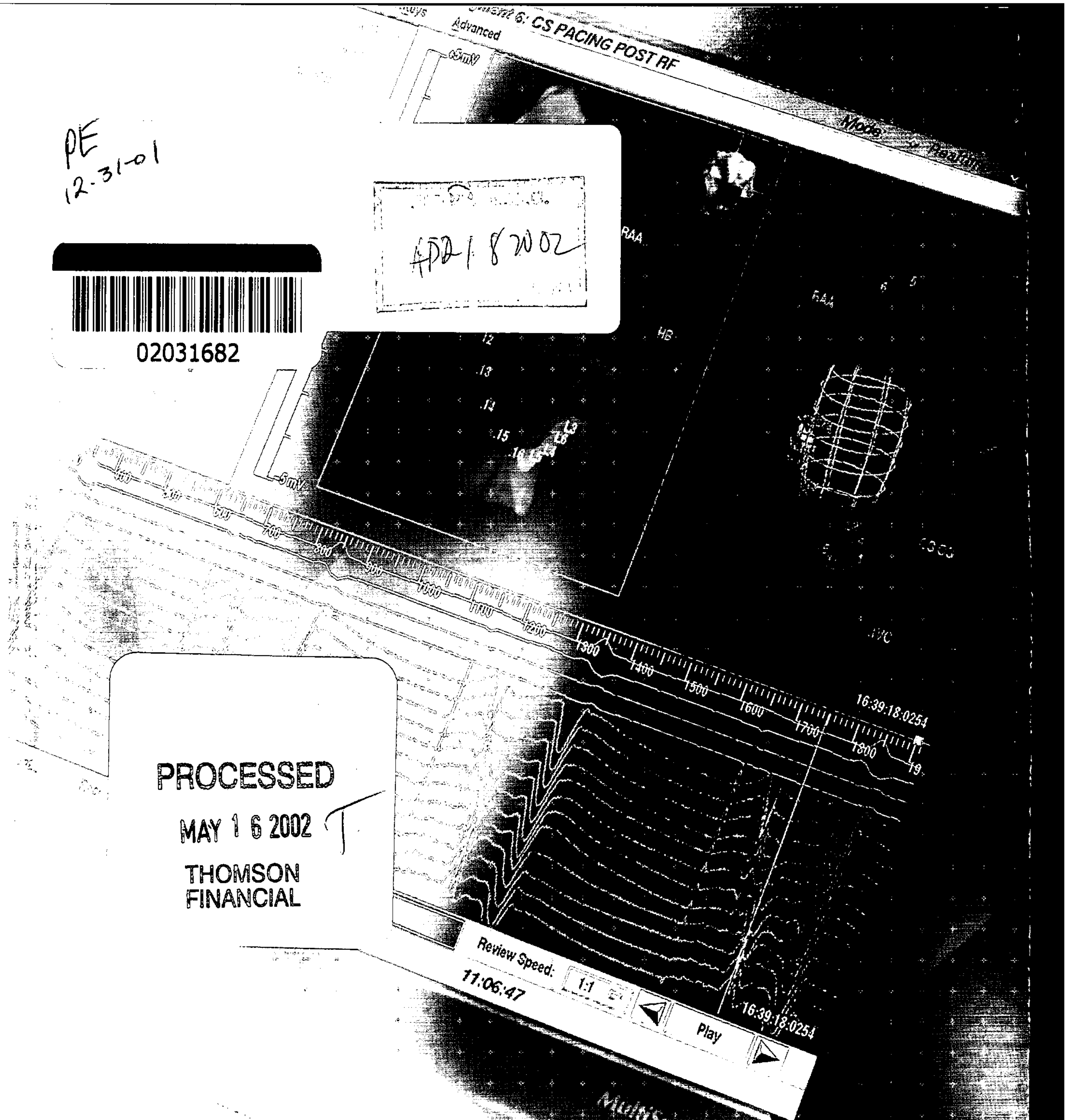


Advanced Diagnostic Solutions

2001 ANNUAL REPORT

ENDOCARDIAL
SOLUTIONS

FINANCIAL HIGHLIGHTS

(In thousands, except per share amounts)

As of December 31,	2001	2000	1999
Statements of Operations			
Net Sales	$ 22,893	$ 14,563	$ 9,597
Net Income (Loss)	$ (8,479)	$ (10,311)	$ (11,729)
Net Income (Loss Per Share)-Basic and Diluted	$ (0.60)	$ (0.92)	$ (1.23)
Weighted Average Shares Outstanding	14,211,318	11,212,420	9,559,494

As of December 31,	2001	2000	1999
Balance Sheet			
Cash and Cash Equivalents	$ 4,550	$ 10,759	$ 7,087
Total Assets	$ 15,797	$ 21,356	$ 17,578
Total Liabilities	$ 7,081	$ 11,492	$ 9,324
Stockholder's Equity	$ 8,716	$ 9,864	$ 8,254

Revenue (In Millions)

2001	2000	1999
$ 22,893	$ 14,563	$ 9,597

Gross Margin

2001	2000	1999
59.6%	50.7%	31.3%

Net Income (Loss Per Share)

2001	2000	1999
$ (.60)	$ (.92)	$ (1.23)

MOVING FORWARD 2001 was a remarkable year for our company. We achieved record growth for several quarters and for the year end, initiated a significant new clinical trial, achieved our year-long goal of placing 200 total systems worldwide, and launched a very successful software upgrade to the EnSite 3000® System. As 2002 begins, we see even greater potential for Endocardial Solutions.

STRONG FINANCIALS Throughout the year we consistently reported record-breaking quarters in all areas of our business, indicating that we are achieving widespread acceptance in the medical community as an alternative to conventional diagnosis of arrhythmias. Our 2001 revenue of $22.9 million was a 57% increase over the previous year. We are also seeing increases in the use of our catheter in existing accounts. Our manufacturing efficiencies also continue to help us on the bottom line, where our gross margin of 59.6% increased over the year 2000 by nearly 20%.

PRODUCT IMPROVEMENTS Late in 2001, we announced the release of our Precision™ software upgrade–our most significant product improvement to date. The Precision™ software allows physicians to create 3D maps of the heart that nearly replicate each patient's unique anatomy. The software also accurately guides therapeutic catheters in 3D, which should dramatically reduce the amount of x-ray fluoroscopy necessary for ablation procedures. We have been very pleased with the overwhelming reception to this upgrade.

GLOBAL EXPANSION In September we began building our direct effort in Europe. With our core team in place, our customers are enjoying the same level of service that we provide in the U.S. Early in 2001, we reached a distribution agreement with Nihon Kohden to expand into the Japanese market. Nihon Kohden has a significant share of the Japanese market for electrophysiology devices and catheters. We also continue to grow in other areas of the Asia Pacific region, with many new systems sold in China, Taiwan, Korea, Malaysia, and New Zealand.

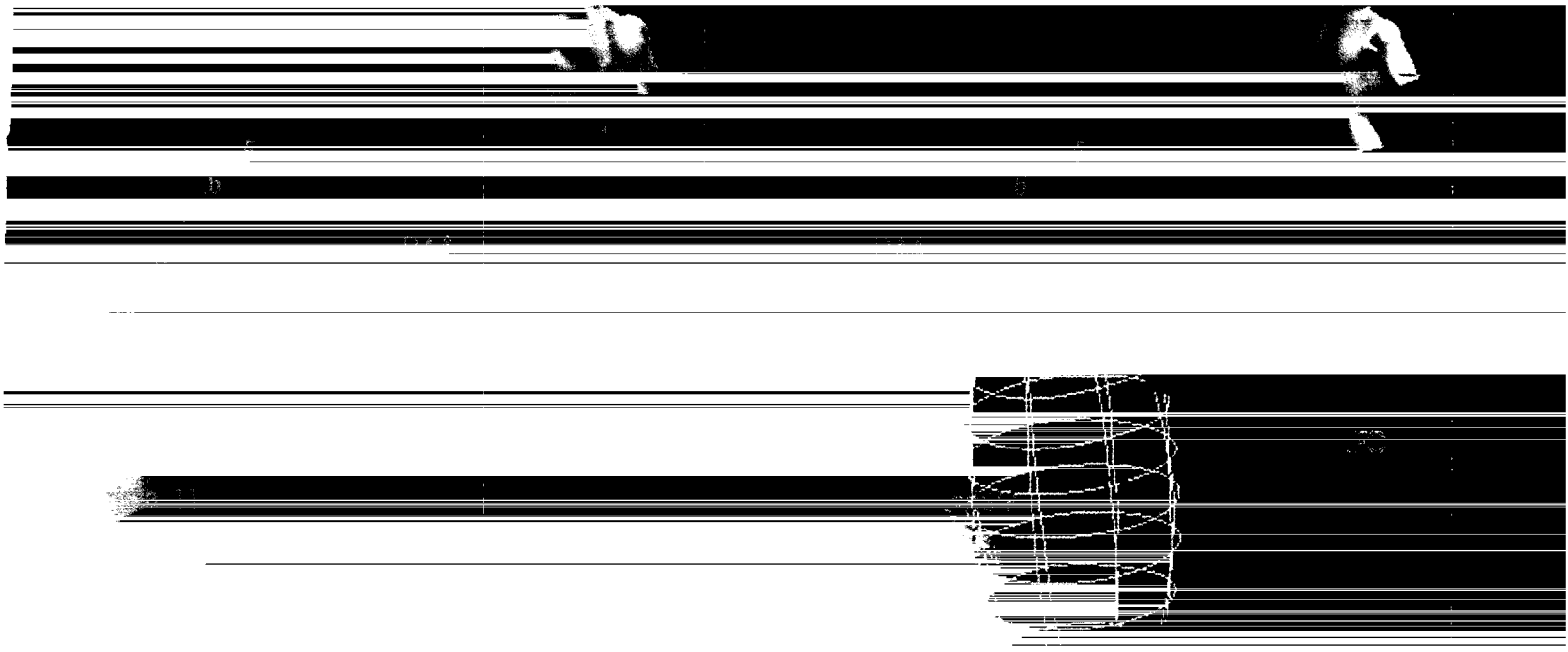
NEW CLINICAL TRIAL In 2001, we also began the first studies in our Left Atrial Mapping Protocol (LAMP) to study the efficacy of the EnSite 3000® System for mapping and guiding therapy in the left atrium of the heart. We are encouraged by the early results of this trial. Our technology provides unique advantages for the treatment of atrial fibrillation, one of the most common types of arrhythmias and also one of the most challenging to treat. We fully expect that the results of LAMP will allow us to help physicians treat and cure some of the more than 2.2 million patients who have been diagnosed with atrial fibrillation.

NEW GROWTH As 2002 begins, we are the leader in advanced mapping of arrhythmias, and we are turning our resources and technology to achieve similar success in the market for conventional mapping. To achieve this end, we sold $10 million in stock early in 2002 to allow us to fund several key research and development projects. We are also exploring ways to incorporate advanced digital images into the EnSite 3000® System, which will permit even more accurate diagnosis. As the demand for our current product increases, we continue to prepare for the future. In 2001, we secured a $3.5 million lease financing; we will use a portion of that lease to expand our catheter manufacturing capacity to meet our growing demand.

LOOKING AHEAD We expect 2002 to be even more eventful and productive than the past year. We look forward with great anticipation to achieving our first profitable quarter in the current year and to the next exciting generation of products.

Each day, I look forward to the case reports from our field engineers, who relate how physicians use our technology to either treat more patients or cure the impossible cases–patients with multiple failed ablations or very rapid arrhythmias. To play even a small part in the daily miracles that physicians like Dr. Gregory Buser perform (story on following page) is a reward that sustains me and all the employees at Endocardial Solutions.

James W. Bullock
President, Chief Executive Officer and Director



Simplifying Arrhythmia Mapping

Endocardial Solutions develops, manufactures and markets innovative diagnostic technology that is rapidly changing the way patients are treated for cardiac arrhythmias. The EnSite 3000® System allows physicians to record cardiac signals from an entire heart chamber simultaneously. The recorded data is displayed as an accurate 3D map of the heart with an animated display of cardiac electrical activity. Because more data can be collected in a shorter period of time than through conventional mapping, both complex and simple procedures are easier to perform.

ESI's technology has undergone rapid changes since its early clinical testing. (Inset left, circa, 1996) shows simple ovoid-shaped heart maps created with our early software. More detailed maps of the heart were created in the first clinical release of the EnSite 3000™ System software (Inset center, circa, 1998). In 2001, our Precision™ software was released, combining highly accurate anatomic maps with real-chamber electrical data (Inset right and above).

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, 2001

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. ☐

The aggregate market value of common stock, par value $.01 per share, held by non-affiliates of the registrant as of March 21, 2002 was approximately $116,891,864 (based on the last sale price of such stock as quoted on the Nasdaq National Market ($7.04) on such date).

As of March 21, 2002, the number of shares outstanding of the registrant's common stock, par value $.01 per share, was 16,603,958.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2002 Annual Meeting of Stockholders to be held on May 14, 2002 are incorporated by reference into Part III of this Annual Report on Form 10-K (the "Form 10-K Report").

PART I

ITEM 1. BUSINESS

The Company

Endocardial Solutions, Inc. ("ESI" or the "Company") designs, develops, and manufactures a minimally invasive diagnostic system that diagnoses, within the span of a few heartbeats, potentially fatal abnormal heart rhythms known as arrhythmias. Arrhythmias are caused by irregular electrical activity in the heart that disrupts the heart's normal pumping action. Arrhythmias characterized by an abnormally fast heart rate are known as tachycardias, which can appear in various forms. Ventricular tachycardia ("VT") occurs in the lower two chambers of the heart and frequently lead to serious complications, including sudden cardiac death. Supraventricular tachycardia ("SVT"), including atrial tachycardia, atrial fibrillation and flutter, originates in the upper two chambers of the heart and often result in chest pain, fatigue and dizziness and, while generally not life-threatening, are a leading cause of stroke in the United States.

To date, electrophysiologists have generally been unable to adequately diagnose complex arrhythmias due to the limited capabilities of current technology. The Company believes that its proprietary EnSite® catheter and Ensite 3000® clinical workstation (together, the "EnSite System") is a powerful new diagnostic tool that enables electrophysiologists to rapidly and precisely locate the multiple, unpredictable points of origin of complex arrhythmias and improve the selection of patient treatment options. The EnSite System applies proprietary mathematical algorithms to compute more than 3,000 points of electrical activity within a heart chamber, producing a high resolution, real-time, three-dimensional color display of the electrical activity in the heart chamber. The "virtual electrogram" function of the EnSite System allows electrophysiologists to instantly view the electrical activity at any of the more than 3,000 points. The EnSite System is also capable of tracking and displaying the location and movements of auxiliary catheters introduced into the chamber.

In 1998, ESI received the necessary approval to market the EnSite System in the European Community for use in the right atrium and left ventricle of the heart. Distribution of the EnSite System in Europe began in the second quarter of 1998. In 1999, ESI received clearance from the U.S. Food and Drug Administration (the "FDA") to market the EnSite System in the U.S. for diagnosis of complex arrhythmias in the right atrium of the heart, and the Company continues to work with the FDA for the purpose of extending their marketing approval to the other chambers of the heart. ESI received general approval to market the EnSite System for cardiac mapping in Australia, Korea, Thailand, Malaysia and Hong Kong in 2000, and in China and Taiwan in 2001. 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 will commence pending regulatory approval.

The Company's strategy is to establish the EnSite System as the leading diagnostic tool for diagnosing arrhythmias in the more than 1,200 electrophysiology laboratories worldwide. The EnSite System represents a new technology for mapping arrhythmias. The Company believes that the patient population that suffers from complex arrhythmias that are difficult to map using currently available technology presents a significant market opportunity for the Company's EnSite System. The key elements of the Company's strategy are as follows:

- *Increase Clinical Awareness With Electrophysiologists.* With its multi-center clinical studies and its United States and European product launch, the Company has established relationships with several leading electrophysiologists whom we expect will continue to promote market acceptance of the EnSite System. A Center of Excellence program in the United States is in place with several leading institutions to further enhance market acceptance of the EnSite System. Participants in the program have agreed to provide direct consultation and assistance to the Company in the development and implementation of educational programs and clinical research study design and strategy.

The Company will also continue to demonstrate the clinical efficacy of the EnSite System through the publication of the results of its post-market studies and at various scientific conferences, including those sponsored by the North American Society of Pacing and Electrophysiology, the American Heart Association, and the American College of Cardiology. The Company has over 180 abstracts and 35 peer-reviewed articles that have been published in various scientific journals.

- *Expand Technology*. The Company believes that the EnSite System can be extended from mapping complex arrhythmias such as atrial tachycardia in the right atrium, as currently cleared for marketing by the FDA, to mapping complex VT and atrial fibrillation and flutter, all of 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 and treatment perspective.

  In the U.S., human diagnostic devices are regulated under the federal Food, Drug and Cosmetic Act, and are subject to clinical testing mandated by the FDA before they will give clearance for marketing. The Food, Drug and Cosmetic Act provides two basic review procedures, including a shortened submission procedure under Section 510(k) whereby the manufacturer notifies the FDA of its intent to market the product and attempts to establish that the product to be marketed is substantially equivalent to another FDA-cleared product. If a device does not qualify for the 510(k) procedure, the manufacturer must file a premarket approval ("PMA") application, which typically involves more clinical testing and a significantly longer FDA review process.

  In September 1998, the Company filed a Section 510(k) application with the FDA containing the results of its right atrial multi-center clinical trials and in April 1999 received FDA approval to market the EnSite System for use in the right atrium. In December 1998, the Company filed a Section 510(k) application with the FDA containing the results of its left ventricular multi-center clinical trials. In March 1999, the Company announced that its FDA application for left ventricular use of the EnSite System will be submitted as a premarket approval ("PMA") application. Portions of the application have been submitted and approved, but ESI 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.

  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 January 2001, the Company received FDA approval for the use of its EnSite System 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.

The Company intends to continue to focus on the ability of its technology to provide improved speed, increased accuracy and cost-effectiveness in mapping other arrhythmias. This improved mapping power should benefit electrophysiologists in performing diagnostic procedures and prescribing treatments for an expanded patient population. In January 1998, the Company signed a license agreement with Medtronic, Inc. which gives the Company co-exclusive use of 3D intracardiac location technology for its EnSite System. Integration of the technology with the EnSite System is still under review, but the Company believes it will improve intracardiac catheter positioning while significantly reducing the use of harmful radiation. In October 2001, the Company received FDA clearance for the Company's release of its Precision™ software, an upgraded version of the software used in the EnSite System that provides more realistic heart chamber geometry and new catheter positioning techniques designed to improve orientation, speed up procedure times and reduce the use of fluoroscopy.

In the first quarter of 1999, the Company announced a financing agreement with Medtronic, Inc. Under the agreement, the Company received $7 million from Medtronic Asset Management. This loan was repaid in February 2001. In July 1999, the Company received proceeds of $10,000,000 in 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 in 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 in a private placement of 2,449,666 shares of its common stock to accredited investors. In February 2002, the Company received proceeds of $10,000,000 in a private placement of 1,666,667 shares of its common stock to accredited investors. Proceeds from this most recent sale of shares are being used for general working capital including expenses associated with new product development.

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 offices are 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*.

Background

The heart consists of four chambers: the ventricles, the lower two chambers, and the atria, 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 chambers, the electrical activation wave enters the ventricles and produces a coordinated contraction of the ventricles that pump 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 due to heart attacks or arteriosclerosis (the deposition of fatty substances in the inner layer of the arteries) and other diseases, that accelerate, delay or redirect the transmission of electrical activity, thereby disrupting the normal coordinated contractions of the chambers. Arrhythmias characterized by an abnormally fast heart rate (more than 100 beats per minute) are known as tachycardia.

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. Individuals with VT are at risk of imminent death due to its unpredictable nature.

Many VT result from 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 and VT typically originate at these sites. As the average age of the U.S. population increases, it is expected that the number of persons who suffer heart attacks and are at risk of VT will also increase.

VT is a highly complex and transient form of cardiac arrhythmia, that varies significantly from patient to patient. A small percentage of ventricular tachycardia patients have simple forms of the disease, which are focused on a single anatomic site within the ventricle. The Company estimates, however, that of the one million patients that 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 nonsustained and, consequently, are only detectable for several heartbeats.

Diagnosing Ventricular Tachycardia. Patients suspected of suffering from VT are initially screened by a cardiologist by means of external cardiac monitoring, typically in the form of an electrocardiogram or Holter recording, which captures electrical activity from surface leads placed on the patient's chest for 24 hours. When 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, 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) through two-dimensional fluoroscopic (x-ray) projections. 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 limited number of patients suffering from simple forms of VT have been effectively diagnosed using existing single-point contact catheter technology with diagnostic procedures that can be time consuming, tedious and invasive. However, single-point contact catheters have limited utility in diagnosing complex ventricular tachycardia, including those that are hemo-dynamically ill-tolerated or short in duration. The limited data produced in point-by-point mapping often does not provide the electrophysiologist with sufficient diagnostic power for a complete understanding of the ventricular tachycardia. Moreover, when attempted, diagnosing complex ventricular tachycardia with single-point, contact catheters can take from six to twelve hours and requires significant use of fluoroscopy to guide the catheter, which exposes both the patient and the medical staff to radiation.

In an effort to address the diagnostic shortcomings of single-point contact catheters, there are currently under development several "basket" contact catheters measuring multiple points of electrical activity simultaneously. These basket catheters will require contact with the heart's surface for measurement of electrical activity, and the Company believes that these catheters will suffer from many of the shortcomings of single-point contact catheters.

Treatments Following Diagnosis of Ventricular Tachycardia. The Company's EnSite System is designed for the diagnosis of tachycardia. The Company does not currently design products for the treatment of this disease. However, the Company believes that the EnSite System will provide electrophysiologists with a diagnostic tool to improve their ability to select among available tachycardia treatment options.

Once a patient's VT is diagnosed, the electrophysiologist chooses among the various treatment options available. Noncurative treatments include 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 cause of the tachycardia. Historically, the only curative treatment available for VT was open heart surgery, but it has been rarely used due to its high morbidity and mortality. More recently, however, catheter ablation, a potentially curative treatment currently under development, has been used in

a limited number of cases for complex VT Often electrophysiologists prescribe a combination of drugs, defibrillators and ablation for the treatment of VT.

Antiarrhythmic drugs, which are prescribed to chemically suppress the arrhythmic activity, have to date been the most common treatment of VT Antiarrhythmic drugs are not curative and can result in considerable side effects limiting the effectiveness of the drugs and the ability of patients to use them 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.

There is increasing interest in the United States and Europe in using catheter ablation to treat VT Catheter ablation is a minimally invasive and potentially curative treatment in which a high radio frequency current is emitted from a catheter guided to the heart through a vein in the neck or groin to selectively destroy the heart tissue responsible for the abnormal electrical activity. The use of catheter ablation to date has been limited due to the inability of single-point contact catheters to effectively map complex VT cases. Although catheter ablation is not yet commonly prescribed to treat VT and the devices have not yet been approved by the FDA for marketing in the United States for treatment of VT, it is the subject of increasing technological research and development. The Company believes catheter ablation could become a more commonly used treatment for VT with advances in diagnostic technology such as that being developed by the Company.

Supraventricular Tachycardia

Approximately three million of the four million people in the United States who suffer from tachycardia have some form of 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"), and atrial fibrillation, atrial flutter, and atrial tachycardia.

Approximately one million people in the United States suffer from WPW or AVNRT The tachycardia associated with WPW and AVNRT are generally easy to diagnose and locate due to their more simple, single-site nature and predictable location within the atria. WPW and AVNRT have been effectively treated by catheter ablation with available contact catheters.

Approximately two million people in the United States suffer from atrial fibrillation or atrial flutter. Atrial fibrillation is the most common type of sustained 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 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 atrial fibrillation using current single-point 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 the disease.

Antiarrhythmic drugs and anticoagulation therapy are the most commonly prescribed treatments for atrial fibrillation, but they are not curative and have undesirable side effects. The only known curative treatment for atrial fibrillation is 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. In addition, an atrial defibrillator is under development for detecting and controlling atrial fibrillation with low energy shocks.

Catheters have been approved for ablation treatments in the atria; however, due to the limited understanding of atrial fibrillation, to date they have not proven effective. Catheters are under development for potentially curative ablation of atrial fibrillation. One type of catheter under development is designed to create linear lesions along the interior wall of the atrium to electrically isolate regions of the chamber in a manner similar to the surgical maze procedure. Other emerging methods are aimed at more localized ablation treatment based on a hypothesis that atrial fibrillation is maintained in an electrically localized region of the chamber, requiring detailed mapping.

The Company believes that the complexity of atrial fibrillation and the search for effective and curative treatments, including catheter ablation, will require a diagnostic mapping technology that provides much greater resolution and diagnostic capabilities than currently available technology. In January 2001, the Company received FDA approval for the use of the EnSite System in the left atrium in a multi-center clinical study for diagnosing arrhythmias including atrial fibrillation, which the Company began in the second quarter of 2001.

The EnSite System

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 arrhythmia. The high resolution, three-dimensional, color display generated by the EnSite System is designed to provide electrophysiologists greater diagnostic capabilities than single-point contact catheter mapping devices currently available. The EnSite System provides electrophysiologists with a real time, virtual image of the electrical activity of the heart without contacting the heart's surface. The EnSite System displays more than 3,000 points of electrical activity using the Company's proprietary algorithms. Diagnosis is enhanced by the "virtual electrogram" function of the EnSite System workstation that allows electrophysiologists to instantaneously view the electrical activity at any of the more than 3,000 points displayed by selecting a specified point on the workstation's three-dimensional color map of the heart with the workstation's mouse pointer. 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.

The Company's EnSite System consists of the EnSite catheter and clinical workstation that together form an integrated system. The EnSite System is designed to map ventricular and atrial arrhythmia.

The EnSite Catheter

The EnSite catheter is a non-contact, single-use, multi-electrode array, and percutaneous catheter, designed for use with the EnSite clinical workstation. The EnSite catheter's multi-electrode array senses electrical activity generated from the endocardial wall while positioned in the heart chamber. The array area of the EnSite catheter is comprised of an inflatable polyurethane balloon within a mechanically expandable multi-electrode array. The multi-electrode array contains a wire braid consisting of 64 braided wires. A handle and cable connector are located at the proximal end of the catheter to allow the physician to position the distal end of the catheter, deploy the multi-electrode array and make electrical connection from the array to the patient interface unit of the EnSite System's workstation.

The EnSite catheter is inserted percutaneously over a standard guidewire into a selected chamber of the heart. When positioned, the wire braid is mechanically expanded and the balloon residing under the

wire braid in the array area of the catheter is inflated with a radiopaque solution to form an ellipsoidal, multi-electrode array. When deployed, the array is small enough to permit the normal functioning of the heart. In addition to the EnSite catheter, a standard single-point diagnostic catheter is inserted in a chamber of the heart in order to facilitate establishing the chamber's spatial boundaries. The multi-electrode braid array collects data used to compute more than 3,000 points of the heart chamber's electrical activity in the span of a few heartbeats by gathering a large amount of the electrical conduction information from the entire chamber and transmitting this information through the wire braid back down the catheter shaft to the EnSite System's clinical workstation.

The Ensite 3000 Clinical Workstation

The EnSite System's clinical workstation consists of the Company's proprietary patient interface unit and a Silicon Graphics-based workstation and other third-party peripherals, such as a color monitor, a printer and an optical disk drive. The patient interface unit is designed to amplify and digitize the electrical information transmitted by the EnSite catheter. The patient interface unit also accepts information generated by other auxiliary sensors, including 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 workstation. The workstation is programmed with software containing the Company's proprietary algorithms, which process the electrical information transmitted by the EnSite catheter and reconstruct the heart's geometric layout and the distribution of electrical activity. The heart and the electrical activity are displayed on the 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 ablation.

The electrical activity displayed on the workstation's three-dimensional map can also be displayed as time-waveforms, called "Virtual Electrograms," at multiple selected sites on the endocardium. Virtual Electrograms are produced by the Company's software contained in the workstation. The electrophysiologist can instantaneously select any of the more than 3,000 sites and waveforms to be displayed by 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 of positioning a standard contact catheter at the same site on the endocardium-but without the need for actual physical contact.

The EnSite System's workstation also generates the EnGuide™ locator signal that can be emitted from selected electrodes on standard EP catheters introduced into the heart along with the EnSite catheter. The EnGuide locator signal provides electrophysiologists with an interactive method for locating and positioning auxiliary or therapy catheters. The locator function is designed to allow electrophysiologists to diagnose and treat complex tachycardia with significantly less use of fluoroscopy than is currently required when using presently available single-point contact catheters. The EnGuide locator signal is detected and displayed on the workstation's three-dimensional map to provide real-time feedback to the electrophysiologist as to the precise location of the catheter and to assist in guiding the catheter (or catheters) to a specific site on the endocardium.

The EnSite System is designed to function as a complete, integrated electrophysiology laboratory system to provide a wide range of accurate and versatile diagnostic tools in one product. In addition to displaying high resolution, graphical, three-dimensional maps, the EnSite System provides multi-channel recording from standard EP electrode catheters and standard waveform displays. In the second quarter of 2000, the Company released Clarity™, an upgraded version of the Company's software product for use in the EnSite System that offers a more simplified user interface and increased automation of arrhythmia analysis. The Clarity software is designed to simplify use of the EnSite System and reduce training time for hospital staff. In October 2001, the Company received FDA clearance for the Company's release of its Precision software, an upgraded version of the software used in the EnSite System that provides more

realistic heart chamber geometry and new catheter positioning techniques designed to improve orientation, speed up procedure times and reduce the use of fluoroscopy. The Company intends to develop and market periodic software upgrades and new applications for use with the EnSite System.

Research and Development

To date, the Company's primary activity has been research, development and testing of the EnSite catheter and the clinical workstation. Virtually all of the Company's research and development activity is performed internally by the Company's team of scientists, engineers and technicians, in consultation with the Company's outside consultants. The Company's research and development team is divided among 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 goals, the Company is now pursuing the optimization of the EnSite System functionality for future software releases, incorporating location technology for use in conventional EP studies and developing new catheter technologies for reduced size and cost. The Company expects that its future research and development objectives will include developing new mapping and catheter configurations and software upgrades to enhance the capabilities and ease-of-use of the EnSite System as well as supporting the Company's manufacturing personnel in refining manufacturing processes, improvements and scale-up in connection with the commercialization of the EnSite System. The Company incurred research and development expenses of approximately $5.1 million, $4.4 million and $5.3 million for the fiscal years ended December 31, 1999, 2000 and 2001, respectively. The Company anticipates that it will continue to make significant investments in research and development.

Manufacturing

The Company manufactures its EnSite catheters in its 3,200 square foot clean-room facility at its world corporate headquarters in St. Paul, Minnesota. During the second quarter of 2002 the Company will complete construction on an additional 1,700 square feet of clean-room space which will approximately double the existing production capacity for the EnSite catheter. The Company also performs final assembly and system level testing of all hardware and software components for the EnSite System clinical workstation at this facility.

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

The manufacturing of the EnSite System clinical workstation, including the patient interface unit, involves the assembly, integration and testing of components purchased from third parties. The Company purchases the basic computer workstation from Silicon Graphics, and ESI software engineers program the workstation with its proprietary software, including advanced 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 the component parts it purchases meet its specifications and standards. Certain of the components are purchased from sole source suppliers, including the computer workstation. 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 FDAs good manufacturing practices ("GMP") in order to distribute its products in the United States, and the requirements for ISO 9001 and CE Mark certification in order to continue to distribute products in Europe. During the fourth quarter 2001, the Company passed a FDA inspection of the facility and the manufacturing processes. The Company received ISO 9001 certification for its catheter and quality system in August 1997, and ISO 9002 certification for the clinical work station and a CE Mark for each of the EnSite catheter and the EnSite 3000 clinical workstation in the first quarter of 1998. ISO 9001 certification for our workstation was subsequently received in November 1998. As part of the regulatory requirements, the Company's facilities and manufacturing processes will be subject to inspection and audit. If the Company fails to satisfy the 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 will also be 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 3000 clinical workstation, allowing the Company to begin marketing its products in the European Community for right atrial and left ventricular use. Distribution in Europe of the EnSite System and EnSite catheter began in the second quarter of 1998. In the second quarter 1999, the Company received FDA approval to market the EnSite catheter and EnSite System for right atrial use in the United States. In 2000, the Company received general approval to market the EnSite System for cardiac mapping in the following countries: Australia, Korea, Thailand and Taiwan. The Company has also begun marketing the EnSite System in Malaysia, Hong Kong and Japan.

The Company has employed a direct sales force in the United States and Europe, and uses distributors for certain international markets. In 2001, the Company ended an exclusive distribution arrangement in Europe and Japan with Medtronic, Inc., but 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 have additional distributors in various markets throughout the world. The Company retains all distribution rights in the United States.

The Company believes that prominent electrophysiology labs are generally more likely to keep abreast of and utilize new technologies such as the EnSite System for diagnosing and treating tachycardia. After the Company establishes a presence in major medical centers housing such electrophysiology labs, it then intends to broaden its sales and marketing efforts to include the growing number of smaller, community-based electrophysiology labs. As part of its strategy to gain the awareness of and acceptance by electrophysiology laboratories, the Company has focused on and intends to continue to focus on developing peer reviewed journal articles authored by leading experts in electrophysiology, sponsoring publication of papers based on research covering the performance and benefits of the EnSite System and conducting informational seminars. In addition, as part of its marketing program the Company holds technical seminars and training sessions to educate physicians and its direct sales force and distributors in the use of the Company's products.

Patents and Proprietary Rights

The Company's success will depend in part on its ability to obtain patent protection for its products and processes, to preserve its trade secrets and to operate without infringing or violating the proprietary rights of third parties. The Company actively pursues patent 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. Currently, the Company has fifteen (15) U.S. patent applications pending by which it is seeking to obtain protection for certain

enhancements currently embodied in the EnSite System, relating to the catheter, catheter localization techniques and user interface elements. Additionally, one U.S. patent application has been allowed, with issuance expected with the year. The Company also has four issued U.S. patents, which relate to the technology underlying the EnSite System and development-stage versions of the system. One of these patents covers the catheter of the EnSite System and its development-stage versions. The remaining three patents are directed to measurement methodologies used in the development-stage versions of the EnSite System. The Company has also filed and has pending several foreign patent applications directed to various aspects of the technology underlying the EnSite System.

In January 1998, the Company signed a license agreement with Medtronic, Inc. which gives the Company co-exclusive use of 3D intracardiac location technology for its EnSite System. The license, as currently in use by the Company, is not royalty-bearing. A required royalty equal to 2% of net sales of licensed products only occurs if the Company is acquired by one of the competitors of Medtronic named in the license agreement. ESI's right to use the technology for intracardiac mapping applications in the treatment of arrhythmias is co-exclusive with Medtronic and its affiliates, and the license lasts until the patents on the technology expire beginning in 2015 unless extended. Integration of the technology with the EnSite System is still under review but the Company believes it will improve intracardiac catheter positioning while significantly reducing the use of harmful radiation.

The Company, like other firms that engage in the development and marketing of medical devices, must address issues and risks relating to patents and trade secrets. The coverage sought in a patent application can be denied or significantly reduced before or after the 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 secret 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. Further, 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, 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, which could result in substantial cost and uncertainty to the Company, 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 that its competitive success will depend primarily upon its ability to demonstrate the clinical efficacy of the EnSite System; effectively create market awareness and acceptance of the system while maintaining its proprietary nature; and manufacture and deliver the system on a timely basis. The tachycardia diagnostic mapping field of the medical device industry has attracted a high level of interest both from companies with an established presence in the field of electrophysiology and 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 for diagnosing tachycardia that use multiple electrodes to provide more data points for the measurement of the heart's electrical activity. The Company is also aware of other medical device companies that are developing alternatives to single-point contact catheter mapping technology.

The Company believes that participants in the market for mapping tachycardia compete on the basis of clinical effectiveness, ease of use, cost and on the basis of acceptance by health care professionals. Competition is also affected by the length of time required for products to be developed and receive 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 products.

Many of the Company's competitors and potential competitors have substantially greater capital resources, research and development staffs and facilities than the Company. 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 and marketing medical devices. There can be no assurance that the Company will succeed in developing and marketing technologies and products that are clinically more efficacious and cost-effective than the more established diagnostic products or the 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 its competitors' products. The failure by the Company to demonstrate the 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 payors, principally federal Medicare, state Medicaid and private health insurance plans, to reimburse all or a part of the costs and fees

associated with the procedures performed using these products. The Company's success will be dependent upon, among other things, the ability of health care providers to obtain satisfactory reimbursement from third-party payors for medical procedures in which the Company's products are used. Third-party reimbursement will depend upon decisions by the Center for Medicare and Medicaid Services, as well as by individual health maintenance organizations and private insurers and other payors. Third-party payors 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 catheter is currently reimbursable under both inpatient and outpatient procedure scenarios. For inpatient procedures, the EnSite procedure will most typically be reimbursed under Diagnosis Related Group 518. For outpatient procedures the EnSite catheter is eligible for separate reimbursement in addition to the hospital's Ambulatory Payment Classification for cardiac 3-dimensional mapping. Third-party payors 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, payors may deny reimbursement if they determine that the device used in the treatment was unnecessary, inappropriate or not cost-effective, experimental or used for a non-approved indication.

The Company's EnSite catheter is sold at a premium in comparison to existing single point catheters used in current diagnostic or mapping procedures and requires an initial capital outlay for the companion clinical workstation. In addition to establishing the safety and efficacy of the EnSite System, and assuming no increase in the level of reimbursement for cardiovascular 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 enhanced benefits of the EnSite System to health care providers and payors in terms of such factors as enhanced patient procedural efficiencies, reduced radiation exposure and improved patient outcomes.

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 that less invasive procedures generally provide less costly overall therapies as compared to conventional drug, surgery and other treatments. The Company anticipates that hospital administrators and physicians would justify the use of the Company's products by the attendant cost savings and clinical benefits that the Company believes would be derived from the use of its products. However, there can be no assurance that this will be the case. Accordingly, reimbursement for the Company's products may not be in 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 payors, or changes in government and private third-party payors' 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 requires premarket 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, failure of the government to grant premarket approval for devices, 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 GMPs). Class II devices are subject to general controls and to special controls (e.g., performance standards, and premarket notification). Generally, Class III devices are those which must receive premarket 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 IDE application prior to commencing human clinical trials. The IDE application must be supported by data, typically including the results of animal and, possibly, mechanical testing. If the IDE application is approved by the FDA, human clinical trials may begin at a specific 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 an 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, wherein the manufacturer gives the FDA a premarket 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 legally marketed product. Marketing may 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 premarket approval ("PMA") application. This procedure requires more extensive prefiling testing than the 510(k) procedure and involves a significantly longer FDA review process.

A PMA application must be supported by extensive data, including preclinical and clinical trial data, as well as extensive literature to prove 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 premarket 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 in the United Kingdom in late 1995, 1996 and 1997 under an authorization of the Medical Devices Agency ("the MDA") 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 IDE application. In December 1996, the FDA granted the Company an IDE to conduct in the United States a limited clinical trial of the EnSite System for left ventricular tachycardia mapping in five patients at one institution. The Company conducted in early 1997 a limited five patient clinical study authorized under the IDE. 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 testing of the EnSite System in 73 patients at up to five institutions in the United States. In December 1998, the Company filed a premarket 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 discussion with the FDA, in March 1999, the Company announced that its FDA application for left ventricular use of the EnSite System will be submitted as a PMA 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.

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 an IDE approval 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 received FDA approval to market the EnSite System for use in the right atrium. In January 2001, the Company received IDE approval from the FDA for use in 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.

The Company is also required to register as a medical device manufacturer with the FDA and state agencies, and to list its products with the FDA. As such, the Company will be inspected by both the FDA for compliance with the FDAs GMP and other applicable regulations. These regulations require that the Company manufacture its products and maintain its documents in a prescribed manner with respect to manufacturing, testing and control activities. Further, 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 the 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 regulatory agency product registration requirements of each country. The regulatory review process varies from country to country. There can be no assurance that such approvals will be obtained on a timely basis or at all.

The Company received ISO 9001 certification for its catheter and quality system in August 1997, and ISO 9001 certification for the clinical workstation in November 1998. The Company has obtained CE certification for the EnSite catheter and for the Ensite 3000 clinical workstation. The ISO 9000 series of standards for quality operations have been 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, by mid-1998, 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.

Product Liability and Insurance

The development, manufacture and sale of medical products entail significant risk of product liability claims and product failure claims. The Company has conducted only limited clinical trials and does not yet have, and will not have for a number of years, sufficient clinical data to allow the Company to measure the risk of such claims with respect to its products. The Company faces an inherent business risk of financial exposure to product liability claims in the event that 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 190 full-time employees as of December 31, 2001. Of this number, 26 persons were engaged in research and development, 11 were involved in regulatory and quality assurance, 81 were involved with manufacturing and 72 were involved with administration, sales and marketing and support functions. No employee of the Company is covered by a collective bargaining agreement. In addition to its full-time workforce, the Company has consulting or other contractual relationships with 3 other individuals. The Company expects to add such new employees as are necessary to expand its manufacturing capacity for future commercial production.

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	45	President and Chief Executive Officer and Director
Michael D. Dale	42	Vice President, Sales and Marketing
Frank J. Callaghan	48	Vice President, Research and Development
Richard J. Omilanowicz .	49	Vice President, Manufacturing and Operations
Graydon E. Beatty	45	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. Mr. Bullock is a director of Appriva Medical, a manufacturer of medical devices.

Michael D. Dale has been Vice President of Sales and Marketing since March 2000. Mr. Dale joined the Company in December 1998 as Vice President Worldwide Sales. From October 1996 until joining the Company, Mr. Dale was Vice President of Global Sales for Cyberonics, Inc., a medical device company, and additionally as managing director of Cyberonics Europe S.A. From July 1988 to October 1996, Mr. Dale served in several capacities at St. Jude Medical, most recently as the Business Unit Director for St. Jude Medical Europe.

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 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.

Graydon E. Beatty is a founder of the Company and has been Chief Technical Officer of the Company since May 1995 and a Director since August 1992. Since the Company's inception in May 1992, Mr. Beatty has served in several technical and management positions. In addition, from May 1992 until December 1993, Mr. Beatty served as a consultant with GMN Consulting, an engineering consulting firm, and as a consulting engineer of AngeMed, a division of Angeion Corp., a cardiovascular device company, from February 1992 to September 1992. 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 Form 10-K Annual Report and the Company's financial statements, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 and other documents incorporated by reference contain "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 our expectations or beliefs, including, but not limited to, our current assumptions about future financial performance, anticipated problems, and our plans for future operations, which are subject to various risks and uncertainties. When used in this Form 10-K and in future filings by the Company with the Securities and Exchange Commission, in our press releases, presentations to securities analysts or investors, 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. We caution that these statements by their nature involve risks and uncertainties, certain of which are beyond our control, and actual results may differ materially depending upon a variety of important factors, including those described in Exhibit 99 to this Form 10-K.

ITEM 2. PROPERTIES

The Company leases approximately 33,000 square feet in St. Paul, Minnesota as its world corporate headquarters and production facility. The facility is leased through March 2004. The Company believes that this facility will be adequate to meet its needs through the full commercial introduction of its planned products. The Company's European subsidiary, Endocardial Solutions N.V./S.A., leases office space in Diegem, Belgium as its European headquarters. The office space is leased through September 2002.

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, 2001.

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. 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. On March 26, 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. Proceeds from the sale of these shares are being used for general working capital, including expenses associated with software and hardware product development. The shares of common stock were sold pursuant to Section 4(2) of the Securities Act of 1933, as amended.

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

	2001		2000	
	High	Low	High	Low
First Quarter	$6.500	$2.875	$10.500	$5.625
Second Quarter	7.156	3.125	10.000	6.000
Third Quarter	6.297	3.500	10.000	6.375
Fourth Quarter	6.188	3.750	6.750	1.313

On March 21, 2002, the closing sales price per share of the Company's common stock as quoted on the Nasdaq National Market was $7.04 per share. On March 21, 2002, there were approximately 120 holders of record of the Company's common stock, representing approximately 3,700 stockholder 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,				
	2001	2000	1999	1998	1997
	(in thousands, except share and per share amounts)				
Statement of Operations Data:					
Revenue	$ 22,893	$ 14,563	$ 9,597	$ 1,950	—
Cost of Goods Sold	9,241	7,174	6,592	3,624	—
Gross Margin	13,652	7,389	3,005	(1,674)	—
Operating Expenses:					
Research & Development	5,271	4,460	5,102	10,652	$ 6,745
General & Administrative	2,267	2,074	2,005	1,774	2,106
Sales & Marketing	14,750	11,093	7,713	1,310	831
Operating Loss	(8,636)	(10,238)	(11,815)	(15,410)	(9,682)
Net Interest Income (Expenses)	157	(73)	86	725	1,127
Net Loss	$ (8,479)	$ (10,311)	$ (11,729)	$ (14,685)	$ (8,555)
Net loss per share—basic and diluted	$ (.60)	$ (.92)	$ (1.23)	$ (1.63)	$ (1.21)
Weighted average shares outstanding	14,211,318	11,212,420	9,559,494	8,989,477	7,065,378

	Year Ended December 31,				
	2001	2000	1999	1998	1997
	(in thousands)				
Balance Sheet Data:					
Cash and cash equivalents	$ 4,550	$ 10,759	$ 7,087	$ 8,715	$ 22,230
Working capital	6,341	7,273	9,700	8,920	21,495
Total assets	15,797	21,356	17,578	13,728	25,036
Long-term debt and capital lease obligations less current portion	301	584	4,564	812	439
Accumulated deficit	(70,486)	(62,007)	(51,696)	(39,864)	(25,178)
Total stockholders' equity	8,716	9,864	8,254	10,463	22,776

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 Management's Discussion and Analysis of Financial Condition and Results of Operations contains descriptions of the Company's expectations regarding future trends affecting its business. These forward-looking statements and other forward-looking statements made elsewhere in this document are made in reliance upon safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The following discussion sets forth certain factors the Company believes could cause actual results to differ materially from those contemplated by the forward looking statements.

Summary

The Company was incorporated in May 1992. The Company develops, manufactures and markets the Ensite 3000 clinical workstation and EnSite catheter for use by electrophysiologists in diagnosing and mapping abnormal heart rhythms known as tachycardias. The Ensite 3000 clinical workstation and EnSite catheter received FDA approval for right atrial use in the U.S. during the second quarter 1999. The products are also available in full market release to electrophysiologists in Europe.

Results of Operations

Years ended December 31, 2001 and 2000

General. Net losses decreased to $8,479,043, or $0.60 per share, for the year ended December 31, 2001, from $10,311,147, or $.92 per share, for the year ended December 31, 2000. The Company is in a period of growth in sales and marketing expenses related to market penetration, including increases in personnel costs. The Company believes that it will still post an overall loss for the year 2002, but is expecting to show a profit for its fourth quarter of 2002.

Revenue and Cost of Goods Sold. Worldwide revenue for the year ended December 31, 2001 was $22.9 million, a $8.3 million, or 57%, increase over the same period in 2000. In the U.S., revenues increased approximately $7.5 million, or 70%, during 2001 over 2000 revenues. Approximately $5.9 million of the $7.5 million revenue increase in the U.S. during 2001 came from EnSite catheter sales, where unit sales increased approximately 90% over 2000. Increased utilization per system per month during 2001 contributed to these higher unit and revenue numbers.

International revenues increased approximately $790,000, or 21%, during 2001 over 2000 revenues. International revenues include sales direct to the end-user in Europe and Canada, and to distributors in Europe and Asia Pacific. A majority of the increase in international revenues was related to EnSite catheter sales, where unit sales increased approximately 31% over 2000. International revenues were also positively impacted in the fourth quarter of 2001, due to higher average selling prices on both the EnSite catheter and EnSite clinical workstation, when the Company launched its direct selling efforts in Europe after 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 improve sales in the European market.

Other revenue, which represents approximately 6.0% and 6.6% of worldwide sales for the years ended December 31, 2001 and 2000, respectively, includes revenue generated from extended service contracts, repairs and accessories sales related to the EnSite clinical workstation.

EnSite clinical workstation sales were $11.5 million for fiscal year 2001, compared to $8.4 million for the same period in 2000, or an increase of 37%. The increase is due mainly to the higher sales of the EnSite clinical workstation in the U.S. Domestic sales accounted for 78% of total EnSite clinical workstation sales during fiscal year 2001, compared to 72% for the same period in 2000. The Company believes EnSite clinical workstation sales will be approximately 35% to 40% of total revenues in 2002.

EnSite catheter sales were $11 million for fiscal year 2001, compared to $5.9 million for the same period in 2000, or an increase of 87%. Domestic sales accounted for 83% of total EnSite catheter sales during fiscal year 2001, compared to 77% for the same period in 2000. The Company believes EnSite catheter sales will be approximately 60% to 65% of total revenues in 2002.

Cost of goods sold including unabsorbed manufacturing expenses was $9,241,039 and $7,174,431 for the years ended December 31, 2001 and 2000, respectively.

The gross profit margin was 59.6% for the year ended December 31, 2001, compared with 50.7% during the same period in 2000. The increase in margins is mainly attributed to the better EnSite catheter absorption of manufacturing overhead from the growth in domestic sales over the prior year. Additionally, because the Company's margins on its domestic sales are substantially higher than those of its international

sales, the Company saw more favorable results in margins due to 81% of the revenue recorded during the year being from domestic sales, compared to 74% from the same period in 2000. Also, EnSite catheter margin increased approximately eight percentage points above last year's margin. The Company believes gross profit margins will be, in aggregate, 5 to 6 percentage points higher in 2002 as compared to the 59.6% attained in 2001.

Research and Development Expenses. Research and development expenses include compensation and benefit costs within the clinical, software, hardware, catheter and applied research departments as well as costs associated with regulatory expenses. Research and development expenses were $5,271,169 for the year ended December 31, 2001, compared to $4,459,737 during the same period in 2000, an increase of $811,432. The Company believes research and development expenditures will increase for the 2002 year, in the range of $300,000 to $600,000, mainly due to its on-going left atrium study.

General and Administrative Expenses. General and administrative expenses were $2,266,907 and $2,073,795 for the years ended December 31, 2001 and 2000, respectively, an increase of $193,112. The increase is due primarily to higher personnel costs and professional service expenses. The Company expects general and administrative expenses to increase slightly during the 2002 year.

Sales and Marketing. Sales and marketing expenses increased to $14,750,075 during the year ended December 31, 2001, from $11,093,095 during the same period in 2000, an increase of $3,656,980. The increase is primarily attributable to increases in personnel and costs associated with building and training of the U.S. and European sales and clinical team. As the Company continues to penetrate the U.S. and European markets, sales and marketing expenses are expected to increase in 2002 over 2001 as additional headcount is added in both the selling and field clinical engineering areas.

Interest Income and Expense. Interest income was $318,208 and $604,691 for the years ended December 31, 2001 and 2000, respectively. The decrease was due primarily to lower average cash and cash equivalent balances and lower interest rates. Interest expense was $161,367 and $677,674 for the years ended December 31, 2001 and 2000, respectively. The decrease is directly related to the repayment of the loan to Medtronic, Inc. during February 2001.

Years ended December 31, 2000 and 1999

General. Net losses decreased to $10,311,147, or $0.92 per share, for the year ended December 31, 2000, from $11,728,656, or $1.23 per share, for the year ended December 31, 1999. The Company is in a period of growth in sales and marketing expenses related to market introduction, including increases in personnel costs.

Revenue and Cost of Goods Sold. Worldwide revenue for the year ended December 31, 2000 was $14.6 million, a $5 million, or 52%, increase over the same period in 1999. Revenue for domestic sales increased $5.3 million, or 99%, compared to the same period in 1999. This increase in revenue can be directly attributed to a higher number of EnSite clinical workstations sold during fiscal 2000, compared to the same period in 1999. Additionally, with a 158% increase in the installed base of the EnSite clinical workstation since December 31, 1999 and an overall increase in EnSite catheter utilization per system per month, EnSite catheter revenue increased 143%. However, revenue for international sales, which includes sales to distributors in Europe and Asia Pacific, decreased $382,000, or 9%, over the same period in 1999. A majority of this decline related to our European distributor, Medtronic, which purchased a limited number of EnSite clinical workstations during the year and also did not increase its purchases of EnSite catheter sales over the previous fiscal year. The Company does not believe there occurred any fundamental decline in the European market for the EnSite workstation. Rather, the Company believes that Medtronic did not devote sufficient resources during fiscal 2000 necessary to further develop the European market. Other revenues, which represents 6.6% and 7.8% of worldwide sales for the years ending December 31,

2000 and 1999, respectively, includes revenues generated from extended service contracts, repairs and accessories sales related to the EnSite System.

EnSite clinical workstation sales were $8.4 million for fiscal year 2000, compared to $6.2 million for the same period in 1999. The increase is due mainly to the higher sales of the EnSite clinical workstation in the U.S., compared to last year's comparable period, or an increase of 76%. Domestic sales accounted for 72% of total EnSite clinical workstation sales during fiscal year 2000, compared to 56% for the same period in 1999.

EnSite catheter sales were $5.9 million for fiscal year 2000, compared to $3 million for the same period in 1999, or an increase of 97%. Domestic sales accounted for 77% of total EnSite catheter sales during fiscal year 2000, compared to 63% for the same period in 1999.

Cost of goods sold including unabsorbed manufacturing expenses was $7,174,431 and $6,592,409 for the years ended December 31, 2000 and 1999, respectively.

The gross profit margin was 50.7% for the year ended December 31, 2000, compared with 31.3% during the same period in 1999. The increase in margins is mainly attributed to the better absorption of manufacturing overhead from the growth in domestic sales over the prior year. Additionally, because the Company's margins on its domestic sales are substantially higher than those of its international sales, the Company saw more favorable results in margins due to 74% of the revenue recorded during the year being from domestic sales, compared to 56% from the same period in 1999.

Research and Development Expenses. Research and development expenses include compensation and benefit costs within the clinical, software, hardware, catheter and applied research departments as well as costs associated with regulatory expenses. Research and development expenses were $4,459,737 for the year ended December 31, 2000, compared to $5,102,378 during the same period in 1999, a decrease of $642,641. The decrease is attributable to the capitalization beginning in late 1999, after reaching technological feasibility, of software development costs related to the Clarity release.

General and Administrative Expenses. General and administrative expenses were $2,073,795 and $2,004,991 for the years ended December 31, 2000 and 1999, respectively, an increase of $68,804. The increase is due primarily to a rise in personnel costs and professional services expense.

Sales and Marketing. Sales and marketing expenses increased to $11,093,095 during the year ended December 31, 2000, from $7,712,522 during the same period in 1999, an increase of $3,380,573. The increase is primarily attributable to increases in personnel and costs associated with building and training of the U.S. sales and clinical team.

Interest Income and Expense. Interest income was $604,691 and $465,060 for the years ended December 31, 2000 and 1999, respectively. The increase was due primarily to higher average cash and cash equivalent balances. Interest expense was $677,674 and $378,609 for the years ended December 31, 2000 and 1999, respectively. The increase is due the amount of principal outstanding on the loan to Medtronic, Inc. during 2000 versus 1999.

Liquidity and Capital Resources

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. The Company's operations since inception have been funded by net proceeds from the sales of stock totaling approximately $79.9 million through December 31, 2001. As of December 31, 2001 and December 31, 2000, the Company had cash, cash equivalents and short-term investments of approximately $4.6 million and $10.8 million, respectively.

For the year ended December 31, 2001, the Company used approximately $5.7 million of cash for operations, compared to approximately $9.6 million for the same period in 2000. The Company saw an increase in its accounts receivable balances of approximately $1.6 million from December 31, 2000. The increase in accounts receivable is attributed to the Company's direct selling efforts in Europe and the timing of fourth quarter 2001 sales in relation to the payment terms of these sales. Inventories decreased approximately $480,000 during 2001. In 2001, the Company implemented a more efficient manner of managing the levels of raw material, work-in-process, and finished goods inventories, resulting in the reduced levels of inventory. The Company believes inventory balances will increase slightly during 2002 as sales are projected to increase 47% to 49% over 2001. Accounts payable increased approximately $1.4 million since December 31, 2000. The increase is directly attributed to the efforts of having receivable and payable turns more closely match each other in order to produce less negative cash flows. The Company expects accounts payable to grow throughout fiscal 2002 as operating and production expenses increase to support revenue growth. Accrued salaries and related expenses increased approximately $730,000 since December 31, 2000. A majority of this increase is attributed to a higher payout in the Company's incentive bonus program and higher quarterly bonus payouts to the sales and clinical engineers, related to fourth quarter 2001 sales, compared to those in the comparable periods in 2000. The Company expects this accrual balance at December 31, 2002 to be slightly higher compared to that of the December 31, 2001 balance. The Company had no short-term investment portfolio as of December 31, 2001, a decrease of $2,987,588 from the December 31, 2000 balance. The reduction is due to the Company continuing to use its available resources to fund its operating losses and to take advantage of higher interest rates in money market funds.

In January 1999, the Company announced a financing agreement with Medtronic, Inc. Under the agreement, the Company received $7 million from Medtronic Asset Management, which was repayable by February 2001 or, if earlier, at the close of a significant round of debt or equity financing. The Company received $3.5 million of the financing in February 1999 and the remaining $3.5 million in January 2000. The $7 million was repaid to Medtronic Asset Management in February 2001.

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 placement was priced at $3.00 per share. In June 2001, the Company also announced a $3.5 million credit facility agreement with Silicon Valley Bank, consisting of a $1.5 million capital lease line and a $2 million revolving line of credit. The credit facility expires in June 2002, but the Company expects to be able to renew the facility under similar terms. As of December 31, 2001 the Company has drawn $352,403 on the capital lease line and has $750,000 outstanding on the revolving line of credit. The agreement specifies certain restrictive covenants, which the Company was in compliance with as of December 31, 2001.

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. The placement was priced at $6.00 per share.

The Company believes that its existing cash, cash equivalents, short-term investments and bank financing will be sufficient to fund the operations of the Company to profitability, which the Company anticipates will occur in the fourth quarter of 2002. If the Company achieves profitability as expected, 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 market acceptance, the cost, 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.

Critical Accounting Policies

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 financial statements, management has made its best estimates and judgments of certain amounts included in the financial statements, giving due consideration to materially. 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, the fee charged is fixed and determinable, and collection is probable. Revenue from service and customer support contracts is deferred and recognized ratably over the period the services are provided. The Securities and Exchange Commission's Staff Accounting Bulletin (SAB) No. 101, "Revenue Recognition" provides guidance on the application of generally accepted accounting principals to selected revenue recognition issues. The Company has concluded that its revenue recognition policy is appropriate and in accordance with SAB No. 101.

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.

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.

New Accounting Standards. In October 2001, the FASB issued SFAS No. 144, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of*, which is effective for fiscal years beginning after June 15, 2002. This statement addresses financial accounting and reporting for the impairment or disposal of long-lived assets and supersedes SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of*, and the accounting and reporting provisions of Accounting Principles Board (APB) Opinion No. 30, *Reporting the Results of Operations* for a disposal of a segment of a business. The adoption of this pronouncement is not expected to have a material impact on the Company's consolidated results of operations, financial position, or cash flows.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company had approximately $4.6 million of cash and investments on December 31, 2001. Substantially all of the investments were U.S. government or investment grade, fixed income securities from domestic issuers. 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, 2001 and 2000, 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, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements 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 financial statements referred to above present fairly, in all material respects, the consolidated financial position of Endocardial Solutions, Inc. at December 31, 2001 and 2000, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

Minneapolis, Minnesota
January 23, 2002, except for Note 15 as to
which the date is February 27, 2002

Endocardial Solutions, Inc.

Consolidated Balance Sheets

	December 31	
	2001	2000
Assets		
Current assets:		
Cash and cash equivalents	**$ 4,550,059**	$ 7,771,540
Short-term investments	**—**	2,987,588
Accounts receivable, net of allowance for doubtful accounts (2001—$60,000; 2000—$60,000)	**5,084,412**	3,522,166
Inventories	**2,733,145**	3,211,818
Prepaid expenses and other current assets	**554,202**	500,694
Total current assets	**12,921,818**	17,993,806
Furniture and equipment	**7,329,598**	6,441,544
Less accumulated depreciation	**(4,721,350)**	(3,631,642)
	2,608,248	2,809,902
Deposits	**49,947**	40,174
Patents, net of accumulated amortization (2001—$111,489; 2000—$102,511)	**19,809**	28,137
Software development costs, net of accumulated amortization (2001—$891,107; 2000—$308,201)	**197,185**	484,314
Total assets	**$ 15,797,007**	$ 21,356,333
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**$ 2,287,338**	$ 938,866
Accrued salaries and expenses	**2,363,200**	1,634,346
Bank line of credit	**750,000**	—
Current portion of capital lease obligations	**594,010**	593,264
Current portion of long-term debt	**—**	7,000,000
Current portion of deferred revenue	**586,104**	554,374
Total current liabilities	**6,580,652**	10,720,850
Long-term liabilities:		
Capital lease obligations	**301,187**	584,252
Deferred revenue	**199,368**	187,062
Stockholders' equity:		
Undesignated Preferred Stock, par value $.01 per share: Authorized shares—10,000,000 Issued and outstanding shares—none	**—**	—
Common Stock, $.01 par value: Authorized shares—40,000,000 Issued and outstanding shares—December 31, 2001—14,934,624; December 31, 2000—12,249,695	**149,346**	122,497
Additional paid-in capital	**79,707,845**	71,769,626
Less notes receivable from officer	**(371,250)**	—
Accumulated deficit	**(70,486,214)**	(62,007,171)
Accumulated other comprehensive loss	**(9,556)**	—
Deferred compensation	**(274,371)**	(20,783)
Total stockholders' equity	**8,715,800**	9,864,169
Total liabilities and stockholders' equity	**$ 15,797,007**	$ 21,356,333

See accompanying notes.

Endocardial Solutions, Inc.

Consolidated Statements of Operations

	Year Ended December 31		
	2001	**2000**	**1999**
Revenue	**$22,893,306**	$ 14,562,894	$ 9,597,193
Cost of goods sold	**9,241,039**	7,174,431	6,592,409
Gross margin	**13,652,267**	7,388,463	3,004,784
Operating expenses:			
Research and development	**5,271,169**	4,459,737	5,102,378
General and administrative	**2,266,907**	2,073,795	2,004,991
Sales and marketing	**14,750,075**	11,093,095	7,712,522
Operating loss	**(8,635,884)**	(10,238,164)	(11,815,107)
Other income (expense):			
Interest income	**318,208**	604,691	465,060
Interest expense	**(161,367)**	(677,674)	(378,609)
	156,841	(72,983)	86,451
Net loss	**$(8,479,043)**	$(10,311,147)	$(11,728,656)
Net loss per share—basic and dilutive	**$ (.60)**	$ (.92)	$ (1.23)
Weighted average shares outstanding	**14,211,318**	11,212,420	9,559,494

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	Loss	Compensation	From Officer	Total
Balance at December 31, 1998	9,011,762	$ 90,118	$50,329,703	$(39,863,607)	$ —	$ (92,792)	$ —	$ 10,463,422
Value of warrants exercised, net of issuance in connection with lease agreement	30,565	306	103,455	(103,761)	—	—	—	—
Private placement at $9.00 per share in July 1999, net of offering costs	1,111,111	11,111	9,346,787	—	—	—	—	9,357,898
Exercise of stock options	31,747	317	61,870	—	—	—	—	62,187
Redemption of Common Stock	(2)	—	(9)	—	—	—	—	(9)
Deferred compensation related to stock options	—	—	35,628	—	—	(35,628)	—	—
Amortization of deferred compensation	—	—	—	—	—	98,730	—	98,730
Net loss	—	—	—	(11,728,656)	—	—	—	(11,728,656)
Balance at December 31, 1999	10,185,183	101,852	59,877,434	(51,696,024)	—	(29,690)	—	8,253,572
Private placement at $6.25 per share in June 2000, net of offering costs	2,030,000	20,300	11,846,268	—	—	—	—	11,866,568
Exercise of stock options	34,512	345	38,112	—	—	—	—	38,457
Deferred compensation related to stock options	—	—	7,812	—	—	(7,812)	—	—
Amortization of deferred compensation	—	—	—	—	—	16,719	—	16,719
Net loss	—	—	—	(10,311,147)	—	—	—	(10,311,147)
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 agreement	—	—	**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**

See accompanying notes.

Endocardial Solutions, Inc.

Consolidated Statements of Cash Flows

	Year Ended December 31		
	2001	2000	1999
Operating activities			
Net loss	**$(8,479,043)**	$(10,311,147)	$(11,728,656)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	**1,705,221**	1,526,297	810,249
Amortization of deferred compensation	**61,412**	16,719	98,730
Value of warrants granted in connection with bank financing	**8,750**	—	—
Loss on disposal of equipment	**8,118**	1,394	6,398
Changes in operating assets and liabilities:			
Accounts receivable	**(1,572,713)**	209,751	(3,256,167)
Inventories	**478,093**	(404,853)	(979,904)
Prepaid expenses and other assets	**(64,538)**	104,076	(252,111)
Accounts payable	**1,350,965**	(752,560)	929,279
Accrued salaries and expenses	**728,854**	(105,081)	1,032,703
Deferred revenue	**44,036**	92,812	542,661
Net cash used in operating activities	**(5,730,845)**	(9,622,592)	(12,796,818)
Investing activities			
Purchase of short-term investments	**(2,938,753)**	(3,926,782)	(8,110,503)
Maturities of short-term investments	**5,926,341**	6,255,000	10,855,000
Purchase of furniture and equipment	**(567,398)**	(781,727)	(571,691)
Patent expenditures	**(650)**	(13,566)	—
Software development costs	**(295,777)**	(493,967)	(298,548)
Proceeds from sale of equipment	**—**	2,200	980
Net cash provided by investing activities	**2,123,763**	1,041,158	1,875,238
Financing activities			
Proceeds from notes payable	**—**	3,500,000	3,500,000
Proceeds from bank line of credit	**750,000**	—	—
Principal payments on notes payable and capital lease obligations	**(7,634,722)**	(823,031)	(882,045)
Proceeds from issuance of common stock	**7,270,068**	11,905,025	9,420,076
Net cash provided by financing activities	**385,346**	14,581,994	12,038,031
Effect of exchange rate changes on cash	**255**	—	—
(Decrease) increase in cash and cash equivalents	**(3,221,481)**	6,000,560	1,116,451
Cash and cash equivalents at beginning of year	**7,771,540**	1,770,980	654,529
Cash and cash equivalents at end of year	**$ 4,550,059**	$ 7,771,540	$ 1,770,980
Supplemental disclosure of non-cash investing and financing activities			
Purchase of equipment and inventory through capital lease obligations	**$ 352,403**	$ 255,610	$ 937,684
Note receivable from officer	**371,250**	—	—

See accompanying notes.

1. Description of Business

Endocardial Solutions, Inc. (the Company) designs, develops and manufactures a minimally invasive and integrated system that locates and facilitates treatment of cardiac arrhythmias. 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 products to diagnose ventricular tachycardia, a widespread, complex and serious form of arrhythmia, and intends to utilize its technology to produce products to diagnose atrial arrhythmias, including atrial fibrillation. The Company believes that its proprietary technology will enable physicians to rapidly and accurately map the heart's electrical activity and locate the abnormal heart rhythms through three-dimensional imaging.

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 intercompany 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, 2001 and 2000, the Company's cash equivalents consisted of investments in government securities carried at amortized cost which approximated market value, with no resulting unrealized gains and losses recognized.

Revenue Recognition

Revenue from the sale of the Company's system is recognized at the time of shipment in instances where the Company has evidence of a contract, the fee charged is fixed and determinable, and collection is probable.

Deferred revenue originates from maintenance agreements the Company enters into with its customers. With the initial sale of an EnSite clinical workstation the Company offers a standard one-year maintenance agreement on the system, which covers repairs and service of the patient interface unit and the Silicon Graphics display workstation. It also covers any software upgrades released during this time frame. Subsequent to the expiration of the first year standardized maintenance agreement, customers are able to purchase an extended one-year maintenance agreement to cover repair and service costs and also any software upgrade released in this time frame. Long-term deferred revenue originates from sales of extended maintenance agreements. Revenue from maintenance agreements is recognized ratably over the period the services are provided.

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. The Company amortizes these costs over an estimated economic useful life of 18 months.

2. Summary of Significant Accounting Policies (Continued)

Furniture and Equipment

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

Patents

Patent costs are being amortized on a straight-line basis over five years. The Company periodically reviews its patents for impairment in value. Any adjustment from the analysis is charged to operations.

Short-Term Investments

Short-term investments consist of U.S. Government obligations and corporate debt securities with maturities of less than one year. At December 31, 2000, the Company had $523,170 in U.S. Government obligations and $2,464,418 in corporate debt securities. Management determines the appropriate classification of debt and equity securities at the time of purchase and reevaluates such designation as of each balance sheet date. Management has classified the debt securities as available for sale. Available for sale securities are carried at fair value with the unrealized gains and losses, net of tax, reported as a separate component of shareholders' equity. At December 31, 2000, the fair value of the Company's investments approximates cost.

Income Taxes

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

The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation*, but applies Accounting Principles Board Opinion No. 25 (APB 25) and related interpretations in accounting for its options granted to employees and directors. Under APB 25, when the exercise price of employee stock options equals the market price of the underlying stock on the date of grant, no compensation is recognized.

2. Summary of Significant Accounting Policies (Continued)

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 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 antidilutive.

Foreign Currency Translation and Transactions

Foreign assets and liabilities are translated using the year-end exchange rate. Results of operations are translated using the average exchange rates throughout the year. Translation gains or losses, net of applicable deferred taxes are accumulated as a separate component of stockholders' equity.

New Accounting Standards

In October 2001, the FASB issued SFAS No. 144, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of*, which is effective for fiscal years beginning after June 15, 2002. This statement addresses financial accounting and reporting for the impairment or disposal of long-lived assets and supersedes SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of*, and the accounting and reporting provisions of Accounting Principles Board (APB) Opinion No. 30, *Reporting the Results of Operations* for a disposal of a segment of a business. The adoption of this pronouncement is not expected to have a material impact on the Company's consolidated results of operations, financial position, or cash flows.

3. Inventories

Inventories consist of the following:

	December 31	
	2001	*2000*
Raw materials	**$1,191,782**	$1,923,329
Work in progress	**594,437**	320,805
Finished goods	**946,926**	967,684
	$2,733,145	$3,211,818

4. Debt and Capital Lease Obligations

In February 1999, the Company entered into a $7,000,000 note agreement bearing interest at 8% per year with Medtronic. Under the agreement, the Company received $3,500,000 in February 1999 and an

4. Debt and Capital Lease Obligations (Continued)

additional $3,500,000 in January 2000. In February 2001, amounts outstanding under the note agreement were repaid and a related warrant agreement was canceled.

In June 2001, the Company obtained a line of credit from a bank. The maximum amount available to the Company under this arrangement is $2,000,000 and expires in June 2002. Advances under the line of credit are charged a variable rate of interest equal to the prime rate plus one half of a percent (6.25% at December 31, 2001). At of December 31, 2001, $750,000 was borrowed under the line of credit. The agreement specifies certain restrictive covenants, which the Company was in compliance with as of December 31, 2001.

In June 2001, the Company issued a warrant to purchase 35,000 shares of common stock at an exercise price of $5.02 per share in connection with a bank line of credit and equipment lease agreement. The warrant expires five years from the grant date and was deemed to have a value of $8,750, which was expensed during the year ended December 31, 2001.

Capital Lease Obligations

The Company has leasing line of credit agreements with a venture leasing company and a bank for the acquisition of furniture, fixtures and research and development equipment. As of December 31, 2001 and 2000, the Company had outstanding lease obligations under these agreements of $895,197 and $1,177,516, respectively. At December 31, 2001, the Company had $1,147,597 available for borrowing under these agreements.

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

	December 31	
	2001	2000
Research and development equipment	**$2,310,589**	$3,237,425
Less accumulated amortization	**1,272,324**	1,791,108
Net assets under capital leases	**$1,038,265**	$1,446,317

Future minimum lease payments under capital leases consisted of the following as of December 31, 2001:

Year ending December 31:	
2002	$639,778
2003	250,365
2004	63,340
Total minimum payments	953,483
Less amount representing interest	58,286
Present value of net minimum payments	895,197
Less current portion	594,010
Long-term obligations, net of current portion	$301,187

Interest paid for the years ended December 31, 2001, 2000, and 1999 was $301,198, $607,098, and $308,034, respectively.

5. Operating Leases

The Company leases its office facility and certain equipment under operating lease agreements which expire on various dates through 2004. Under the office facility agreement, the Company is required to pay a base rent plus certain operating expenses. Rent expense was $461,754, $493,576, and $386,112 for the years ended December 31, 2001, 2000, and 1999, respectively.

Future minimum lease commitments required under non-cancelable operating leases as of December 31, 2001 are as follows:

Year ending December 31:	
2002	$ 561,682
2003	530,584
2004	133,240
	$1,225,506

6. Stock Options and Warrants

The Company has adopted the 1993 Long-Term Incentive and Stock Option Plan (the Plan) under which directors, officers, employees and consultants of the Company may receive options to purchase Common Stock. The options granted under the Plan can either be incentive stock options or non-statutory stock options. Options granted under the Plan may not be at a price less then the fair market value of the Common Stock on the date of grant.

In 1997, the Company adopted the Directors' Stock Option Plan (the Directors' Plan). The Directors' Plan provides 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 of a share of Common Stock as of the grant date.

6. Stock Options and Warrants (Continued)

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

	Director's Plan		1993 Long-Term Plan Options Outstanding			Weighted Average Exercise Price Per Share
	Shares Available for Grant	Options Outstanding	Shares Available for Grant	NSO	ISO	
Balance at December 31, 1998	130,000	70,000	421,679	37,500	942,131	$5.26
Additional shares reserved for issuance	—	—	300,000	—	—	—
Granted	(20,000)	20,000	(465,500)	—	465,500	9.08
Canceled	11,667	(11,667)	125,017	—	(125,017)	9.57
Exercised	—	—	—	—	(31,747)	2.05
Balance at December 31, 1999	121,667	78,333	381,196	37,500	1,250,867	6.25
Granted	(33,333)	33,333	(155,747)	36,247	119,500	7.94
Canceled	—	—	118,877	—	(118,877)	9.56
Exercised	—	—	—	—	(34,512)	1.12
Balance at December 31, 2000	88,334	111,666	344,326	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**
Canceled	**—**	**—**	**108,955**	**(36,247)**	**(72,708)**	**8.43**
Exercised	**—**	**—**	**—**	**—**	**(2,813)**	**1.44**
Balance at December 31, 2001	**48,334**	**151,666**	**402,031**	**37,500**	**1,942,707**	**5.64**

The following table summarizes information about the stock options outstanding at December 31, 2001:

	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	338,855	2.86	$ .33	338,855	$ .33
0.60 - 2.40	92,250	4.33	2.05	95,250	2.05
3.50 - 7.88	870,078	8.85	4.41	248,189	4.63
8.00 - 12.38	807,190	6.79	9.43	560,702	9.56
12.50 - 13.13	20,500	6.17	12.88	19,665	12.88
0.20 - 13.13	2,131,873	6.87	5.63	1,262,661	5.59

Options outstanding under the stock option plans expire at various dates during the period from April 2003 through October 2011. Exercise prices for options outstanding as of December 31, 2001 ranged from $.20 to $13.13 per share. The number of options exercisable as of December 31, 2001, 2000 and 1999 were 1,262,661, 988,584, and 766,414, respectively, at weighted-average exercise prices of $5.59, $5.32, and $3.97 per share, respectively.

6. Stock Options and Warrants (Continued)

The weighted-average grant date fair value of options granted during the years ended December 31, 2001, 2000 and 1999 was $2.21, $4.83, and $4.63 per share, respectively.

Pro forma information regarding net loss and loss per share is required by Statement 123, and has been determined as if the Company had accounted for its employee stock options under the fair value method of Statement 123. The fair value for these options was estimated at the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions for 2001, 2000 and 1999: risk-free interest rates ranging from 4.42% to 6.18%, dividend yields of -0-, volatility factors of the expected market price of the Company's stock ranging from .61 to .87 and a weighted-average expected life of the options of four years.

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period. The Company's pro forma information is as follows:

	2001	2000	1999
Pro forma net loss	**$(9,636,893)**	$(11,745,304)	$(12,921,011)
Pro forma net loss per common share	**$ (.68)**	$ (1.05)	$ (1.35)

The Company also has an Employee Stock Purchase 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 the first or last day of the offering period. Offering periods are each 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.

7. Deferred Compensation

During the years ended December 31, 2001, 2000, and 1999, the Company granted stock options for the purchase of 125,000 shares, 31,247 shares, and 95,000 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 for accounting purposes of the common stock issuable upon exercise of such options over the aggregate exercise price of such options of $315,000, $7,812, and $35,628, respectively, in 2001, 2000, and 1999. For the years ended December 31, 2001, 2000, and 1999, the Company recognized expense of $61,412, $16,719, and $98,730, respectively, associated with such stock option grants.

7. Deferred Compensation (Continued)

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

2002	$ 87,657
2003	81,719
2004	78,750
2005	26,245
Total	$274,371

8. Income Taxes

At December 31, 2001, the Company had net operating loss carryforwards of approximately $67,090,000. The net operating loss carryforwards are available to offset future taxable income and begin to expire in the year 2009. No benefit has been recorded for such loss carryforwards, and utilization in future years may be limited under Section 382 of the Internal Revenue Code if significant ownership changes have occurred.

Components of deferred tax assets are as follows:

	December 31	
	2001	2000
Deferred tax assets:		
Net operating loss carryforwards	**$ 25,494,000**	$ 23,793,000
Accrued liabilities	**143,000**	121,000
Other	**34,000**	12,000
	25,671,000	23,926,000
Deferred tax liabilities:		
Depreciation and amortization	**22,000**	308,000
Capitalized software costs	**75,000**	194,000
Net deferred tax assets	**25,574,000**	23,424,000
Valuation allowance	**(25,574,000)**	(23,424,000)
Total net deferred tax assets	**$ —**	$ —

9. Sources of Supply

The Company purchases raw materials and certain key components of its products, including the computer workstation and certain components for its catheter 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.

10. License Agreement

In January 1998, the Company entered into a license agreement with Medtronic, Inc. to license certain technology developed by Medtronic. As consideration for the rights to utilize the developed technology, the Company paid Medtronic $1,500,000 and granted Medtronic a warrant to purchase 447,554 shares of the Company's common stock at an exercise price of $11.1125. The warrant expires in January 2002. The warrant was deemed to have a value of $2,085,602. This amount, along with the cash payment to Medtronic, has been expensed as research and development. If the Company develops a product that reaches commercialization, the Company will grant to Medtronic an additional warrant to purchase 223,777 shares of common stock. The exercise price of the warrant will be 1.25 times the average closing price of the Company's common stock for the twenty days prior to the commercial products introduction. The value of the additional warrants will be amortized over the shorter of the license agreement or the life of the developed product.

This additional warrant becomes exercisable one year after being granted and remains outstanding for five years. The additional warrant will also be granted if the Company undergoes a change in control. If the warrant is granted due to a change in control, it becomes immediately exercisable.

11. Note Receivable Officer

In January 2001, the Company entered into a $371,250 full recourse note agreement with an officer of the Company for the purchase of 110,000 shares of the Company's common stock. The note bears interest at 9.5% per year and is due in full in January 2006.

12. Significant Customer

The Company had a distributor that represented 6%, 16%, and 42% of all net revenues for the years ended December 31, 2001, 2000 and 1999, respectively.

13. Segment Reporting

Sales by geographic distinction as percentages of total sales were as follows for the years ended December 31:

	2001	2000	1999
Domestic	**81%**	74%	56%
International:			
Europe	**10**	16	43
Asia Pacific	**7**	8	1
Canada	**2**	2	—

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

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2001				
Net revenue	**$ 4,602**	**$ 5,578**	**$ 5,818**	**$ 6,895**
Gross profit	**2,524**	**3,355**	**3,531**	**4,242**
Net loss	**(2,491)**	**(2,462)**	**(1,994)**	**(1,532)**
Basic and diluted net loss per share	**$ (.20)**	**$ (.17)**	**$ (.13)**	**$ (.10)**
2000				
Net revenue	$ 3,360	$ 3,737	$ 3,097	$ 4,369
Gross profit	1,484	1,808	1,573	2,524
Net loss	(2,502)	(3,137)	(2,791)	(1,880)
Basic and diluted net loss per share	$ (.25)	$ (.31)	$ (.23)	$ (.15)

15. Subsequent Event

On February 27, 2002, the Company completed the sale of 1,666,667 shares of its common stock at a price of $6.00 per share, resulting in gross proceeds of $10,000,002.

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

None.

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 14, 2002 (the "2002 Proxy Statement"), which definitive 2002 Proxy Statement will be filed within 120 days after the close of the fiscal year ended December 31, 2001, are incorporated herein by reference.

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

ITEM 11. EXECUTIVE COMPENSATION

The section under the heading "Election of Directors" entitled "Compensation of Directors" and the section entitled "Executive Compensation" in the 2002 Proxy Statement, which definitive 2002 Proxy Statement will be filed within 120 days after the close of the fiscal year ended December 31, 2001, are incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The section entitled "Security Ownership of Certain Beneficial Owners and Management" in the 2002 Proxy Statement, which definitive 2002 Proxy Statement will be filed within 120 days after the close of the fiscal year ended December 31, 2001, is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The section entitled "Certain Transactions" in the 2002 Proxy Statement, which definitive 2002 Proxy Statement will be filed within 120 days after the close of the fiscal year ended December 31, 2001, is incorporated herein by reference.

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a) Documents filed as part of this Report

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

(2) Financial Statement Schedules

None. All financial statement schedules are omitted because of the absence of conditions under which they are required.

(3) **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	Warrant Agreement dated November 18, 1993 between the Company and Tikkun Resource Development relating to warrant issued to Tikkun Resource Development relating to warrant issued to Tikkun Resource Development to purchase shares of common stock (incorporated by reference to Exhibit 4.2 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))
4.2	Rights Agreement dated as of August 25, 1999 between the company and Norwest Bank Minnesota, National Association, 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., with Exhibits (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. 0-333-20677))
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	Investment Agreement dated April 26, 1996 between the Company and Medtronic, Inc. (incorporated by reference to Exhibit 10.8 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))

10.8 Amended and Restated Investors Rights Agreement dated January 31, 1995, together with Amendments thereto dated March 1, 1995 and April 26, 1996, respectively, between the Company and the holders of the Company's Series A and Series B Preferred Stock (incorporated by reference to Exhibit 10.9 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))

10.9 Stock Purchase Agreement between the Company and Medtronic, Inc. (incorporated by reference to Exhibit 10.10 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))

10.10 Purchase Agreement between the Company, Piper Jaffray Inc., and Volpe, Welty & Company LLC (incorporated by reference to Exhibit 1.1 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))

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10.14 Amendment to Distribution/Supply Agreement dated December 11, 1998 between the Company and Medtronic, Inc. (incorporated by reference to Exhibit 10.15 to the Company's Annual Report on Form 10-K for the year ended December 31, 1998 (File No. 0-22233))

10.15 Note Purchase Agreement dated February 2, 1999, between the Company and Medtronic Asset Management, Inc. (incorporated by reference to Exhibit 10.16 to the Company's Annual Report on Form 10-K for the year ended December 31, 1998 (File No. 0-22233))

10.16 Warrant, dated February 2, 1999, to purchase shares of common stock, issued by the Company to Medtronic Asset Management, Inc. (incorporated by reference to Exhibit 10.17 to the Company's Annual Report on Form 10-K for the year ended December 31, 1998 (File No. 0-22233))

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10.19 Registration Rights Agreement dated July 9, 1999, among the Company and the Investors named therein (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1999 (File No. 0-22233))

10.20 Third Amendment, dated March 31, 2000, to the Distribution/Supply Agreement 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, 2000 (File No. 0-22233))

10.21 Form of Stock Purchase Agreement, dated June 27, 2000, among the Company and the Investors named therein (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2000 (File No. 0-22233))

10.22*	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))
10.23*	Employment and Noncompetition Agreement, dated as of November 3, 2000, between the Company and Michael D. Dale (incorporated by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000 (File No. 0-22233))
10.24*	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))
10.25*	Form of Change in Control Agreement dated November 3, 2000, between the Company and each of Graydon Beatty, Frank Callaghan, Michael Dale, 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))
10.26	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))
10.27	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))
10.28*	Stock Purchase and Restriction Agreement, dated January 22, 2001, by and between the Company and Michael Dale (incorporated by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000 (File No. 0-22233))
10.29	Form of Stock Purchase Agreement, dated March 22, 2001, among the Company and the Investors named therein (incorporated by reference to Exhibit 10.29 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000 (File No. 0-22233))
10.30	Stock Purchase Warrant, dated March 26, 2001, between the Company and U.S. Bancorp Piper Jaffray (incorporated by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000 (File No. 0-22233))
10.31	Fourth Amendment to the Distribution/Supply Agreement dated September 4, 1997 between the Company and Medtronic, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001 (File No. 0-22233))
10.32	Loan and Security Agreement dated June 28, 2001, between the Company 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 June 30, 2001 (File No. 0-22233))
10.33	Warrant to Purchase Stock, dated June 28, 2001, issued by the Company to Silicon Valley Bank (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001 (File No. 0-22233))
10.34	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))
10.35	Form of Stock Purchase Agreement, dated February 25, 2002, among the Company and the Investors named therein (Filed herewith)
21	List of Subsidiaries (filed herewith)
23	Consent of Ernst & Young LLP (Filed herewith)
24	Power of Attorney (included on signature page)

99 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 14(c) of the Form 10-K Report.

(b) Reports on Form 8-K

A report on Form 8-K, dated October 2, 2001 was filed by the Registrant; such report contained information under Item 9 (Regulation FD Disclosure) and included as an exhibit under Item 7 a copy of a press release issued by the Registrant announcing U.S. Food and Drug Administration clearance of the Registrant's Precision™ software.

A report on Form 8-K, dated October 22, 2001, 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 its third quarter earnings results.

A report on Form 8-K, dated October 31, 2001 was filed by the Registrant; such report contained information under Item 9 (Regulation FD Disclosure) and included as an exhibit a copy of a press release issued by the Registrant announcing the 200th installation of its EnSite 3000 System.

(c) See Item 14(a)(3) above.

(d) See Item 14(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 29, 2002

ENDOCARDIAL SOLUTIONS, INC.

By /s/ JAMES W. BULLOCK

James W. Bullock,
President and Chief Executive Officer
(Principal Executive, Financial and Accounting 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 29th day of March, 2002.

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints James W. Bullock, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, 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, Financial and Accounting Officer)
/s/ GRAYDON E. BEATTY Graydon E. Beatty	Director
James E. Daverman	Director
/s/ ROBERT G. HAUSER, M.D. Robert G. Hauser, M.D.	Director
Warren S. Watson	Director
/s/ RICHARD D. RANDALL Richard D. Randall	Director
/s/ MARK WAGNER Mark Wagner	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	Warrant Agreement dated November 18, 1993 between the Company and Tikkun Resource Development relating to warrant issued to Tikkun Resource Development to purchase shares of common stock (incorporated by reference to Exhibit 4.2 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))
4.2	Rights Agreement dated as of August 25, 1999 between the Company and Norwest Bank Minnesota, National Association, 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., with Exhibits (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	Investment Agreement dated April 26, 1996 between the Company and Medtronic, Inc. (incorporated by reference to Exhibit 10.8 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))

10.8 Amended and Restated Investors Rights Agreement dated January 31, 1995, together with Amendments thereto dated March 1, 1995 and April 26, 1996, respectively, between the Company and the holders of the Company's Series A and Series B Preferred Stock (incorporated by reference to Exhibit 10.9 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))

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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 14(c) of the Form 10-K Report.

CORPORATE INFORMATION

EXECUTIVE OFFICERS

James W. Bullock
President,
Chief Executive Officer
and Director

Graydon E. Beatty
Chief Technical Officer
and Director

Frank J. Callaghan
Vice President,
Research and Development

Michael D. Dale
Vice President,
Sales and Marketing

Richard J. Omilanowicz
Vice President,
Manufacturing and Operations

Mark J. Wagner
Chief Executive Officer
Neomedics, Inc.

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

BOARD OF DIRECTORS

James W. Bullock
President and
Chief Executive Officer
Endocardial Solutions, Inc.

Graydon E. Beatty
Chief Technical Officer
Endocardial Solutions, Inc.

James E. Daverman
Managing General Partner
Marquette Venture Partners

Robert G. Hauser, M.D.
Cardiologist
Minneapolis Heart Institute

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

TRANSFER AGENT AND REGISTRAR

Wells Fargo Bank
Minnesota, N.A.
South Saint Paul, MN
800-689-8788

AUDITORS

Ernst & Young LLP
Minneapolis, MN

LEGAL COUNSEL

Dorsey & Whitney LLP
Minneapolis, MN

ANNUAL MEETING

The Company's Annual Meeting of Stockholders will be held on May 14, 2002 at 9:00 A.M. at:

Hilton Minneapolis & Towers
1001 Marquette Avenue
Minneapolis, MN 55403

FORM 10-K

A copy of the Company's Form 10-K filed with the Securities and Exchange Commission is available free of charge by calling Investor Relations at the number below.

CORPORATE HEADQUARTERS

1350 Energy Lane, Suite 110
Saint Paul, MN 55108-5254

Telephone: 651-523-6900
Facsimile: 651-644-7897

INVESTOR INQUIRIES

Telephone: 651-523-6917
E-mail: investor@endocardial.com

LISTING

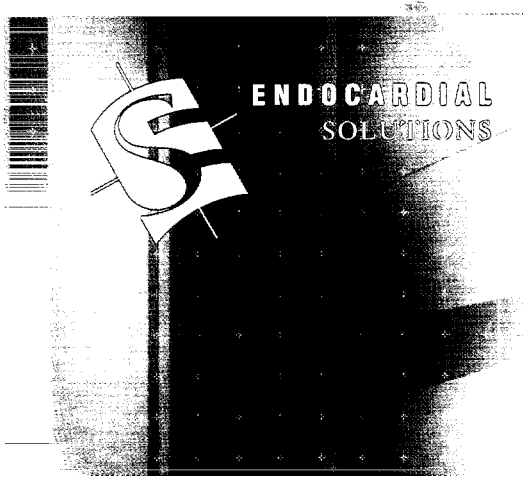
Trades on Nasdaq Stock Market®
under the symbol "ECSI"

"With the EnSite System, I am able to treat patients with complex arrhythmias myself rather than sending them to another facility for treatment."

Dr. Gregory Buser, Northeast Baptist Hospital

MILESTONE 200™ ENSITE 3000® SYSTEM

In October 2001, Endocardial Solutions achieved a milestone by placing the 200th worldwide EnSite 3000® System at Northeast Baptist Hospital in San Antonio, Texas. Dr. Gregory Buser, an electrophysiologist at Northeast Baptist, was instrumental in acquiring the first EnSite® System in the San Antonio area, after viewing cases he ultimately referring several patients to a center 80 miles away that offered the technology.



WORLD HEADQUARTERS

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