of $7,349,000 from a private placement of 2,449,666 shares of its common stock to accredited investors. The Company also issued warrants to purchase an additional 122,450 shares of common stock, at an exercise price of $4.00 per share, to the placement agent in the transaction, which warrants have been exercised. In February 2002, the Company received proceeds of $10,000,000 from a private placement of 1,666,667 shares of its common stock to accredited investors. In January 2003, the Company received proceeds of $8,516,750 from a private placement of 3,097,000 shares of its common stock to accredited investors. In August 2003, the Company received proceeds of $7,361,123 in a private placement of 1,732,029 shares of its common stock to accredited investors. Proceeds from these sales of shares were used for general working capital including expenses associated with new product development, clinical studies, and the commercial introduction of its EnSite products following receipt of the appropriate regulatory approvals. The shares of common stock were sold in these private placements pursuant to Section 4(2) of the Securities Act of 1933, as amended.

The following table sets forth, for the periods indicated, the high and low sales prices of the Company's common stock, as quoted on the Nasdaq National Market.

	2003		2002	
	High	Low	High	Low
First Quarter	$3.74	$2.64	$8.58	$4.52
Second Quarter	6.25	2.78	9.25	5.20
Third Quarter	6.13	4.66	7.45	2.02
Fourth Quarter	8.00	4.57	4.53	2.20

On March 5, 2004, the closing sales price per share of the Company's common stock as quoted on the Nasdaq National Market was $10.55 per share. On March 5, 2004, there were approximately 133 holders of record of the Company's common stock, representing approximately 4,957 stockholders accounts.

The Company has never declared or paid cash dividends on its capital stock. The Company currently intends to retain future earnings for use in its business and does not anticipate paying any cash dividends in the foreseeable future.

ITEM 6. SELECTED FINANCIAL DATA

The selected consolidated financial data below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 below and the Consolidated Financial Statements and the Notes thereto included in Item 8 below.

	Year Ended December 31,				
	2003	2002	2001	2000	1999
	(in thousands, except share and per share amounts)				
Statement of Operations Data:					
Revenue	$ 36,557	$ 26,265	$ 22,893	$ 14,563	$ 9,597
Cost of Goods Sold	12,236	9,473	9,241	7,174	6,592
Gross Margin	24,321	16,792	13,652	7,389	3,005
Operating Expenses:					
Research & Development	5,627	5,506	5,271	4,460	5,102
General & Administrative	3,137	3,024	2,241	2,065	2,003
Sales & Marketing	19,911	18,134	14,750	11,093	7,713
Total Operating Expenses	28,675	26,664	22,262	17,618	14,818
Operating Loss	(4,354)	(9,872)	(8,610)	(10,229)	(11,813)
Net Interest Income (Expenses) and Other	(100)	(89)	131	(82)	84
Net Loss	$ (4,454)	$ (9,961)	$ (8,479)	$ (10,311)	$ (11,729)
Net loss per share—basic and diluted	$ (.22)	$ (.61)	$ (.60)	$ (.92)	$ (1.23)
Weighted average shares outstanding	20,322,481	16,324,066	14,211,318	11,212,420	9,559,494

	December 31,				
	2003	2002	2001	2000	1999
	(in thousands)				
Balance Sheet Data:					
Cash and cash equivalents	$10,216	$ 1,348	$ 4,550	$10,759	$ 7,087
Working capital	17,094	6,896	6,341	7,273	9,700
Total assets	30,276	17,721	15,797	21,356	17,578
Long-term debt and capital lease obligations less current portion	64	363	301	584	4,564
Accumulated deficit	(84,956)	(80,448)	(70,486)	(62,007)	(51,696)
Total stockholders' equity	20,313	8,815	8,716	9,864	8,254

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

The following discussion of the financial condition and results of operations of the Company should be read in conjunction with the Company's Consolidated Financial Statements and Notes thereto, and the other financial information included elsewhere in this Form 10-K. This annual report contains forward-looking statements that involve risks and uncertainties. We use words such as "anticipate", "believe", "plan", "expect", "future", "intend" and similar expressions to identify forward-looking statements. These forward-looking statements, made in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this document, are made in reliance upon safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements are statements regarding our intent, belief, or current expectations, primarily with respect to our operations and related industry developments. You should not place

undue reliance on these forward-looking statements, which apply only as of the date of this annual report. The following discussion, and the Company's cautionary statements included in Exhibit 99.1 to this Form 10-K, set forth certain factors the Company believes could cause actual results to differ materially from those contemplated by the forward looking-statements.

Overview

Endocardial Solutions, Inc. develops, manufactures and markets the EnSite clinical workstation and the EnSite Array catheter for use by electrophysiologists in diagnosing and mapping abnormal heart rhythms known as tachycardias, and EnSite NavX surface electrodes for use by electrophysiologists in visualizing and navigating the precise placement of conventional linear catheters used during diagnostic and therapeutic electrophysiology procedures. The EnSite clinical workstation and EnSite Array were first available in full market release to electrophysiologists in Europe in 1998. The EnSite clinical workstation and EnSite Array catheter received FDA approval for right atrial use in the U.S. and Canada in 1999, and the Company received general approval to market the EnSite System for cardiac mapping in Australia, Korea, Thailand, Malaysia, China and Hong Kong in 2000, and in Taiwan in 2001. The Company commercially released EnSite NavX worldwide during the second quarter of 2003 following clearance from the FDA. The Company commercially released EnSite DIF, a software application that enables physicians to view segmented CT images of a patient's cardiac anatomy on the EnSite workstation, in the fourth quarter of 2003 following clearance from the FDA; EnSite DIF also is approved for use in Europe and all other geographies where the EnSite System is currently sold and distributed. The Company derives revenues from the sale of these EnSite products, as well as from the sale of extended warranty service and support agreements and miscellaneous ancillary support products used in conjunction with the EnSite System. The Company reported net sales for the fiscal year ended December 31, 2003 of $36.6 million, an increase of 39.2% over the previous year, and reported the fourth quarter of 2003 as the Company's first profitable quarter. The gross profit margin was 66.5% for the year ended December 31, 2003, compared with 63.9% during the same period in 2002.

The EnSite System is an innovative and expanding technology platform for mapping cardiac arrhythmias, and enabling the precise 3D, non-fluoroscopic visualization and navigation of a variety of linear electrophysiology catheters used in the diagnosis and treatment of cardiac arrhythmias. The Company's ability to increase revenues and derive future profits from this business in the future depends, in part, on the Company's ability to effectively market and sell the EnSite System to the more than 2,200 electrophysiology laboratories worldwide in which these electrophysiology procedures are performed, and to have the physicians who perform these electrophysiology procedures continue to increase their clinical adoption and use of the EnSite System, together with adopting future products introduced by the Company. The Company employs a direct sales force in the United States and Europe, and uses distributors for certain other international markets. The Company has established an exclusive distribution arrangement in Japan with Nihon Kohden, one of Japan's leading manufacturers, developers and distributors of medical electronic products, and expects regulatory approval for the sale of its products in Japan in 2004. With more than 350 EnSite Systems now installed globally, the Company has broadened its sales and marketing efforts to include a growing number of smaller, regional and community-based electrophysiology labs who are seeking to acquire and utilize advanced EP mapping and navigation technologies such as the EnSite System.

Many of the Company's competitors and potential competitors in this market have substantially greater experience than the Company in researching and developing new products, testing products in clinical trials, obtaining regulatory approvals, and manufacturing, marketing and selling medical devices. The Company's future success will depend on its ability to continue to develop, manufacture, market, and sell technologies and products that are clinically more efficacious and cost-effective than more established products or new approaches and products developed and marketed by its competitors, as

well as the continued availability of capital resources from the electrophysiology centers who purchase the Company's products. The Company's failure to demonstrate the clinical efficacy and/or cost-effective advantages of its products over those of its competitors could have a material adverse effect on the Company's business and results of operations.

The Company placed 82 new EnSite Systems in 2003. Revenue from the sale of disposable products (EnSite Array catheters and EnSite NavX surface electrode kits) continued to grow in 2003 as well. Initial market response to the release of EnSite NavX has been positive; the Company has 236 EnSite Systems globally that are "NavX-ready", including 175 EnSite Systems in the U.S., which means approximately two-thirds of the Company's global installed base of EnSite Systems are capable of doing NavX procedures. Conversion of the EnSite clinical workstation to the new higher power Intel Xeon platform has enabled the commercial release of EnSite DIF, which is expected to further improve the utility and ease of use of the EnSite System. Management will continue to monitor and track its performance through a variety of financial and operating measurements on an ongoing basis, including unit and revenue growth, gross margins, and operating expenses for functional organization.

Results of Operations

Years ended December 31, 2003 and 2002

General. Net losses decreased to approximately $4.5 million, or $0.22 per share, for the year ended December 31, 2003, from $10.0 million, or $0.61 per share, for the year ended December 31, 2002. The Company is in a period of growth in sales and marketing expenses related to market penetration, including increases in personnel costs.

Revenue and Cost of Goods Sold. Worldwide revenue for the year ended December 31, 2003 was $36.6 million, a $10.3 million, or 39.2%, increase over the same period in 2002. In the U.S., 2003 revenues increased approximately $7.4 million, or 36.7%, over 2002. Revenue from the sale of EnSite clinical workstations in the U.S. during 2003 increased by approximately $0.6 million, or 7.7%, over 2002. With the commercial release of EnSite NavX in the second quarter of 2003, revenue from the sale of EnSite disposable products (EnSite Array catheters and EnSite NavX surface electrode kits) in the U.S. increased by approximately $4.4 million, or 36.7%.

International revenues during 2003 increased approximately $3.0 million, or 50.1%, over 2002. International revenues include sales direct to end-users in certain countries in Europe and Canada, and to distributors in other areas of Europe and in the Asia Pacific region. International revenue from EnSite clinical workstation sales during 2003 increased by approximately $0.7 million, or 22.9%, over 2002. With the commercial release of EnSite NavX in the second quarter of 2003, international revenue from the sale of EnSite disposable products (EnSite Array catheters and EnSite NavX surface electrode kits) increased by approximately $1.1 million, or 38.2%.

Other revenue, which includes revenue generated from extended warranty and service contracts, revenue from hardware upgrades for compatibility with EnSite NavX, as well as revenue from the sale of accessories and repairs related to the EnSite clinical workstation, increased $3.6 million or 336% in 2003 compared to 2002. This increase was primarily related to the sale of EnSite NavX hardware and software upgrades to the EnSite System. The portion of deferred revenue related to the upgrade of the EnSite System was recognized at the time the upgrade was installed. The portion of deferred revenue related to the extended warranty and service contracts is recognized ratably over the warranty and service period (typically one year).

Revenue in 2003 from EnSite clinical workstation sales was $11.6 million, compared to $10.4 million during 2002, an increase of 11.5%. The increase was due to the increased sales of the EnSite clinical workstation in the U.S. and overseas. Domestic sales accounted for 69.4% of total EnSite clinical workstation sales during 2003, compared to 72.1% during 2002.

Revenue in 2003 from the sale of EnSite disposable products was $20.3 million, compared to $14.8 million during 2002 (which included only EnSite Array catheter sales), an increase of 37.0%. Domestic revenue from the sale of EnSite disposable products accounted for 80.2% of total EnSite disposable product revenue during 2003, compared to 80.2% (which included only EnSite Array catheter sales) during 2002.

Cost of goods sold including unabsorbed manufacturing expenses was $12.2 million and $9.5 million for the years ended December 31, 2003 and 2002, respectively.

The gross profit margin was 66.5% for the year ended December 31, 2003, compared with 63.9% during the same period in 2002. The increase in gross profit margins was primarily attributable to the commercial release of EnSite NavX in the second quarter of 2003, improved margins on EnSite Array catheters throughout the year, and improved margins on the sale of EnSite clinical workstations in the fourth quarter of 2003. Gross margins on EnSite disposable products (EnSite Array catheters and EnSite NavX surface electrode kits) improved to 75.9% in 2003, up from 68.5% in 2002.

Research and Development Expenses. Research and development expenses include compensation and benefit costs for the clinical, software, hardware, catheter, and applied research departments, as well as costs associated with regulatory expenses. Research and development expenses were approximately $5.6 million for the year ended December 31, 2003, compared to $5.5 million during the same period in 2002, an increase of $0.1 million, or 1.8%. The Company expects to make continued significant R&D investments in product development and clinical studies during 2004.

General and Administrative Expenses. General and administrative expenses were approximately $3.1 million and $3.0 million for the years ended December 31, 2003 and 2002, respectively, an increase of approximately $0.1 million, or 3.3%. This increase was primarily due to professional service expenses associated with various information technology projects, and actions undertaken by the Company to comply with certain requirements of the Sarbanes-Oxley Act of 2002. The Company also incurred fees and professional service expenses associated with filing for trademark protection in various international jurisdictions, and the execution of a new credit facility with Silicon Valley Bank. The Company expects general and administrative expenses to remain relatively constant, or decrease slightly in 2004.

Sales and Marketing Expenses. Sales and marketing expenses were approximately $19.9 million for the year ended December 31, 2003, an increase of $1.8 million from $18.1 million during the same period in 2002, or 9.9%. This increase was primarily attributable to travel and training costs associated with the installation of more than 185 EnSite clinical workstation hardware upgrades worldwide during 2003 to make the EnSite workstations "NavX-ready", and an increase in commissions for certain distributor sales in the U.S. and Europe. The Company expects sales and marketing expenses to increase slightly during 2004 commensurate with an expected increase in sales.

Interest Income and Expense. Interest income was $49,339 and $68,258 for the years ended December 31, 2003 and 2002, respectively. The decrease was due primarily to lower average cash and cash equivalent balances and lower interest rates. Interest expense was $115,672 and $134,782 for the years ended December 31, 2003 and 2002, respectively.

Years ended December 31, 2002 and 2001

General. Net losses increased to approximately $10.0 million, or $0.61 per share, for the year ended December 31, 2002, from $8.5 million, or $0.60 per share, for the year ended December 31, 2001. The Company was in a period of growth in sales and marketing expenses related to market penetration, including increases in personnel costs.

Revenue and Cost of Goods Sold. Worldwide revenue for the year ended December 31, 2002 was $26.3 million, a $3.4 million, or 14.7%, increase over the same period in 2001. In the U.S., 2002 revenues increased approximately $1.7 million, or 9.4%, over 2001. EnSite Array revenue in the U.S. during 2002 increased approximately $2.8 million, or 30.2%, over 2001. Revenue from the sale of EnSite clinical workstations in the U.S. during 2002 declined by approximately $1.5 million, or 16.6%, from 2001.

International revenues during 2002 increased approximately $1.6 million, or 36.5%, over 2001. International revenues include sales direct to end-users in certain countries in Europe and Canada, and to distributors in other areas of Europe and in the Asia Pacific region. International revenue from EnSite Array sales during 2002 increased approximately $1.1 million, or 57.2%, over 2001. International revenue from the sale of EnSite clinical workstations during 2002 increased by approximately $0.4 million, or 15.5%, over 2001. International revenues were positively impacted due to higher average selling prices on both the EnSite Array and EnSite clinical workstation, as a result of the Company's direct selling efforts in Europe following the termination of its distribution agreement with Medtronic at the end of September 2001. The Company believes that selling directly to the end-user will continue to improve sales in the European market.

Other revenue, which represents approximately 4.1% and 1.8% of worldwide revenue for the years ended December 31, 2002 and 2001, respectively, includes deferred revenue generated from extended service contracts, as well as revenue from accessories sales and repairs related to the EnSite clinical workstation.

Revenue in 2002 from EnSite clinical workstation sales was $10.4 million, compared to $11.5 million during 2001, a decrease of 9.6%. The decrease was due to the lower sales of the EnSite clinical workstation in the U.S. Domestic sales accounted for 72.1% of total EnSite clinical workstation sales during 2002, compared to 78.1% during 2001.

Revenue in 2002 from EnSite Array catheter sales was $14.8 million, compared to $11.0 million during 2001, an increase of 34.7%. Domestic sales accounted for 80.4% of total EnSite Array sales during 2002, compared to 83.2% during 2001.

Cost of goods sold including unabsorbed manufacturing expenses was $9.5 million and $9.2 million for the years ended December 31, 2002 and 2001, respectively.

The gross profit margin was 63.9% for the year ended December 31, 2002, compared with 59.6% during the same period in 2001. The increase in gross profit margins was primarily attributable to improvements in the EnSite Array manufacturing process and material costs, together with improved absorption of manufacturing overhead from increased EnSite Array revenue during 2002. Gross margins on the sale of EnSite Arrays improved to 68.5% in 2002, up from 63.2% in 2001. Additionally, because the Company's gross margins on its domestic sales are substantially higher than the gross margins on its international sales, the Company's margins were positively impacted due to the fact that 76.7% of the Company's revenue during 2002 was from domestic sales.

Research and Development Expenses. Research and development expenses include compensation and benefit costs for the clinical, software, hardware, catheter, and applied research departments, as well as costs associated with regulatory expenses. Research and development expenses were approximately $5.5 million for the year ended December 31, 2002, compared to $5.3 million during the same period in 2001, an increase of $0.2 million, or 4.4%.

General and Administrative Expenses. General and administrative expenses were approximately $3.0 million and $2.2 million for the years ended December 31, 2002 and 2001, respectively, an increase of approximately $0.8 million, or 34.9%. The increase in 2002 was due primarily to several one-time charges, including the hiring and relocation of the Company's Chief Financial Officer, additional legal fees related to increased patent activities for EnSite NavX, EnSite DIF and congestive heart failure applications, and professional service expenses related to business development activities.

Sales and Marketing Expenses. Sales and marketing expenses were approximately $18.1 million for the year ended December 31, 2002, an increase of $3.4 million from $14.8 million during the same period in 2001, or 22.9%. This increase was primarily attributable to costs associated with the hiring of additional sales and field clinical personnel to build and train the U.S. and European field organizations.

Interest Income and Expense. Interest income was $68,258 and $318,209 for the years ended December 31, 2002 and 2001, respectively. The decrease was due primarily to lower average cash and cash equivalent balances and lower interest rates. Interest expense was $134,782 and $161,367 for the years ended December 31, 2002 and 2001, respectively.

Liquidity and Capital Resources

The Company's operations since inception have been funded by net proceeds from the sales of common stock totaling approximately $104.3 million through December 31, 2003. As of December 31, 2003 and December 31, 2002, the Company had cash, cash equivalents and short-term investments of approximately $10.2 million and $1.3 million, respectively.

For the year ended December 31, 2003, the Company used approximately $4.1 million of cash for operations, compared to approximately $11.9 million for the same period in 2002. The Company's net accounts receivable balance was approximately $10.4 million at December 31, 2003, an increase of $2.2 million from December 31, 2002. The increase in accounts receivable was, in part, attributable to the increase in revenues during 2003 compared to 2002, and the Company's transition from a distributor organization to direct sales in Europe during 2002. In addition, the increase in accounts receivable was attributable to the timing of fourth quarter 2003 sales in relation to the payment terms of these sales, and the Company's sale, throughout 2003, of extended maintenance agreements with hardware upgrades to its current installed base of EnSite customers in the U.S., Europe and Asia Pacific. The Company deferred all or a portion of the revenue from the sale of each of these extended maintenance agreements (the portion of any agreement related to a hardware upgrade of the EnSite System is recognized at the time of installation), as well as deferring the portion of revenue from each EnSite System related to the one-year warranty coverage of the EnSite clinical workstation. This deferred revenue is reflected in the current liability portion of deferred revenue of $2.6 million at December 31, 2003, which compares to $2.2 million at December 31, 2002. The accounts receivable associated with the deferred revenue from these extended maintenance agreements are included in the $10.4 million balance at December 31, 2003.

The inventories balance at December 31, 2003 was approximately $4.7 million, an increase of approximately $0.1 million, or 2.2%, over December 31, 2002. This increase in inventory was primarily attributable to certain "end-of-life component purchases" the Company made in order to meet the anticipated production of EnSite Version 3.2 workstations for the 2004 sales forecasts in Japan, as provided by the Company's Japan distributor. The Company has not yet received approval to market Version 3.2 of the EnSite clinical workstation and EnSite Array catheter in Japan, although the review process between the Company's Japan distributor and the medical device regulatory approval authority in Japan continues. The Company believes its inventory of EnSite clinical workstations will decrease during 2004, while inventories of EnSite Array catheters and EnSite NavX surface electrode kits will remain relatively constant.

Accounts payable (including accrued expenses) of approximately $5.7 million at December 31, 2003 increased $1.3 million from December 31, 2002. The increase reflects the Company's continued efforts to closely match turnover of both receivables and payables in order to optimize the Company's cash flows. The Company expects accounts payable to increase during 2004 as operating and production expenses increase to support continued growth in revenue. The Company had no short-term investment portfolio as of December 31, 2003.

In September 2003, the Company entered into a $4.5 million credit facility agreement with Silicon Valley Bank ("SVB"). This credit facility replaced a prior credit facility with SVB that the Company entered into in June of 2001, and modified in May 2002 to extend the term of the initial agreement. The September 2003 credit facility with SVB consists of a $3.0 million domestic line of credit, and a $1.5 million international (EXIM) credit line. This facility operates as a revolving line of credit, with $1.3 million reserved for use as a capital lease line. The terms of the credit facility include certain restrictive financial covenants, including the Company's obligation to maintain a specified ratio of "current assets" to "current liabilities" ("quick ratio"), as well as a minimum "tangible net worth." As of December 31, 2003, the Company was in compliance with the financial covenants of the credit facility. As of December 31, 2003, the Company had $0.4 million outstanding related to capital leases and had an additional $1.0 million outstanding on the credit line.

In January 2003, the Company received gross proceeds of $8.5 million from a private placement of 3,097,000 shares of its common stock to accredited investors. In August 2003, the Company received gross proceeds of $7.4 million in a private placement of 1,732,029 shares of its common stock to accredited investors.

The Company believes its existing cash, cash equivalents and bank financing will be sufficient to fund the operations of the Company, and the need for additional financing to fund any capital expenditures during 2004 is not presently anticipated. If the Company continues to achieve profitability, the need for additional financing is not presently anticipated. The Company's future liquidity and capital requirements will depend on numerous factors, including the timing of regulatory actions regarding the Company's products, the results of clinical trials and competition, the extent to which the Company's EnSite System gains additional market acceptance, the costs, timing and method of expansion of sales, marketing, research and development and manufacturing activities, and the ability of the Company to obtain additional bank financing, if necessary.

Disclosures about Contractual Obligations and Commercial Commitments

The following table aggregates all contractual commitments and commercial obligations that affect the Company's financial condition and liquidity position as of December 31, 2003:

	Payments Due by Period				
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**4-5 years**	**After 5 years**
Line of Credit	$1,000,000	$1,000,000	$ —	$ —	$—
Capital Lease Obligations	381,967	318,011	63,956	—	—
Operating Leases	691,127	307,168	307,168	76,791	—
Total Contractual Cash Obligations	$2,073,094	$1,625,179	$371,124	$76,791	$—

Critical Accounting Policies and Estimates

The consolidated financial statements are prepared in accordance with accounting principles generally accepted in the U.S., which require the Company to make estimates and assumptions in certain circumstances that affect amounts reported in the accompanying consolidated financial statements and related footnotes. In preparing these consolidated financial statements, management has made its best estimates and judgments of certain amounts included in the consolidated financial statements, giving due consideration to materiality. The Company does not believe there is a great likelihood that materially different amounts would be reported related to the accounting policies described below. However, application of these accounting policies involves the exercise of judgment and use of assumptions as to future uncertainties and, as a result, actual results could differ from these estimates.

Revenue Recognition. Revenue from the sale of the Company's EnSite clinical workstation is recognized at the time of shipment in instances where the Company has evidence of a contract or binding commitment, delivery has occurred, the fee is fixed and determinable, and collection is probable. Revenue from service and support contracts and extended maintenance and hardware upgrade agreements is deferred and recognized ratably over the period the services are provided or as the upgrades are performed. The Securities and Exchange Commission's Staff Accounting Bulletins (SAB) Nos. 101 and 104, "Revenue Recognition" and Emerging Issues Task Force, or ETIF, No. 00-21 "Accounting for Revenue Arrangements with Multiple Deliverables" provides guidance on the application of generally accepted accounting principles to selected revenue recognition issues. Effective July 1, 2003, the Company adopted the provisions of EITF No. 00-21, on a prospective basis. The principles and guidance outlined in EITF No. 00-21 provide a framework to (a) determine whether an arrangement involving multiple deliverables contains more than one unit of accounting, and (b) determine how the arrangement consideration should be measured and allocated to the separate units of accounting in the arrangement. The Company determined that its multiple-element arrangements are generally comprised of the following elements that would qualify as separate units of accounting: system sales and extended maintenance agreements. Each of these elements represents individual units of accounting as the delivered item has value to a customer on a stand-alone basis, objective and reliable evidence of fair value exists for undelivered items, and arrangements generally do not contain a general right of return relative to the delivered item. The Company determines fair value based on the price of the undelivered element when it is sold separately. In accordance with the guidance in EITF No. 00-21, the Company uses the residual method to allocate the arrangement consideration when it does not have fair value of the system sale. Under the residual method, the amount of consideration allocated to the delivered item equals the total arrangement consideration less the aggregate fair value of the undelivered items. The Company has concluded that its revenue recognition policy is appropriate and in accordance with this guidance.

Allowance for Doubtful Accounts. Accounts receivable are reduced by an allowance for amounts that may become uncollectible in the future. The estimated allowance is based on management's review of accounts receivable balances and historic write-offs. As of December 31, 2003, the Company has not taken any material write-offs of outstanding accounts receivable balances.

Inventories and Related Allowance for Excess and Obsolete Inventory. Inventories are valued at the lower of cost or market and have been reduced by an allowance for excess and obsolete inventories. The estimated allowance is based on management's review of inventories on hand compared to estimated future usage and sales. As of December 31, 2003, the Company's allowance for excess and obsolete inventories has been adequate.

New Accounting Standards

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." This statement establishes standards for the classification and measurement of certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. This statement is effective for financial instruments entered into or modified after May 31, 2003 and otherwise is effective at the beginning of the first interim period beginning after June 14, 2003. These effective dates are not applicable to the provisions of paragraph 9 and 10 of SFAS No. 150 as they apply to mandatory redeemable non-controlling interests, as the FASB has delayed these provisions. The Company does not believe the adoption of this statement will have a material impact upon its financial condition, results of operations or cash flows.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company had approximately $10.2 million of cash and cash equivalents on December 31, 2003. The Company received gross proceeds of $15.9 million from private placements of 4,829,029 shares of its common stock to accredited investors in January and August 2003. Substantially all of this cash is invested in money market funds. Because of the credit risk criteria of the Company's investment policies, the primary market risk associated with these investments is interest rate risk. The Company does not use derivative financial instruments to manage interest rate risk or to speculate on future changes in interest rates. A rise in interest rates could negatively affect the fair value of the Company's investments; however, because management considers it unlikely that the Company would need or choose to substantially liquidate the Company's investments prior to their maturity, management believes that such an increase in interest rates would not have a material impact on the Company's future earnings or cash flows. Even though the Company conducts sales in foreign currencies through its European subsidiary, management does not believe the Company is exposed to any material foreign currency exchange rate risk.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Auditors

Board of Directors and Stockholders
Endocardial Solutions, Inc.

We have audited the accompanying consolidated balance sheets of Endocardial Solutions, Inc. as of December 31, 2003 and 2002, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2003. Our audits also included the financial statement schedule listed in the Index at Item 15(a)(2). These consolidated financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Endocardial Solutions, Inc. at December 31, 2003 and 2002, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

/s/ Ernst & Young LLP

Minneapolis, Minnesota
January 26, 2004

Endocardial Solutions, Inc.
Consolidated Balance Sheets

	December 31	
	2003	2002
Assets		
Current assets:		
Cash and cash equivalents	**$ 10,216,385**	$ 1,347,753
Accounts receivable, net of allowance for doubtful accounts (2003—$151,996; 2002—$60,000)	**10,378,401**	8,148,723
Inventories	**4,700,507**	4,634,635
Prepaid expenses and other current assets	**1,435,102**	872,684
Total current assets	**26,730,395**	15,003,795
Furniture and equipment	**9,331,606**	8,278,575
Less accumulated depreciation	**(6,628,801)**	(5,827,679)
	2,702,805	2,450,896
Deposits	**51,179**	49,344
Notes receivable	**206,226**	206,226
Intangible assets, net of accumulated amortization (2003—$125,266; 2002—$120,494)	**585,032**	10,804
Total assets	**$ 30,275,637**	$ 17,721,065
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**$ 2,354,471**	$ 1,705,316
Accrued compensation expenses	**3,328,901**	2,671,764
Bank line of credit	**1,000,000**	1,000,000
Current portion of capital lease obligations	**318,011**	513,593
Current portion of deferred revenue	**2,634,751**	2,217,285
Total current liabilities	**9,636,134**	8,107,958
Long-term liabilities:		
Capital lease obligations	**63,956**	363,195
Deferred revenue	**262,282**	435,170
Stockholders' equity:		
Undesignated Preferred Stock, par value $.01 per share: Authorized shares—10,000,000 Issued and outstanding shares—none	**—**	—
Common Stock, $.01 par value: Authorized shares—40,000,000 Issued and outstanding shares—December 31, 2003—21,597,241; December 31, 2002—16,567,593	**215,972**	165,676
Additional paid-in capital	**104,680,168**	88,986,908
Accumulated deficit	**(84,956,006)**	(80,447,669)
Accumulated other comprehensive income	**486,525**	308,537
Deferred compensation	**(113,394)**	(198,710)
Total stockholders' equity	**20,313,265**	8,814,742
Total liabilities and stockholders' equity	**$ 30,275,637**	$ 17,721,065

See accompanying notes.

Endocardial Solutions, Inc.
Consolidated Statements of Operations

	Year ended December 31		
	2003	**2002**	**2001**
Revenue	**$36,556,681**	$26,265,155	$22,893,306
Cost of goods sold	**12,235,565**	9,472,885	9,241,039
Gross margin	**24,321,116**	16,792,270	13,652,267
Operating expenses:			
Research and development	**5,626,940**	5,506,593	5,271,169
General and administrative	**3,136,572**	3,023,657	2,240,737
Sales and marketing	**19,911,154**	18,134,496	14,750,075
Total Operating Expenses	**28,674,666**	26,664,746	22,261,981
Operating loss	**(4,353,550)**	(9,872,476)	(8,609,714)
Other income (expense):			
Interest income	**49,339**	68,258	318,208
Interest expense	**(115,672)**	(134,782)	(161,367)
Other	**(33,554)**	(22,455)	(26,170)
	(99,887)	(88,979)	130,671
Net loss	**$(4,453,437)**	$(9,961,455)	$(8,479,043)
Net loss per share—basic and diluted	**$ (0.22)**	$ (0.61)	$ (0.60)
Weighted average shares outstanding	**20,322,481**	16,324,066	14,211,318

See accompanying notes.

Endocardial Solutions, Inc.
Consolidated Statements of Changes in Stockholders' Equity

	Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Deferred	Notes Receivable	
	Shares	Amount	Capital	Deficit	Income/(Loss)	Compensation	From Officer	Total
Balance at December 31, 2000	12,249,695	$122,497	$ 71,769,626	$(62,007,171)	$ —	$ (20,783)	$ —	$ 9,864,169
Private placement at $3.00 per share in March 2001, net of offering costs	2,449,666	24,497	6,751,724	—	—	—	—	6,776,221
Exercise of warrants	122,450	1,224	488,576	—	—	—	—	489,800
Value of warrant issued with bank financing	—	—	8,750	—	—	—	—	8,750
Value of full recourse note receivable from officer in connection with stock purchase	110,000	1,100	370,150	—	—	—	(371,250)	—
Exercise of stock options	2,813	28	4,019	—	—	—	—	4,047
Deferred compensation related to stock options	—	—	315,000	—	—	(315,000)	—	—
Amortization of deferred compensation	—	—	—	—	—	61,412	—	61,412
Comprehensive loss:								
Net loss	—	—	—	(8,479,043)	—	—	—	(8,479,043)
Foreign currency translation adjustment	—	—	—	—	(9,556)	—	—	(9,556)
Comprehensive loss								(8,488,599)
Balance at December 31, 2001	14,934,624	149,346	79,707,845	(70,486,214)	(9,556)	(274,371)	(371,250)	8,715,800
Private placement at $6.00 per share in February 2002, net of offering costs	1,666,667	16,667	9,323,941	—	—	—	—	9,340,608
Purchase of common stock	(48,880)	(489)	(134,465)	—	—	—	165,024	30,070
Reclassification of note receivable	—	—	—	—	—	—	206,226	206,226
Value of warrants issued in connection with consulting agreement	—	—	42,250	—	—	—	—	42,250
Exercise of stock options	15,182	152	32,937	—	—	—	—	33,089
Deferred compensation related to stock options	—	—	14,400	—	—	(14,400)	—	—
Amortization of deferred compensation	—	—	—	—	—	90,061	—	90,061
Comprehensive loss:								
Net loss	—	—	—	(9,961,455)	—	—	—	(9,961,455)
Foreign currency translation adjustment	—	—	—	—	318,093	—	—	318,093
Comprehensive loss								(9,643,362)
Balance at December 31, 2002	16,567,593	165,676	88,986,908	(80,447,669)	308,537	(198,710)	—	8,814,742
Private placement at $2.75 per share in January 2003, net of offering costs	**3,097,000**	**30,970**	**7,910,186**	—	—	—	—	**7,941,156**
Private placement at $4.25 per share in August 2003, net of offering costs	**1,732,029**	**17,320**	**6,864,056**	—	—	—	—	**6,881,376**
Value of warrants exercised, net of issuance, in connection with bank debt agreements	**10,378**	**104**	**54,796**	**(54,900)**				—
Value of warrant issued in connection with technology license	—	—	**579,000**	—	—	—	—	**579,000**
Exercise of stock options	**190,241**	**1,902**	**285,222**	—	—	—	—	**287,124**
Amortization of deferred compensation	—	—	—	—	—	**85,316**	—	**85,316**
Comprehensive loss:								
Net loss	—	—	—	**(4,453,437)**	—	—	—	**(4,453,437)**
Foreign currency translation adjustment	—	—	—	—	**177,988**	—	—	**177,988**
Comprehensive loss								**(4,275,449)**
Balance at December 31, 2003	**21,597,241**	**$215,972**	**$104,680,168**	**$(84,956,006)**	**$486,525**	**$(113,394)**	$ —	**$20,313,265**

See accompanying notes.

Endocardial Solutions, Inc.
Consolidated Statements of Cash Flows

	Year ended December 31		
	2003	2002	2001
Operating activities			
Net loss	**$(4,453,437)**	$(9,961,455)	$(8,479,043)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	**1,008,664**	1,312,405	1,705,221
Increase in allowance for doubtful accounts	**91,996**	—	—
Amortization of deferred compensation	**85,316**	90,061	61,412
Value of warrants issued in connection with bank financing	—	—	8,750
Value of warrants issued in connection with consulting agreement	—	42,250	—
Loss on disposal of equipment	**23,131**	—	8,118
Receipt of stock as note receivable payment	—	30,070	—
Changes in operating assets and liabilities:			
Accounts receivable	**(1,839,124)**	(2,826,816)	(1,572,713)
Inventories	**20,584**	(1,850,886)	478,093
Prepaid expenses and other assets	**(438,120)**	(273,923)	(64,538)
Accounts payable	**614,690**	(603,117)	1,350,965
Accrued compensation expenses	**593,615**	287,937	728,854
Deferred revenue	**159,120**	1,830,359	44,036
Net cash used in operating activities	**(4,133,565)**	(11,923,115)	(5,730,845)
Investing activities			
Purchase of short-term investments	—	—	(2,938,753)
Maturities of short-term investments	—	—	5,926,341
Purchase of furniture and equipment	**(1,275,923)**	(222,678)	(567,398)
Patent expenditures	—	—	(650)
Software development costs	—	—	(295,777)
Net proceeds from sale of equipment	**95**	—	—
Net cash (used in) provided by investing activities	**(1,275,828)**	(222,678)	2,123,763
Financing activities			
Proceeds from bank line of credit	—	250,000	750,000
Principal payments on notes payable and capital lease obligations	**(494,821)**	(743,239)	(7,634,722)
Proceeds from issuance of common stock	**15,109,657**	9,373,697	7,270,068
Net cash provided by financing activities	**14,614,836**	8,880,458	385,346
Effect of exchange rate changes on cash	**(336,811)**	63,029	255
Increase (decrease) in cash and cash equivalents	**8,868,632**	(3,202,306)	(3,221,481)
Cash and cash equivalents at beginning of year	**1,347,753**	4,550,059	7,771,540
Cash and cash equivalents at end of year	**$10,216,385**	$ 1,347,753	$ 4,550,059
Supplemental disclosure of non-cash investing and financing activities			
Purchase of equipment through capital lease obligations	**$ —**	$ 724,830	$ 352,403
Note receivable from officer	—	—	371,250
Acquisition of technology license through issue of warrant	**579,000**	—	—

See accompanying notes.

1. Description of Business

Endocardial Solutions, Inc. (the "Company") designs, develops and manufactures an integrated advanced mapping and navigation system that locates and facilitates treatment of cardiac arrhythmias. Cardiac arrhythmias are abnormal heart rhythms caused by disorders interfering with the normal electrical activity of the heart, which, if undetected and untreated, can cause palpitations, dizziness and fainting, or sudden cardiac death. The Company is developing and marketing products that assist in the diagnosis of various types of ventricular arrhythmias (including ventricular tachycardia, a widespread, complex and serious form of arrhythmia), and atrial arrhythmias (including atrial fibrillation), and products that assist electrophysiologists to navigate and precisely locate conventional linear catheters used in a variety of electrophysiology procedures. The Company believes its proprietary technology enables physicians to more rapidly and accurately map the heart's electrical activity, locate abnormal heart rhythms through three-dimensional imaging, and visualize, navigate and precisely locate a variety of diagnostic and therapeutic catheters used in connection with the diagnosis and treatment of cardiac arrhythmias.

2. Summary of Significant Accounting Policies

Basis of Consolidation

The consolidated financial statements include the accounts of Endocardial Solutions, Inc. and its wholly owned subsidiary after elimination of inter-company accounts and transactions.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. At December 31, 2003 and 2002, the Company's cash equivalents consisted of investments in government securities carried at an amortized cost which approximated market value, with no resulting unrealized gains and losses recognized.

Revenue Recognition

Revenue from the sale of the Company's EnSite clinical workstations is recognized at the time of shipment in instances where the Company has evidence of a contract or binding commitment, delivery has occurred, the fee charged is fixed and determinable, and collection is probable. Effective July 1, 2003, the Company adopted the provisions of Emerging Issues Task Force, or EITF, Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables" on a prospective basis. The principles and guidance outlined in EITF No. 00-21 provide a framework to (a) determine whether an arrangement involving multiple deliverables contains more than one unit of accounting, and (b) determine how the arrangement consideration should be measured and allocated to the separate units of accounting in the arrangement. The Company determined that its multiple-element arrangements are generally comprised of the following elements that would qualify as separate units of accounting: system sales and extended maintenance agreements. Each of these elements represents individual units of accounting as the delivered item has value to a customer on a stand-alone basis, objective and reliable evidence of fair value exists for undelivered items, and arrangements generally do not contain a general right of return relative to the delivered item. The Company determines fair value based on the price of the undelivered element when it is sold separately. In accordance with the guidance in EITF No. 00-21, the Company uses the residual method to allocate the arrangement consideration when it does not have

2. Summary of Significant Accounting Policies (Continued)

fair value of the system sale. Under the residual method, the amount of consideration allocated to the delivered item equals the total arrangement consideration less the aggregate fair value of the undelivered items.

Deferred revenue originates from the Company's sale to its customers of software service, support maintenance agreements (including the right to receive software upgrades) ("Maintenance Agreements") and the sale of extended service, support and maintenance agreements (with and without the right to receive hardware upgrades) ("Extended Warranty Agreements"). With the initial sale of an EnSite clinical workstation, the Company provides a standard one-year Maintenance Agreement, which covers repairs, service and technical support of the patient interface unit and the computer platform for the clinical workstation. This standard Maintenance Agreement also covers any software upgrades released during the term of the Maintenance Agreement. Subsequent to the expiration of the first year Maintenance Agreement, customers are able to purchase an Extended Warranty Agreement for comparable levels of service and support, software upgrades, and optional hardware upgrades, all to be performed during the term of the Extended Warranty Agreement either as part of the initial system sale or in a stand-alone transaction. Long-term deferred revenue originates from sale of these Maintenance Agreements and Extended Warranty Agreements. Revenue from the service and support provided under these agreements is recognized ratably over the period the services are provided. Revenue from the hardware upgrades provided under the Extended Warranty Agreements is recognized at the time the EnSite clinical workstation hardware is upgraded.

Shipping and handling costs are included in the cost of goods sold.

Software Development Costs

The Company capitalizes software development costs in accordance with Statement of Financial Accounting Standards No. 86, *Accounting for the Costs of Computer Software to be Sold, Leased or Otherwise Marketed*. The capitalization of these costs begins when a product's technological feasibility has been established and ends when the product is available for general release to customers. Any amounts capitalized are amortized over an estimated economic useful life of 18 months.

Furniture and Equipment

Furniture and equipment are recorded at cost. Depreciation is recorded using the straight-line method over the estimated useful lives of the assets ranging from three to ten years. Amortization of assets recorded under capital leases is provided using the straight line method over the life of the lease. Estimated useful lives are as follows:

	Useful Lives (Years)
Plant equipment and furniture and fixtures	7 to 10
Computer hardware and software	3 to 5
Leasehold improvements	2

2. Summary of Significant Accounting Policies (Continued)

Intangible Assets

Intangible assets represents patents and a technology license used, in part, to develop Ensite NavX. These intangible assets are amortized on a straight-line basis over their economic useful life, ranging from five to ten years. The Company periodically reviews its intangible assets for impairment in value. Any impairment from the analysis is charged to operations.

Income Taxes

Income taxes are accounted for under the liability method. Deferred income taxes are provided for temporary differences between financial reporting and tax basis of assets and liabilities.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Inventories

Inventories are valued at the lower of cost (first-in, first-out method) or market.

Stock-Based Compensation

At December 31, 2003, the Company had two stock-based employee compensation plans and one non-employee director's plan, which are described more fully in Note 7. The Company accounts for those plans under the recognition and measurement principles of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations. No stock-based employee compensation cost is reflected in net loss, as all options granted under those plans had an exercise price equal to the market value of the underlying common stock on the date of grant.

The following table illustrates the effect on net loss and loss per share if the Company had applied the fair value recognition provisions of Financial Accounting Standards Board (FASB) Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-based Compensation*, to stock-based employee compensation.

	2003	2002	2001
Net loss as reported	**$(4,453,437)**	$ (9,961,455)	$(8,479,043)
Add: Stock-based compensation, as reported	**85,316**	90,061	61,412
Deduct: Stock-based compensation determined under fair-value method for all awards	**(1,335,438)**	(1,681,434)	(1,219,262)
Pro forma net loss	**$(5,703,559)**	$(11,552,828)	$(9,636,893)
Basic and diluted loss per share, as reported	**$ (0.22)**	$ (0.61)	$ (0.60)
Basic and diluted loss per share, pro forma	**$ (0.28)**	$ (0.71)	$ (0.68)

2. Summary of Significant Accounting Policies (Continued)

Pro forma information regarding net loss and loss per share is required by SFAS No. 123, and has been determined as if the Company had accounted for its employee stock options under the fair value method of SFAS No. 123. The fair value for these options was estimated at the date of grant using a Black-Scholes option pricing model with the following assumptions:

	2003	2002	2001
Risk-free interest rate	**2.97%**	3.82%	4.42%
Dividend yield	**0%**	0%	0%
Volatility factor	**.99**	.96	.87
Weighted average expected life	**6.51 years**	7.03 years	6.87 years

Impairment of Long-Lived Assets

The Company will record impairment losses on long-lived assets used in operations when indicators of impairment are present and the undiscounted cash flows estimated to be generated by those assets are less than the long-lived assets' carrying amount.

Net Loss Per Share

Basic loss per share is computed using the weighted average number of common shares outstanding. Diluted loss per share is computed using the combination of dilutive common share equivalents and the weighted average number of common shares outstanding. Diluted earnings per share is not separately presented, as the effect of outstanding options and warrants is anti-dilutive.

New Accounting Standards

In November 2002, the EITF issued EITF No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. EITF Issue No. 00-21 addresses certain aspects of the accounting by a vendor for arrangements under which it will perform multiple revenue-generating activities. EITF Issue No. 00-21 establishes three principles: revenue arrangements with multiple deliverables should be divided into separate units of accounting, arrangement consideration should be allocated among the separate units of accounting based on their relative fair values, and revenue recognition criteria should be considered separately for separate units of accounting. EITF Issue No. 00-21 is effective for all revenue arrangements entered into in fiscal periods beginning after June 15, 2003, with early adoption permitted. The adoption of EITF Issue No. 00-21 did not have a material effect on the consolidated results of operations, financial position, or cash flows of the Company.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." This statement establishes standards for the classification and measurement of certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. This statement is effective for financial instruments entered into or modified after May 31, 2003 and otherwise is effective at the beginning of the first interim period beginning after June 14, 2003. These effective dates are not applicable to the provisions of paragraph 9 and 10 of SFAS No. 150 as they apply to mandatory redeemable non-controlling interests, as the FASB has delayed these provisions.

2. Summary of Significant Accounting Policies (Continued)

The Company does not believe the adoption of this statement will have a material impact upon its financial condition, results of operations or cash flows.

3. Inventories

Inventories consisted of the following at December 31:

	2003	2002
Raw materials	**$2,852,690**	$2,099,943
Work-in-progress	**168,231**	497,589
Finished goods	**1,679,586**	2,037,103
	$4,700,507	$4,634,635

4. Comprehensive Loss

The components of comprehensive loss, net of related tax, were as follows:

	2003	2002	2001
Net loss	**$(4,453,437)**	$(9,961,455)	$(8,479,043)
Foreign currency translation adjustment	**177,988**	318,093	(9,556)
Comprehensive loss	**$(4,275,449)**	$(9,643,362)	$(8,488,599)

5. Long-Term Debt and Contractual Obligations

Long-Term Debt

In September 2003, the Company entered into a $4.5 million credit facility agreement with Silicon Valley Bank ("SVB"). This new credit facility replaced a prior credit facility with SVB that the Company entered into in June of 2001, and modified in May 2002 to extend the term of the initial agreement. The September 2003 credit facility with SVB consisted of a $3.0 million domestic line of credit, and a $1.5 million international (EXIM) credit line. This facility operates as a revolving line of credit, with $1.3 million reserved for use as a capital lease line. The terms of the credit facility include certain restrictive financial covenants, including the Company's obligation to maintain a specified ratio of "current assets" to "current liabilities" ("quick ratio"), as well as a minimum "tangible net worth." As of December 31, 2003, the Company was in compliance with the financial covenants of the credit facility. As of December 31, 2003, the Company had $0.4 million outstanding related to capital leases and had an additional $1.0 million outstanding on the credit line.

Guarantees

In November 2002, the Financial Accounting Standards Board issued Interpretation No. 45 (FIN 45), *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* (the "Interpretation"). The Interpretation requires disclosure in periodic financial statements of certain guarantee arrangements. The Interpretation also clarifies situations

5. Long-Term Debt and Contractual Obligations (Continued)

where a guarantor is required to recognize the fair value of certain guarantees in the financial statements. The Company does not have any guarantees that require recognition at fair value under the Interpretation.

The Company sells extended warranty agreements that include service and support, and may also include software and/or hardware upgrades. Revenue from the sale of extended warranty contracts is deferred and recognized ratably over the period in which the services are provided, and/or at the time the upgrades are performed. The Company does not recognize revenue from minor periodic upgrades to versions of previously released software. Costs associated with extended warranty contracts are recognized at the time the service is provided, and/or the upgrades are performed.

Changes in the recorded deferred revenue amounts during the period were as follows:

Balance, December 31, 2002	$2,652,455
Additional deferred revenue during the period	4,457,900
Deferred revenue recognized during the period	(4,213,322)
Balance, December 31, 2003	$2,897,033

Capital Lease Obligations

The Company has entered into equipment leasing line of credit agreements with two different venture leasing companies for the acquisition of furniture, fixtures and research and development equipment. As of December 31, 2003 and 2002, the Company had outstanding lease obligations under these agreements of $381,967, and $876,788, respectively.

The cost of furniture and equipment in the accompanying balance sheets includes the following amounts under capital leases as of December 31:

	2003	2002
Research and development equipment	**$3,142,831**	$3,142,831
Less accumulated amortization	**(2,486,567)**	(1,858,001)
Net assets under capital leases	**$ 656,264**	$1,284,830

5. Long-Term Debt and Contractual Obligations (Continued)

Future minimum lease payments under capital leases consisted of the following as of December 31, 2003:

Year ending December 31:	
2004	$330,910
2005	63,956
Total minimum payments	394,866
Less amount representing interest	12,899
Present value of net minimum payments	381,967
Less current portion	318,011
Long-term obligations, net of current portion	$ 63,956

Interest paid for the years ended December 31, 2003, 2002 and 2001 was $120,672, $130,056, and $301,198, respectively.

6. Operating Leases

The Company leases its office facility and certain equipment under operating lease agreements which expire on various dates through 2006. Under the office facility agreement, the Company is required to pay a base rent plus certain operating expenses. Rent expense was $545,924, $570,904, and $461,754 for the years ended December 31, 2003, 2002 and 2001, respectively.

Future minimum lease commitments required under non-cancelable operating leases as of December 31, 2003 are as follows:

Year ending December 31:	
2004	$307,168
2005	307,168
2006	76,791
Total	$691,127

7. Stock Options and Warrants

The Company adopted the 1993 Long-Term Stock Option Plan ("the 1993 Plan") under which directors, officers, employees and consultants of the Company received options to purchase Common Stock. The options granted under the 1993 Plan can either be incentive stock options or non-statutory stock options. Options granted under the 1993 Plan may not be at a price less than the fair market value of the Common Stock on the date of grant. The 1993 Plan expired in April 2003 in accordance with its terms and was replaced with the 2003 Stock Incentive Plan discussed below.

In 1997, the Company adopted the Directors' Stock Option Plan ("the Directors' Plan"). The Directors' Plan provided for the automatic grant of non-statutory stock options of Common Stock to non-employee directors. The option price for non-employee directors is equal to the fair market value

7. Stock Options and Warrants (Continued)

of a share of Common Stock as of the grant date. In conjunction with the approval of the Endocardial Solutions, Inc. 2003 Stock Incentive Plan in May 2003 (see below for details), the Directors' Plan was terminated and no additional options will be granted thereunder. Future options or awards granted to non-employee directors will be made under the 2003 Stock Incentive Plan.

In May 2003, the Company adopted the 2003 Stock Incentive Plan ("the Incentive Plan") to replace the 1993 Plan and the Director's Plan discussed above. Under the Incentive Plan, all employees, officers, consultants, independent contractors and directors of the Company and its subsidiaries and affiliates are eligible to receive awards. The Incentive Plan terminates on April 15, 2013, and no awards may be made after such date. The Incentive Plan permits the granting of: (a) stock options to purchase the Company's Common Stock, including "incentive stock options" meeting the requirements of Section 422 of the Internal Revenue Code ("Incentive Stock Options") and stock options that do not meet such requirements ("Nonqualified Stock Options"), (b) stock appreciation rights based on the price of the Company's Common Stock, (c) restricted stock and restricted stock units, (d) performance awards, (e) dividend equivalents and (f) other stock grants and other stock-based awards. 1,250,000 shares of Common Stock were reserved for issuance under the Incentive Plan. Stock options granted under the Plan typically vest pro-rata over a four (4) year vesting period; provided, however, that the Company's Board of Directors has the authority to approve shorter or longer vesting schedules for any such grant.

The following table summarizes the activity under the Company's stock option plans:

	Director's Plan(1)		1993 Long-Term Plan(1)(2)			2003 Stock Incentive Plan			
	Shares Available For Grant	Options Outstanding	Shares Available For Grant	Options Outstanding NSO	Options Outstanding ISO	Shares Available For Grant	Options Outstanding NSO	Options Outstanding ISO	Weighted Average Exercise Price Per Share
Balance at December 31, 2000	88,334	111,666	144,326	73,747	1,216,978	—	—	—	$6.34
Additional shares reserved for issuance	—	—	750,000	—	—	—	—	—	—
Granted	(40,000)	40,000	(801,250)	—	801,250	—	—	—	4.81
Cancelled	—	—	108,955	(36,247)	(72,708)	—	—	—	8.43
Exercised	—	—	—	—	(2,813)	—	—	—	1.44
Balance at December 31, 2001	48,334	151,666	202,031	37,500	1,942,707	—	—	—	5.64
Additional shares reserved for issuance	100,000	—	750,000	—	—	—	—	—	—
Granted	(45,000)	45,000	(1,073,000)	25,000	1,048,000	—	—	—	4.08
Cancelled	—	—	327,377	—	(327,377)	—	—	—	6.66
Exercised	—	—	—	—	(15,182)	—	—	—	2.18
Balance at December 31, 2002	103,334	196,666	206,408	62,500	2,648,148	—	—	—	4.94
Additional shares reserved for issuance	—	—	—	—	—	1,250,000	—	—	—
Granted	(70,000)	70,000	(166,000)	—	166,000	(153,900)	—	153,900	**4.02**
Cancelled	(33,334)	—	(148,587)	—	(108,179)	—	—	—	**5.21**
Exercised	—	—	—	—	(190,241)	—	—	—	**5.97**
Balance at December 31, 2003	—	266,666	—	62,500	2,515,728	1,096,100	—	153,900	**6.51**

(1) As discussed above, in May 2003 the 1993 Long-Term Stock Option Plan expired and the Directors' Stock Option Plan was terminated. Accordingly, no further shares are available for issuance under either plan.

(2) The table does not include the 200,000 shares reserved for purchase by employees under the Employee Stock Purchase Plan discussed below.

7. Stock Options and Warrants (Continued)

The following table summarizes information about the stock options outstanding at December 31, 2003:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price Per Share	Number Exercisable	Weighted-Average Exercise Price Per Share
$ 0.20 - $ 0.34	204,500	1.15	$ .33	204,500	$ .34
0.60 - 2.40	93,750	2.32	2.04	93,750	2.04
2.73 - 7.88	1,924,478	7.91	3.90	893,079	4.07
8.00 - 12.38	755,566	4.99	9.33	687,354	9.42
12.50 - 13.13	20,500	4.17	12.88	20,500	12.88
0.20 - 13.13	2,998,794	6.51	5.03	1,899,183	5.60

Options outstanding under the stock option plans expire at various dates from March 2004 through October 2013.

The weighted-average grant date fair value of options granted during the years ended December 31, 2003, 2002 and 2001 was $4.02, $2.63, and $2.21 per share, respectively.

The Company also has an Employee Stock Purchase Plan ("the Plan") under which 200,000 shares have been reserved for purchase by employees. The purchase price of the shares under the Plan is the lesser of 85% of the fair market value on either the first or last day of the offering period. Each offering period is three months. Employees may designate up to 15% of their compensation for the purchase of stock under the Plan. There have been no shares issued under the Plan as of December 31, 2003.

As of December 31, 2003, there was an outstanding warrant to purchase 223,777 shares of the Company's common stock at an exercise price of $3.81 per share, issued in connection with a patent and technology licensing agreement. This warrant can be exercised at any time between May 1, 2004 and May 1, 2007.

8. Deferred Compensation

During the years ended December 31, 2002, and 2001, the Company granted stock options for the purchase of 45,000 shares and 125,000 shares, respectively, of common stock to individuals where the exercise price was less than the fair market value of the stock on the date of grant. As a result, the Company recorded deferred compensation for the excess of deemed value of the common stock to be issued upon exercise of such options over the aggregate exercise price of such options of $14,400 and $315,000 in 2002 and 2001, respectively. For the years ended December 31, 2003, 2002, and 2001, the Company recognized expense of $85,316, $90,061, and $61,412, respectively, associated with such stock option grants.

8. Deferred Compensation (Continued)

The remaining unamortized deferred compensation is expected to be charged to operations as follows:

2004	$ 82,350
2005	29,845
2006	1,199
Total	$113,394

9. Income Taxes

At December 31, 2003, the Company had net operating loss carry-forwards of approximately $77,384,000. The net operating loss carry-forwards are available to offset future taxable income and begin to expire in the year 2009. No benefit has been recorded for such loss carry-forwards, and utilization in future years may be limited under Section 382 of the Internal Revenue Code if significant ownership changes occur.

Components of deferred tax assets are as follows:

	December 31	
	2003	2002
Deferred tax assets:		
Net operating loss carryforwards	**$ 29,406,000**	$ 28,829,000
Accrued liabilities	**232,000**	180,000
Allowance for bad debt	**58,000**	23,000
Other	**11,000**	11,000
	29,707,000	29,043,000
Deferred tax liabilities:		
Depreciation and amortization	**16,000**	33,000
Net deferred tax assets	**29,691,000**	29,010,000
Valuation allowance	**(29,691,000)**	(29,010,000)
Total net deferred tax assets	**$ —**	$ —

Reconciliation of the statutory federal income tax rate to the Company's effective tax rate is as follows:

	2003	2002	2001
Tax at statutory rate	35%	35%	35%
State income taxes	3%	3%	3%
Impact of net operating loss carryforward	(38)%	(38)%	(38)%
Effective income tax rate	—%	—%	—%

10. Sources of Supply

The Company purchases raw materials and certain key components of its products, including the computing platform, certain components of the clinical workstation, certain components for the EnSite Array catheters, and the EnSite NavX surface electrode kits, from sole, single or limited source suppliers. The Company currently has no agreements that would ensure delivery of raw materials and components from such suppliers. Establishing additional or replacement suppliers for any of the numerous components used in the Company's products, if required, may not be accomplished quickly and could involve significant additional costs. The inability of any of the Company's suppliers to provide an adequate supply of components in a timely manner, or the inability of the Company to locate qualified alternative suppliers for material and components at reasonable costs, could adversely affect the Company's business, financial condition and results of operations.

11. Note Receivable

In January 2001, the Company entered into a $371,250 full recourse note agreement with a then officer of the Company for the purchase of 110,000 restricted shares of the Company's common stock. The note bore interest at 9.5% per year and was due in full in January 2006. This officer left the employment of the Company in 2002, at which time 61,120 shares of the Company's common stock held by the employee had fully vested. The Company elected to purchase the 48,880 unvested shares of restricted Company common stock from the former officer at a purchase price of $165,024, which shares were cancelled. In connection with the repurchase of the unvested shares, the Company recorded expense of $30,070. Concurrently, the former officer executed an amended, interest-free, full recourse note agreement in the amount of $206,226. This note is payable to the Company on the earlier of (i) January 2, 2011, or (ii) within twenty (20) days following the former officer's sale of any of the 61,120 shares of Company common stock that were subject to the original agreement.

In October 2002, the Company issued a stock option grant of 25,000 shares of common stock at an exercise price of $2.76 per share in connection with a consulting agreement between the former officer and the Company. The option expires in seven years from the grant date and was deemed to have a value of $42,250 using a Black-Scholes option pricing model, which was expensed during the year ended December 31, 2002.

12. Significant Customer

For the years ended December 31, 2003, 2002 and 2001, the Company did not have any customers accounting for more than 10% of net revenues.

13. Segment Reporting

Revenue by geographic distinction as percentages of total revenue was as follows:

	Years ended December 31,		
	2003	2002	2001
Domestic	75%	77%	81%
International:			
Europe	16%	16%	10%
Asia Pacific	7%	5%	7%
Canada/Mexico	2%	2%	2%

14. Quarterly Financial Data (unaudited, in thousands, except per share data)

	For the Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
2003				
Net revenue	$ 7,292	$ 9,293	$ 9,696	$10,275
Gross margin	4,878	5,846	6,326	7,271
Net (loss)/income	(2,162)	(1,419)	(879)	7
Basic and diluted net loss per share	$ (0.11)	$ (0.07)	$ (0.04)	$ 0.00
2002				
Net revenue	$ 7,108	$ 7,532	$ 5,508	$ 6,117
Gross margin	4,507	4,743	3,467	4,075
Net loss	(1,795)	(1,930)	(3,118)	(3,118)
Basic and diluted net loss per share	$ (0.12)	$ (0.12)	$ (0.19)	$ (0.19)

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures. Under the supervision and with the participation of management, including the Company's Chief Executive Officer and Chief Financial Officer, the Company evaluated the effectiveness of the design and operation of its disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")). Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures were effective in timely alerting them to the material information relating to the Company (or the Company's consolidated subsidiaries) required to be included in the reports the Company files or submits under the Exchange Act.

(b) Changes in internal controls over financial reporting. During the quarter ended December 31, 2003, there has been no change in the Company's internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The section under the heading "Election of Directors" and the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" in the Company's Proxy Statement for its Annual Meeting of Stockholders to be held on May 18, 2004 (the "2004 Proxy Statement"), which definitive 2004 Proxy Statement will be filed within 120 days after the close of the fiscal year ended December 31, 2003, are incorporated herein by reference.

See Item 1 in Part I hereof for information regarding Executive Officers of the Company.

In response to Item 401(h)(1) of Regulation S-K under the Securities Act of 1933 and the Exchange Act ("Regulation S-K"), the Board has determined that the Company has at least one audit committee financial expert who is independent, as defined by Item 401(h)(2) of Regulation S-K.

The Board of Directors of the Company intends to approve the adoption of a Code of Business Conduct and Ethics ("Business Conduct Code") prior to the 2004 Annual Meeting of Stockholders and in compliance with NASDAQ Listing requirements. The Business Conduct Code will apply to the Company's Chief Executive Officer, Chief Financial Officer (who is both the Company's principal financial and principal accounting officer), as well as all other employees. Following adoption, a copy of the Business Conduct Code will be posted on the Company's website, and filed with the SEC with the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2004.

ITEM 11. EXECUTIVE COMPENSATION

The section under the heading "Election of Directors" entitled "Compensation of Directors" and the section entitled "Executive Compensation" in the 2004 Proxy Statement, which definitive 2004 Proxy Statement will be filed within 120 days after the close of the fiscal year ended December 31, 2003, are incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

(a) Equity Compensation Plans

The following table sets forth information with respect to securities authorized for issuance under the Company's equity compensation plans as of December 31, 2003:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in the first column)
Equity compensation plans approved by security holders . . .	2,998,794	$5.03	1,296,100(1)
Equity compensation plans not approved by security holders . . .	—	—	—
Total	2,998,794	$5.03	1,296,100

(1) Includes stock available for issuance under the Company's 2003 Stock Incentive Plan and the Employee Stock Purchase Plan. Specifically, 1,096,100 shares remain available under the 2003 Stock Incentive Plan and 200,000 shares remain available under the Employee Stock Purchase Plan. Shares available under the Employee Stock Purchase Plan are issued based on employees' elections to participate in the plan. In May 2003 the 1993 Long-Term Stock Option Plan expired and the Directors' Stock Option Plan was terminated. Accordingly, no further shares are available for issuance under either plan.

(b) Security Ownership

The section entitled "Security Ownership of Certain Beneficial Owners and Management" in the 2004 Proxy Statement, which definitive 2004 Proxy Statement will be filed within 120 days after the close of the fiscal year ended December 31, 2003, is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The section entitled "Certain Transactions" in the 2004 Proxy Statement, which definitive 2004 Proxy Statement will be filed within 120 days after the close of the fiscal year ended December 31, 2003, is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The section entitled "Independent Accountants" in the 2004 Proxy Statement, which definitive 2004 Proxy Statement will be filed within 120 days after the close of the fiscal year ended December 31, 2003, is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a) Documents filed as part of this Report

(1) Consolidated Financial Statements. The following consolidated financial statements of the Company are included in Part II, Item 8, Financial Statements and Supplementary Data, of this Annual Report on Form 10-K.

	Page in this Annual Report
Report of Independent Auditors	35
Audited Financial Statements:	
Consolidated Balance Sheets as of December 31, 2003 and 2002	36
Consolidated Statements of Operations for the three years ended December 31, 2003	37
Consolidated Statements of Changes in Stockholders' Equity for the three years ended December 31, 2003	38
Consolidated Statements of Cash Flows for the three years ended December 31, 2003	39
Notes to Consolidated Financial Statements	40

(2) Consolidated Financial Statement Schedules:

Schedule II—Valuation and Qualifying Accounts. Such schedule should be read in conjunction with the consolidated financial statements. All other supplemental schedules are omitted because of the absence of conditions under which they are required.

SCHEDULE II
VALUATION AND QUALIFYING ACCOUNTS
YEARS ENDED DECEMBER 31, 2003, 2002 AND 2001

	Balance at Beginning of Year	Additions Charged to Costs and Expenses	Less Deductions	Balance at End of Year
Year ended December 31, 2003				
Reserve for Obsolete Inventory	$30,000	$ —	$ —	$ 30,000
Allowance for doubtful accounts	60,000	91,996	—	151,996
Total	$90,000	$91,996	$ —	$181,996
Year ended December 31, 2002				
Reserve for Obsolete Inventory	$30,000	$ —	$ —	$ 30,000
Allowance for doubtful accounts	60,000	—	—	60,000
Total	$90,000	$ —	$ —	$ 90,000
Year ended December 31, 2001				
Reserve for Obsolete Inventory	$ —	$30,000	$ —	$ 30,000
Allowance for doubtful accounts	60,000	—	—	60,000
Total	$60,000	$30,000	$ —	$ 90,000

(3) **EXHIBITS**

See Exhibit Index on page 56 for a description of the documents that are filed as Exhibits to this report on Form 10-K or incorporated by reference herein. Any document incorporated by reference is identified by a parenthetical referencing the SEC filing which included the document. The Company will furnish to a security holder upon request a copy of any Exhibit at cost.

(b) Reports on Form 8-K

A report on Form 8-K, dated October 7, 2003, was filed by the Registrant; such report contained information under Item 5 (Other Events) and included as an exhibit under Item 7, a copy of a press release issued by the Registrant announcing the release of the next software version of its EnSite NavX product.

A report on Form 8-K, dated October 24, 2003 was furnished by the Registrant; such report contained information under Item 12 (Results of Operations and Financial Condition) and included as an exhibit under Item 7 a copy of a press release issued by the Registrant announcing its third quarter earnings results.

(c) See Item 15(a)(3) above.

(d) See Item 15(a)(2) above.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of St. Paul, Minnesota.

Date: March 15, 2004

ENDOCARDIAL SOLUTIONS, INC.

By

/s/ JAMES W. BULLOCK

James W. Bullock, *President and Chief Executive Officer (Principal Executive Officer)*

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed by the following persons on behalf of the registrant and in the capacities indicated on the 15th day of March, 2004.

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints James W. Bullock and J. Robert Paulson, Jr., as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and re-substitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to the Annual Report on Form 10-K of Endocardial Solutions, Inc., and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, lawfully do or cause to be done by virtue hereof.

Signature	Title
/s/ JAMES W. BULLOCK James W. Bullock	President, Chief Executive Officer and Director (Principal Executive Officer)
/s/ J. ROBERT PAULSON J. Robert Paulson, Jr.	Chief Financial Officer (Principal Financial and Accounting Officer)
/s/ GRAYDON E. BEATTY Graydon E. Beatty	Director, Chief Technical Officer
/s/ ROBERT G. HAUSER Robert G. Hauser, M.D.	Director
/s/ WARREN S. WATSON Warren S. Watson	Director
/s/ RICHARD D. RANDALL Richard D. Randall	Director
/s/ MARK T. WAGNER Mark T. Wagner	Director
/s/ RICHARD NIGON Richard Nigon	Director
/s/ J.P. PELTIER J.P. Peltier	Director

INDEX TO EXHIBITS

3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-1, dated January 29, 1997, as amended on March 5, 1997, March 13, 1997 and March 18, 1997 (File No. 333-20677))
3.2	Amended Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999 (File No. 0-22233)
3.3	Certificate of Designation of Series A Junior Participating Preferred Stock (incorporated by reference to Exhibit 3.3 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999 (File No. 0-22233))
4.1	Rights Agreement dated as of August 25, 1999 between the Company and Wells Fargo Bank Minnesota, National Association (formerly Norwest Bank Minnesota), as Rights Agent (incorporated by reference to Exhibit 1 to the Company's Registration Statement on Form 8-A dated August 25, 1999 (File No. 0-22233))
10.1	Real Property Lease Agreement dated September 15, 1993 between the Company and the Port Authority of St. Paul, together with Amendment Nos. 1, 2 and 3 thereto dated February 6, 1995, May 16, 1995, June 4, 1996, respectively (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1, dated January 29, 1997, as amended on March 5, 1997, March 13, 1997 and March 18, 1997 (File No. 333-20677))
10.2	Amendment No. 4 to the Real Property Lease Agreement dated September 15, 1993 between the Company and the Port Authority of St. Paul (incorporated by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 1997 (File No. 0-22233)).
10.3	Master Lease Agreement dated November 14, 1994, as amended, between the Company and Comdisco, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1, dated January 29, 1997, as amended on March 5, 1997, March 13, 1997 and March 18, 1997 (File No. 333-20677))
10.4*	Amended and Restated 1993 Long Term Incentive and Stock Option Plan, as amended May 15, 2001 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001 (File No. 0-22233))
10.5*	Directors' Stock Option Plan (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1, dated January 29, 1997, as amended on March 5, 1997, March 13, 1997 and March 18, 1997 (File No. 333-20677))
10.6*	1997 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1, dated January 29, 1997, as amended on March 5, 1997, March 13, 1997 and March 18, 1997 (File No. 333-20677))
10.7	License Agreement, dated January 30, 1998, between the Company and Medtronic, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 1998, as amended on July 31, 1998 (File No. 0-22233))
10.8	Master Lease Agreement dated May 4, 1998, between the Company and Transamerica Business Credit Corporation (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1998 (File No. 0-22233))

10.9 Extension of Lease Commitment, dated February 12, 1999, by Transamerica Business Credit Corporation (incorporated by reference to Exhibit 10.18 to the Company's Annual Report on Form 10-K for the year ended December 31, 1998 (File No. 0-22233))

10.10* Employment and Noncompetition Agreement, dated as of November 3, 2000, between the Company and James W Bullock (incorporated by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000 (File No. 0-22233))

10.11* Change in Control Agreement, dated November 3, 2000, between the Company and James W Bullock (incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000 (File No. 0-22233))

10.12* Form of Change in Control Agreement between the Company and each of J. Robert Paulson, Jr., Graydon Beatty, Frank Callaghan and Richard Omilanowicz (incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000 (File No. 0-22233))

10.13 Amendment No. 5, dated August 2, 1999, to the Real Property Lease dated September 15, 1993 between the Company and the Port Authority of St. Paul (incorporated by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000 (File No. 0-22233))

10.14 Amendment No. 6, dated January 29, 2001, to the Real Property Lease dated September 15, 1993 between the Company and Place & Plaza LLC (acquired from the Port Authority of St. Paul) (incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000 (File No. 0-22233))

10.15 Real Property Lease dated August 13, 2001 between the Company and Place & Plaza LLC (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001 (File No. 0-22233))

10.16 Form of Stock Purchase Agreement, dated February 25, 2002, among the Company and the Investors named therein (incorporated by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K for the year ended December 31, 2001 (File No. 0-22233))

10.17 Form of Stock Purchase Agreement, dated January 2, 2003, among the Company and the Investors named therein (incorporated by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002 (File No. 0-22233))

10.18* 2003 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003 (File No. 0-22233))

10.19 Form of Stock Purchase Agreement, used in transactions dated August 20, 2003 and August 25, 2003, among Endocardial Solutions, Inc. and the Investors named therein (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on August 26, 2003, as amended on Form 8-K/A filed on August 27, 2003 and Form 8-K/A filed on September 2, 2003 (File No. 0-22233))

10.20 Loan and Security Agreement, dated September 24, 2003, by and between Endocardial Solutions, Inc. and Silicon Valley Bank (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003 (File No. 0-22233))

10.21 Loan and Security Agreement (Exim Program), dated September 24, 2003, by and between Endocardial Solutions, Inc. and Silicon Valley Bank (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003 (File No. 0-22233))

10.22	Secured Promissory Note (Exim Program) dated September 24, 2003 (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003 (File No. 0-22233))
10.23	Warrant, dated effective May 1, 2003 to purchase shares of common stock, issued by the Company to Medtronic International, Ltd. (Filed herewith)
21	List of Subsidiaries (Filed herewith)
23	Consent of Ernst & Young LLP (Filed herewith)
24	Power of Attorney (Included on signature page)
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Filed herewith).
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Filed herewith).
32.1	Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Filed herewith).
32.2	Certification of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Filed herewith).
99.1	Cautionary Statement for Purposes of the "Safe Harbor" Provisions of the Private Securities Litigation Reform Act of 1995 (Filed herewith)

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* Management contract or compensatory plan or arrangement required to be filed as an exhibit to Form 10-K pursuant to Item 15(c) of the Form 10-K Report.

CORPORATE INFORMATION

EXECUTIVE OFFICERS

J. Robert Paulson, Jr.
Chief Financial Officer

Patrick J. Wethington
Vice President,
Sales, North America

BOARD OF DIRECTORS

Richard J. Nigon
Executive Vice President
Miller Johnson Steichen Kinnard, Inc.

Jean-Paul (J.P.) Peltier
Vice President,
Business Development
HomeServices of America, Inc.

Richard D. Randall
President and
Chief Executive Officer
TranS1, Inc.

Mark T. Wagner
President and
Chief Executive Officer
ProVation Medical, Inc.

Warren S. Watson
Vice President of Arrhythmia
Business Operations
Medtronic Cardiac Rhythm Management

TRANSFER AGENT AND REGISTRAR

Wells Fargo Bank, N.A.
Shareowner Services
P.O. Box 64854
St. Paul, MN 55164-0854
Telephone: 651-450-4064
Facsimile: 651-843-2362

AUDITORS

Deloitte & Touche LLP
Minneapolis, MN

LEGAL COUNSEL

Dorsey & Whitney LLP
Minneapolis, MN

ANNUAL MEETING

The Company's Annual Meeting of Stockholders will be held on May 18, 2004 at 9:00 A.M. at:

Hilton Minneapolis & Towers
1001 Marquette Avenue
Minneapolis, MN 55403

FORM 10-K

A copy of the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission may be obtained without charge by writing to:

Investor Relations
Endocardial Solutions, Inc.
2535 Pilot Knob Road, Suite 120
Eagan, MN 55121

CORPORATE HEADQUARTERS

2535 Pilot Knob Road, Suite 120
Eagan, MN 55121
Telephone: 651-406-7800
Facsimile: 651-406-7801

INVESTOR INQUIRIES

Telephone: 651-523-6959
e-mail: investor@endocardial.com

LISTING

Trades on Nasdaq Stock Market® under the symbol "ECSI"

ABOUT ENDOCARDIAL SOLUTIONS, INC.

Endocardial Solutions (NASDAQ: ECSI) develops, manufactures and internationally markets the EnSite System, a unique computer-based technology that creates three-dimensional graphical display of the heart and abnormal heart rhythms called arrhythmias. The system is used in diagnostic mapping of complex arrhythmias and for replicating cardiac structures to display electrophysiology catheters in any chamber of the heart. Its website is www. endocardial.com.

ENDOCARDIAL
SOLUTIONS

WORLD HEADQUARTERS

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