

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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FORM 10-K  
FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

(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, 1998

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: 0-28440

RADIANCE MEDICAL SYSTEMS, INC.  
(Exact name of Registrant as specified in its charter)

Delaware (State of Incorporation) 68-0328265 (I.R.S. Employer Identification No.)

13700 Alton Parkway, Suite 160, Irvine, California 92618  
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (949) 457-9546

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

Title of each class -----	Name of each exchange on which registered -----
None	None

Securities to be registered pursuant to Section 12(g) of the Act: Common Stock,  
\$.001 par value.

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

Indicate by a 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 the voting stock held by non-affiliates of the  
Registrant, as of March 15, 1999, was approximately \$33,788,000 (based upon the  
closing price for shares of the Registrant's Common Stock as reported by the  
Nasdaq National Market for the last trading date prior to that date). Shares of  
Common Stock held by each officer, director and holder of 5% or more of the  
outstanding Common Stock have been excluded in that such persons may be deemed  
to be affiliates. This determination of affiliate status is not necessarily a  
conclusive determination for other purposes.

On March 15, 1999, approximately 10,597,000 shares of the Registrant's Common  
Stock, \$.001 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE.

Portions of the Registrant's Proxy Statement for the 1999 Annual Meeting of Stockholders to be held on June 9, 1999 are incorporated by reference into Part III.

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#### FORWARD-LOOKING STATEMENTS

Radiance cautions stockholders that, in addition to the historical financial information included herein, this Annual Report on Form 10-K includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 that are based on management's beliefs, as well as on assumptions made by and information currently available to management. All statements other than statements of historical fact included in this offering memorandum, including without limitation, certain statements under "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," and statements located elsewhere herein regarding Radiance's financial position and business strategy, may constitute forward-looking statements. In addition, forward-looking statements generally can be identified by the use of forward-looking terminology such as "believes," "may," "will," "expects," "intends," "estimates," "anticipates," "plans," "seeks," or "continues," or the negative thereof or variations thereon or similar terminology. Such forward-looking statements involve known and unknown risks, including, but not limited to, economic and market conditions, the regulatory environment in which Radiance operates, competitive activities or other business conditions. There can be no assurance that Radiance's actual results, performance or achievements will not differ materially from any future results, performance or achievements expressed or implied from such forward-looking statements. Important factors that could cause actual results to differ materially from Radiance's expectations ("Cautionary Statements") are disclosed in this Annual Report on Form 10-K, including, but not limited to, those discussed in "Item 7--Risk Factors." All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by these Cautionary Statements.

#### PART I

#### ITEM 1. BUSINESS

##### INTRODUCTION

Radiance Medical Systems, Inc. ("Radiance," or the "Company") develops, manufactures and markets proprietary devices for the prevention of the recurrence of atherosclerotic blockages following the interventional treatment of atherosclerosis. Radiance's primary product under development is the RDX Catheter, a balloon catheter-based delivery system designed to deliver radioactive materials to the area of an artery that has been treated with conventional interventional therapy such as Percutaneous Transluminal Coronary Angioplasty ("PTCA"), atherectomy and/or stent deployment. See "Item 1--Products."

The Company is the result of an acquisition effected by the merger of the (former) Radiance Medical Systems, Inc. ("RMS") with and into CardioVascular Dynamics, Inc. (now named Radiance Medical Systems, Inc.). RMS originally was formed by the Company as a separate entity to focus on the development of radiation therapy technology for the treatment of cardiovascular disease, and to obtain financing for such development from sources other than the Company. As a result of the merger, the Company reacquired all of the shares of RMS which it did not own. The Company was incorporated on March 16, 1992.

##### INDUSTRY BACKGROUND

##### CORONARY ARTERY DISEASE

Coronary artery disease is the leading cause of death in the United States. More than 13 million people in the United States currently have been diagnosed with coronary artery disease, which is generally characterized by the progressive accumulation of plaque as a result of the deposit of cholesterol and other fatty materials on the walls of arteries. The accumulation of plaque leads to a narrowing of the interior passage, or lumen, of the arteries, reducing blood flow to the heart. When blood flow to the heart becomes insufficient, the oxygen supply is restricted, resulting in heart attack and/or death. Each year

more than 900,000 revascularization procedures are performed in the United States, and approximately 1.5 million such procedures are performed worldwide, to treat coronary artery disease and increase blood flow to the heart.

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#### TYPES OF TREATMENT

The two most common forms of treatment for coronary artery disease are: (i) the coronary artery bypass graft ("CABG"); and (ii) PTCA and other catheter-based technologies. CABG is a highly invasive, open surgical procedure in which blood vessel grafts are used to bypass the site of a blocked artery, thereby restoring blood flow. CABG, still considered the most effective and long-lasting treatment for coronary artery disease, is generally the primary treatment for severe coronary artery disease involving multiple vessels. In addition, CABG is often a treatment of last resort for patients who have undergone other less invasive procedures but require reintervention. CABG, however, has significant limitations, including medical complications, such as stroke, multiple organ dysfunction, inflammatory response, respiratory failure and post-operative bleeding, each of which may result in death. In addition, CABG is a very expensive procedure and requires a long recovery period. In the United States, the cost of undergoing CABG is approximately \$32,000 to \$36,000 and the average post-operative recovery period following CABG is approximately six to eight weeks. Approximately 400,000 CABG procedures are performed annually in the United States. Currently, several minimally invasive surgical techniques are being developed to lessen the cost and trauma of CABG procedures.

PTCA is the principal, less invasive alternative to CABG. PTCA is a procedure performed in a cath lab by an interventional cardiologist. During PTCA, a guidewire is inserted into a blood vessel through a puncture in the leg (or arm in some cases) and guided through the vasculature to a diseased site in the coronary artery. A balloon-tipped catheter is then guided over the wire to the deposit of plaque ("lesion") occluding the artery. Once the balloon is positioned across the lesion inside the vessel, the balloon is inflated and deflated several times. Frequently, successively larger balloons are inflated at the lesion site, requiring the use of multiple balloon catheters. The inflation of the balloon cracks or reshapes the plaque and the arterial wall, thereby expanding the arterial lumen. Though injury to the arterial wall often occurs under balloon pressure, PTCA typically results in increased blood flow without the actual removal of any plaque. In 1997, more than 600,000 PTCA procedures were performed in the United States. The average cost of each PTCA procedure is approximately \$15,000, or less than one half of the average cost of CABG, and the length of stay and recuperation period are substantially less than required for CABG.

The principal limitation of PTCA is the high rate of restenosis, a re-narrowing of a treated artery, which generally requires reintervention. Due to the effects of restenosis, the long-term cost-effectiveness of PTCA has not proven greater than that of CABG. Studies have indicated that within six months after PTCA, between 25% and 45% of PTCA patients experience restenosis. In addition, 60% of patients with multi-vessel coronary artery disease who received PTCA have been shown to require reintervention within three years of treatment. Although the average cost of PTCA initially is less than one-half of the cost of CABG, a recent study indicated that three years after the procedure, PTCA has no cost advantage over CABG due to the need for subsequent interventional treatment.

A variety of other catheter-based, minimally invasive, interventional devices for coronary artery disease have been developed in an attempt to reduce the frequency of restenosis following PTCA. These devices include atherectomy devices (catheter devices that cut and remove plaque from the arterial wall), rotational ablation devices (catheter devices which use a rotating burr to remove plaque), and laser catheter devices (devices that use laser energy to reduce plaque in arteries). Although these new approaches to coronary artery disease have been found to be effective in certain lesion types and in certain locations in the coronary arteries, they still exhibit high rates of restenosis.

#### RESTENOSIS

Clinical restenosis is typically defined as a re-narrowing of a coronary artery within six months of a revascularization treatment to less than 50% of its original size. Restenosis is a vascular response to arterial injury and

occurs frequently after a revascularization procedure, which stretches coronary arteries or otherwise damages

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the treated segment of the artery. Due to multiple mechanisms controlling vascular repair, restenosis may occur within a short period after a revascularization procedure or may develop over the course of months or years. Restenosis that occurs shortly after a revascularization procedure is usually attributed to elastic recoil (acute loss of lumen diameter) of the artery.

Restenosis occurring a longer period of time after a revascularization procedure may result from excessive proliferation of cells at the treatment site ("hyperplasia") or from a generalized geometric remodeling of the arterial segment, the causes of which are not well understood. Hyperplasia is a physiological response to injury, similar to scarring which occurs in wound healing. In response to an arterial injury from revascularization, the body initiates a biochemical response to repair the injury site and protect it from further harm. This response will include a signal to adjacent cells of the arterial wall to multiply. Often this cell proliferation goes unchecked, resulting in a much thicker and inelastic arterial wall and in reduced blood flow. CVD and Radiance believe that hyperplasia and vascular remodeling may be responsible for a large portion of the overall effect of restenosis.

#### CORONARY STENTING

Coronary stents are expandable, implantable metal devices permanently deployed at a lesion site. Stents maintain increased lumen diameter by mechanically supporting the diseased site in a coronary artery. Of all the non-surgical treatments which have sought to improve upon PTCA, stents have demonstrated the best results in reducing the rate of restenosis. In a typical stent procedure, the artery is pre-dilated at the lesion site with a balloon catheter and the stent is delivered to the site of the lesion and deployed with the use of a second balloon catheter, which expands the stent and firmly positions it in place. This positioning is often followed by a third dilatation using a high pressure balloon to fully expand and secure the stent. Once placed, stents exert radial force against the walls of the coronary artery to enable the artery to remain open and functional.

Recent studies have concluded that the rate of restenosis in patients who receive coronary stents following PTCA is approximately 30% lower than in patients treated only by PTCA. Additional clinical studies with stents which incorporate a specialized coating may show a greater reduction in the rate of restenosis. Stents appear to be effective in reducing the frequency of restenosis resulting from elastic recoil and appear to limit vascular remodeling, but may increase, rather than decrease, hyperplasia.

The use of stents has grown rapidly since commercial introduction in the United States in 1994. Approximately 300,000 of the approximately 600,000 PTCA procedures performed in the United States in 1997 utilized stents. Despite their rapid adoption, stents have certain disadvantages. Not only are they permanent implants which may result in unforeseen long-term adverse effects, but they cannot be used in cases where the coronary arteries are too tortuous or too narrow. In addition, the use of stents approximately doubles the cost of a PTCA procedure and restenosis still may occur, often requiring reintervention.

#### RADIOTHERAPY

For more than 50 years, radiotherapy has been used routinely to treat proliferative cellular disorders in humans. While externally applied radiation has shown little beneficial effect on treated arteries, the application of Beta and Gamma radiation at the site of arterial injury has proven more useful in treating restenosis.

Gamma radiation has been demonstrated in a number of models to inhibit the cellular proliferation associated with the restenosis mechanism. Gamma is compatible with vessels of all sizes but is more complicated to use in the cath lab because of its activity.

Beta radiation has been demonstrated to inhibit intimal hyperplasia. Since Beta radiation travels only a short distance (2-4 mm) before losing its

therapeutic value, it is imperative that the source be placed as close as possible to the arterial wall. This relatively short distance of travel makes its compatible with current cath lab practices. Dosage is calculated by knowing the energy level of the source and the distance from the treatment target. Uniform dosage to the intended area is dependent upon maintaining a consistent energy field.

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The placement of guidewire based systems of radiation transport in the curved coronary anatomy has been shown to produce inconsistent dosages to actual tissue because of the different distances the guidewire lays from the vessel wall over the length of the active wire. When guidewire centering balloons are used, the beneficial effect of the radiation is lost over the distance from the wire to the arterial wall. As the vessel diameter increases, the therapeutic effect also diminishes. The Company believes that if any benefit is to be realized with guidewire based techniques it would be limited to small diameter, straight arteries. The extended inflation times of the centering balloon required to insure adequate dosage also may result in ischemia and unacceptable discomfort or hazard to the patient.

A stent activated to emit Beta radiation would overcome the proximity issues inherent in a guidewire delivery system by placing the Beta source directly opposed to the vessel. This approach also assumes a one dose for all patients, removing control of dose from the clinician. This approach also assumes a vessel of fixed size and that the energy level of the implanted stent will be adequate to deliver the required radiation dosage after implant. Vessel diameter is often difficult to quantify. As a stent expands, the space between its active elements increases. Since the radioactive stent cannot be removed after placement, the patient continues to receive the ionizing effects until the radiation dissipated over five half lives of the isotope used. In the case of Beta p32, this is approximately 70 days.

#### PRODUCTS

In addition to research and development of radiotherapy products, Radiance also manufactures and markets catheters and coronary stent systems used in conjunction with angioplasty and vascular stenting. The Company's proprietary Focus catheter technology enables physicians to deliver therapeutic radial force and stents accurately and effectively to the treatment site. The Company's proprietary stent designs offer characteristics enabling physicians to access varying coronary anatomy. RMS believes that these products enable physicians to perform challenging interventional procedures effectively, resulting in improved treatment outcomes and lower costs. RMS owns the rights to 21 issued U.S. patents, one issued European patent and two Japanese patents covering certain aspects of its catheter and SEAL stent technologies.

#### RADIATION PRODUCTS TECHNOLOGY

Radiance believes that its radiation source technology, combined with its existing catheter and stent delivery systems, can deliver radioactive materials to the localized site safely and effectively. The Company's radiation technology enables solid form radioactive material of virtually any isotope to be integrated into the wall of the balloon material itself, which creates a balloon/source angioplasty catheter. The Radiance approach combines the demonstrated benefits of Beta radiation with the utility of direct vessel wall apposition associated with balloon dilatation.

Radiance currently is focusing on the development of the RDX catheter, a radiation delivery balloon catheter system. The RDX Catheter consists of an expandable dual balloon system which enables the radiation dosage to be delivered precisely to the vessel wall. Because the balloon is in contact with the wall, this method of delivering Radiotherapy is appropriate for vessels of any diameter with proper balloon size selection.

This dual balloon concept also enables the RDX Catheter to be used to perform both PTCA and/or stent deployment and deliver Radiotherapy on a single catheter. Radiance is unaware of any competing technology that provides this combination of benefits, versatility and multifunctionality.

Because the Beta source is positioned relatively close to the vessel wall and the exact radiation strength is known prior to delivery, accurate dose

calculations can be made to customize patient treatment. This device may also incorporate a perfusion system to maintain blood flow distal to the inflated balloon to permit longer inflation times, if required, to optimize radiation dosage delivery effectively.

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Radiance believes that the RDX Catheter has several technical and clinical advantages for the treatment of restenosis.

- o The RDX Catheter provides complete apposition to the arterial wall, reducing the problems of distance determination and closing with current vascular radiotherapy devices.
- o The RDX Catheter can deliver equal or higher radioisotope activity with less total radiation dose than other technologies.
- o The fully-deployable radiation source is independent of vessel size. Coronary arteries range from 1.5 - 6.0 millimeters. With other devices, a different dose of radiation has to be calculated and/or delivered for each vessel size. With the RDX Catheter, the dose is the same regardless of the vessel dimensions. This also makes the RDX Catheter system useful in other vascular applications such as coronary, peripheral vascular leg arteries, renal, carotid and kidney dialysis grafts. This potentially broadens the clinical utility and market potential for the RDX system.
- o The RDX Catheter is simple and easy-to-use. Use of the RDX Catheter is consistent with the use of other types of catheters by interventional cardiologists.
- o The solid film substrate is totally protected by the double balloon construction. The use of the Beta isotope within the system increases the safety of the RDX Catheter as a vascular radiotherapy delivery device.

The Company currently is focusing on developing products for the treatment of restenosis following the interventional treatment of atherosclerosis. The Company believes, however, that its Radiotherapy technology may eventually be utilized to prevent and treat restenosis in all vascular segments of the body, including coronary, peripheral vascular, carotid, neurovascular and renal arteries. However, there is no assurance that Radiance will develop and market the RDX Catheter technology or any other radiation therapy technology successfully, that such products or radiation therapy in general will receive market acceptance or that such products, whether under development or commercialized, will not be rendered obsolete as a result of other technology.

#### EXISTING CATHETER PRODUCTS TECHNOLOGY

Radiance has utilized its Focus technology to develop catheter products that address the principal challenges physicians experience in treating vascular diseases: restenosis of a treated vessel, chronic total occlusions and acute reclosure of a vessel during or soon after a procedure. Traditional balloon extrusion technology does not enable the combination of compliant and non-compliant materials, resulting in a catheter that can be inflated only to a uniform diameter. Therefore, existing uniform diameter catheters require cardiologists to use multiple balloons to treat vessels of varying diameters, resulting in unnecessary costs. The Company's patented Focus technology combines compliant and non-compliant balloon materials on a single catheter, creating an angioplasty balloon that has an adjustable, larger center diameter with fixed, smaller diameters at each end. The center compliant section of the Focus catheter enlarges predictably at a rate of 0.1 mm per atmosphere of pressure when inflation pressures exceed six atmospheres. The ends of the balloon remain at their nominal diameters and do not expand with increased pressure. These characteristics allow a single balloon to expand to multiple diameters, enabling the physician to deliver stents and perform interventional procedures in vessels of varying diameters and anatomical locations.

Radiance believes the Focus catheters deliver stents more effectively by focusing the radial deployment force on the stented section, rather than along the entire balloon, which may reduce the damage to the adjacent vessel. The technology also is available in various combinations on a multiple-purpose catheter, thereby enabling physicians to treat vascular disease cost-effectively. The Company's products are designed to be low profile (small, uninflated diameter), enabling cardiologists to advance them along narrow vessels, as well as flexible and trackable, enabling cardiologists to advance and control them accurately within the vasculature.

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The following table lists the Company's catheter products which currently are marketed:

PRODUCTS -----	INTENDED APPLICATIONS -----	U.S. REGULATORY STATUS -----	FIRST COMMERCIAL SALE -----
FOCUS CATHETERS			
Guardian Over-the-wire design	PTCA (i.e., balloon angioplasty in coronary arteries)	PMA Supplement Approved	Q2 1998
Lynx F/X Rail Design	PTCA or Stent Delivery(2)	N/A(1)	Q1 1997
ARC Over-the-wire design	PTCA	PMA Supplement Approved	Q3 1996
FACT Catheter	PTCA	PMA Supplement Approved	Q1 1996

(1) Available only outside the United States due to patent restrictions.

(2) Not approved in the United States for stent delivery. The marketing of this product in the United States for such use will require Radiance to obtain a PMA supplement approval. Radiance is not currently seeking such approval.

EXISTING STENT PRODUCTS TECHNOLOGY

Radiance's line of coronary integrated stent delivery systems provide physicians with unique products of varying measures of strength and flexibility to allow optimal placement and stenting characteristics to aid in the minimization of restenosis.

The following table lists Radiance's currently marketed stent products which are not available in the United States due to Radiance's decision not to apply for regulatory approval.

PRODUCTS -----	INTENDED APPLICATIONS -----	FIRST COMMERCIAL SALE -----
Synthesis Stent	Coronary Stenting	Q1 1998
Synthesis Star System (1)	Coronary Stenting	Q1 1998
Enforcer Stent	Coronary Stenting	Q3 1997
Enforcer Stent System	Coronary Stenting	Q4 1997

(1) Pre-mounted stent on a Star balloon catheter delivery system.

In June 1998, Radiance entered into a technology license agreement with Guidant Corporation, an international interventional cardiology products company, granting Guidant rights to manufacture and distribute products using Radiance's Focus technology for delivery of stents, including exclusive marketing rights in the United States. In exchange for those rights Radiance has received, and will receive, certain milestone payments based upon the transfer of the technological knowledge to Guidant, and royalty payments based upon the sale of products by Guidant using Focus technology. However, there is no assurance that Guidant will successfully manufacture and distribute products based on the technology, or that Radiance will realize any such royalty payments.

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#### SEAL TECHNOLOGY

In addition to its development of Radiotherapy technology, the Company is developing its SEAL stent technology, which it believes may prove to be state of the art technology for the treatment of restenosis. The SEAL stent is a unique and new concept in vascular stenting which is designed to isolate the diseased segment of the vessel wall from blood flow. The SEAL is self-expanding metallic stent with a microporous surface for use as either a stent or a stent graft. By developing metal foil of the proper thickness and strength, Radiance believes it will be able to form devices with low profiles, high expansion ratios and excellent hoop strength, which are factors critical for successful device placement. Two patents have been issued to date for this technology.

Radiance believes that covering a high percentage of the diseased vessel wall with a proprietary metal liner will result in a lower restenosis rate in diseased vessels. The SEAL technology presently is being tested in animal studies to determine its efficacy in large diameter coronary vessels and saphenous vein grafts. If the animal studies are successful, Radiance anticipates commencing human clinical trials in Europe prior to the end of 1999. Radiance, depending on the outcome of clinical trials, intends to promote the SEAL stent as an effective primary stent for the treatment and prevention of restenosis in selected patient indications. Radiance has developed a proprietary delivery system to place the SEAL stent accurately at the location of the diseased segment of the vessel wall. However, there can be no assurance that the SEAL stent will perform in animal studies or clinical trials, that Radiance will complete the development of a new product successfully, that Radiance will be able to obtain FDA approval, or that the SEAL stent ever will gain market acceptance.

Radiance will be required to seek FDA approval for any new product and expects that some of these products will be subject to the PMA process. The Company also will be subject to federal, state and/or local laws and regulations governing the use and handling of radioactive materials. See "Item 1--Government Regulation." There can be no assurance that Radiance will complete the development of any products successfully or that any such products will receive any required regulatory approvals. The failure of Radiance to develop new products successfully or to obtain regulatory approvals could have a material adverse effect on the business and results of operations of the Company.

#### VASCULAR ACCESS PRODUCTS

Radiance's vascular access products utilized patented technology to provide rapid, accurate access to the body's vascular system for guidewire and catheter entry. In January 1999, Radiance sold the assets and operations of its vascular access business unit to Escalon Medical Corp. The Company believes that the sale of its vascular access business unit, combined with the CVD/RMS merger, focuses the Company's business on developing its proprietary technologies for the interventional cardiology market.

#### MANUFACTURING

With the exception of certain final assembly and sterilization procedures for those products designed to be sold only outside the United States, and the manufacture of those products which Radiance has licensed to third parties, all of Radiance's products are produced in its facilities in Irvine, California. Radiance fabricates certain proprietary components, then

assembles, inspects, tests and packages all components into finished products. By designing and assembling its catheter products, Radiance believes it is better able to control quality and costs, limit third-party access to its proprietary technology, and better manage manufacturing process enhancements and new product introductions. In addition, Radiance purchases many standard and custom-built components from independent suppliers and subcontracts certain processes from independent vendors. Most of these components and processes are available from more than one vendor. However, certain manufacturing processes currently are performed by single vendors. While Radiance believes that there are other vendors available to perform these processes, an interruption of performance by any of these vendors could have a material adverse effect on Radiance's ability to manufacture its products until a new source of supply were qualified and, as a result, could have a material adverse effect on Radiance's business, financial condition and results of operations.

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Radiance has obtained the right to affix the CE (Conformite Europeene) marking to all of its products sold in all countries of the European Economic Area and Switzerland. CE marking is a European symbol of conformance to strict product manufacturing and quality system standards. As part of the CE marking process, Radiance also received ISO 9001/EN46001 certification with respect to the manufacturing of all of its currently marketed products.

Radiance's success will depend in part upon its ability to manufacture its products in compliance with ISO 9001, the FDA's quality system regulations ("QSR") requirements, and California Department of Health Services ("CDHS") licensing and other regulatory requirements, in sufficient quantities and on a timely basis, while maintaining product quality and acceptable manufacturing costs. Radiance began manufacturing certain of its products at its facilities in July 1995. Accordingly, Radiance has limited experience in manufacturing its products. Radiance has undergone and expects to continue to undergo regular "QSR" inspections in connection with the manufacture of its products at Radiance's facilities. Radiance's success will depend upon, among other things, its ability to manage the simultaneous manufacture of different products efficiently and to integrate the manufacture of new products with existing products. There can be no assurance that Radiance will not encounter difficulties in scaling up production of new products, including problems involving production yields, quality control and assurance, component supply and shortages of qualified personnel. Radiance's failure to commence the manufacturing of these new products successfully, or to increase production volumes of new and existing products in a timely manner, would materially and adversely affect Radiance's business, financial condition and results of operations. Failure to increase production volumes in a timely or cost-effective manner or to maintain compliance with ISO 9001, QSR requirements, CDHS or other regulatory requirements could have a material adverse effect on Radiance's business, financial condition and results of operations.

#### MARKETING AND SALES

Radiance does not have any products based on radiation therapy currently available for commercial marketing and sale to the public. Radiance's existing catheter and coronary stent system products are sold in the United States and international markets, principally Europe and Japan. However, certain of Radiance's products are not available in each market due to regulatory and intellectual property restrictions. Radiance currently sells its products through a combination of strategic partners, medical device distributors and direct sales personnel. Radiance also has distribution agreements with companies covering countries outside the United States and Japan. Radiance previously distributed certain products in Japan through an exclusive distribution agreement with Fukuda, which the Company terminated in April 1997. Radiance subsequently entered into an exclusive distribution agreement in Japan with Cathex in May 1997 which terminates in January 2001. Sales of Radiance's products to Fukuda accounted for 15% and 7% of Radiance's total product sales in 1996 and 1997, respectively. Sales to Cathex accounted for 13% and 22% of Radiance's total product sales in 1997 and 1998, respectively. In addition, sales to Medtronic accounted for 22%, 13% and 0% of total product sales in 1996, 1997 and 1998, respectively. See "Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations Overview." Radiance intends to expand its sales and marketing capability and to distribute selected new

products through strategic partnerships.

In 1996, 1997 and 1998, total export sales were \$3,514,000, \$6,579,000 and \$5,887,000, respectively, or approximately 42%, 58% and 63% respectively, of total product sales. In 1996, 1997 and 1998, sales to Europe accounted for \$1,614,000, \$3,020,000 and \$2,476,000, respectively; sales to Japan represented \$1,240,000, \$2,350,000 and \$2,622,000, respectively; and sales to other regions represented \$660,000, \$1,209,000 and \$789,000, respectively. Radiance expects to continue to derive significant revenue from international sales and therefore a significant portion of Radiance's revenues will continue to be subject to the risks associated with international sales, including economic or political instability, shipping delays, changes in applicable regulatory policies, inadequate protection of intellectual property, fluctuations in foreign currency exchange rates and various trade restrictions, all of which could have a significant impact on Radiance's ability to deliver products on a competitive and timely basis. However, all of the Company's foreign sales are denominated in dollars, except for sales in Germany by Radiance Germany, which totaled \$1.4 million, or 15% of total product sales in 1998. Future imposition of, or significant increases in the level of, customs duties, export quotas or other trade restrictions, could have an adverse effect on Radiance's business, financial condition and results of operation. In foreign countries,

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Radiance's products are subject to a wide variety of governmental review and certification. The regulation of medical devices, particularly in the European Community, continues to expand and there can be no assurance that new laws or regulations will not have an adverse effect on Radiance. See "Item 1--Government Regulation," and "Note 1 of Notes to Consolidated Financial Statements."

#### POST-MARKETING CLINICAL STUDIES

Radiance has completed the clinical trials required for FDA approval of those products which are marketed in the United States.

In a Comparative Performance and Pathological Study conducted at the University of Texas Department of Medicine, Radiance's FACT Focus catheter was compared with conventional percutaneous transluminal coronary angioplasty ("PTCA") catheters from other leading manufacturers in an animal study. The investigators concluded that the use of the Focus catheter resulted in reduced arterial damage without reduction in catheter performance as determined by catheter preparation, trackability, pushability, inflation/deflation and angiographic visualization.

The Focus Lesion Expansion Optimizes Results Study ("FLEXOR Study") compared Focus PTCA catheter with conventional PTCA catheters. The FLEXOR Study evaluated the efficacy of Focus technology in improving clinical results following angioplasty procedures. Success was evaluated based on the ability of Focus technology to improve the minimal lumen diameter ("MLD") of the arterial opening, and to reduce the number of catheters necessary for PTCA procedures. MLD is a commonly-used measurement of the ability of a therapeutic tool to open a blocked artery and reestablish required blood flow. The FLEXOR Study commenced in the fourth quarter of 1996 and was completed in the first quarter of 1997. Results of the study were presented at the 1997 Transcatheter Therapeutics symposium in Washington D.C. Data from this study of 80 patients demonstrated a trend toward fewer balloons used per procedure with Focus technology, especially when stent implantation was required, without any increase in complications. Additionally, the Focus technology group of patients had a lower residual stenosis than the conventional angioplasty group.

Certain of Radiance's products which utilize Focus technology have received FDA approval for PTCA and percutaneous transluminal angioplasty ("PTA") indications. However, none of these products has received FDA approval for use in stent delivery. An investigator-controlled study is currently testing Radiance's Focus technology with respect to stent implantation. The Optimal Stent Implantation Study ("OSTI-2 Study") is evaluating the ability of stent delivery with Focus technology compared with conventional delivery techniques to reduce acute outcomes and restenosis rates. The study is being conducted using two patient subgroups of approximately 100 patients each divided according to vessel size. In the first group, stent delivery is being evaluated in vessels

greater than three millimeters in diameter; in the second group stent delivery is being evaluated in vessels less than three millimeters in diameter. Each subgroup presents different clinical issues related to stent delivery and the OSTI-2 Study protocol is evaluating the efficacy of Focus technology in each subgroup. The OSTI-2 Study began in February 1996 and completed enrollment of patients in the first quarter of 1998. Follow-up to this study is in progress. Preliminary results of the study were reported at the American Heart Association Scientific Sessions in November 1997 and additional results were reported at the American College of Cardiology meeting in March 1998 and at American Heart Association Scientific Sessions in November 1998. Early results demonstrate that Focus technology facilitates achieving a larger in stent MLD following conventional stent expansion techniques and also following optimal PTCA. These increased MLDs were achieved without increased complication rates. In June 1998, Radiance signed a technology license agreement with Guidant Corporation, an international interventional cardiology products company, granting Guidant rights to manufacture and distribute products using Radiance's Focus technology for delivery of stents. See the discussion below in this section "Strategic Relationships."

Radiance recently completed a clinical study in Europe of its proprietary Synthesis (TM) coronary stent. The multicenter study enrolled 85 patients at four centers in Germany. Procedural and 30 day follow-up results demonstrate a high technical success rate with low complication and low major adverse event rates. Six month clinical and angiographic follow-up is ongoing.

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#### STRATEGIC RELATIONSHIPS

Radiance evaluates on an ongoing basis potential strategic relationships with corporate and other partners where such relationships may complement and expand Radiance's research, development, sales and marketing capabilities. Radiance currently is a party to four such agreements, described below.

Guidant Corporation. In June 1998, Radiance entered into a Technology License Agreement with Guidant Corporation, an international interventional cardiology products company, to grant them a license to manufacture and distribute products using Radiance's Focus Technology. Under the Agreement, Radiance has received, and will receive, certain milestone payments based upon the transfer of the technological knowledge to Guidant, and royalty payments based upon the sale of products using Focus technology by Guidant. However, there is no assurance that Guidant will successfully manufacture and distribute products based on the technology, or that Radiance will realize any such royalty payments.

SCIMED Life Systems, Inc. Radiance entered into a Stock Purchase and Technology License Agreement, dated September 10, 1994, with SCIMED, now a unit of Boston Scientific Corporation (the "SCIMED Agreement"). Pursuant to the SCIMED Agreement, SCIMED purchased a 19% equity position in Radiance, which is now diluted to 5%. SCIMED also was granted an exclusive worldwide license to certain combined site-specific solution delivery and coronary angioplasty technology in exchange for license and royalty fees. The SCIMED Agreement may be terminated (i) in the event of breach on 90 days notice by the non-breaching party; or (ii) on 30 days notice in certain limited circumstances or (iii) by SCIMED upon 180 days notice.

Cathex Co., Ltd. Radiance entered into a Distribution Agreement dated May 1, 1997 with Cathex Co., Ltd. ("Cathex"), whereby Cathex serves as Radiance's exclusive distributor for certain of Radiance's products in Japan. In exchange for this exclusive distributorship, certain Cathex shareholders agreed to purchase \$200,000 of Radiance Common Stock (approximately 25,000 shares) and Cathex agreed to purchase predetermined minimum quantities of Radiance's products. The initial term of the agreement expires on January 1, 2001 and is subject to a five-year extension. The agreement may be terminated in the event of breach upon 90 days notice by the non-breaching party, subject to cure within the notice period.

Endosonics Corporation. Radiance has entered into a license agreement with Endosonics Corporation ("EndoSonics"), dated December 22, 1995 (the "EndoSonics Agreement"), in which Radiance granted EndoSonics the non-exclusive,

royalty-free right to Radiance's Focus technology for the development and sale of a device with a Radiance Focus technology balloon when it is combined only on the same catheter with an Endosonics' ultrasound product. In exchange, Radiance received the non-exclusive, royalty-free right to submit PMA supplement applications utilizing an EndoSonics PMA as a reference and to manufacture and distribute Radiance products as a supplement to the EndoSonics PMA. In February 1998, the FDA approved Radiance's PMA application and, as a result, Radiance can obtain independent FDA supplemental approvals on its products. The EndoSonics Agreement may be terminated in the event of breach upon 60 days notice by the nonbreaching party, subject to the breaching party's right to cure. In addition, in March of 1996, EndoSonics purchased 400,000 shares of Radiance's Series B Preferred Stock for a purchase price of \$8,000,000, which converted into 800,000 shares of Common Stock upon the consummation of Radiance's initial public offering on June 19, 1996. In February 1998, Radiance repurchased 300,000 shares of its own common stock from Endosonics for an aggregate price of \$1,275,000.

#### PATENTS AND PROPRIETARY INFORMATION

Radiance's policy is to protect its proprietary position by, among other methods, filing U.S. and foreign patent applications to protect technology, inventions and improvements that are important to the development of its business. Radiance owns or has the rights to 21 issued U.S. patents, one issued European patent and two Japanese patents covering certain aspects of its catheter, vascular access and SEAL stent technologies. No assurance can be given that any issued patents will provide competitive advantages for Radiance's products, or that they will not be challenged or circumvented by competitors.

The interventional cardiovascular market in general and the stent and balloon angioplasty catheter market (including the type of catheters offered by Radiance) in particular have been characterized by substantial litigation regarding patent and other intellectual property rights. There can be no assurance that Radiance's products do not

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infringe such patents or rights. During 1997, Radiance was sued for trademark infringement regarding Radiance's use of the product name "Lynx" in connection with one of Radiance's balloon angioplasty catheter product lines. Radiance paid no monetary damages but agreed to a consent judgment which prohibits Radiance from using this name in the United States. In the event that any such third-parties assert claims against Radiance for patent infringement and such patents are upheld as valid and enforceable, Radiance could be prevented from utilizing the subject matter claimed in such patents, or would be required to obtain licenses from the owners of any such patents or redesign its products or processes to avoid infringement. There can be no assurance that such licenses would be available or, if available, would be so on terms acceptable to Radiance or that Radiance would be successful in any attempt to redesign its products or processes to avoid infringement. In addition, foreign intellectual property laws may not provide protection commensurate with that provided by U.S. intellectual property laws, and there can be no assurance that foreign intellectual property laws will protect Radiance's foreign intellectual property rights adequately. Radiance also relies on trade secrets and proprietary technology and enters into confidentiality and non-disclosure agreements with its employees, consultants and advisors. There can be no assurance that the confidentiality of such trade secrets or proprietary information will be maintained by employees, consultants, advisors or others, or that Radiance's trade secrets or proprietary technology will not otherwise become known or be independently developed by competitors in such a manner that Radiance has no practical recourse. Litigation may be necessary to defend against claims of infringement or invalidity, to enforce patents issued to Radiance or to protect trade secrets. There can be no assurance that any such litigation would be successful. Any litigation could result in substantial costs to, and diversion of resources by, Radiance and its officers, which would have a material adverse effect on its business, financial condition and results of operations.

#### COMPETITION

There are more than ten competing development programs in the area of vascular radiotherapy. The major competitors include Novoste Corporation, Johnson & Johnson, Guidant Corporation and the U.S. Surgical division of Tyco International Ltd. The radiation sources being developed by our competition vary

between gamma, beta and x-ray.

One alternative competitive approach is represented by the radioactive guidewire. Three companies are in the pivotal clinical trial stage in the United States. Johnson & Johnson has completed patient enrollment into its trial, the Gamma One trial, which purpose is to assess the use of Best Medical International's manually advanced gamma wire in treating "in-stent" restenosis. The U.S. Surgical division of Tyco International Ltd. is investigating its gamma wire/afterloader system in an "in-stent" restenosis trial called the ARTISTIC Trial. Finally, Guidant currently is evaluating its beta wire/afterloader system in the INHIBIT Trial, also for "in-stent" restenosis. Boston Scientific, through its Schneider AG subsidiary, is also developing a beta wire/afterloader system which is under investigation in Europe and in a pilot study in the United States.

Most of the radioactive guidewires are used in conjunction with an afterloader, a specialized piece of equipment that is typically computer controlled. It is used to automatically calculate treatment times, control movement of the guidewire, and to store and shield the guidewire when not in use. This equipment is large, complex, and expensive. Guidewires with gamma-emitting radioactive tips have been used for some time in cancer therapy. Gamma radiation is significantly more penetrating and therefore more hazardous to use than beta radiation. For example, health care workers must leave the cath lab during administration of gamma radiation to ensure their safety by limiting their ongoing exposure to gamma radiation. In addition, gamma radiation impacts patient tissue beyond the treatment site.

In addition to the guidewire approach, radioactive fluid filled balloon catheters have been investigated in small pilot clinical studies, and very little clinical data is currently available. Mallinckrodt, Inc., Tyco International Ltd., and Guidant are developing radioactive fluid filled balloon catheters. This approach would involve injecting a short half-life radioactive liquid down a catheter to inflate a balloon. The disadvantages of this approach include the risks of fluid leaks inside the cath lab, balloon rupture, the need to fractionate dosing to prevent ischemia, and the disposal of the catheter which has been contaminated with radioactive material.

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Competition in the market for devices used in the treatment of cardiovascular and peripheral vascular disease is intense and characterized by extensive research and development and rapidly advancing technology. The interventional cardiology market is characterized by rapid technological innovation and change, and Radiance's products could be rendered obsolete as a result of future innovations. Radiance's catheters, stents and other products under development compete or will compete with catheters and stents marketed by a number of manufacturers, including Guidant Corporation, Boston Scientific Corporation, Johnson & Johnson, Medtronic, Inc., and Arterial Vascular Engineering (which was acquired by Medtronic, Inc.). Such companies have significantly greater financial, management and other resources, established market positions, and significantly larger sales and marketing organizations than does Radiance. Radiance also faces competition from manufacturers of other catheter-based atherectomy devices, vascular stents and pharmaceutical products intended to treat vascular disease. In addition, Radiance believes that many of the purchasers and potential purchasers of Radiance's products prefer to purchase catheter and stent products from a single source. Accordingly, many of Radiance's competitors, because of their size and range of product offerings, have a competitive advantage over Radiance.

We believe that the primary competitive factors in the market for interventional cardiology devices are clinical effectiveness, product safety, catheter size, flexibility and trackability, ease of use, reliability, price and availability of third party reimbursement. In addition, a company's distribution capability and the time in which products can be developed and receive regulatory approval are important competitive factors. Although we believe we compete favorably with respect to the foregoing factors, most of our competitors and potential competitors have substantially greater capital resources than we do and also have greater resources and expertise in the areas of research and development, obtaining regulatory approvals, manufacturing and marketing.

We believe that our competitive position is dependent upon our ability to continue to develop innovative new catheter technologies, including the RDX Catheter, and to obtain rapid regulatory approval. However, we cannot assure you that competitors and potential competitors will not succeed in developing, marketing and distributing technologies and products that are more effective than those we will develop and market or that would render our technology and products obsolete or noncompetitive. We may be unable to compete effectively against such competitors and other potential competitors in terms of manufacturing, marketing and sales. There can be no assurance that our competitors will not succeed in developing or marketing technologies and products that are more clinically or cost effective than any that are being marketed or developed by us, or that such competitors will not succeed in obtaining regulatory approval for introducing or commercializing any such products before we can.

#### THIRD-PARTY REIMBURSEMENT

In the United States, the Company's products are purchased primarily by medical institutions, which then bill various third-party payors, such as Medicare, Medicaid, and other government programs and private insurance plans, for the health care services provided to patients. Government agencies, private insurers and other payors determine whether to provide coverage for a particular procedure and reimburse hospitals for medical treatment at a fixed rate based on the diagnosis-related group ("DRG") established by the U.S. Healthcare Finance Administration ("HCFA"). The fixed rate of reimbursement is based on the procedure performed, and is unrelated to the specific devices used in that procedure. If a procedure is not covered by a DRG, payors may deny reimbursement. In addition, some payors may deny reimbursement if they determine that the device used in a treatment was unnecessary, inappropriate or not cost-effective, experimental or used for a non-approved indication. Reimbursement of interventional procedures utilizing Radiance's products is currently covered under a DRG. There can be no assurance that reimbursement for such procedures will continue to be available, or that future reimbursement policies of payors will not adversely affect Radiance's ability to sell its products on a profitable basis. Failure by hospitals and other users of Radiance's products to obtain reimbursement from third-party payors, or changes in government and private third-party payors' policies toward reimbursement for procedures employing Radiance's products, would have a material adverse effect on Radiance's business, financial condition and results of operations.

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#### GOVERNMENT REGULATION

The manufacturing and marketing of Radiance's products are subject to extensive and rigorous government regulation in the United States and in other countries. All new products will require regulatory approval by appropriate governmental agencies prior to commercialization and will be subject to rigorous pre-clinical and human clinical testing and patient follow-up. Federal regulations control the ongoing safety, efficacy, manufacture, storage, labeling, record-keeping, and marketing of all medical devices. Radiance believes its success also will depend upon commercial sales of improved versions of its catheter products. Radiance will not be able to market these new products in the United States unless and until Radiance obtains approval or clearance from the FDA. Foreign and domestic regulatory approvals, if granted, may include significant limitations on the indicated uses for which a product may be marketed.

If a medical device manufacturer can establish that a newly developed device is "substantially equivalent" to a legally marketed Class I or Class II device, or to a Class III device that the FDA has not called for a premarket approval application ("PMA"), the manufacturer may seek clearance from the FDA to market the device by filing a premarket notification with the FDA under Section 510(k) of the Federal Food, Drug, and Cosmetic Act. All of the 510(k) clearances received for Radiance's catheters were based on substantial equivalence to legally marketed devices. There can be no assurance that 510(k) clearance for any future product or significant modification of an existing product will be granted or that the process will not be unduly lengthy. In addition, if the FDA has concerns about the safety or effectiveness of any of Radiance's products, it could act to withdraw approval or clearances of those

products or request Radiance present additional data. Any such actions would have a material adverse effect on Radiance's business, financial condition and results of operations.

If substantial equivalence cannot be established, or if the FDA determines the device or the particular application for the device requires a more rigorous review to assure safety and effectiveness, the FDA will require the manufacturer to submit a PMA which must be reviewed and approved by the FDA prior to sales and marketing of the device in the United States. The PMA process is significantly more complex, expensive and time consuming than the 510(k) clearance process and always requires the submission of clinical data. The PMA process may require as many as 1,000 patients depending on indications with at least one year follow-up. Radiance expects that the RDX Catheter and certain other products under development will be subject to this PMA process. In addition to the FDA, the Company expects to file an application with the Ministry of Health and Welfare in Japan. This procedure requires completion of 60-100 patients in two to three Japanese clinical investigation sites. The Company expects the Japanese approval process to take approximately 18-24 months.

Because the RDX Catheter is expected to utilize radiation sources, its manufacture, distribution, transportation import/export, use and disposal also will be subject to federal, state and/or local laws and regulations relating to the use and handling of radioactive materials. Specifically, after PMA approval is obtained, approval by the U.S. Nuclear Regulatory Commission ("NRC"), or an equivalent state agency, of Radiance's radiation sources for certain medical uses will be required to distribute the radiation sources commercially to licensed recipients in the U.S. In addition, Radiance and/or its supplier of radiation sources must obtain a specific license from the NRC to distribute such radiation sources commercially as well as comply with all applicable regulations. Radiance and/or its supplier of radiation sources also must comply with NRC and U.S. Department of Transportation regulations on the labeling and packaging requirements for shipment of radiation sources to hospitals or other users of the RDX Catheter. In addition, hospitals may be required to obtain or expand their licenses to use and handle beta radiation prior to receiving radiation sources for use in the RDX Catheter. The Company expects to comply with comparable radiation regulatory requirements and/or approvals in markets outside the U.S.

Radiance is required to register as a medical device manufacturer with the FDA and maintain a license with certain state agencies, such as the CDHS. As such, Radiance is inspected on a routine basis by both the FDA and the CDHS for compliance with QSR regulations. These regulations require that Radiance manufacture its products and maintain related documentation in a prescribed manner with respect to manufacturing, testing and control activities. Radiance has undergone and expects to continue to undergo regular QSR inspections in connection with the manufacture of its products at Radiance's facilities. Further, Radiance is required to comply with various FDA requirements for labeling. The Medical Device Reporting laws and regulations require Radiance to provide

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information to the FDA on deaths or serious injuries alleged to have been associated with the use of its 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. Radiance has received FDA approval to market the FACT and ARC catheters, which utilize the FOCUS technology, for coronary balloon angioplasty. These catheters are marketed outside the United States for use in stent deployment. However, without specific FDA approval for stent deployment, these catheters may not be marketed by Radiance in the United States for such use.

Failure to comply with applicable regulatory requirements can, among other consequences, result in fines, injunctions, civil penalties, suspensions or loss of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. In addition, government regulations may be established in the future that could prevent or delay regulatory clearance or approval of Radiance's products. Delays in receipt of clearances or approvals, failure to receive clearances or approvals or the loss of previously received

clearances or approvals would have a material adverse effect on Radiance's business, financial condition and results of operations.

Radiance also is subject to other federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices. The extent of government regulation that might result from any future legislation or administrative action cannot be predicted accurately. Failure to comply with regulatory requirements could have a material adverse effect on Radiance's business, financial condition and results of operations.

International sales of Radiance's products are subject to the regulatory requirements in many countries. The regulatory review process varies from country to country and may in some cases require the submission of clinical data. Radiance typically relies on its distributors in such foreign countries to obtain the requisite regulatory approvals. There can be no assurance, however, that such approvals will be obtained on a timely basis or at all. In addition, the FDA must approve the export to certain countries of devices which require a PMA but are not yet approved domestically.

In order to sell its products within the European Economic Area and Switzerland, Radiance must achieve compliance with the requirements of the Medical Devices Directive ("MDD") and affix CE marking on its products to attest to such compliance. To achieve compliance, Radiance's products must meet the "Essential Requirements" of the MDD relating to safety and performance and Radiance must successfully undergo verification of its regulatory compliance ("conformity assessment") by a Notified Body selected by Radiance. Radiance has selected TUV Product Service of Munich, Germany as its Notified Body. The level of scrutiny of such assessment depends on the regulatory class of the product, and many of Radiance's coronary products are currently in Class III, the highest risk class, and therefore subject to the most rigorous controls.

In December 1996, Radiance received ISO 9001/EN46001 certification from its Notified Body with respect to the manufacturing of all of its products in its Irvine facilities. Radiance's contracted manufacturing facility in The Netherlands received such certification in 1993. This certification demonstrates that Radiance manufactures its products in accordance with certain international quality requirements. A manufacturer must receive ISO 9001/EN46001 certification prior to applying for CE marking of specific products. In January 1998, Radiance obtained the right to affix CE marking to all of its products currently sold in all countries of the European Economic Area and Switzerland. Radiance is subject to continued supervision by its Notified Body and will be required to report any serious adverse incidents to the appropriate authorities. Radiance also must comply with additional requirements of individual nations. Failure to maintain compliance required for CE marking could have a material adverse effect upon Radiance's business, financial condition and results of operations. There can be no assurance Radiance will be able to achieve or maintain such compliance on all or any of its products or that it will be able to produce its products timely and profitably while complying with the MDD and other regulatory requirements.

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#### PRODUCT LIABILITY

Radiance faces the risk of financial exposure to product liability claims. Radiance's products are often used in situations in which there is a high risk of serious injury or death. Such risks will exist even with respect to those products that have received, or in the future may receive, regulatory approval for commercial sale. Radiance is currently covered under a product liability insurance policy with coverage limits of \$10.0 million per occurrence and \$10.0 million per year in the aggregate. There can be no assurance that Radiance's product liability insurance is adequate or that such insurance coverage will remain available at acceptable costs. There can be no assurance that Radiance will not incur significant product liability claims in the future. A successful claim brought against Radiance in excess of its insurance coverage could have a material adverse effect on Radiance's business, financial condition and results of operations. Additionally, adverse product liability actions could negatively affect the reputation and sales of Radiance's products and Radiance's ability to obtain and maintain regulatory approval for its products, as well as substantially divert the time and effort of management away from Radiance's

operations.

#### EMPLOYEES

As of December 31, 1998, Radiance had 98 employees, including 49 in manufacturing, 19 in research, development, and regulatory and clinical affairs, 19 in sales and marketing and 11 in administration. Radiance believes that the success of its business will depend, in part, on its ability to attract and retain qualified personnel. Radiance believes it has good relations with its employees.

#### RESEARCH AND DEVELOPMENT

Expenditures for research and development amounted to \$7,957,000 in fiscal year 1998, \$7,041,000 in fiscal 1997 and \$3,582,000 in fiscal 1996.

#### ITEM 2. PROPERTIES

Currently, Radiance leases facilities aggregating approximately 28,000 square feet in Irvine, California under various lease agreements, most of which expire in May 2001. Radiance also leases approximately 2,700 square feet in Koln, Germany expiring in April 2003. Radiance believes that its facilities are adequate to meet its requirements through fiscal 1999.

#### ITEM 3. LEGAL PROCEEDINGS

Radiance is a party to ordinary disputes arising in the normal course of business. Management is of the opinion that the outcome of these matters will not have a material adverse effect on Radiance's consolidated financial position.

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

None.

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#### EXECUTIVE OFFICERS OF THE REGISTRANT

The executive officers and key employees of the Company, and their ages as of March 1, 1999, are as follows:

NAME - - - - -	AGE ---	POSITION -----
Michael R. Henson.....	53	President, Chief Executive Officer and Chairman of the Board of Directors
Stephen R. Kroll.....	52	Vice President, Finance and Administration, Chief Financial Officer and Corporate Secretary
Jeffrey H. Thiel.....	43	Executive Vice President
Claire K. Walker.....	52	Vice President, Clinical Affairs
Duane Dickens.....	53	Vice President, Research and Development Engineering
William Rigas.....	56	Vice President, Worldwide Sales

#### BACKGROUND

The principal occupations of each executive officer and key employee of the Company for at least the last five years are as follows:

Michael R. Henson joined the Company in February 1992 as President, Chief Executive Officer and Chairman of the Board of Directors, positions in which he currently serves the Company. From June 1997 until March 1999, Mr. Henson served Chairman of the Board, Chief Executive Officer and President of the (former) Radiance Medical Systems, Inc., and as Chairman of the Board of the Company. Prior to joining the Company, Mr. Henson served as the Chief Executive Officer of Endosonics Corporation from 1988 to February 1995, and as Chairman of

the Board from February 1993 to November 1996. Between April 1983 and February 1988, Mr. Henson served as President and Chief Executive Officer of Trimedyne, Inc., a manufacturer of medical lasers and catheters. Prior to joining Trimedyne in 1983, Mr. Henson held positions as Vice President for G.D. Searle & Company, Director of Marketing for the Hospital Products Division of Abbott Laboratories, and Marketing Manager for Bristol Myers and Company. Mr. Henson also serves as a director of two private companies, Endologix, Inc. and Micrus Corporation.

Jeffrey H. Thiel was appointed Executive Vice President of the Company in February 1999, and served as Vice President, Operations since October 1996. Prior to joining Radiance, Mr. Thiel served as Director of Operations of BEI Medical Systems from May 1995 to October 1996. From July 1989 to November 1994, Mr. Thiel held various Manufacturing and Operations Management positions with St. Jude Medical.

Stephen R. Kroll joined the Company in April 1998 as Vice President of Finance and Administration, Chief Financial Officer and Corporate Secretary. From May 1989 until May 1991, Mr. Kroll served as Vice President of Finance and Corporate Secretary, and from May 1991 until March 1997 as Vice President of Administration and Corporate Secretary, for Viking Office Products.

Claire K. Walker has served as Vice President of Clinical Affairs since April 1997. She joined the Company in November 1994 as Director of Clinical Affairs. From May 1992 to November 1994, Ms. Walker provided clinical marketing consulting services to the Company. From September 1990 to November 1992, Ms. Walker served as a principal of CKW and Associates providing project specific consulting services to InterVentional Technologies, Inc., a medical device company.

Duane Dickens joined the Company in August of 1998 as Vice President of Research and Development. Prior to joining Radiance, Mr. Dickens founded and served as Vice President of New Product Development at Cardima, Inc. from 1993 to 1998. From 1992 to 1993, Mr. Dickens founded and served as President and CEO of Rhythmtrix Inc., a company that develops catheter ablation systems. Prior to 1992, Mr. Dickens held various senior management positions for Medtronic Interventional Vascular, Inc., Advanced Cardiovascular Systems and American Bentley, Inc.

William Rigas was hired as Vice President of Worldwide Sales in August of 1998. Mr. Rigas previously served as Vice President of Worldwide Sales at Neuro Navigational Corporation from 1993 to 1997. Prior to 1993, Mr. Rigas held various senior management positions at Intertherapy Corporation, GE Medical Systems and Honeywell's Biosound.

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PART II

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

The Company's Common Stock commenced trading on the Nasdaq National Market on June 20, 1996 and is traded under the symbol "RADX". The following table sets forth for the periods indicated the high and low sale prices for the Common Stock as reported on the Nasdaq National Market.

	HIGH ----	LOW ---
FISCAL 1997		
First Quarter	\$13 1/4	\$7 1/2
Second Quarter	10 1/4	6 5/8
Third Quarter	9 3/8	6 5/8
Fourth Quarter	8	4 3/4
FISCAL 1998		
First Quarter	\$ 6 3/8	\$4 3/16
Second Quarter	7 3/4	4 5/8

Third Quarter	6 1/4	2 1/2
Fourth Quarter	5	2 1/4
FISCAL 1999		
First Quarter (through 3/25/99)	\$ 4 3/4	\$3 3/8

On March 25, 1999 the closing sale price on the Nasdaq National Market was \$3.94 per share and there were approximately 281 record holders of Radiance Common Stock.

#### SALES OF UNREGISTERED SECURITIES

None.

#### USE OF PROCEEDS

The Company has used approximately \$2.7 million of the net proceeds from the initial public offering ("IPO") for repayment of certain outstanding indebtedness to Endosonics, Inc., a holder of in excess of ten percent of the Common Stock of the Company. From the date of the IPO until December 31, 1998, in the normal course of business, the Company has paid salaries and bonuses in excess of \$0.1 million each to eight officers of the Company and used \$7.0 million for working capital. The Company also has used approximately \$1.7 million of the net proceeds for machinery and equipment and leasehold improvement purchases. From August 1997 to December 1998, the Company used approximately \$3.7 million to repurchase 686,000 shares of the Company's Common Stock on the open market. In September 1998, the Company exercised a warrant to acquire 1,500,000 Series B Preferred Stock of RMS for \$1.5 million. At December 31, 1998, approximately \$23.4 million was held in temporary investments, of which approximately \$6.0 million was invested in U.S. Treasury and other agencies debt securities, and \$14.4 million was invested in corporate debt securities and \$3.0 million was invested in foreign government obligations.

#### DIVIDEND POLICY

The Company has never paid any dividends. The Company currently intends to retain all earnings, if any, for use in the expansion of its business and therefore does not anticipate paying any dividends in the foreseeable future.

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#### ITEM 6. SELECTED FINANCIAL DATA.

	YEAR ENDED DECEMBER 31,				
	1994	1995	1996	1997	1998
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(In thousands)

#### CONSOLIDATED STATEMENT OF OPERATIONS DATA:

Revenue:	1994	1995	1996	1997	1998
Sales.....	\$ 1,169	\$ 3,462	\$ 8,384	\$ 11,332	\$ 9,415
License fee and other (1).....	1,000	--	150	--	2,760
Contract.....	220	641	200	--	--
Total revenue.....	2,389	4,103	8,734	11,332	12,175
Operating costs and expenses:					
Cost of sales.....	848	2,051	4,111	6,418	6,152
Research and development.....	1,228	1,683	3,582	7,041	7,957
Marketing and sales.....	748	1,526	3,358	6,691	5,371
General and administrative.....	587	1,331	1,548	2,179	2,937
Charge for acquired in-process research and development(2).....	--	488	2,133	--	234
Minority interest.....	--	--	--	--	(992)
Total operating costs and expenses.....	3,411	7,079	14,732	22,329	21,659

Loss from operations.....	(1,022)	(2,976)	(5,998)	(10,997)	(9,484)
Other income.....	51	102	1,374	2,225	1,498
	-----	-----	-----	-----	-----
Net loss.....	\$ (971)	\$ (2,874)	\$ (4,624)	\$ (8,772)	\$ (7,986)
	=====	=====	=====	=====	=====
Basic and diluted net loss per share (pro forma through June 1996).....	\$ (0.28)	\$ (0.71)	\$ (0.69)	\$ (0.96)	\$ (0.90)
	=====	=====	=====	=====	=====
Shares used in computing basic and diluted net loss per share (pro forma through June 1996).....	3,487	4,052	6,755	9,118	8,862
	=====	=====	=====	=====	=====

DECEMBER 31,

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	1994	1995	1996	1997	1998
	----	----	----	----	----
	(In thousands)				

CONSOLIDATED BALANCE SHEET DATA:

Cash and cash equivalents.....	\$ 3,379	\$ 1,568	\$17,192	\$ 6,141	\$ 1,437
Marketable securities available-for-sale....	--	--	25,733	24,773	23,375
Working capital (deficit).....	1,366	(774)	46,142	33,828	24,905
Total assets.....	4,340	4,002	50,084	41,361	33,781
Convertible obligation.....	--	750	--	--	--
Accumulated deficit.....	(3,551)	(6,425)	(11,049)	(19,821)	(27,807)
Total stockholders' equity (net capital deficiency).....	\$ 1,288	\$ (1,098)	\$47,623	\$37,873	\$29,245

- (1) The revenue for 1994 was received from a related party, SCIMED. See Note 3 of Notes to Consolidated Statements.
- (2) The charge for acquired in-process research and development reflects a change in the basis of the Company's assets and liabilities as a result of the acquisition by Endosonics which has been allocated to the Company for the year ended December 31, 1995 and the excess of the purchase price over the net assets acquired for Intraluminal Devices, Inc. and (the former) Radiance Medical Systems, Inc., and the associated acquisition expenses for the years ended December 31, 1996 and 1998, respectively. See Notes 1 and 2 of Notes to Consolidated Financial Statements.

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

OVERVIEW

Radiance Medical Systems, Inc. ("Radiance," or the "Company") develops, manufactures and markets proprietary devices for the prevention of the recurrence of atherosclerotic blockages following the interventional treatment of atherosclerosis. Radiance's primary product under development in its main focus area is the RDX Catheter, a balloon catheter-based delivery system designed to deliver radioactive materials to the area of an artery that has been treated with conventional interventional therapy such as Percutaneous Transluminal Coronary Angioplasty ("PTCA"), atherectomy and/or stent deployment. See "Item 1--Products."

The Company is the result of an acquisition effected by the merger of the (former) Radiance Medical Systems, Inc. ("RMS") with and into CardioVascular Dynamics, Inc. (now named Radiance Medical Systems, Inc.). RMS originally was formed by the Company as a separate entity to focus on the development of radiation therapy technology for the treatment of cardiovascular disease, and to obtain financing for such development from sources other than the Company. As a result of the merger, the Company reacquired all of the shares of RMS which it did not own. The Company was incorporated on March 16, 1992.

From inception (March 16, 1992) through the first quarter of 1994, the Company's operations were limited and consisted primarily of research and development and other start-up activities. On June 15, 1992, EndoSonics acquired a 40% interest in the Company in exchange for \$0.5 million in cash. Pursuant to an Agreement and Plan of Reorganization between EndoSonics and the Company dated on June 9, 1993, EndoSonics acquired all of the outstanding capital stock of the Company in exchange for \$0.3 million in cash and 250,000 shares of EndoSonics' Common Stock with an aggregate market value of \$1.6 million. The acquisition by EndoSonics resulted in a new basis for the Company's assets and liabilities. Accordingly, the purchase price paid by EndoSonics has been allocated to the Company's identifiable assets and liabilities, including \$2.0 million to acquired in-process research and development which was immediately expensed, as none of the Company's products had received regulatory approval and the technology did not have alternative future uses. Pursuant to the terms of the Agreement and Plan of Reorganization, in June 1995, EndoSonics became obligated to issue 50,000 shares of its Common Stock, with an aggregate market value of \$0.5 million, to the former shareholders of Radiance because the market price of EndoSonics' stock did not exceed a specified price for a specified period during the two-year period following the acquisition. The fair value of such shares was charged to acquired in-process technology. In March 1996, EndoSonics purchased 400,000 shares of the Company's Series B Preferred Stock for a purchase price of \$8.0 million, which converted into 800,000 shares of Common Stock upon the consummation of the Company's initial public offering.

In September 1994, Radiance and SCIMED, now a unit of Boston Scientific Corporation, entered into a Stock Purchase and Technology License Agreement to develop and license Radiance's patented combination balloon angioplasty/site-specific drug delivery technology (the Transport product line) for use in the coronary vessels. Through December 31, 1996, Radiance had received in the aggregate approximately \$2.2 million in license fees, research and development funding and technical assistance from SCIMED under this agreement. Radiance received no revenues from SCIMED January 1, 1997 through December 31, 1998. In 1994, SCIMED purchased a 19% equity position in Radiance for a purchase price of \$2.5 million. In August 1997, SCIMED exercised warrants to purchase 120,000 shares of Radiance's Common Stock at a price of \$3.29 per share. See "BUSINESS OF Radiance - Strategic Relationships."

In January 1995, Radiance and ACS, subsequently purchased by Guidant Corporation, entered into an agreement pursuant to which Radiance acquired certain rights to ACS' SmartNeedle Technology, subject to the payment of certain royalties. The parties subsequently confirmed their understanding with respect to certain matters in a second agreement dated March 4, 1996 (collectively, the "ACS Agreements"). Pursuant to the ACS Agreements, ACS was granted the option to acquire the exclusive worldwide rights to certain Radiance perfusion

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technology, which ACS exercised on February 14, 1996. In exchange for this perfusion technology, ACS is obligated to make milestone and minimum annual royalty payments to Radiance, and also has certain obligations to develop and market the perfusion technology. Through December 31, 1996, Radiance had received approximately \$0.35 million in milestone payments under the ACS Agreements. Radiance received no payments during 1997 or 1998. In February 1998, ACS exercised its right to terminate the perfusion technology Agreement. See "Item 1 - Strategic Relationships."

Radiance currently sells its products primarily through medical device distributors and a limited number of direct sales personnel. Radiance is a party to three agreements for the U.S. distribution of products incorporating its Focus technology. Radiance distributed certain products in Japan through an exclusive distribution agreement with Fukuda which was terminated and replaced by Radiance in May 1997 with a similar agreement with Cathex. Radiance also has distribution agreements with 30 companies covering 35 countries outside the United States and Japan. See "BUSINESS OF Radiance -- Strategic Relationships."

On July 15, 1996, Radiance entered into co-distribution agreements with Medtronic, providing for the co-distribution of Radiance's FACT, CAT and ARC balloon angioplasty catheters. Under the terms of these agreements, Medtronic purchased a minimum number of angioplasty catheters manufactured by Radiance for distribution worldwide for a period of up to three years. Specific products to

be distributed by Medtronic differ in individual country markets. The initial term of the Medtronic agreements was for a period of three years from the date of first delivery of a product. In May 1997, Medtronic advised Radiance of its election to not make minimum purchases of product for the second year of the agreement. In June 1997, Medtronic informed Radiance that it would not fulfill its commitment for the first year of the agreement and that it did not believe it was required to fulfill such commitment. This dispute adversely affected Radiance's financial results for the second half of 1997 and first half of 1998.

In June 1998, Radiance entered into a technology license agreement with Guidant Corporation, an international interventional cardiology products company, granting Guidant rights to manufacture and distribute products using Radiance's Focus technology for delivery of stents, including exclusive rights in the United States. In exchange for those rights Radiance has received, and will receive, certain milestone payments based upon the transfer of the technological knowledge to Guidant, and royalty payments based upon the sale of products by Guidant using Focus technology. However, there is no assurance that Guidant will successfully manufacture and distribute products based on the technology, or that Radiance will realize any such royalty payments.

In January 1999, the Company sold substantially all of the properties and assets used exclusively in its Vascular Access Business Unit to Escalon Medical Corporation. The Company received an initial payment of \$1.1 million for actual inventory transferred, will receive an additional \$1.0 million upon the completion of the transfer of the assets and technology, and also is entitled to receive royalty payments upon the sale of products for a five-year period. The Company will continue to manufacture certain vascular access products for up to 180 days following the completion of the sale.

In January 1999, Cardiovascular Dynamics, Inc. (now named Radiance Medical Systems, Inc.) ("Radiance," or the "Company") acquired through a merger all of capital stock which it did not own of the (former) Radiance Medical Systems, Inc. ("RMS"). Pursuant to the Merger, the Company paid the former stockholders of RMS \$3.00 for each share of RMS preferred stock and \$2.00 for each share of RMS common stock, for a total consideration of approximately \$7.0 million, excluding the value of RMS common stock options to be provided to RMS optionholders in exchange for their RMS common stock options. The consideration was paid by delivery of an aggregate of 1,900,157 shares of Company Common Stock, and \$0.7 million in cash to certain RMS stockholders who elected cash. Options for 546,250 shares of RMS common stock accelerated and vested immediately prior to the completion of the Merger. Of these, 1,250 were exercised, and holders received the same consideration for their shares of RMS Common Stock as other holders of RMS Common Stock. The options not exercised prior to the completion of the Merger were assumed by the Company and converted into options at the same exercise price to purchase an aggregate of 317,775 share of the Company Common Stock.

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In addition, the former RMS stockholders and optionholders may receive product development milestone payments of \$2.00 for each share of RMS preferred stock and \$3.00 for each share of RMS common stock. The milestone payments may be increased up to 30%, or reduced or eliminated if the milestones are reached earlier or later, respectively, than the milestone target dates. The milestones represent important steps in the United States Food and Drug Administration and European approval process which the Company has determined are critical to bringing the Company's technology to the marketplace.

#### RESULTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 1997 AND DECEMBER 31, 1998

**SALES REVENUE.** Sales Revenue in 1998 decreased 17% to \$9.4 million compared to \$11.3 million for the same period of 1997. The decrease resulted primarily from sales to one large former international distributor of approximately \$1.5 million made in 1997.

During 1998, the Company licensed its focus technology and reduced its domestic direct sales force. In January 1999, it sold its Vascular Access

Business Unit and acquired RMS as the Company sought to maximize the value of existing technology, while acquiring a technology which management believes will have greater potential for future product sales. In 1999, the Company intends to devote relatively more of its resources to research and development and less to sales and marketing.

Because 1998 sales of Vascular Access Products totaled approximately \$2.7 million, or 22% of total revenues, and the Company licensed its focus technology in 1998, management anticipates significantly lower product sales and associated revenue in 1999 compared with 1998.

LICENSE FEE AND OTHER REVENUE. In 1998, the Company signed a technology license agreement with Guidant Corporation resulting in \$2.8 million in license fees.

COST OF SALES. The cost of sales decreased to \$6.2 million in 1998 compared with \$6.4 million in 1997. The cost of sales for 1998 decreased to 51% compared to 57% for 1997. This decrease was primarily attributable to \$2.8 million from licensing fees received in 1998 that had no associated cost of sales.

The Company agreed to produce Vascular Access products for six months following the sale of the Vascular Access Division in January 1999 on a "cost plus" reimbursement basis for the acquiring company. Thus, the margin that the Company earned on sales of such products will be substantially lower in 1999 compared with 1998.

CHARGE FOR ACQUIRED IN-PROCESS RESEARCH AND DEVELOPMENT. Due to the acquisition of a controlling interest in RMS, the Company recognized a charge of \$0.2 million for acquired in-process research and development in 1998. See Note 1 - Intangible Assets.

RESEARCH AND DEVELOPMENT. Research, development and clinical expenses increased by 13% to \$8.0 million for 1998 from \$7.0 million in 1997. The primary reason for this increase was additional spending on development of the Company's new Radiation catheter and SEAL technology and increased spending on clinical trials for these products. The Company anticipates that the research, development and clinical expenses could be substantially higher in 1999 compared with 1998, primarily due to higher costs for the development of radiotherapy technology.

MARKETING AND SALES. Marketing and sales expenses declined 20% to \$5.4 million in 1998, from \$6.7 million in 1997. This decrease primarily reflects reductions in the Company's domestic sales force and related expenses.

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GENERAL AND ADMINISTRATIVE. General and administrative expenses increased by 35% to \$2.9 million for 1998 from \$2.2 million for 1997. The increase was due primarily to additions to the allowance for uncollectible accounts receivable and the salary expense of an additional executive officer.

OTHER INCOME. Interest income declined to \$1.5 million in 1998 compared with \$2.2 million in 1997. The decrease was due to a reduction of \$6.1 million in cash, cash equivalents and marketable securities during 1998, due to the use of funds for operations, the purchase of treasury stock and capital expenditures.

YEARS ENDED DECEMBER 31, 1996 AND DECEMBER 31, 1997

SALES REVENUE. Sales revenue increased to \$11.3 million in 1997 from \$8.4 million in 1996, representing an increase of 35%. The increase resulted primarily from increased sales of the Company's Focus catheters, and, to a lesser extent, the introduction of new coronary stent products. Sales of products through Medtronic under the Company's co-exclusive distribution agreement and sales of products in Japan through the Company's exclusive distribution relationships with Fukuda and Cathex accounted for 7 % and 13 %, respectively, of total product sales in 1997. The Agreements with Medtronic and Fukuda were terminated in 1997. See "Item 1. Business--Strategic Relationships."

LICENSE FEE AND OTHER REVENUE. There were no license fees or other

revenues from ACS in 1997, compared with \$0.2 million in 1996. In February of 1998, ACS elected to terminate the technology license agreement with the Company. See "Item 1. Business--Strategic Relationships."

CONTRACT REVENUE. There were no contract revenues from SCIMED in 1997, compared with \$0.2 million in 1996. See "Item 1. Business--Strategic Relationships."

COST OF SALES. Cost of sales increased to \$6.4 million in 1997 from \$4.1 million in 1996. This increase resulted primarily from increased manufacturing volumes related to increased product sales and reserves and allowances of approximately \$1.0 million for excess product inventories. The increase in the allowance for excess inventories resulted from increased product manufactured for sales forecasts, which were subsequently lowered, and unfulfilled purchase commitments. The Company considered remaining shelf life and anticipated sales volume in determining the amount of allowance needed.

CHARGE FOR ACQUIRED IN-PROCESS RESEARCH AND DEVELOPMENT. The Company incurred a charge of \$2.1 million in 1996 in connection with the acquisition of Intraluminal Devices, Inc. ("IDI"). The excess of the purchase price of IDI over the fair market value of the net assets acquired was recorded as in-process research and development. The acquired in-process research and development was immediately written off as IDI was in the development stage and had not yet received regulatory approval for any of its products at the time of the acquisition. There were no similar charges in 1997.

RESEARCH AND DEVELOPMENT. Research and development increased to \$7.0 million in 1997 compared to \$3.6 million in 1996, representing an increase of 97%. This increase resulted primarily from expenditures on the development of Focus technology, vascular stents and vascular access products.

MARKETING AND SALES. Marketing and sales expenses increased to \$6.7 million in 1997 from \$3.4 million in 1996, representing an increase of 99%. This increase resulted mainly from the expansion of the Company's direct sales force in the United States and marketing expenses related to the product launch of the coronary stent products in foreign markets.

GENERAL AND ADMINISTRATIVE. General and administrative expenses increased to \$2.2 million in 1997 from \$1.5 million in 1996, representing an increase of 41%. The added costs were primarily due to additions in administrative staff and the added costs of operating as a public company for an entire year. The Company began trading as a public company on June 20, 1996.

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OTHER INCOME. Other income, principally interest income, increased to \$2.2 million in 1997 from \$1.4 million in 1996. The 62% increase primarily resulted from the investment of the net proceeds of the Company's initial public offering for the entire year of 1997.

Radiance has experienced an operating loss for each of the last three years and expects to continue to incur operating losses through at least 2000. Radiance's results of operations have varied significantly from quarter to quarter. Quarterly operating results depend upon several factors, including the timing and amount of expenses associated with expanding the Company's operations, the conduct of clinical trials and the timing of regulatory approvals, new product introductions both in the United States and internationally, the mix between pilot production of new products and full-scale manufacturing of existing products, the mix between domestic and export sales, variations in foreign exchange rates, changes in third-party payors' reimbursement policies and healthcare reform. The Company does not operate with a significant backlog of customer orders, and therefore revenues in any quarter are significantly dependent on orders received within that quarter. In addition, the Company cannot predict ordering rates by distributors, some of whom place infrequent stocking orders. The Company's expenses are relatively fixed and difficult to adjust in response to fluctuation revenues. As a result of these and other factors, the Company expects to continue to experience significant fluctuations in quarterly operating results, and there can be no assurance that the Company will be able to achieve or maintain profitability in the future.

LIQUIDITY AND CAPITAL RESOURCES

Since inception, the Company has financed its operations primarily from the sale of its equity securities, advances from Endosonics, licensing its technologies and through international product distribution agreements. Prior to the Company's initial public offering, the Company had raised an aggregate of approximately \$11.4 million from the private sales of preferred and common stock and \$2.7 million in working capital from Endosonics, which was repaid to Endosonics during the third quarter of 1996. In the third quarter of 1996, the Company closed its initial public offering of common stock, resulting in net proceeds of \$42.8 million after deducting underwriting discounts and commissions and other expenses of the offering. For the years ended December 31, 1998, 1997 and 1996, the Company's net cash used in operating activities was \$5.0, \$9.8 and \$6.2 million, respectively. The decrease in 1998 was primarily the result of a lower net loss and a decrease in net working capital. The increases in 1997 and 1996 were primarily due to funding of operating losses and the charges for acquired in-process research and development.

At December 31, 1998, Radiance had cash, cash equivalents and marketable securities available for sale of \$24.8 million. The Company expects to incur substantial costs related to, among other things, clinical testing, product development, marketing and sales expenses, and to utilize increased levels of working capital to finance its accounts receivable and inventories prior to achieving positive cash flow from operations. The Company anticipates that its existing capital resources will be sufficient to fund its operations through June 30, 2000. Radiance's future capital requirements will depend on many factors, including its research and development programs, the scope and results of clinical trials, the regulatory approval process, the costs involved in intellectual property rights enforcement or litigation, competitive products, the establishment of manufacturing capacity, the establishment of sales and marketing capabilities, and the establishment of collaborative relationships with other parties. The Company may need to raise funds through additional financings, including private or public equity offerings and collaborative arrangements with existing or new corporate partners. There can be no assurance that funds will be raised on favorable terms, or at all. If adequate funds are not available, the Company may be required to delay, scale back or eliminate one or more of its development programs or obtain funds through arrangements with collaborative partners or others that may require the Company to grant rights to certain technologies or products that the Company would not otherwise grant.

#### RISK FACTORS

OPERATING LOSSES, ANTICIPATED FUTURE LOSSES AND FUTURE CAPITAL REQUIREMENTS. From our formation in 1992 to the date of this prospectus, we have had substantial annual operating losses and expect to have them at least through 2000, if not longer, due to our continued research and development activities, and expenditures related to clinical testing and product development. We had an accumulated deficit of approximately \$27,807,000 as of December 31, 1998.

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Our activities are highly capital intensive. Although we believe that our present capital and anticipated revenues from operations will be sufficient to meet our presently planned capital needs at least through the second quarter of 2000, there can be no assurance that we will not require additional capital during that time or thereafter. Our cash requirements in the future may be significantly different from our current estimates and depend on many factors, including:

- o Research and development programs;
- o Scope and results of clinical trials;
- o Time and costs involved in obtaining regulatory approvals;
- o Costs involved in obtaining and enforcing patents or any litigation by third parties regarding intellectual property;
- o Status of competitive products;

- o Establishment and scale-up of manufacturing capacity;
- o Establishment of sales and marketing capabilities; and
- o Establishment of collaborative relationships with other parties and costs related to the acquisition of new technologies and product development.

We may require additional funds to finance these activities and for working capital requirements, and may seek such funds through additional rounds of financing, including private or public equity or debt offerings and collaborative arrangements with corporate partners. In addition, we may be required to undertake significant capital expenditures to achieve and maintain any technological and competitive position in our industry. There can be no assurance that funds will be raised on favorable terms, if at all. If adequate funds are not available, we may be required to delay, scale back or eliminate one or more of our development programs or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain technologies, product candidates or products that we would not otherwise relinquish. If we are successful in raising additional funds, we may issue additional equity securities which may dilute our earnings and net tangible book value per share.

DEPENDENCE ON NEW AND UNPROVEN RADIATION TECHNOLOGY. The RDX Catheter is designed to reduce the frequency of restenosis following the interventional treatment of atherosclerosis by locally applying Beta radiation to the diseased blood vessel. This and other radiation technologies and products which we intend to develop are in the early stages of development and require significant research, development and testing. Our development of these products is subject to the risks of failure commonly experienced in the development of new products based on innovative or novel technologies. While early clinical results by our competitors indicate that radiation will reduce local restenosis, there are no extensive clinical trials of the technology showing positive and lasting clinical results. The possibility also exists that any or all of these proposed technologies and products will be found to be ineffective or unsafe, will fail to meet applicable regulatory standards or will fail to obtain required regulatory approvals. In addition, even if radiation technology and products are developed successfully and are effective, they may be uneconomical to market, or other companies hold the proprietary rights which preclude us from marketing such technologies and products.

To achieve profitable operations, we must develop and obtain regulatory approval for products based on radiation technology, and introduce and market these products successfully. Most of the preclinical and clinical development work for the products based on the Radiance technologies remains to be completed. We have not

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generated, nor do we expect to generate in the near future, any operating revenues based on new products. We cannot assure you that we will develop, obtain regulatory approval for or introduce and market these products successfully, and any failure on our part could have a material adverse effect on our business and results of operations.

DEPENDENCE UPON NEW PRODUCTS AND TECHNOLOGY; RAPID TECHNOLOGICAL CHANGE; RISK OF OBSOLESCENCE. We are in the rapidly changing, competitive and heavily regulated medical device industry, which makes it difficult for us to predict our risks and expenses with any amount of certainty. We cannot say with any certainty that our research and development activities will enable us to produce any products able to withstand competition. Our development of each product is subject to the risks of failure commonly experienced in the development of products based upon innovative technologies and the expense and difficulty of obtaining approvals from regulatory agencies. All of our potential products currently under development will require significant additional funding and development and pre-clinical and clinical testing before we are able to submit them to any of the regulatory agencies for approval for commercial use. We cannot assure you that we will be able to license any technologies or proposed products or to complete successfully any of our research and development activities. Even if we do complete them, there is no assurance that we will be

able to market successfully any of the products, or that we will be able to obtain the necessary regulatory approval, or that customers will like our products. We also face the risk that any or all of our products will not work as intended or that they will be toxic, or that, even if they do work and are safe, that our products will be difficult to manufacture or market on a large scale. We also face the risk that the proprietary rights of other persons or entities will prevent us from marketing any of our products or that other persons or entities might market their products as well as we market our products or even better.

Even if we overcome all of the above obstacles successfully, our products are subject to rapid technological change and obsolescence. In addition, our competitors may introduce new products or new technology which could render our products obsolete or unmarketable. We therefore may be required to make significant capital expenditures to maintain any technological and competitive position in our industry. Most of the preclinical and clinical development work for the products based on the Radiance technologies remains to be completed. We have not generated, nor do we expect to generate in the near future, any operating revenues based on new products. We cannot assure you that we will develop, obtain regulatory approval for or introduce and market these products successfully, and any failure on our part could have a material adverse effect on our business and results of operations.

LIMITED SALES OF PRODUCTS TO DATE; UNCERTAINTY OF MARKET ACCEPTANCE. Our catheters and stents are used in conjunction with angioplasty and other intravascular procedures such as vascular stenting and solution delivery. Although we have received regulatory clearance for a total of 97 product models, only certain of these product models have been marketed, and then only in limited quantities, or in certain markets, or in certain countries. Although interventional catheters are used widely by physicians, because our catheter designs are relatively new, our product's commercial success will depend upon their acceptance by the medical community as useful, cost-effective components of interventional vascular procedures and localized solution delivery. Continued good relations with certain prominent doctors and researchers in the medical community are essential for us to promote the uses and acceptance of our approved products.

No products utilizing the Radiance radiotherapy technology are currently commercially available. The use of stents during percutaneous transluminal coronary angioplasty ("PTCA") in an attempt to reduce the frequency of restenosis has grown rapidly since commercial introduction in the U.S. in 1994. We cannot predict the clinical acceptance by physicians of the Radiance technology -- integrating Beta radiation with traditional minimally invasive techniques - as compared to more conventional treatment modalities. Other companies may have superior resources to market similar products or technologies or have superior technologies and products to market.

SIGNIFICANT COMPETITION. We believe the primary competitive factors in the market for interventional cardiology devices are clinical effectiveness, product safety, catheter size, flexibility and trackability, ease of use, reliability, price and availability of third party reimbursement. In addition, a company's distribution capability and the time in which products can be developed and receive regulatory approval are important competitive factors. Although we believe we compete favorably with respect to the foregoing factors, we also believe that our competitive position depends upon our ability to continue to develop innovative new catheter technologies, to obtain rapid regulatory approval and to manufacture and distribute such products efficiently.

Competition in the market for devices used in the treatment of cardiovascular and peripheral vascular disease is intense, and is expected to increase. There is rapid technological innovation and change in the interventional cardiology device market and our products could be rendered obsolete as a result of future innovations. The catheters, stents and other products we are developing compete or will compete with catheters and stents marketed by a number of manufacturers, including Guidant Corporation, Boston Scientific Corporation, Johnson & Johnson, Medtronic, Inc., and Arterial Vascular Engineering (which has recently entered into an agreement to be acquired by Medtronic, Inc.). Such companies have significantly greater

financial, management and other resources, established market positions, and significantly larger sales and marketing organizations than we do. We also face competition from manufacturers of other catheter-based atherectomy devices, vascular stents and pharmaceutical products intended to treat vascular disease. In addition, we believe that many of the purchasers and potential purchasers of our competitors prefer to purchase catheter and stent products from a single source. Accordingly, many of our competitors, because of their size and range of product offerings, have a competitive advantage over Radiance. It is also possible that our competitors may succeed in developing products that are safer or more effective than those that we are developing and may obtain FDA approvals for their products faster than we can.

Several companies are developing devices to improve the outcome of coronary revascularization procedures, such as PTCA, including several companies that have various radiation therapy products under investigation to reduce the frequency of restenosis. The radiation therapy devices being developed by our competitors include intravessel radiation delivered through a variety of means and a variety of radiation sources, including Gamma, Beta and X-ray. We are not certain that our research and development activities into the Radiance technology will enable us to produce any products able to withstand competition. There are more than ten competing development programs in the area of vascular radiotherapy and our major competitors include the Novoste Corporation, Johnson & Johnson, Guidant Corporation and United States Surgical Corporation. Each of these competitors have significantly greater financial, marketing, personnel and other resources compared to us and there is no assurance that we can develop the products able to compete with these larger competitors.

RELIANCE ON PATENTS AND PROPRIETARY TECHNOLOGY; RISK OF PATENT INFRINGEMENT. Our success will depend, in part, on our ability to get patent protection for our products and processes in the United States and elsewhere. We have filed and intend to continue to file patent applications as we need them. We cannot say with any certainty, however, that any additional patents will issue from any of these applications or, if patents do issue, that the claims allowed will be sufficiently broad to protect our technology or that the issued patents will provide competitive advantages for our products. If we are unable to obtain sufficient protection of our proprietary rights in our products or processes prior to or after obtaining regulatory clearances, our competitors may be able to obtain regulatory clearance and market competing products by demonstrating the equivalency of their products to our products. If they are successful at demonstrating the equivalency between the products, our competitors would not have to conduct the same lengthy clinical tests that we have conducted.

The interventional cardiovascular and peripheral vascular device market, and more specifically, the market for balloon angioplasty catheters and coronary stents (including those products we offer) has been subject to substantial litigation regarding patent and other intellectual property rights. There can be no assurance that our products do not infringe such patents or rights, and we cannot say with any certainty that any patents issued to us or licensed by us can withstand challenges made by others or that we will be able to protect our rights. We are aware of patent applications and issued patents belonging to our competitors, and we are uncertain whether any of these, or of any patent applications which we do not know about, will require us to alter or cease our potential products or processes. We cannot say with any certainty that we will be able to obtain any licenses to technology that we will require or, if obtainable, that the cost will be reasonable. Our failure to obtain any necessary licenses to any technology could hurt our business substantially if we could not redesign our products or processes to avoid infringement. Expensive and drawn-out litigation also may be necessary for us to assert any of our rights or to determine the scope and validity of rights claimed by other parties. Litigation could be too expensive for us to pursue with no certainty as to the outcome. Our failure to pursue litigation could result in the loss of our rights which could hurt our business substantially. In addition, the laws of certain foreign countries do not protect the Company's intellectual property rights to the same extent as do the laws of the United States, if at all.

protect by entering into confidentiality agreements with other parties. We cannot be certain that any of the confidentiality agreements will be honored, or, if breached, that we would have enough remedies to protect our confidential information. Further, our competitors may independently learn our trade secrets or develop similar or superior technologies. To the extent that our consultants, key employees or others apply technological information independently developed by them or by others to our projects, disputes may arise regarding the proprietary rights to such information and there is no guarantee that such disputes will be resolved in our favor.

LIMITED MANUFACTURING EXPERIENCE. The Company's manufacturing experience is limited; we only began manufacturing certain products at our facilities in July 1995, introducing a number of new products in 1996 and 1997. We must manufacture our products in compliance with a variety of licensing and other regulatory requirements, including the ISO 9001, the FDA's QSR requirements, the U.S. Nuclear Regulatory Commission ("NRC") requirements, and the requirements of the California Department of Health Services ("CDHS") in order to succeed. In addition, building and operating production facilities which can handle the radiation sources required for the manufacture of the RDX Catheter will require substantial additional funds and other resources. We also need to manage the simultaneous manufacture of different products efficiently and to integrate the manufacture of new products with existing product lines. During this process, we may encounter difficulties in scaling up production of new products, including problems involving production yields, quality control and assurance, component supply and shortages of qualified personnel.

In addition, we purchase many standard and custom built components from independent suppliers and we subcontract certain manufacturing processes from independent vendors. Most of these components and processes are available from more than one vendor; however, we may not be able to enter into any arrangements with outside manufacturers on terms favorable to us, if at all. Moreover, certain manufacturing processes are currently performed by single vendors. An interruption of performance by any of these vendors could cripple our ability to manufacture our products until a new source of supply was qualified.

NO ASSURANCE OF FDA APPROVAL; GOVERNMENT REGULATION. The FDA and other similar agencies in foreign countries have substantial requirements for therapeutic and diagnostic pharmaceutical and biological products. Such requirements involve lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures. It often takes companies several years to satisfy these requirements, depending on the complexity and novelty of the product. The review process also is extensive, which may delay the approval process even more. These regulatory requirements could substantially hurt our ability to clinically test and manufacture our potential products. Government regulation also could delay our marketing of new products for a considerable period of time, impose costly procedures upon our activities and give our competitors an advantage. Moreover, the FDA and other regulatory agencies may not grant us approval for any of our products on a timely basis, if at all. Any delay in obtaining, or failure to obtain, such approvals could substantially hurt our marketing of any proposed products and our ability to earn product revenue. Further, regulation is subject to change and any additional regulation could limit or restrict our ability to use any of our technologies, which could have a material adverse effect on our business and results of operations.

Because the RDX Catheter uses radiation sources, its manufacture, distribution, transportation, import/export, use and disposal will also be subject to federal, state and/or local laws and regulations relating to the use and handling of radioactive materials. We must obtain a license from the NRC to commercially distribute such radiation sources and comply with all applicable regulations, as does our supplier of radiation sources. We and our supplier of radiation sources also must comply with NRC and U.S. Department of Transportation regulations on the labeling and packaging requirements for shipment of radiation sources to hospitals or to the other users of the RDX Catheter. In addition, hospitals may be required to obtain or expand their licenses to use and handle Beta radiation prior to receiving radiation sources for use in the RDX Catheter. Comparable radiation regulatory requirements and/or approvals are anticipated in markets outside the U.S.

Finally, we are subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. We may be required to incur significant costs to comply with such laws and regulations now or in the future. In the future, we could also be subject to other federal, state or local regulations which could affect our research and development programs. We are unable to predict whether any agency will adopt any rule which could substantially hurt our business and our results of operations.

**UNCERTAINTY RELATED TO HEALTH CARE REIMBURSEMENT AND REFORM MEASURES.** Health care providers such as hospitals and physicians that purchase or lease medical devices in the United States generally rely on third-party payors, principally Medicare, Medicaid and private health insurance plans, including health maintenance organizations, to reimburse all or part of the cost of the treatment for which the medical device is being used. Third party payors increasingly have challenged the cost of medical products and services, which have and could continue to have a significant effect on the ratification of such products and services by many health care providers. Several proposals have been made by federal and state government officials that may lead to health care reforms, including a government directed national health care system and health care cost-containment measures. The effect of changes in the health care system or method of reimbursement for any medical device which we may market in the United States cannot be determined.

Moreover, our success in developing products based on novel or innovative technology, such as the RDX Catheter, may depend, in part, on whether we will be reimbursed by government health administrative authorities, private health insurers and other organizations. There is significant uncertainty if costs associated with newly approved health care products will be reimbursed. There is no assurance that sufficient insurance coverage will be available for us to establish and maintain price levels sufficient to realize an appropriate return on developing our new products. Government and other third party payors are attempting to contain health care costs more every day by limiting both coverage and the level of reimbursement of new therapeutic and diagnostic products approved for marketing by the FDA and by refusing, in some cases, to provide any coverage of uses of approved products for disease indications for which the FDA has not granted market approval. If adequate coverage and reimbursement levels are not provided by government and third party payors for use of our new products, it will be very difficult for us to market our products to doctors and hospitals because their patients might not be able to pay for the products without any insurance coverage or reimbursement.

We cannot predict what additional legislation or regulations, if any, may be enacted or adopted in the future relating to our business or the health care industry, including third party coverage and reimbursement, or what effect any such legislation or regulations may have on us. Furthermore, significant uncertainty exists as to the reimbursement status of newly approved healthcare products, and there can be no assurance that adequate third-party coverage will be available with respect to any of our products in the future. Failure by physicians, hospitals, nursing homes and other users of our products to obtain sufficient reimbursement for treatments using our products would have a material adverse effect on our business and results of operations.

**FLUCTUATIONS IN QUARTERLY OPERATING RESULTS.** We have experienced operating losses for each of the last five years. Considering the anticipated operating losses of Radiance, we expect to continue to incur consolidated operating losses through at least 2000, and there can be no assurance that we will ever be able to achieve or sustain profitability in the future. Our results of operations have varied significantly from quarter to quarter. Quarterly operating results will depend upon several factors, including timing and amount of expenses associated with expanding our operations, the conduct of clinical trials and the timing of regulatory approvals, new product introductions both in the United States and internationally, the mix between pilot production of new products and full-scale manufacturing of existing products, the mix between domestic and export sales, variations in foreign exchange rates, changes in third-party payor's reimbursement policies and healthcare reform. We do not operate with a significant backlog of customer orders, and therefore revenues in any one quarter are mainly dependent on orders received within that quarter. In addition, we cannot predict ordering rates by distributors, some of whom place infrequent stocking orders. Our expenses are relatively fixed and difficult to adjust in response to fluctuating revenues. As a result of these and other factors, we expect to continue to experience significant fluctuations in

quarterly operating results and we may not be able to achieve or maintain profitability in the future.

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LIMITED MARKETING AND SALES RESOURCES; DEPENDENCE UPON STRATEGIC PARTNERS. We depend on medical device distributors, our direct sales organization and certain strategic relationships, some of which are with our competitors, to distribute our products. Recently, there has been significant consolidation among medical device suppliers as the major suppliers have attempted to broaden their product lines in order to respond to cost pressures from health care providers. This consolidation has made it increasingly difficult for smaller suppliers, like us, to distribute products effectively without a relationship with one or more of the major suppliers. We currently market certain of our products in the U.S. through a licensing agreement with Guidant Corporation. Revenue generated from these distributor relationships will directly depend upon their efforts to market our products.

PRODUCT LIABILITY AND INSURANCE. Clinical testing, manufacturing and marketing of our products may expose us to product liability claims. Although we never have been subject to a product liability claim, we cannot assure you that there will not be any claims brought against us in the future. Even then, the coverage limits of our insurance policies may not be adequate and one or more successful claims brought against us may have a material adverse effect upon our business, financial condition and results of operations. Additionally, adverse product liability actions could negatively affect the reputation and sales of our products and our ability to obtain and maintain regulatory approval for our products.

DEPENDENCE UPON INTERNATIONAL SALES. We derive significant revenue from international sales, and therefore a significant portion of our revenues will continue to be subject to the risks associated with international sales. These risks include economic or political instability, shipping delays, changes in applicable regulatory policies, inadequate protection of intellectual property, fluctuations in foreign currency exchange rates and various trade restrictions, all of which could have a significant impact on our ability to deliver products on a competitive and timely basis. In foreign countries, our products are subject to governmental review and certification. The regulation of medical devices in foreign countries, particularly in the European Union, continues to expand and we cannot be certain that new laws or regulations will not have an adverse effect on our business.

LIMITED PUBLIC MARKET; VOLATILITY OF STOCK PRICE. Our Common Stock has been traded on the Nasdaq National Market since June 1996 and the price of our Common Stock has fluctuated significantly. We are in the medical device industry and the market price of securities of small life sciences companies in general has been very unpredictable. Announcements by us or our competitors concerning technological innovations, new products, proposed governmental regulations or actions, developments or disputes relating to patents or proprietary rights, public concern over the safety of therapeutic products and other factors that affect the market generally could significantly impact our business and the market price of our securities.

EFFECT OF CERTAIN CHARTER PROVISIONS. Certain provisions of our Amended & Restated Certificate of Incorporation could make it more difficult for a third party to acquire control of our business, even if such change in control would be beneficial to our stockholders. Our Amended & Restated Certificate of Incorporation allows our Board of Directors to issue up to 7,560,000 shares of preferred stock without stockholder approval. Any such issuance could make it more difficult for a third party to acquire our business and may adversely affect the rights of our stockholders. In addition, our Board of Directors is divided into three classes for staggered terms of three years. Although this measure is designed to protect stockholder interests in the event of a hostile takeover attempt against the Company, this provision can have the effect of delaying, deterring or preventing a change in control of the Company, adversely affecting the market price of our Common Stock.

IMPACT OF YEAR 2000. We have completed an assessment of our hardware and software and are in the process of upgrading them so that our computer systems will function properly on and after the Year 2000. Of the total cost of \$15,000 estimated for the Year 2000 upgrade, approximately \$15,000 has been spent.

Future expenditures for upgrades and other project costs are not expected to exceed this estimate by a material amount. Our Year 2000 upgrade was completed in the first quarter of 1999.

We will contact our vendors and customers to assess the impact the Year 2000 issue will have on our supply and service relationships we have with our vendors and customers. Based upon our assessment of our systems and software, we believe that the planned system enhancements and upgrades should prevent related problems that could affect our ability to supply or service our customers. We anticipate completing our assessment

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of significant vendor and customer Year 2000 issues by the end of the second quarter of 1999 and will formulate a contingency plan based upon the apparent "worst-case" scenarios. However, depending upon the response level by customers and vendors and the information received from them, this assessment may not be completed as anticipated or may be inadequate to assess or address the related risks. We cannot be certain that all of our systems and software will be Year 2000 ready nor have any assurance that our vendors' or customers' systems and software will be Year 2000 ready. To prepare for any vendor problems, we will try to identify alternative supply sources, but there is no guaranty that these alternative sources will be Year 2000 ready or to be able to provide the same level of service and supply as our current vendors. If our customers' systems and software are not Year 2000 ready, any operational problems which may result could cause slowed or lower demand of our products. Even if our goal is to be Year 2000 ready, there can be no assurance that our plans will be sufficient to address any third party failures, and any unresolved or undetected internal or external Year 2000 issues could affect our business, financial condition or results of operations.

DIVIDENDS. Since our formation in 1992, we have not paid cash dividends on our Common Stock, nor do we anticipate paying any dividends on our Common Stock in the future.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

The Company does not believe that it has material exposure to interest rate, foreign currency exchange rate or other relevant market risks.

Interest Rate Risk. The Company's exposure to market risk for changes in interest rates relates primarily to the Company's investment profile. The Company does not use derivative financial instruments in its investment portfolio. The Company places its investments with high credit quality issuers and, by policy, limits the amount of credit exposure to any one issuer. The Company is adverse to principal loss and tries to ensure the safety and preservation of its invested funds by limiting default risk, market risk, and reinvestment risk. The Company attempts to mitigate default risk by investing in only the safest and highest credit quality securities and by constantly positioning its portfolio to respond appropriately to a significant reduction in a credit rating of any investment issuer or guarantor. At December 31, 1998, the portfolio includes only high grade corporate bonds and commercial paper and government bonds all with remaining maturities of less than two years.

The table below provides information about our available-for-sale investment portfolio. For investment securities, the table presents principal cash flows and related weighted average fixed interest rates by expected maturity dates.

Principal amounts by expected maturity at December 31, 1998:

	1999	2000	Total	Fair Value 1998
	-----	-----	-----	-----
	(in thousands, except interest rates)			
Cash and cash equivalents.....	693	--	693	693
Weighted average rate.....	4.85%		4.85%	
Investments.....	20,000	3,500	23,500	23,375

Weighted average rate.....	5.38%	5.55%	5.40%	
Total portfolio.....	20,693	3,500	24,193	24,068
Weighted average rate.....	5.36%	5.55%	5.39%	

Foreign Currency Risk. The Company transacts business in various foreign currencies, primarily in certain European countries. The company does not have hedging or similar foreign currency contracts. Although international revenues approximated 48% of the Company's total revenues for the year ended December 31, 1998, only approximately 12% of the revenues are denominated in foreign currencies. Significant currency fluctuations could adversely impact foreign revenues, however the Company does not foresee or expect any significant changes in foreign currency exposure in the near future.

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ITEM 8. FINANCIAL STATEMENTS

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The financial statement schedule listed under Part IV, Item 14, is filed as part of this Form 10-K.

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

Not applicable.

PART III

ITEM 10. DIRECTORS AND OFFICERS OF THE REGISTRANT.

The information required by this item is incorporated by reference from the Company's Proxy Statement, to be mailed to stockholders for the Annual Meeting to be held on or about June 9, 1999. The information concerning the Company's executive officers required by this item is incorporated by reference to the section of Part I hereof entitled "Executive Officers of the Registrant."

ITEM 11. EXECUTIVE COMPENSATION.

The information required by this item is incorporated by reference from the Company's Proxy Statement, to be mailed to stockholders for the Annual Meeting to be held on or about June 9, 1999.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT.

The information required by this item is incorporated by reference from the Company's Proxy Statement, to be mailed to stockholders for the Annual

Meeting to be held on or about June 9, 1999.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

The information required by this item is incorporated by reference from the Company's Proxy Statement, to be mailed to stockholders for the Annual Meeting to be held on or about June 9, 1999.

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PART IV

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

(a) The following documents are filed as a part of this Annual Report on Form 10-K:

1. Financial Statements.

Report of Ernst & Young LLP, Independent Auditors  
Consolidated Balance Sheets - December 31, 1997 and 1998  
Consolidated Statements of Operations  
for the years ended December 31, 1996, 1997 and 1998  
Consolidated Statements of Stockholders' Equity  
for the years ended December 31, 1996, 1997 and 1998  
Consolidated Statements of Cash Flows  
for the years ended December 31, 1996, 1997 and 1998  
Notes to Consolidated Financial Statements  
for the years ended December 31, 1996, 1997 and 1998

2. Financial Statement Schedule.

II - Valuation and Qualifying Accounts

Schedules not listed above have been omitted because they are not applicable or are not required to be set forth herein as such information is included in the Consolidated Financial Statements or the notes thereto.

3. Exhibits. Reference is made to Item 14(c) of this Annual Report on Form 10-K.

(b) REPORTS ON FORM 8-K. The Company filed a Report on Form 8-K as of November 12, 1998 reporting the signing of a merger agreement between CardioVascular Dynamics, Inc. and Radiance Medical Systems, Inc.

(c) EXHIBITS.

- 2.1(3) Agreement and Plan of Reorganization dated as of June 9, 1993 among Endosonics Corporation ("Endosonics"), Endosonics Acquisition Corporation and the Company.
- 2.2(3) First Amendment dated as of June 30, 1993 to the Agreement and Plan of Reorganization among Endosonics, Endosonics Acquisition Corporation and the Company.
- 2.4(12) Agreement and Plan of Merger dated November 3, 1998 by and between CardioVascular Dynamics, Inc. and Radiance Medical Systems, Inc.
- 2.5(13) Assets Sale and Purchase Agreement dated January 21, 1999 by and between the Company and Escalon Medical Corp.
- 3.1(10) Amended and Restated Certificate of Incorporation, and Certificates of Amendment thereof dated January 14, 1999 and November 12, 1998.

3.2(11) Amended and Restated Bylaws of the Company.

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- 4.1(1) Specimen Certificate of Common Stock.
- 10.1(3) Form of Indemnification Agreement entered into between the Registrant and its directors and officers.
- 10.2(3)\*\* The Registrant's 1996 Stock Option Plan and forms of agreements thereunder.
- 10.3(3)\*\* The Registrant's Employee Stock Purchase Plan and forms of agreement thereunder.
- 10.4(3) Series A Supplemental Stock Purchase Agreement dated June 5, 1992, by and between the Company and Radiance.
- 10.5(3) Stock Purchase Option Agreement dated June 5, 1992, by and between Endosonics and the Company.
- 10.7(3)\* Stock Purchase and Technology License Agreement dated September 10, 1994, as amended on September 29, 1995, by and among Endosonics, the Company and SCIMED Life Systems, Inc. ("SCIMED").
- 10.8(3) Waiver and Grant of Warrant dated June 30, 1995 by and between SCIMED, the Company and Endosonics.
- 10.9(3)\* License Agreement dated January 15, 1995 by and between the Company and Advanced Cardiovascular Systems, Inc. ("ACS").
- 10.10(3)\* License Agreement dated March 4, 1996 by and between the Company and ACS.
- 10.11(3) Series B Stock Purchase Agreement dated March 29, 1996 by and between the Company and Endosonics.
- 10.15(3) Industrial Lease dated February 23, 1995 by and between the Irvine Company and the Company.
- 10.16(1) Waiver and Grant of Warrant dated May 2, 1996 by and between SCIMED, the Company and Endosonics.
- 10.18(4)\* Supply Agreement dated July 15, 1996 by and between the Company and Medtronic, Inc.
- 10.19(4)\* OEM Agreement dated July 15, 1996 by and between the Company and Medtronic, Inc.
- 10.20(6) License Agreement dated May 16, 1997, by and between the Company and Endosonics.

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- 10.21(6) Registration Rights Agreement dated as of January 26, 1997 by and between the Company and Endosonics.
- 10.22(7)\*\*Supplemental Stock Option Plan
- 10.23(8) Stock Repurchase Agreement dated as of February 10, 1998 by and between Endosonics and the Company.
- 10.24(9)\* License Agreement by and between the Company and Guidant Corporation dated June 19, 1998.
- 10.25(14)\*\* 1996 Stock Option/Stock Issuance Plan (as Amended and

Restated as of April 8, 1997, March 12, 1998 and November 3, 1998).

- 10.26(15)\*\* 1997 Stock Option Plan (As Amended as of June 15, 1998) assumed by Registrant pursuant to its acquisition of Radiance Medical Systems, Inc. on January 14, 1999.
- 10.27\*\* + Amendment to Employment Agreement dated as of February 1, 1999 between the Company and Michael R. Henson and form of Employment Agreement entered into on January 14, 1999 between the Company and Michael R. Henson.
- 10.28\*\* + Employment Agreement entered into as of February 1, 1999 by and between the Company and Stephen R. Kroll.
- 10.29\*\* + Form of Employment Agreement by and between the Company and Jeffrey Thiel.
- 10.30\*\* + Form of Employment Agreement by and between the Company and Claire Walker.
- 21.1+ List of Subsidiaries.
- 23.1 Consent of Ernst & Young LLP, Independent Auditors.
- 24.1 Power of Attorney. (Reference is made to page 39 of this Annual Report on Form 10-K.)
- 27.1 Financial Data Schedule.

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\* Confidential treatment requested.

\*\* Indicates compensatory plan or arrangement.

+ Filed herewith.

- (1) Previously filed as an exhibit to Amendment No. 2 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on June 10, 1996.
- (3) Previously filed as an exhibit to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on May 3, 1996.
- (4) Previously filed as an exhibit to the Company's report on Form 10-Q filed with the Securities and Exchange Commission on August 14, 1996.

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- (6) Previously filed as an exhibit to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on June 19, 1997.
- (7) Previously filed as an exhibit to the Company's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on December 12, 1997.
- (8) Previously filed as Exhibit 10 to the Company's Report on Form 10-Q filed with the Securities and Exchange Commission as of May 14, 1998.
- (9) Previously filed as Exhibit 10.24 to the Company's Report on Form 10-Q filed with the Securities and Exchange Commission as of August 11, 1998.
- (10) Previously filed as Exhibit 3.5 to the Company's Report on Form 8-K filed with the Securities and Exchange Commission as of January 22, 1999.
- (11) Previously filed as Exhibit 3.4 to the Company's Report on Form 8-K filed with the Securities and Exchange Commission as of January 22, 1999.

- (12) Previously filed as Exhibit 2.4 to the Company's Report on Form 8-K filed with the Securities and Exchange Commission as of November 12, 1998.
- (13) Previously filed as Exhibit 2 to the Company's Report on Form 8-K filed with the Securities and Exchange Commission as of February 5, 1999.
- (14) Previously filed as Annex III to the Company's Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on December 18, 1998.
- (15) Previously filed as Exhibit 99.2 to the Company's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on February 17, 1999.

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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.

RADIANCE MEDICAL SYSTEMS, INC.

Date: March 29, 1999

By: /s/ Michael R. Henson

-----  
 Michael R. Henson  
 Chief Executive Officer  
 (Principal Executive Officer)  
 and Chairman

Date: March 29, 1999

By: /s/ Stephen R. Kroll

-----  
 Stephen R. Kroll  
 Vice President, Finance and  
 Administration,  
 Chief Financial Officer and  
 Secretary (Principal Financial  
 and Accounting Officer)

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POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints, jointly and severally, Michael R. Henson and Stephen R. Kroll, and each of them, as his 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 (including post-effective amendments) to this Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

SIGNATURE -----	TITLE -----	DATE ----
/s/ Michael R. Henson ----- (Michael R. Henson)	Chief Executive Officer (Principal Executive Officer) and Chairman	March 29, 1999
/s/ Stephen R. Kroll ----- (Stephen R. Kroll)	Vice President, Finance and Administration, Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)	March 29, 1999
/s/ Franklin D. Brown ----- (Franklin D. Brown)	Director	March 29, 1999
/s/ William G. Davis ----- (William G. Davis)	Director	March 29, 1999
/s/ Gerard von Hoffmann ----- (Gerard von Hoffmann)	Director	March 29, 1999
/s/ Edward M. Leonard ----- (Edward M. Leonard)	Director and Assistant Secretary	March 29, 1999
/s/ Jeffrey F. O'Donnell ----- (Jeffrey F. O'Donnell)	Director	March 29, 1999
/s/ Maurice Buchbinder ----- (Maurice Buchbinder, M.D.)	Director	March 29, 1999

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REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

The Board of Directors and Shareholders  
Radiance Medical Systems, Inc.

We have audited the accompanying consolidated balance sheets of Radiance Medical Systems, Inc. as of December 31, 1997 and 1998, and the related consolidated statements of operations, stockholders' equity (net capital deficiency) and cash flows for each of the three years in the period ended December 31, 1998. Our audits also included the financial statement schedule listed in the Index at Item 14(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Radiance Medical Systems, Inc. at December 31, 1997 and 1998, and the

consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 1998, in conformity with generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ ERNST & YOUNG LLP

Orange County, California  
February 18, 1999

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RADIANCE MEDICAL SYSTEMS, INC.

CONSOLIDATED BALANCE SHEETS  
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

	DECEMBER 31,	
	1997	1998
ASSETS		
Current Assets:		
Cash and cash equivalents .....	\$ 6,141	\$ 1,437
Marketable securities available-for-sale, including unrealized gains of \$176 and \$209, respectively .....	24,773	23,375
Accounts receivable, net of allowance for doubtful accounts of \$500 and \$583, respectively .....	2,752	2,413
Other accounts receivable .....	282	375
Inventories .....	3,205	1,623
Other current assets .....	163	218
	-----	-----
Total current assets .....	37,316	29,441
Property and Equipment:		
Furniture and equipment .....	1,871	2,326
Leasehold improvements .....	322	326
	-----	-----
	2,193	2,652
Less accumulated depreciation and amortization .....	(643)	(1,120)
	-----	-----
Net property and equipment .....	1,550	1,532
Intangibles, net of amortization of \$84 and \$188 .....	1,978	2,133
Notes receivable from officers .....	273	116
Deferred charges and other assets .....	244	559
	-----	-----
Total assets .....	\$ 41,361	\$ 33,781
	=====	=====

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable and accrued expenses .....	\$ 3,488	\$ 4,286
Deferred license revenue .....	--	250
	-----	-----
Total current liabilities .....	3,488	4,536

Commitments (Note 10)

Stockholders' equity  
Convertible preferred Stock, \$.001 par value;  
7,560,000 shares authorized, no shares issued

and outstanding .....	--	--
Common Stock, \$.001 par value; 30,000,000 shares authorized, 9,389,000 and 9,578,000 shares issued and outstanding at December 31, 1997 and 1998, respectively .....	9	10
Additional paid-in capital .....	60,371	60,664
Deferred compensation .....	(634)	(409)
Accumulated deficit .....	(19,821)	(27,807)
Treasury stock, at cost; 345,000 and 686,000 common shares at December 31, 1997 and 1998, respectively ...	(2,205)	(3,675)
Accumulated other comprehensive income .....	153	462
	-----	-----
Total stockholders' equity .....	37,873	29,245
	-----	-----
Total liabilities and stockholders' equity .....	\$ 41,361	\$ 33,781
	=====	=====

See accompanying notes.

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RADIANCE MEDICAL SYSTEMS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS  
(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

	YEAR END DECEMBER 31,		
	1996	1997	1998
	-----	-----	-----
Revenue:			
Sales .....	\$ 8,384	\$ 11,332	\$ 9,415
License fee and other .....	150	--	2,760
Contract .....	200	--	--
	-----	-----	-----
Total revenue .....	8,734	11,332	12,175
Operating costs and expenses:			
Cost of sales .....	4,111	6,418	6,152
Research and development .....	3,582	7,041	7,957
Marketing and sales .....	3,358	6,691	5,371
General and administrative (including \$156 for the year ended December 31, 1996 paid to Endosonics) .....	1,548	2,179	2,937
Charge for acquired in-process research and development .....	2,133	--	234
Minority interest in losses of RMS .....	--	--	(992)
	-----	-----	-----
Total operating costs and expenses .....	14,732	22,329	21,659
	-----	-----	-----
Loss from operations .....	(5,998)	(10,997)	(9,484)
Other income (expense):			
Interest income .....	1,324	2,201	1,567
Distributorship fees and other income (expense) .	50	24	(69)
	-----	-----	-----
Total other income .....	1,374	2,225	1,498
	-----	-----	-----
Net loss .....	\$ (4,624)	\$ (8,772)	\$ (7,986)
	=====	=====	=====
Basic and diluted net loss per share (pro forma through June 1996) .....	\$ (0.69)	\$ (0.96)	\$ (0.90)
	=====	=====	=====
Shares used in computing basic and diluted net loss per share (pro forma through June 1996) .....	6,755	9,188	8,862
	=====	=====	=====

See accompanying notes

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## RADIANCE MEDICAL SYSTEMS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)  
(IN THOUSANDS, EXCEPT SHARE AMOUNTS)

	Preferred Stock		Common Stock		Additional Paid-In Capital	Deferred Compensation	Accumulated Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 1995	2,000,000	\$ 2	--	\$--	\$ 5,670	\$(345)	\$ (6,425)
Sale of preferred stock to Endosonics	400,000	--	--	--	8,000	--	--
Conversion of preferred stock	(2,400,000)	(2)	4,800,000	5	(3)	--	--
Exercise of common stock options	--	--	139,000	--	138	--	--
Initial public offering of Common Stock	--	--	3,910,000	4	42,764	--	--
Deferred compensation resulting from grant of options	--	--	--	--	150	(150)	--
Amortization of deferred compensation	--	--	--	--	--	119	--
Acquisition of Intraluminal Devices, Inc.	--	--	93,000	--	1,400	--	--
Conversion of \$750,000 debt by Fukuda Denshi	--	--	62,000	--	750	--	--
Net loss	--	--	--	--	--	--	(4,624)
Unrealized gain on investments	--	--	--	--	--	--	--
Balance of December 31, 1996	--	--	9,004,000	9	58,869	(376)	(11,049)
Exercise of common stock options	--	--	208,000	--	238	--	--
Employee stock purchase plan	--	--	33,000	--	266	--	--
SCIMED warrant exercise	--	--	120,000	--	377	--	--
Sale of common stock to Cathex	--	--	25,000	--	200	--	--
Expense repayment by Intraluminal Devices, Inc. by transfer and cancellation of common stock	--	--	(1,000)	--	(16)	--	--
Deferred compensation resulting from grant of options	--	--	--	--	437	(437)	--
Amortization of deferred compensation	--	--	--	--	--	179	--
Treasury common stock	--	--	--	--	--	--	--
Net loss	--	--	--	--	--	--	(8,772)
Unrealized gain on investments	--	--	--	--	--	--	--
Unrealized exchange rate loss	--	--	--	--	--	--	--
Balance at December 31, 1997	--	--	9,389,000	9	60,371	(634)	(19,821)
Exercise of common stock options	--	--	139,000	1	162	--	--
Employee stock purchase plan	--	--	50,000	--	180	--	--
Deferred compensation resulting from grant of options	--	--	--	--	159	(159)	--
Deferred compensation adjustment due to grant revaluation	--	--	--	--	(208)	208	--
Amortization of deferred compensation	--	--	--	--	--	176	--
Treasury shares purchased	--	--	--	--	--	--	--
Net loss	--	--	--	--	--	--	(7,986)
Unrealized gain on investments	--	--	--	--	--	--	--
Unrealized exchange rate gain	--	--	--	--	--	--	--
Balance at December 31, 1998	--	\$--	9,578,000	\$10	\$ 60,664	\$(409)	\$(27,807)

	Treasury		Accumulated Other Comprehensive Income	Total Stockholders' Equity (Net Capital Deficiency)	Comprehensive Income
	Shares	Amount			
Balance at December 31, 1995	--	\$ --	\$ --	\$(1,098)	
Sale of preferred stock to Endosonics	--	--	--	8,000	
Conversion of preferred stock	--	--	--	--	
Exercise of common stock options	--	--	--	138	
Initial public offering of common stock	--	--	--	42,768	
Deferred compensation resulting from grant of options	--	--	--	--	
Amortization of deferred compensation	--	--	--	119	
Acquisition of Intraluminal Devices, Inc.	--	--	--	1,400	
Conversion of \$750,000 debt by Fukuda Denshi	--	--	--	750	
Net loss	--	--	--	(4,624)	\$(4,624)
Unrealized gain on investments	--	--	170	170	170

Balance of December 31, 1996 ....	--	--	170	47,623	\$ (4,454)
Exercise of common stock options	--	--	--	238	=====
Employee stock purchase plan ....	--	--	--	266	
SCIMED warrant exercise .....	--	--	--	377	
Sale of common stock to Cathex ..	--	--	--	200	
Expense repayment by Intraluminal Devices, Inc. by transfer and cancellation of common stock ...	--	--	--	(16)	
Deferred compensation resulting from grant of options .....	--	--	--	--	
Amortization of deferred compensation .....	--	--	--	179	
Treasury common stock .....	345	(2,205)	--	(2,205)	
Net loss .....	--	--	--	(8,772)	\$ (8,772)
Unrealized gain on investments ..	--	--	6	6	6
Unrealized exchange rate loss ...	--	--	(23)	(23)	(23)
	----	-----	----	-----	-----
Balance at December 31, 1997 ....	345	(2,205)	\$153	37,873	\$ (8,789)
Exercise of common stock options	--	--	--	163	=====
Employee stock purchase plan ....	--	--	--	180	
Deferred compensation resulting from grant of options .....	--	--	--	--	
Deferred compensation adjustment due to grant revaluation .....	--	--	--	--	
Amortization of deferred compensation .....	--	--	--	176	
Treasury shares purchased .....	341	(1,470)	--	(1,470)	
Net loss .....	--	--	--	(7,986)	\$ (7,986)
Unrealized gain on investments ..	--	--	33	33	33
Unrealized exchange rate gain ...	--	--	276	276	276
	----	-----	----	-----	-----
Balance at December 31, 1998 ....	686	\$ (3,675)	\$462	\$29,245	\$ (7,677)
	====	=====	=====	=====	=====

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RADIANCE MEDICAL SYSTEMS, INC.  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
(IN THOUSANDS)

	YEAR ENDED DECEMBER 31,		
	1996	1997	1998
	-----	-----	-----
Operating activities:			
Net loss .....	\$ (4,624)	\$ (8,772)	\$ (7,986)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization .....	182	432	576
Amortization of deferred compensation .....	119	179	176
Bad debt expense .....	221	318	295
Charge for acquired in-process research and development .....	1,400	--	234
Minority interest in losses of Radiance .....	--	--	(992)
Changes (net of effects of acquisition of controlling interest in RMS):			
Trade accounts receivable, net .....	(1,372)	(2,767)	44
Inventories .....	(2,145)	10	1,582
Other assets .....	(671)	37	(125)
Accounts payable and accrued expenses .....	698	836	928
Deferred revenue .....	(50)	(79)	250
	-----	-----	-----
Net cash used in operating activities .....	(6,242)	(9,806)	(5,018)
Investing activities:			
Purchase of available-for-sale securities .....	(25,563)	(43,208)	(37,841)
Sales of available-for-sale securities .....	--	44,174	39,272
Capital expenditures for property and equipment .....	(940)	(699)	(431)
Net of cash acquired, purchase of controlling interest in Radiance .....	--	--	587
Net of cash acquired, purchase of Clinitec .....	--	(30)	--
Change in other assets .....	--	(358)	(625)

Net cash (used in) provided by investing activities .....	(26,503)	(121)	962
Financing activities:			
Proceeds from sale of common stock .....	42,768	466	180
Proceeds from exercise of stock warrants .....	--	377	--
Proceeds from exercise of stock options .....	138	238	163
Proceeds from sale of preferred stock to EndoSonics ...	8,000	--	--
Proceeds from repayment of affiliate debt .....	--	--	479
Purchase of treasury common stock .....	--	(2,205)	(1,470)
Payable to Endosonics, net .....	(2,537)	--	--
Net cash provided by (used in) financing activities .....	48,369	(1,124)	(648)
Net increase (decrease) in cash .....	15,624	(11,051)	(4,704)
Cash and cash equivalents, beginning of period .....	1,568	17,192	6,141
Cash and cash equivalents, end of period .....	\$ 17,192	\$ 6,141	\$ 1,437
	=====	=====	=====
Supplemental disclosure of non-cash financing activities:			
The Company exercised preferred stock warrants bringing its ownership of Radiance to approximately 50%. In conjunction with the assumption of control of Radiance, the following liabilities were assumed:			
Fair value of assets acquired .....	\$ --	\$ --	\$ 1,535
Cash paid to exercise preferred stock warrants ...	--	--	(1,463)
Liabilities assumed .....	\$ --	\$ --	\$ 72
	=====	=====	=====
The Company purchased all of the capital stock of Clinitec for \$30. In conjunction with the acquisition, the Company forgave \$1,630 in debt and assumed the following liabilities:			
Fair value of assets acquired .....	\$ --	\$ 401	\$ --
Cash paid for the capital stock .....	--	(30)	--
Liabilities assumed .....	\$ --	\$ 371	\$ --
	=====	=====	=====
Common stock issued upon the acquisition of Intraluminal Devices, Inc., Note 1 .....	\$ 1,400	\$ --	\$ --
Conversion of Debentures to Common Stock, Note 5 .....	750	--	--

See accompanying notes

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RADIANCE MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

1. BUSINESS, BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

BUSINESS AND BASIS OF PRESENTATION

Radiance Medical Systems, Inc. (formerly Cardiovascular Dynamics, Inc and herein after referred to the "Company" or "Radiance") was incorporated in March 1992 in the State of California. The Company and its subsidiaries design, develop, manufacture and market proprietary therapeutic catheters and stents used to treat certain vascular diseases. Accordingly, the Company operates in a single business segment.

The consolidated financial statements for December 31, 1996, 1997 and 1998 include the accounts of the Company and its subsidiaries. Intercompany transactions have been eliminated. To conform with the 1998 financial statement presentation, certain reclassifications have been made to the 1997 and 1996 financial statements.

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 reported amounts of assets and liabilities at the date of the

financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

#### CASH AND CASH EQUIVALENTS

Cash and cash equivalents includes cash on hand, demand deposits, and short-term investments with original maturities of three months or less.

#### MARKETABLE SECURITIES AVAILABLE-FOR-SALE

The Company accounts for its investments pursuant to Statement of Financial Accounting Standards No. 115, Accounting for Certain Investments in Debt and Equity Securities ("SFAS No. 115").

The Company has classified its entire investment portfolio as available-for-sale. Available-for-sale securities are stated at fair value with unrealized gains and losses included in stockholders' equity. The amortized cost of debt securities is adjusted for amortization of premiums and accretions of discounts to maturity. Such amortization is included in interest income. Realized gains and losses are included in other income (expense). The cost of securities sold is based on the specific identification method.

#### INVENTORIES

Inventories are comprised of raw materials, work-in-process and finished goods and are stated at the lower of cost, determined on an average cost basis, or market value.

#### PROPERTY AND EQUIPMENT

Property and equipment are stated at cost and depreciated or amortized on a straight-line basis over the lesser of the estimated useful lives of the assets or the lease term. The estimated useful lives range from three to seven years.

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#### RADIANCE MEDICAL SYSTEMS, INC.

##### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) (IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

#### ACCOUNTING FOR THE COSTS OF COMPUTER SOFTWARE DEVELOPED FOR OR OBTAINED FOR INTERNAL USE

In March 1998, the AICPA issued SOP 98-1, ACCOUNTING FOR THE COSTS OF COMPUTER SOFTWARE DEVELOPED FOR OR OBTAINED FOR INTERNAL USE ("SOP"). The Company intends to adopt the provisions of the SOP on January 1, 1999. The SOP requires the capitalization of certain costs incurred after the date of adoption in connection with developing or obtaining software for internal use. The Company currently expenses such costs, and it anticipates that the impact of the SOP will not be material on its results of operations or financial position for the foreseeable future as amounts expended to develop or obtain software have not been and are not expected to be material.

#### INTANGIBLE ASSETS

The excess of the purchase price over the net assets of the business acquired ("goodwill") and any other identifiable acquired intangible assets are amortized on the straight-line method over the estimated recovery period. The goodwill and other intangible assets stemming from the acquisition of Clinitec and purchase of a controlling interest in the (former) Radiance Medical Systems, Inc. ("RMS"), \$1.9 million and \$0.5 million, respectively, is being amortized over ten and three to seven years, respectively. Based upon an independent appraisal of intangible assets acquired in the purchase of a controlling interest in RMS, \$0.3 million was classified as developed technology and covenants not to compete and capitalized, and \$0.2 million as acquired in-process research and development and expensed.

#### LONG-LIVED ASSETS

Long-lived assets and certain identifiable intangibles to be held and used are

reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Long-lived assets expected to be disposed of are stated at the estimated fair value less the cost to sell.

CONCENTRATIONS OF CREDIT RISK AND SIGNIFICANT CUSTOMERS

The Company maintains its cash and cash equivalents in deposit accounts and in pooled investment accounts administered by a major financial institution.

The Company sells its products primarily to medical institutions and distributors worldwide. The Company performs on going credit evaluations of its customers' financial condition and generally does not require collateral from customers. Management believes that an adequate allowance for doubtful accounts has been provided.

During 1997 and 1998, product sales to Cathex, the Company's Japanese distributor, comprised 13% and 22%, respectively, of total revenues. Accounts receivable from Cathex represented 44% and 49% of net accounts receivable at December 31, 1997 and 1998, respectively. During 1996 product sales to Fukuda Denshi Co., Ltd., ("Fukuda"), the Company's former Japanese distributor (see Note 5), comprised 14% of total revenue.

Product sales to Medtronic, Inc. ("Medtronic") accounted for 21% and 13% of total revenues during 1996 and 1997, respectively.

In June of 1998, the Company signed a technology license agreement with Guidant Corporation ("Guidant"), an international interventional cardiology products company, to grant them the ability to manufacture and distribute

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RADIANCE MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)  
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

products using the Company's focus technology. During 1998, Radiance recognized license fees from Guidant of \$2.8 million, which represented 23% of total revenues. (See Note 6.)

EXPORT SALES

The Company had export sales by region as follows:

	YEAR ENDED DECEMBER 31,		
	1996	1997	1998
Europe.....	\$1,614	\$3,020	\$2,476
Japan.....	1,240	2,350	2,622
Other.....	660	1,209	789
	-----	-----	-----
	\$3,514	\$6,579	\$5,887
	=====	=====	=====

REVENUE RECOGNITION AND WARRANTY

The Company recognizes revenue from the sale of its products when the goods are shipped to its customers. Reserves are provided for anticipated product returns and warranty expenses at the time of shipment. License revenues are recognized on a contract with SCIMED Life Systems, Inc. ("SCIMED") when distribution rights to certain markets are made available to SCIMED for the sale of products based upon certain limited catheter technology. License revenues are recognized on a contract with Guidant Corporation based upon the achievement of milestones

involving the transfer of technology to Guidant and royalties based upon the sale of products using the Focus technology (See Note 6). Contract revenues are recognized on contracts with SCIMED and Advanced CardioVascular Systems, Inc. ("ACS") for transferring certain limited catheter technology based upon the Company's completion of (1) technical assistance to aid ACS and SCIMED in manufacturing the related products, and (2) research and development to develop the related products for SCIMED (See Note 3).

ACCOUNTING FOR STOCK-BASED COMPENSATION

The Company has elected to follow Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees ("APB 25") and related Interpretations in accounting for its employee stock options because, as discussed below, the alternative fair value accounting provided for under Statement of Financial Accounting

Standards No. 123, Accounting for Stock-Based Compensation ("SFAS No. 123"), requires use of option valuation models that were not developed for use in valuing employee stock options. Under the provisions of APB 25, the Company has not recognized compensation expense because the exercise price of the Company's employee stock options equals the market price of the underlying stock on the date of grant. Pro forma information regarding net income and earnings per share is required by SFAS No. 123, which also requires that the information be determined as if the Company has accounted for its employee stock options granted subsequent to December 31, 1994 under the fair value method of that Statement. The fair value for these options was estimated at the date of grant using the Black-Scholes option pricing model. The Black-Scholes 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 including the expected stock price volatility. 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

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RADIANCE MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)  
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

In calculating pro forma information regarding net income and net income per share the fair value was estimated at the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions for the options on the Company's Common Stock: risk-free interest rate of 6.0%, 5.5% and 5.7%; a dividend yield of 0%, 0% and 0%; volatility of the expected market price of the Company's common stock of 0.475, 0.692 and 0.696; and a weighted-average expected life of the options of 3.5, 5.0 and 5.0 years for 1996, 1997 and 1998, respectively.

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 for the years ended December 31, 1996, 1997 and 1998 follows:

	1996	1997	1998
	----	----	----
Pro forma net loss.....	\$ (5,170)	\$ (9,320)	\$ (9,135)
Pro forma basic and diluted net loss per share.....	\$ (0.77)	\$ (1.02)	\$ (1.03)

Because SFAS No. 123 is applicable only to options granted subsequent to December 31, 1994, its total pro forma effect was not fully reflected until 1997.

REPORTING COMPREHENSIVE INCOME

In 1998, the Company adopted Statement of Financial Accounting Standards No. 130, Reporting Comprehensive Income ("SFAS No. 130"). SFAS No. 130 establishes standards for reporting and displaying comprehensive income and its components with the same prominence as other financial statement information.

DISCLOSURES ABOUT SEGMENTS OF AN ENTERPRISE AND RELATED INFORMATION

For the year beginning January 1, 1998, the Company adopted Statement of Financial Accounting Standards No. 131, Disclosures about Segments of an Enterprise and Related Information ("SFAS No. 131"). SFAS No. 131 establishes standards for the way that public business enterprises report selected information about operating segments in annual and interim financial statements. Because the Company operates in one business segment and has no significant foreign operations, no additional reporting is required under SFAS No. 131.

INCOME TAXES

From June 1993 until June 1996, the Company's results of operations were included in consolidated tax returns filed by EndoSonics, its former parent. There was no income tax provision for the consolidated tax group during the periods covered by these financial statements. All net operating loss and credit carryforwards and deferred tax assets and liabilities have been disclosed herein on a separate company basis for Radiance.

NET LOSS PER SHARE

Net loss per common share is computed using the weighted average number of common shares outstanding during the periods presented. Options to purchase shares of the Company's common stock granted under the Company's

RADIANCE MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)  
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

stock option plan have been excluded from the calculation of diluted earnings per share as they are anti-dilutive. The following table sets forth the computation of basic and diluted net loss per share:

	YEARS ENDED DECEMBER 31,		
	1996	1997	1998
	-----	-----	-----
	(In thousands)		
NUMERATOR:			
Net loss .....	\$ (4,624)	\$ (8,772)	\$ (7,986)
	-----	-----	-----
Net loss used for basic and diluted loss per share--			
Loss attributable to common stockholders ..	\$ (4,624)	\$ (8,772)	\$ (7,986)
	=====	=====	=====
DENOMINATOR:			
Denominator for basic and diluted loss per share--			
Weighted average common shares outstanding	4,715	9,118	8,862
Assumed conversion of Preferred Stock from the date of issuance (Series A and B) .....	2,040	--	--
	-----	-----	-----
	6,755	9,118	8,862

	=====	=====	=====
Basic and diluted net loss per share .....	\$ (0.69)	\$ (0.96)	\$ (0.90)
	=====	=====	=====

## 2. ACQUISITIONS

On October 16, 1996, the Company acquired all of the outstanding shares of Intraluminal Devices, Inc. ("IDI") in exchange for approximately 93,000 shares of Radiance common stock valued at \$1,400. The acquisition was accounted for using the purchase method of accounting. As the assets of IDI were patents for products still in their development stage, the purchase price and the associated costs of acquisition, \$700, were expensed as acquired in-process research and development.

On July 29, 1997, the Company acquired all of the common stock of its independent distributor in Germany and Switzerland, Clinitec GmbH ("Clinitec"). The aggregate purchase price of the acquisition was \$1,630 million and consisted of cash of \$30 and the forgiveness of debt of \$1,600. The transaction was accounted for by the purchase method of accounting and, accordingly, the purchase price was allocated to the assets acquired and the liabilities assumed based on their fair market values at the date of acquisition. In connection with the acquisition, the Company acquired assets and assumed liabilities with fair market values of \$401 and \$652, respectively. The excess of the purchase price over the fair value of the net assets acquired of \$1,900 has been allocated to goodwill. The results of operations of Clinitec are included in the consolidated statement of operations subsequent to the date of acquisition.

RMS was incorporated by the Company in August 1997 to develop radiation products to treat restenosis based on RMS's patented focus delivery systems technology. In consideration for the granting by RMS of a license to this technology, RMS issued to the Company 750,000 shares of Series B Preferred Stock, a warrant to purchase 1,500,000 shares of Series B Preferred Stock, rights of first offer with respect to the commercialization of RMS's products, and a promise to receive royalties on sales of products based upon the licensed technology. Following the organization of RMS and its sale of common stock to investors in a private offering, Radiance did not control RMS and accounted for its investment at zero -- the book value of the assets transferred to RMS by Radiance. In September 1998, the Company exercised warrants to purchase an additional 1,500,000 Preferred Series B shares in RMS for \$0.975 per share or a total of \$1,500, bringing the Company's ownership of the outstanding equity of RMS to approximately 50%.

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### RADIANCE MEDICAL SYSTEMS, INC.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) (IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

In November 1998, the Company signed a definitive merger agreement with RMS and in January 1999, the Company acquired RMS pursuant to that Agreement. Under the terms of the Agreement, the Company paid the shareholders of RMS \$3.00 for each share of Preferred Stock and \$2.00 for each share of Common Stock for a total consideration of approximately \$7,000, excluding the value of Radiance common stock options to be provided to RMS optionholders in exchange for their RMS common stock options. Such consideration was paid by delivery of an aggregate of 1,900,157 shares of Common Stock, and \$700 million in cash to certain RMS stockholders who elected to receive cash pursuant to the definitive merger agreement. Options for 546,250 shares of RMS common stock accelerated and vested immediately prior to the completion of the Merger. Of these, 1,250 were exercised, and the holder received the same consideration for their shares of RMS Common Stock as other holders of RMS Common Stock. The options not exercised prior to the completion of the Merger were assumed by the Company and converted into options at the same exercise price to purchase an aggregate of 317,775 share of the Company's Common Stock.

In addition, RMS share and option holders may receive product development milestone payments of \$2.00 for each share of RMS Preferred Stock and \$3.00 for each share of RMS Common Stock. The development milestone payments may be increased up to 30%, or reduced or eliminated if the milestones are reached

earlier or later, respectively, than the milestone target dates. The milestones represent important steps in the United States Food and Drug Administration and European approval process, which the Company has determined are critical to bringing the RMS technology to the marketplace.

The following table reflects unaudited pro forma combined results of operations of the Company, IDI, Clinitec and RMS on the basis that the acquisitions, or purchase of a controlling interest in the case of Radiance, had taken place and the related charge for IDI, noted above, was recorded at the beginning of 1996 for IDI and Clinitec, as IDI operations were not material to the Company's operations prior to 1996, and at the inception of RMS in August 1997.

	1996 -----	1997 -----	1998 -----
Revenues.....	\$ 8,822	\$11,633	\$12,175
Net Loss.....	(5,060)	(9,589)	(8,511)
Net Loss per common share.....	(0.75)	(1.05)	(0.96)
Shares used in computation.....	6,755	9,118	8,862

In management's opinion, the unaudited pro forma combined results of operations are not indicative of the actual results that would have occurred had the acquisitions been consummated at the beginning of 1996, 1997 or 1998, respectively, or of future operations of the combined companies under the ownership and management of the Company.

### 3. SCIMED LIFE SYSTEMS, INC.

In September 1994, the Company and EndoSonics entered into a Stock Purchase and Technology License Agreement with SCIMED Life Systems, Inc. ("SCIMED"). SCIMED acquired a 19% interest in Radiance in exchange for \$2,500 in cash. Radiance also granted SCIMED an exclusive license to certain patents in the cardiovascular field of use, which allows SCIMED to manufacture the Transport PTCA infusion catheter (the "Transport") developed by Radiance in exchange for a \$1,000 license fee that was paid in 1994. SCIMED will pay royalties to Radiance on

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### RADIANCE MEDICAL SYSTEMS, INC.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED) (IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

sales of the Transport and other products which use this patented technology. Radiance retains rights to this technology and the associated patents for use outside of the cardiovascular field.

During June 1995, the Company issued a warrant to SCIMED to purchase up to 80,000 shares of Series A Preferred Stock at an exercise price of \$3.29 per share in exchange for a waiver of SCIMED's anti-dilution right.

During May 1996, the Company agreed to issue an additional warrant to SCIMED to purchase up to 40,000 shares of Series A Preferred Stock at an exercise price of \$3.29 per share in exchange for a waiver of SCIMED's anti-dilution right related to the shares to be issued under the 1996 Plan. In August 1997, SCIMED exercised all 120,000 warrants, mentioned above.

SCIMED also paid Radiance \$200 in 1996, on a cost reimbursement basis to fund continuing development of the technology and for other support.

### 4. RELATED PARTY TRANSACTIONS

Prior to the Company's initial public offering in June 1996, certain corporate expenses, primarily related to executive management time, accounting, cash management, and other administrative and engineering services, have been allocated to the Company by its former parent, EndoSonics. Total expenses

allocated were \$156 for the year ended December 31, 1996.

#### 5. AGREEMENTS WITH FUKUDA AND CATHEX

The Company entered into a distribution agreement, dated May 1, 1997, with Cathex, Ltd. (The "Cathex Agreement"), whereby Cathex was appointed to serve as Radiance's exclusive distributor for certain of the Company's products in Japan. In exchange for this exclusive distributorship, Cathex shareholders agreed to purchase \$200 in Radiance common stock or approximately 25,000 shares. Cathex also agreed to undertake all necessary clinical trails to obtain approval from Japanese regulator authorities for the sale of the products in Japan. Cathex's purchases under the Cathex Agreement are subject to certain minimum requirements. The initial term of the Cathex Agreement expires on January 1, 2001, subject to a five-year extension. The Cathex Agreement may also be terminated in the event of breach upon 90 days notice by the non-breaching party, subject to cure within the notice period.

The Company previously had a distribution agreement with Fukuda. The agreement provided Fukuda with exclusive distribution rights relative to certain of the Company's products in Japan for periods extending through May 1999. Distribution fee revenues received from Fukuda were deferred and were being recognized as revenue over the initial periods covered by the respective agreement. In July 1995 and May 1996, the distribution agreement with Fukuda was amended. In exchange for the exclusive distribution rights to additional Company products, the Company received \$750 which converted into the right to receive 62,500 shares of Common Stock upon the consummation of the initial public offering. In November, 1996, Fukuda exercised the conversion feature of said obligation. In May 1997, the Company terminated the existing distribution agreement.

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#### RADIANCE MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)  
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

#### 6. LICENSE AGREEMENTS

##### ADVANCED CARDIOVASCULAR SYSTEMS, INC.

In January 1995 the Company entered into a license agreement with Advanced CardioVascular Systems, Inc. ("ACS"), a subsidiary of Guidant Corporation, under which ACS was obligated to make milestone and minimum royalty payments to Radiance. An initial milestone of \$150 was earned in the year ended December 31, 1996. In February 1997, ACS elected to terminate the agreement.

##### ENDOSONICS CORPORATION

The Company entered into a license agreement with EndoSonics pursuant to which the Company granted EndoSonics the non-exclusive, royalty-free right to certain technology for use in the development and sale of certain products. In exchange, Radiance received the non-exclusive, royalty-free right to utilize certain of EndoSonics' product regulatory filings to obtain regulatory approval of Radiance products.

##### GUIDANT CORPORATION

In June of 1998, the Company signed a technology license agreement with Guidant Corporation ("Guidant") to grant Guidant the ability to manufacture and distribute stent delivery products using the Company's focus technology. Under the Agreement, the Company is entitled to receive certain milestone payments based upon the transfer of the technology to Guidant, and royalty payments based upon the sale of products using the focus technology. An initial license payment of \$2,000 was received by the Company upon the signing of the Agreement. In October of 1998, the Company received another \$1,000 license milestone payment upon the completion of the technology transfer to Guidant. Based upon the completion of certain initial technology transfer milestones, the Company recognized \$1,200 and \$1,600 in license revenue in the third quarter and first nine months of 1998, respectively, and will recognize the remaining \$250 of deferred license revenue as remaining milestones are met.

7. MARKETABLE SECURITIES AVAILABLE-FOR-SALE

The Company's investments in debt securities are diversified among high credit quality securities in accordance with the Company's investment policy. The Company's investment portfolio is managed by a major financial institution. The following is a summary of investments in debt securities at December 31, 1997 and 1998.

	DECEMBER 31, 1997			DECEMBER 31, 1998		
	Cost	Gross Unrealized Holding Gains (Losses)	Fair Value	Cost	Gross Unrealized Holding Gains	Fair Value
U.S. Treasury and other agencies debt securities .....	\$ 4,976	\$ 30	\$ 5,006	\$ 5,928	\$ 33	\$ 5,961
Corporate debt securities .....	17,605	150	17,755	14,239	169	14,408
Foreign government debt securities .	2,016	(4)	2,012	2,999	7	3,006
	<u>\$ 24,597</u>	<u>\$ 176</u>	<u>\$ 24,773</u>	<u>\$ 23,166</u>	<u>\$ 209</u>	<u>\$ 23,375</u>

All debt securities mature within one year with the exception of debt securities with a cost and fair value totaling \$2.0 million and \$3.5 million at December 31, 1997 and 1998, respectively, which mature within two years.

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RADIANCE MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)  
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

8. INVENTORIES

Inventories are stated at the lower of cost, determined on an average cost basis, or market value. Inventories consisted of the following:

	DECEMBER 31,	
	1997	1998
Raw materials.....	\$ 1,285	\$ 630
Work in process.....	165	87
Finished goods.....	1,755	906
	<u>\$ 3,205</u>	<u>\$ 1,623</u>

9. INTANGIBLES

Intangibles consisted of the following:

DECEMBER 31,	
1997	1998
-----	-----

Goodwill .....	\$1,809	\$1,746
Developed research and development and other intangible assets .....	--	243
Product license .....	169	144
	-----	-----
	\$1,978	\$2,133
	=====	=====

10. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	DECEMBER 31,	
	1997	1998
	-----	-----
Accounts payable .....	\$1,374	\$1,281
Accrued payroll and related expenses .....	1,317	1,287
Accrued clinical studies ...	548	979
Accrued office closing costs	--	225
Other accrued expenses .....	249	514
	-----	-----
	\$3,488	\$4,286
	=====	=====

11. COMMITMENTS AND CONTINGENCIES

OPERATING LEASES

The Company leases its administrative, research and manufacturing facilities and certain equipment under long-term, noncancellable lease agreements that have been accounted for as operating leases. Certain of these leases include scheduled rent increases and renewal options as prescribed by the agreements.

Future minimum payments by year under long-term, noncancellable operating leases were as follows as of December 31, 1998:

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RADIANCE MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)  
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

1999.....	\$ 468
2000.....	442
2001.....	150
2002.....	47
2003.....	15
	-----
	\$1,122
	=====

Rental expense charged to operations for all operating leases during the years ended December 31, 1996, 1997 and 1998, was approximately \$365, \$574 and \$639, respectively.

12. SHAREHOLDERS EQUITY

PREFERRED STOCK

In March 1996, the Company issued 400,000 shares of Series B Preferred Stock to EndoSonics at \$20.00 per share for aggregate proceeds of \$8,000.

The preferred stockholders converted their shares to common shares upon the consummation of the Company's initial public offering.

STOCK SPLIT

In 1996, the Board of Directors of the Company approved a 2-for-1 Common Stock split which has been reflected retroactively for all periods in the accompanying financial statements.

SALE OF COMMON STOCK

On June 25, 1996, the Company closed its initial public offering (the "Offering") which consisted of 3,400,000 shares of Common Stock at \$12.00 per share. On July 17, 1996, the Company's underwriters exercised their overallotment option to purchase an additional 510,000 shares of Common Stock at \$12.00 per share. The Company received net offering proceeds from the sale of Common Stock of approximately \$42.8 million after deducting underwriting discounts and commissions and other expenses of the Offering.

STOCK OPTION PLAN

In May 1996, the Company adopted the 1996 Stock Option/Stock Issuance Plan (the "1996 Plan") which is the successor to the Company's 1995 Stock Option Plan. In September 1997, the Company adopted the 1997 Supplemental Stock Option Plan (the "1997 Plan"). Under the terms of the 1996 and 1997 Plans, eligible key employees, directors, and consultants can receive options to purchase shares of the Company's Common Stock at a price not less than 100% for incentive stock options and 85% for nonqualified stock options of the fair value on the date of grant, a determined by the Board of Directors. At December 31, 1998 the Company had authorized 2,100,000 and 90,000 shares of Common Stock for issuance under the 1996 and 1997 Plan, respectively. In January 1999, the Company authorized an additional 750,000 shares of Common Stock for issuance under the 1996 Plan. At December 31, 1998, the Company had 152,000 shares and 39,000 shares of Common Stock available for grant under the 1996 and 1997 Plan, respectively. The options granted under the Plans are exercisable over a maximum term of ten years from the date of grant and generally vest over a four year period. Shares underlying the exercise of unvested options are subject to various restrictions as to resale and right of repurchase by the Company which lapses over the vesting period. The activity under both plans is summarized below:

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RADIANCE MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)  
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

	OPTION PRICE PER SHARE	NUMBER OF SHARES
	-----	-----
Balance at December 31, 1995..	\$ 1.00 to \$ 1.50	956,000
Granted.....	\$ 2.50 to \$13.25	346,000
Exercised.....	\$ 1.00 to \$ 1.50	(138,600)
Forfeited.....	\$ 1.00 to \$13.25	(18,875)
Cancelled.....	--	--
	-----	-----
Balance at December 31, 1996..	\$ 1.00 to \$13.25	1,144,525
Granted.....	\$ 5.00 to \$ 9.50	1,000,000
Exercised.....	\$ 1.00 to \$ 2.50	(208,259)
Forfeited.....	\$ 1.00 to \$13.25	(204,229)

Cancelled.....		\$ 6.87	(130,000)
Balance at December 31, 1997..	\$ 1.00 to \$13.25		1,602,037
Granted.....	\$ 3.25 to \$ 6.44		665,100
Exercised.....	\$ 1.00 to \$ 2.50		(138,965)
Forfeited.....	\$ 1.00 to \$ 9.50		(614,794)
Cancelled.....	--		--
Balance at December 31, 1998..	\$ 1.00 to \$12.00		1,513,378

The Board of Directors approved repricing of the following options:

Date Repricing Approved	Option Grant Date	Original Grant Price	New Grant Price
April 21, 1997	August 5, 1996	\$13.25	\$6.88
	November 4, 1996	12.50	6.88
April 7, 1998	January 13, 1997	9.50	4.94
	September 19, 1997	7.31	4.94
December 14, 1998	April 21, 1997	6.88	3.63
	May 20, 1998	6.00	3.63
	May 26, 1998	5.88	3.63
	June 10, 1998	6.44	3.63

As a result of the repricing, the vesting period on the aforementioned options started anew.

The following table summarizes information regarding stock options outstanding at December 31, 1998:

RANGE OF EXERCISE PRICES	OPTIONS OUTSTANDING AT 12/31/98	WEIGHTED- AVERAGE REMAINING CONTRACTUAL LIFE	WEIGHTED AVERAGE EXERCISE PRICE	OPTIONS EXERCISABLE AT 12/31/98	WEIGHTED- AVERAGE EXERCISE PRICE
\$1.00 - \$ 1.50	358,216	6.6	\$1.28	282,049	\$1.23
2.50 - 5.63	983,662	9.0	4.05	65,074	4.10
7.31 - 12.00	171,500	8.6	7.91	19,844	9.41
1.00 - 12.00	1,513,378	8.4	3.84	366,967	2.18

The weighted-average grant-date fair value of options granted during 1996, 1997 and 1998, for options where the exercise price on the date of grant was equal to the stock price on that date, was \$5.12, \$4.50 and \$2.99,

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RADIANCE MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)  
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

respectively. The weighted-average grant-date fair value of options granted during 1996, 1997 and 1998, for options where the exercise price on the date of grant was less than the stock price on that date, was \$3.16, \$0, and \$0, respectively.

During 1996, the Company recorded deferred compensation of approximately \$150 for financial reporting purposes to reflect the difference between the exercise

price of certain options and the deemed fair value, for financial statement presentation purposes, of the Company's shares of Common Stock. An additional \$437 and \$159 of deferred compensation was recorded to recognize compensation for non-employee option grants during the years ended December 31, 1997 and 1998, respectively. Deferred compensation is being amortized over the vesting period of the related options. \$119, \$179 and \$176 of deferred compensation was amortized in the years ended December 31, 1996, 1997 and 1998, respectively.

STOCK PURCHASE PLAN

Under the terms of the Company's 1996 Employee Stock Purchase Plan (the "Purchase Plan"), eligible employees can purchase Common Stock through payroll deductions at a price equal to the lower of 85% of the fair market value of the Company's Common Stock at the beginning or end of the applicable offering period. A total of 200,000 shares of Common Stock are reserved for issuance under the Purchase Plan. During 1998, a total of approximately 50,000 shares, of Common Stock was purchased at an average price of \$3.61 per share.

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RADIANCE MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)  
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

13. INCOME TAXES

Significant components of the Company's deferred tax assets are as follows at December 31:

	1997	1998
	-----	-----
Net operating loss carryforward ....	\$ 3,959	\$ 5,473
Accrued expenses .....	405	572
Tax credits .....	812	953
Bad debt reserve .....	205	236
Depreciation .....	(56)	(85)
Amortization .....	--	58
Inventory write-downs .....	451	749
Capitalized research and development	642	963
Deferred revenue .....	--	100
Deferred Compensation amortization .	--	215
Other .....	191	249
	-----	-----
Gross deferred tax assets .....	6,609	9,483
Valuation allowance .....	(6,609)	(9,483)
	-----	-----
Net deferred tax assets .....	\$ --	\$ --
	=====	=====

The valuation allowance increased by \$2,874 and \$3,150 in 1998 and 1997, respectively.

The Company's effective tax rate differs from the statutory rate of 35% due to federal and state losses which were recorded without tax benefit.

At December 31, 1998, the Company has net operating loss carryforwards for federal and state income tax purposes of approximately \$15,700 and \$406, respectively, which expire in the years 2000 through 2018. In addition, the Company has research and development tax credits for federal and state income tax purposes of approximately \$522, and \$431, respectively, which expire in the years 2011 through 2013.

Because of the "change of ownership" provision of the Tax Reform Act of 1986, utilization of the Company's net operating loss and research credit carryforwards may be subject to an annual limitation against taxable income in

future periods. As a result of the annual limitation, a portion of these carryforwards may expire before ultimately becoming available to reduce future income tax liabilities.

The results of operations includes the net loss of the Company's wholly-owned German subsidiary of \$1,029.

14. EMPLOYEE BENEFIT PLAN

The Company provides a 401(k) Plan for all employees 21 years of age or older with over 3 months of service. Under the 401(k) Plan, eligible employees voluntarily contribute to the Plan up to 15% of their salary through payroll deductions. Employer contributions may be made by the Company at its discretion based upon matching employee contributions, within limits, and profit sharing provided for in the Plan. No employer contributions were made in 1997 and 1998.

15. SUBSEQUENT AND SIGNIFICANT EVENTS

In October 1998, the Company signed a letter of intent to sell substantially all of the properties and assets used exclusively in its Vascular Access Business Unit to Escalon Medical Corporation and in January 1999 the sale was completed under a definitive Sale and Purchase Agreement ("Agreement"). Under the terms of the Agreement, the Company received an initial payment of \$1,100. This payment represented a \$1,000 consideration payment increased by the excess of the actual inventory transferred of \$700 over the contractual estimate of \$600

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RADIANCE MEDICAL SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)  
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

The Company may also receive up to an additional \$1,000 upon the completion of the transfer of the assets and technology, and royalty payments upon the sale of products for a five-year period. The Company will recognize such additional payments as income when it is probable they will be received. In addition, the Company will continue to manufacture certain products for up to 180 days following the Agreement date.

The following table sets forth the Vascular Access operating profits for the periods indicated:

	Year Ended December 31,		
	1996	1997	1998
Revenues.....	\$ 1,810	\$ 2,419	\$ 2,664
Operating costs and expenses:			
Costs of sales.....	1,201	937	1,342
Research and development.....	44	392	480
Marketing and sales.....	248	506	556
General and administrative.....	109	465	671
Total operating costs and expenses.....	1,602	2,300	3,049
	\$ 208	\$ 119	\$ (385)

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RADIANCE MEDICAL SYSTEMS, INC.

SCHEDULE II - VALUATION AND QUALIFYING ACCOUNTS

YEARS ENDED DECEMBER 31, 1998, 1997, AND 1996  
(IN THOUSANDS)

COLUMN A ----- DESCRIPTION -----	COLUMN B ----- BALANCE AT BEGINNING OF PERIOD -----	COLUMN C ----- ADDITIONS ----- CHARGES TO COSTS AND EXPENSES -----		COLUMN D ----- DEDUCTIONS -----	COLUMN E ----- BALANCE AT END OF PERIOD -----
Year ended December 31, 1998					
Allowance for doubtful accounts	\$ 500	\$ 295	\$ --	\$ (212)	\$ 583
Reserve for excess and obsolete inventories .....	\$ 1,100	\$ 1,274	\$ --	\$ (518)	\$ 1,856
Year ended December 31, 1997					
Allowance for doubtful accounts	\$ 377	\$ 318	\$ --	\$ (195)	\$ 500
Accrued warranty expenses .....	\$ 29	\$ --	\$ --	\$ (29)	\$ --
Reserve for excess and obsolete inventories .....	\$ 145	\$ 955	\$ --	\$ --	\$ 1,100
Year ended December 31, 1996					
Allowance for doubtful accounts	\$ 180	\$ 221	\$ --	\$ (24)	\$ 377
Accrued warranty expenses .....	\$ 113	\$ --	\$ --	\$ (84)	\$ 29
Reserve for excess and obsolete inventories .....	\$ 209	\$ --	\$ --	\$ (64)	\$ 145

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EXHIBIT INDEX

EXHIBIT NUMBER -----	DESCRIPTION -----	SEQUENTIALLY NUMBERED PAGE -----
2.1(3)	Agreement and Plan of Reorganization dated as of June 9, 1993 among Endosonics Corporation ("Endosonics"), Endosonics Acquisition Corporation and the Company.	
2.2(3)	First Amendment dated as of June 30, 1993 to the Agreement and Plan of Reorganization among Endosonics, Endosonics Acquisition Corporation and the Company.	
2.4(12)	Agreement and Plan of Merger dated November 3, 1998 by and between CardioVascular Dynamics, Inc. and Radiance Medical Systems, Inc.	
2.5(13)	Assets Sale and Purchase Agreement dated January 21, 1999 by and between the Company and Escalon Medical Corp.	
3.1(10)	Amended and Restated Certificate of Incorporation, and Certificates of Amendment thereof dated January 14, 1999 and November 12, 1998.	
3.2(11)	Amended and Restated Bylaws of the Company.	
4.1(1)	Specimen Certificate of Common Stock.	
10.1(3)	Form of Indemnification Agreement entered into between the Registrant and its directors and officers.	
10.2(3)**	The Registrant's 1996 Stock Option Plan and forms of agreements thereunder.	

- 10.3(3)\*\* The Registrant's Employee Stock Purchase Plan and forms of agreement thereunder.
- 10.4(3) Series A Supplemental Stock Purchase Agreement dated June 5, 1992, by and between the Company and Radiance.
- 10.5(3) Stock Purchase Option Agreement dated June 5, 1992, by and between Endosonics and the Company.
- 10.7(3)\* Stock Purchase and Technology License Agreement dated September 10, 1994, as amended on September 29, 1995, by and among Endosonics, the Company and SCIMED Life Systems, Inc. ("SCIMED").
- 10.8(3) Waiver and Grant of Warrant dated June 30, 1995 by and between SCIMED, the Company and Endosonics.
- 10.9(3)\* License Agreement dated January 15, 1995 by and between the Company and Advanced Cardiovascular Systems, Inc. ("ACS").
- 10.10(3)\* License Agreement dated March 4, 1996 by and between the Company and ACS.
- 10.11(3) Series B Stock Purchase Agreement dated March 29, 1996 by and between the Company and Endosonics.

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EXHIBIT INDEX (Continued)

EXHIBIT NUMBER -----	DESCRIPTION -----	SEQUENTIALLY NUMBERED PAGE -----
10.15(3)	Industrial Lease dated February 23, 1995 by and between the Irvine Company and the Company.	
10.16(1)	Waiver and Grant of Warrant dated May 2, 1996 by and between SCIMED, the Company and Endosonics.	
10.18(4)*	Supply Agreement dated July 15, 1996 by and between the Company and Medtronic, Inc.	
10.19(4)*	OEM Agreement dated July 15, 1996 by and between the Company and Medtronic, Inc.	
10.20(6)	License Agreement dated May 16, 1997, by and between the Company and Endosonics.	
10.21(6)	Registration Rights Agreement dated as of January 26, 1997 by and between the Company and Endosonics.	
10.22(7)**	Supplemental Stock Option Plan	
10.23(8)	Stock Repurchase Agreement dated as of February 10, 1998 by and between Endosonics and the Company.	
10.24(9)*	License Agreement by and between the Company and Guidant Corporation dated June 19, 1998.	
10.25(14)**	1996 Stock Option/Stock Issuance Plan (as Amended and Restated as of April 8, 1997, March 12, 1998 and November 3, 1998).	
10.26(15)**	1997 Stock Option Plan (As Amended as of June 15, 1998) assumed by Registrant pursuant to its acquisition of Radiance Medical Systems, Inc. on January 14, 1999.	
10.27**	+ Amendment to Employment Agreement dated as of February 1, 1999 between the Company and Michael R. Henson and form of Employment Agreement entered into on January 14, 1999 between the Company and Michael R. Henson.	
10.28**	+ Employment Agreement entered into as of February 1, 1999 by and between the Company and Stephen R. Kroll.	
10.29**	+ Form of Employment Agreement by and between the Company and	

EXHIBIT NUMBER -----	DESCRIPTION -----	SEQUENTIALLY NUMBERED PAGE -----
10.30**	+ Form of Employment Agreement by and between the Company and Claire Walker.	
21.1	+ List of Subsidiaries.	
23.1	Consent of Ernst & Young LLP, Independent Auditors.	
24.1	Power of Attorney. (Reference is made to page 39 of this Annual Report on Form 10-K.)	
27.1	Financial Data Schedule.	

\* Confidential treatment requested.

\*\* Indicates compensatory plan or arrangement.

+ Filed herewith.

- (1) Previously filed as an exhibit to Amendment No. 2 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on June 10, 1996.
- (2) Previously filed as an exhibit to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on May 17, 1996.
- (3) Previously filed as an exhibit to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on May 3, 1996.
- (4) Previously filed as an exhibit to the Company's report on Form 10-Q filed with the Securities and Exchange Commission on August 14, 1996.
- (5) Previously filed as an exhibit to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on November 12, 1996.
- (6) Previously filed as an exhibit to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on June 19, 1997.
- (7) Previously filed as an exhibit to the Company's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on December 12, 1997.
- (8) Previously filed as Exhibit 10 to the Company's Report on Form 10-Q filed with the Securities and Exchange Commission as of May 14, 1998.
- (9) Previously filed as Exhibit 10.24 to the Company's Report on Form 10-Q filed with the Securities and Exchange Commission as of August 11, 1998.
- (10) Previously filed as Exhibit 3.5 to the Company's Report on Form 8-K filed with the Securities and Exchange Commission as of January 22, 1999.
- (11) Previously filed as Exhibit 3.4 to the Company's Report on Form 8-K filed with the Securities and Exchange Commission as of

January 22, 1999.

- (12) Previously filed as Exhibit 2.4 to the Company's Report on Form 8-K filed with the Securities and Exchange Commission as of November 12, 1998.

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- (13) Previously filed as Exhibit 2 to the Company's Report on Form 8-K filed with the Securities and Exchange Commission as of February 5, 1999.
- (14) Previously filed as Annex III to the Company's Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on December 18, 1998.
- (15) Previously filed as Exhibit 99.2 to the Company's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on February 17, 1999.

## EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the "Agreement") is made and entered into as of \_\_\_\_\_, \_\_\_\_\_ by and between CARDIOVASCULAR DYNAMICS, INC., a Delaware corporation (the "Company"), and Michael R. Henson, an individual (the "Executive").

## R E C I T A L

The Company desires to employ Executive in the capacity hereinafter stated, and the Executive desires to enter into the employ of the Company in that capacity pursuant to the terms and conditions set forth herein.

## A G R E E M E N T

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements set forth herein, the Company and the Executive, intending to be legally bound, hereby agree as follows:

1. Employment. The Company hereby agrees to employ the Executive as the Chairman of the Board of Directors of the Company, effective as of \_\_\_\_\_, 1999, and as the President and Chief Executive Officer of the Company effective \_\_\_\_\_, 1999, and the Executive accepts such employment and agrees to devote substantially all his business time and efforts and skills on such reasonable duties as shall be assigned to him by the Company commensurate with such position.

2. Term. The initial term of the Executive's employment hereunder shall commence \_\_\_\_\_, \_\_\_\_\_, ("Effective Date") and shall be for a period of two (2) years, and shall automatically extend for successive one year periods following the initial term unless either party delivers written notice to the other no later than sixty (60) days prior to the end of the second anniversary of the Effective Date or any successive anniversary of the Effective Date, as the case may be, of intent not to renew. Executive's employment is subject to earlier termination as hereafter specified.

## 3. Position and Duties.

3.1 Service with the Company. During the term of this Agreement, the Executive agrees to perform such reasonable duties and on such basis as shall be assigned to him from time to time by the Board of Directors (the "Board of Directors"); such duties, however, to be commensurate with the Executive's position as Chairman, President and Chief Executive Officer of the Company. In particular, and without limitation, such duties shall include:

- (a) developing strategic policies for the Company,
- (b) coordinating the Board of Directors activities and the various committees of the Board of Directors, including but not limited to the Audit Committee and the Compensation Committee,
- (c) participating as the Chairman and member of the Coronary Radiation Management Committee, and
- (d) managing projects as requested by the Company's Board of Directors.

3.2 No Conflicting Duties. Except as provided in Exhibit A hereto, during the term hereof, the Executive shall not serve as an officer, director, employee, consultant or advisor to any other business; provided, however, that the Executive may serve as a director of another corporation so long as (i) such corporation does not compete, directly or indirectly, with the Company or any of its Affiliates for such products as defined as "Competitive Products" in Exhibit B attached to this Agreement, and (ii) such services do not adversely affect Executive's ability to perform his duties under this Agreement, unless such

other service is approved by the Board of Directors of the Company. For purposes of this Agreement, the term "Affiliate" means any corporation, association or other business entity of which more than 50% of the total voting power of shares of stock entitled to vote in the election of directors, managers or trustees thereof is at the time owned or controlled by the Company. Notwithstanding the foregoing, nothing contained herein shall prevent Executive from making and expending any time of passive personal investments and/or expending reasonable amounts of time for educational and charitable activities. Except as provided in Exhibit A hereto, the Executive confirms that he is under no contractual commitment inconsistent with his obligations set forth in this Agreement.

#### 4. Compensation.

4.1 Base Salary. As compensation for all services to be rendered by the Executive under this Agreement, the Company shall pay to the Executive a base salary of \$264,000 ("Base Salary"), which shall be paid on a regular basis in accordance with the Company's normal payroll procedures and policies. The amount of the Base Salary shall be reviewed by the Compensation Committee of the Board of Directors, which may annually increase Executive's Base Salary in amounts consistent with industry practices as determined in its sole discretion. Executive's performance, the performance of the Company and such other factors as the Board of Directors deem appropriate shall also be considered.

4.2 Incentive Compensation Plans. In addition to the Base Salary, Executive shall be eligible to participate in management incentive compensation plans approved by the Company's Board of Directors, such participation to be on terms similar to those afforded to other management employees holding positions with the Company. In addition to the Base Salary, the Executive shall be entitled to earn up to thirty-five percent (35%) of his Base Salary as incentive compensation. All amounts to which the Executive may be entitled under any incentive compensation plans shall be subject to the provisions, rules and regulations of any such plan which apply to other management employees.

4.3 Participation in Benefit Plans. During the term of this Agreement, Executive shall be entitled to participate in all employee benefit plans, profit-sharing, stock options, vacation and other perquisite plans and programs for which key employees of the Company are generally eligible. The Executive's participation in any such plan or program shall be subject to the provisions, rules and regulations thereof that are generally available to all participants thereon, provided, however, in no event shall Executive's benefits be less than the benefits described in Exhibit C.

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4.4 Expenses. In accordance with the Company's policies established from time to time, the Company will pay or reimburse the Executive for all reasonable and necessary out-of-pocket expenses incurred by him in the performance of his duties under this Agreement, provided that Executive submits appropriate vouchers and expense reports substantiating the amount thereof and the business purposes for which such expenses were incurred.

#### 5. Termination.

5.1 Termination by the Company for Cause. Any of the following acts or omissions shall constitute grounds for the Company to terminate the Executive's employment pursuant to this Agreement for "cause":

(a) Willful misconduct by Executive causing material harm to the Company but only if Executive shall not have discontinued such misconduct within 30 days after receiving written notice from the Company describing the misconduct and stating that the Company will consider the continuation of such misconduct as cause for termination of this Agreement.

(b) Any material act or omission by the Executive involving gross negligence in the performance of the Executive's duties to, or material deviation from any of the policies or directives of, the Company, other than a deviation taken in good faith by the Executive for the benefit of the Company;

(c) Any illegal act by the Executive which materially and adversely affects the business of the Company or any felony committed by Executive, as evidenced by conviction thereof, provided that the Company may suspend the Executive with pay while any allegation of such illegal or felonious act is investigated.

Termination by the Company for cause shall be accomplished by written notice to the Executive and shall be preceded by a written notice providing a reasonable opportunity for the Executive to correct his conduct.

5.2 Termination for Death or Disability. In addition to termination for cause pursuant to Section 5.1 hereof, the Executive's employment pursuant to this Agreement shall be immediately terminated without notice by the Company (i) upon the death of the Executive or (ii) upon the Executive becoming totally disabled. For purposes of this Agreement, the term "totally disabled" means an inability of Executive, due to a physical or mental illness, injury or impairment, to perform a substantial portion of his duties for a period of one hundred eighty (180) or more consecutive days, as determined by a competent physician selected by the Company's Board of Directors and reasonably agreed to by the Executive, following such one hundred eighty (180) day period.

5.3 Termination for Good Reason. Executive's employment pursuant to this Agreement may be terminated by the Executive for "good reason" if the Executive voluntarily terminates his employment as a result of any of the following:

(a) Without the Executive's prior written consent, a reduction in his then current Base Salary;

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(b) Without Executive's prior written consent, a relocation of the Executive's place of employment outside of Orange County, California;

(c) Resignation as a result of unlawful discrimination, as evidenced by a final court order;

(d) A reduction in duties and responsibilities which results in the Executive no longer having duties customary for a Chairman, President and Chief Executive Officer; or

(e) The Company materially breaches any provision of this Agreement.

5.4 Termination Without Cause. The Company may terminate this Agreement, and the employment of the Executive under this Agreement, without cause at any time upon at least thirty (30) days prior written notice to the Executive.

5.5 Payments Upon Removal or Termination. If during the term of this Agreement, the Executive resigns for one of the reasons stated in Section 5.3, or the Company terminates the Executive's service, except as provided in Sections 5.1 or 5.2 hereof, the Executive shall be entitled to the following compensation: (i) the portion of his then current Base Salary which has accrued through his date of termination, (ii) any payments for unused vacation and reimbursement expenses, which are due, accrued or payable at the date of Executive's termination, (iii) severance payment in an amount (the "Severance Amount") equal to Executive's then-current Base Salary, payable for the remainder of the Term; and (iv) all of Executive's options to purchase shares of the Company's common stock and restricted stock shall accelerate and automatically vest by one additional year, and such options shall otherwise be exercisable in accordance with their terms.

All payments required to be made by the Company to the Executive pursuant to this Section 5.5 shall be paid on a regular basis in accordance with the Company's normal payroll procedures and policies, including, without limitation, the Severance Amount which shall be paid at such times and in such amounts consistent with the Company's normal payroll procedures and policies over the number of months immediately succeeding the date of termination that is equal to the number of months of Base Salary payable as the Severance Amount. If the Company terminates the Executive's employment pursuant to Sections 5.1 or 5.2, or if the Executive voluntarily resigns (except as provided in Section 5.3), then the Executive shall be entitled to only the compensation set forth in items (i) and (ii) or the first paragraph of this Section 5.5.

6. Assignment. This Agreement shall not be assignable, in whole or

in part, by either party without the written consent of the other party, except that the Company may, without the consent of the Executive, assign its rights and obligations under this Agreement to an Affiliate or to any corporation, firm or other business entity (i) with or into which the Company may merge or consolidate, or (ii) to which the Company may sell or transfer all or substantially all of its assets. After any such assignment by the Company, the Company shall be discharged from all further liability hereunder and such assignee shall thereafter be deemed to be the Company for the purposes of all provisions of this Agreement including this Section 6.

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7. Successors. This Agreement shall inure to the benefit of and be enforceable by the Executive's personal and legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees. If the Executive should die while any amounts are still payable to him hereunder, all such amounts, unless otherwise provided herein, shall be paid in accordance with the terms of this Agreement to the Executive's devisee, legatee, or other designee or, if there be no such designee, to the Executive's estate.

8. Miscellaneous.

8.1 Governing Law. This Agreement is made under and shall be governed by and construed in accordance with the laws of the State of California.

8.2 Prior Agreements. This Agreement contains the entire agreement of the parties relating to the subject matter hereof and supersedes all prior agreements and understanding with respect to such subject matter, and the parties hereto have made no agreements, representations or warranties relating to the subject matter of this Agreement which are not set forth herein.

8.3 Arbitration. In the event of any controversy, claim or dispute between the parties hereto arising out of or relating to this Agreement, the matter shall be determined by arbitration, which shall take place in Orange County, California, under the rules of the American Arbitration Association. The arbitrator shall be a retired Superior Court judge mutually agreeable to the parties and if the parties cannot agree such person shall be chosen in accordance with the rules of the American Arbitration Association. The arbitrator shall be bound by applicable legal precedent in reaching his or her decision. Any judgment upon such award may be entered in any court having jurisdiction thereof. Any decision or award of such arbitrator shall be final and binding upon the parties and shall not be appealable. The parties hereby consent to the jurisdiction of such arbitrator and of any court having jurisdiction to enter judgment upon and enforce any action taken by such arbitrator. The fees payable to the American Arbitration Association and the arbitrator shall be paid by the Company.

8.4 Withholding Taxes. The Company may withhold from any salary and benefits payable under this Agreement all federal, state, city or other taxes or amounts as shall be required to be withheld pursuant to any law or governmental regulation or ruling.

8.5 Amendments. No amendment or modification of this Agreement shall be deemed effective unless made in writing signed by the parties hereto.

8.6 No Waiver. No term or condition of this Agreement shall be deemed to have been waived nor shall there be any estoppel to enforce any provisions of this Agreement, except by a statement in writing signed by the party against whom enforcement of the waiver or estoppel is sought. Any written waiver shall not be deemed a continuing waiver unless specifically stated, shall operate only as to the specific term or condition waived and shall not constitute a waiver of such term or condition for the future or as to any act other than that specifically waived.

8.7 Severability. To the extent any provision of this Agreement shall be invalid or unenforceable, it shall be considered deleted herefrom and the remainder of such provision and of this Agreement shall be unaffected and shall continue in full force and effect.

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8.8 Counterpart Execution. This Agreement may be executed by facsimile and in counterparts, each of which shall be deemed an original and all of which when taken together shall constitute but one and the same instrument.

8.9 Attorneys Fees. Should any legal action or arbitration be required to resolve any dispute over the meaning or enforceability of this Agreement or to enforce the terms of this Agreement, the prevailing party shall be entitled to recover its or his reasonable attorneys fees and costs incurred in such action, in addition to any other relief to which that party may be entitled.

8.10 Notices. Any notice required or permitted to be given hereunder shall be in writing and may be personally served or sent by United States Mail, and shall be deemed to have been given when personally served or two days after having been deposited in the United States Mail, registered mail, return receipt requested, with first class postage prepaid and properly addressed as follows:

If to Executive: Michael Henson  
Two Via Presea  
Coto de Caza, CA 92679

If to the Company: Cardiovascular Dynamics, Inc.  
13700 Alton Parkway, Suite 160  
Irvine, CA 92618  
Attn: Chief Executive Officer

8.11 Proprietary Information and Inventions Agreement. Executive agrees to sign the Company's standard form of employee proprietary information and inventions agreement.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year set forth above.

"COMPANY"  
CARDIOVASCULAR DYNAMICS, INC.,  
a Delaware corporation

By: \_\_\_\_\_  
Its: \_\_\_\_\_

"EXECUTIVE"

\_\_\_\_\_  
Michael R. Henson

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EXHIBIT A

M. Henson Board of Director Memberships

--Endologix, Inc.

--Micrus Corporation

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Exhibit B

"Competitive Products"

1. PTCA Catheters
2. Conventional Coronary Stents - Without Drug Delivery
3. Conventional Coronary Stents - with Radiation
4. Coronary and Peripheral Vascular Radiation Catheters

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Exhibit C

M. Henson Benefits

- Health Insurance
- Dental Insurance
- Prescription Drug Insurance
- 401K Program Participation
- Employee Stock Purchase Program Participation
- Paid Company Holidays
- Paid vacation per company policy
- Monthly automobile allowance of \$850.00 per month
- Administrative assistant support services

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AMENDMENT TO EMPLOYMENT AGREEMENT

THIS AMENDMENT TO EMPLOYMENT AGREEMENT (the "Amendment") is made and entered into as of February 1, 1999 by and between RADIANCE MEDICAL SYSTEMS, INC., a Delaware corporation (the "Company"), and Michael R. Henson, an individual (the "Executive").

R E C I T A L

The Company and Executive are parties to an Employment Agreement dated January 14, 1999, and the parties thereto desire to amend such Employment Agreement as set forth herein.

A G R E E M E N T

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements set forth herein, the Company and the Executive, intending to be legally bound, hereby agree as follows:

1. Article 4 of the Employment Agreement is amended to add a new Section 4.5 to read as follows:

"4.5 ACCELERATION OF OPTIONS. Notwithstanding any provisions of the Company's option or stock incentive plan, or of the Executive's stock option or restricted stock agreements, in the event of a "Corporate Transaction" or "Change of Control," as defined below, during the period of the Executive's employment hereunder; all of the Executive's stock options shall vest in full and all rights of the company to repurchase restricted stock of the Executive shall terminate. For purposes hereof, "Change in Control" shall mean a change in ownership or control of the Company effected through either of the

following transactions:

(i) the acquisition, directly or indirectly, by any person or related group of persons (other than the Company or a person that directly or indirectly controls, is controlled by, or is under common control with, the Company), of beneficial ownership (within the meaning of Rule 13d-3 of the 1934 Act) of securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities pursuant to a tender or exchange offer made directly to the Company's stockholders which the Board does not recommend such stockholders to accept, or

(ii) a change in the composition of the Board over a period of thirty-six (36) consecutive months or less such that a majority of the Board members ceases, by reason of one or more contested elections for Board membership, to be comprised of individuals who either (A) have been Board members continuously since the beginning of such period or (B) have been elected or nominated for election as Board members during such period by at least a majority of the Board members described in clause (A) who were still in office at the time the Board approved such election or nomination.

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"Corporate Transaction" shall mean either of the following stockholder-approved transactions to which the Company is a party:

(i) a merger or consolidation in which securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities are transferred to a person or persons different from the persons holding those securities immediately prior to such transaction; or

(ii) the sale, transfer or other disposition of all or substantially all of the Company's assets in complete liquidation or dissolution of the Company."

2. Section 5.5 is amended to add the following at the end of such section:

"To the extent that any or all of the payments and benefits provided for in this Agreement constitute "parachute payments" within the meaning of Section 280G of the Internal Revenue Code (the "Code") and, but for this paragraph, would be subject to the excise tax imposed by Section 4999 of the Code, then at the Executive's election:

(A) the Executive shall receive all such payments and benefits the Executive is entitled to receive hereunder, and any liability for taxes pursuant to the above shall be the liability solely of the Executive; or

(B) the aggregate amount of such payments and benefits shall be reduced such that the present value thereof (as determined under the Code and applicable regulations) is equal to 2.99 times the Executive's "base amount" (as defined in the Code).

The determination of any reduction or increase of any payment or benefits under this paragraph 5 pursuant to the foregoing provision shall be made by a nationally recognized public accounting firm chosen by the Company in good faith, and such determination shall be conclusive and binding on the Company and the Executive."

3. All other terms and provisions of the Employment Agreement shall remain in full force and effect.

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IN WITNESS WHEREOF, the parties have executed this Amendment as of the day and year set forth above.

"COMPANY"  
RADIANCE MEDICAL SYSTEMS, INC.,  
a Delaware corporation

By: \_\_\_\_\_  
Its: \_\_\_\_\_

"EXECUTIVE"

\_\_\_\_\_  
Michael R. Henson

## EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the "Agreement") is made and entered into as of February 1, 1999 by and between RADIANCE MEDICAL SYSTEMS, INC., a Delaware corporation (the "Company"), and Stephen R. Kroll, an individual (the "Executive").

## R E C I T A L

The Company desires to employ Executive in the capacity hereinafter stated, and the Executive desires to enter into the employ of the Company in that capacity pursuant to the terms and conditions set forth herein.

## A G R E E M E N T

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements set forth herein, the Company and the Executive, intending to be legally bound, hereby agree as follows:

1. EMPLOYMENT. The Company hereby agrees to employ the Executive as the Vice President and Chief Financial Officer of the Company, reporting to the Chief Executive Officer ("CEO") of the Company, and the Executive accepts such employment and agrees to devote substantially all his business time and efforts and skills on such reasonable duties as shall be assigned to him by the Company commensurate with such position.

2. TERM. The initial term of the Executive's employment hereunder shall commence February 1, 1999 ("Effective Date") and shall be for a period of two (2) years, and shall automatically extend for successive one year periods following the initial term unless either party delivers written notice to the other no later than sixty (60) days prior to the end of the second anniversary of the Effective Date or any successive anniversary of the Effective Date, as the case may be, of intent not to renew. Executive's employment is subject to earlier termination as hereafter specified.

## 3. POSITION AND DUTIES.

3.1 SERVICE WITH THE COMPANY. During the term of this Agreement, the Executive agrees to perform such reasonable duties and on such basis as shall be assigned to him from time to time by the CEO; such duties, however, to be commensurate with the Executive's position as Vice President and Chief Financial Officer of the Company. In particular, and without limitation, such duties shall include, within the guidelines set by the CEO, setting up long-range strategic plans, guidance of day-to-day operations of the Company, preparing operating budgets for presentation to the CEO, implementation of operating plans as approved by the CEO and communicating the Company's goals and objects to the financial community.

3.2 NO CONFLICTING DUTIES. Except as provided in Exhibit A hereto, during the term hereof, the Executive shall not serve as an officer, director, employee, consultant or advisor to any other business; provided, however, that the Executive may serve as a director of another corporation so long as (i) such corporation does not compete, directly or indirectly, with the

Company or any of its Affiliates for such products as defined as "Competitive Products" in Exhibit B attached to this Agreement, and (ii) such services do not adversely affect Executive's ability to perform his duties under this Agreement, unless such other service is approved by the CEO or Board of Directors of the Company. For purposes of this Agreement, the term "Affiliate" means any corporation, association or other business entity of which more than 50% of the total voting power of shares of stock entitled to vote in the election of directors, managers or trustees thereof is at the time owned or controlled by the Company. Notwithstanding the foregoing, nothing contained herein shall prevent Executive from making and expending any time of passive personal

investments and/or expending reasonable amounts of time for educational and charitable activities. Except as provided in Exhibit A hereto, the Executive confirms that he is under no contractual commitment inconsistent with his obligations set forth in this Agreement.

#### 4. COMPENSATION.

4.1 BASE SALARY. As compensation for all services to be rendered by the Executive under this Agreement, the Company shall pay to the Executive a base salary of \$175,000 ("Base Salary"), which shall be paid on a regular basis in accordance with the Company's normal payroll procedures and policies. The amount of the Base Salary shall be reviewed by the Compensation Committee of the Board of Directors, which may annually increase Executive's Base Salary in amounts consistent with industry practices as determined in its sole discretion. Executive's performance, the performance of the Company and such other factors as the Compensation Committee of the Board of Directors deem appropriate shall also be considered.

4.2 INCENTIVE COMPENSATION PLANS. In addition to the Base Salary, Executive shall be eligible to participate in management incentive compensation plans approved by the Company's Board of Directors, such participation to be on terms similar to those afforded to other management employees holding positions with the Company. In addition to the Base Salary, the Executive shall be entitled to earn up to thirty percent (30%) of his Base Salary as incentive compensation. All amounts to which the Executive may be entitled under any incentive compensation plans shall be subject to the provisions, rules and regulations of any such plan which apply to other management employees.

4.3 PARTICIPATION IN BENEFIT PLANS. During the term of this Agreement, Executive shall be entitled to participate in all employee benefit plans, profit-sharing, stock options, vacation and other perquisite plans and programs for which key employees of the Company are generally eligible. The Executive's participation in any such plan or program shall be subject to the provisions, rules and regulations thereof that are generally available to all participants thereon, provided, however, in no event shall Executive's benefits be less than the benefits described in Exhibit C.

4.4 EXPENSES. In accordance with the Company's policies established from time to time, the Company will pay or reimburse the Executive for all reasonable and necessary out-of-pocket expenses incurred by him in the performance of his duties under this Agreement, provided that Executive submits appropriate vouchers and expense reports substantiating the amount thereof and the business purposes for which such expenses were incurred.

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4.5 ACCELERATION OF OPTIONS. Notwithstanding any provisions of the Company's option or stock incentive plan, or of the Executive's stock option or restricted stock agreements, in the event of a "Corporate Transaction" or "Change of Control," as defined below, during the period of the Executive's employment hereunder; all of the Executive's stock options shall vest in full and all rights of the company to repurchase restricted stock of the Executive shall terminate. For purposes hereof, "Change in Control" shall mean a change in ownership or control of the Company effected through either of the following transactions:

(i) the acquisition, directly or indirectly, by any person or related group of persons (other than the Company or a person that directly or indirectly controls, is controlled by, or is under common control with, the Company), of beneficial ownership (within the meaning of Rule 13d-3 of the 1934 Act) of securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities pursuant to a tender or exchange offer made directly to the Company's stockholders which the Board does not recommend such stockholders to accept, or

(ii) a change in the composition of the Board over a period of thirty-six (36) consecutive months or less such that a majority of the Board members ceases, by reason of one or more contested elections for Board membership, to be comprised of individuals who either (A) have been Board members continuously since the beginning of such period or (B) have been elected or nominated for election as Board members during such period by at least a majority of the Board members

described in clause (A) who were still in office at the time the Board approved such election or nomination.

"Corporate Transaction" shall mean either of the following stockholder-approved transactions to which the Company is a party:

(i) a merger or consolidation in which securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities are transferred to a person or persons different from the persons holding those securities immediately prior to such transaction; or

(ii) the sale, transfer or other disposition of all or substantially all of the Company's assets in complete liquidation or dissolution of the Company.

#### 5. TERMINATION.

5.1 TERMINATION BY THE COMPANY FOR CAUSE. Any of the following acts or omissions shall constitute grounds for the Company to terminate the Executive's employment pursuant to this Agreement for "cause":

(a) Willful misconduct by Executive causing material harm to the Company but only if Executive shall not have discontinued such misconduct within 30 days after receiving written notice from the Company describing the misconduct and stating that the Company will consider the continuation of such misconduct as cause for termination of this Agreement.

(b) Any material act or omission by the Executive involving gross negligence in the performance of the Executive's duties to, or material deviation from any of the policies or directives of, the Company, other than a deviation taken in good faith by the Executive for the benefit of the Company;

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(c) Any illegal act by the Executive which materially and adversely affects the business of the Company or any felony committed by Executive, as evidenced by conviction thereof, provided that the Company may suspend the Executive with pay while any allegation of such illegal or felonious act is investigated.

Termination by the Company for cause shall be accomplished by written notice to the Executive and shall be preceded by a written notice providing a reasonable opportunity for the Executive to correct his conduct.

5.2 TERMINATION FOR DEATH OR DISABILITY. In addition to termination for cause pursuant to Section 5.1 hereof, the Executive's employment pursuant to this Agreement shall be immediately terminated without notice by the Company (i) upon the death of the Executive or (ii) upon the Executive becoming totally disabled. For purposes of this Agreement, the term "totally disabled" means an inability of Executive, due to a physical or mental illness, injury or impairment, to perform a substantial portion of his duties for a period of one hundred eighty (180) or more consecutive days, as determined by a competent physician selected by the Company's Board of Directors and reasonably agreed to by the Executive, following such one hundred eighty (180) day period.

5.3 TERMINATION FOR GOOD REASON. Executive's employment pursuant to this Agreement may be terminated by the Executive for "good reason" if the Executive voluntarily terminates his employment as a result of any of the following:

(a) Without the Executive's prior written consent, a reduction in his then current Base Salary;

(b) Without Executive's prior written consent, a relocation of the Executive's place of employment outside of Orange County, California;

(c) Resignation as a result of unlawful discrimination, as evidenced by a final court order;

(d) A reduction in duties and responsibilities which results in the Executive no longer having duties customary for a Vice President and Chief Financial Officer; or

(e) The Company materially breaches any provision of this Agreement.

5.4 TERMINATION WITHOUT CAUSE. The Company may terminate this Agreement, and the employment of the Executive under this Agreement, without cause at any time upon at least thirty (30) days prior written notice to the Executive.

5.5 PAYMENTS UPON REMOVAL OR TERMINATION. If during the term of this Agreement, the Executive resigns for one of the reasons stated in Section 5.3, or the Company terminates the Executive's service, except as provided in Sections 5.1 or 5.2 hereof, the Executive shall be entitled to the following compensation: (i) the portion of his then current Base Salary which

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has accrued through his date of termination, (ii) any payments for unused vacation and reimbursement expenses, which are due, accrued or payable at the date of Executive's termination, (iii) severance payment in an amount (the "Severance Amount") equal to Executive's then-current Base Salary, payable for the remainder of the Term; and (iv) all of Executive's options to purchase shares of the Company's common stock and restricted stock shall accelerate and automatically vest by one additional year, and such options shall otherwise be exercisable in accordance with their terms.

All payments required to be made by the Company to the Executive pursuant to this Section 5.5 shall be paid on a regular basis in accordance with the Company's normal payroll procedures and policies, including, without limitation, the Severance Amount which shall be paid at such times and in such amounts consistent with the Company's normal payroll procedures and policies over the number of months immediately succeeding the date of termination that is equal to the number of months of Base Salary payable as the Severance Amount. If the Company terminates the Executive's employment pursuant to Sections 5.1 or 5.2, or if the Executive voluntarily resigns (except as provided in Section 5.3), then the Executive shall be entitled to only the compensation set forth in items (i) and (ii) or the first paragraph of this Section 5.5.

To the extent that any or all of the payments and benefits provided for in this Agreement constitute "parachute payments" within the meaning of Section 280G of the Internal Revenue Code (the "Code") and, but for this paragraph, would be subject to the excise tax imposed by Section 4999 of the Code, then at the Executive's election:

(A) the Executive shall receive all such payments and benefits the Executive is entitled to receive hereunder, and any liability for taxes pursuant to the above shall be the liability solely of the Executive; or

(B) the aggregate amount of such payments and benefits shall be reduced such that the present value thereof (as determined under the Code and applicable regulations) is equal to 2.99 times the Executive's "base amount" (as defined in the Code).

The determination of any reduction or increase of any payment or benefits under this paragraph 5 pursuant to the foregoing provision shall be made by a nationally recognized public accounting firm chosen by the Company in good faith, and such determination shall be conclusive and binding on the Company and the Executive.

6. ASSIGNMENT. This Agreement shall not be assignable, in whole or in part, by either party without the written consent of the other party, except that the Company may, without the consent of the Executive, assign its rights and obligations under this Agreement to an Affiliate or to any corporation, firm or other business entity (i) with or into which the Company may merge or consolidate, or (ii) to which the Company may sell or transfer all or substantially all of its assets. After any such assignment by the Company, the Company shall be discharged from all further liability hereunder and such assignee shall thereafter be deemed to be the Company for the purposes of all provisions of this Agreement including this Section 6.

7. SUCCESSORS. This Agreement shall inure to the benefit of and be enforceable by the Executive's personal and legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees. If the Executive should die while any amounts are still payable to him hereunder, all such amounts, unless otherwise provided herein, shall be paid in accordance with the terms of this Agreement to the Executive's devisee, legatee, or other designee or, if there be no such designee, to the Executive's estate.

8. MISCELLANEOUS.

8.1 GOVERNING LAW. This Agreement is made under and shall be governed by and construed in accordance with the laws of the State of California.

8.2 PRIOR AGREEMENTS. This Agreement contains the entire agreement of the parties relating to the subject matter hereof and supersedes all prior agreements and understanding with respect to such subject matter, and the parties hereto have made no agreements, representations or warranties relating to the subject matter of this Agreement which are not set forth herein.

8.3 ARBITRATION. In the event of any controversy, claim or dispute between the parties hereto arising out of or relating to this Agreement, the matter shall be determined by arbitration, which shall take place in Orange County, California, under the rules of the American Arbitration Association. The arbitrator shall be a retired Superior Court judge mutually agreeable to the parties and if the parties cannot agree such person shall be chosen in accordance with the rules of the American Arbitration Association. The arbitrator shall be bound by applicable legal precedent in reaching his or her decision. Any judgment upon such award may be entered in any court having jurisdiction thereof. Any decision or award of such arbitrator shall be final and binding upon the parties and shall not be appealable. The parties hereby consent to the jurisdiction of such arbitrator and of any court having jurisdiction to enter judgment upon and enforce any action taken by such arbitrator. The fees payable to the American Arbitration Association and the arbitrator shall be paid by the Company.

8.4 WITHHOLDING TAXES. The Company may withhold from any salary and benefits payable under this Agreement all federal, state, city or other taxes or amounts as shall be required to be withheld pursuant to any law or governmental regulation or ruling.

8.5 AMENDMENTS. No amendment or modification of this Agreement shall be deemed effective unless made in writing signed by the parties hereto.

8.6 NO WAIVER. No term or condition of this Agreement shall be deemed to have been waived nor shall there be any estoppel to enforce any provisions of this Agreement, except by a statement in writing signed by the party against whom enforcement of the waiver or estoppel is sought. Any written waiver shall not be deemed a continuing waiver unless specifically stated, shall operate only as to the specific term or condition waived and shall not constitute a waiver of such term or condition for the future or as to any act other than that specifically waived.

8.7 SEVERABILITY. To the extent any provision of this Agreement shall be invalid or unenforceable, it shall be considered deleted herefrom and the remainder of such provision and of this Agreement shall be unaffected and shall continue in full force and effect.

8.8 COUNTERPART EXECUTION. This Agreement may be executed by facsimile and in counterparts, each of which shall be deemed an original and all of which when taken together shall constitute but one and the same instrument.

8.9 ATTORNEYS FEES. Should any legal action or arbitration be required to resolve any dispute over the meaning or enforceability of this Agreement or to enforce the terms of this Agreement, the prevailing party shall be entitled to recover its or his reasonable attorneys fees and costs incurred in such action, in addition to any other relief to which that party may be entitled.

8.10 NOTICES. Any notice required or permitted to be given hereunder shall be in writing and may be personally served or sent by United States Mail,

and shall be deemed to have been given when personally served or two days after having been deposited in the United States Mail, registered mail, return receipt requested, with first class postage prepaid and properly addressed as follows:

If to Executive: Stephen R. Kroll  
3591 Courtside Circle  
Huntington Beach, CA 92649

If to the Company: Radiance Medical Systems, Inc.  
13700 Alton Parkway, Suite 160  
Irvine, CA 92618  
Attn: Chief Executive Officer

9.11 PROPRIETARY INFORMATION AND INVENTIONS AGREEMENT. Executive agrees to sign the Company's standard form of employee proprietary information and inventions agreement.

8

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year set forth above.

"COMPANY"  
RADIANCE MEDICAL SYSTEMS, INC.,  
a Delaware corporation

By: \_\_\_\_\_  
Its: \_\_\_\_\_

"EXECUTIVE"

\_\_\_\_\_  
Stephen R. Kroll

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Exhibit A

Stephen R. Kroll Board of Director Memberships

None.

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Exhibit B

"Competitive Products"

1. PTCA Catheters
2. Conventional Coronary Stents - Without Drug Delivery
3. Conventional Coronary Stents - with Radiation
4. Coronary and Peripheral Vascular Radiation Catheters

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Exhibit C

S. Kroll Benefits

- Health Insurance
- Dental Insurance
- Long Term Disability Insurance
- Prescription Drug Insurance
- 401K Program Participation
- Employee Stock Purchase Program Participation
- Paid Company Holidays
- Paid vacation per company policy

## EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the "Agreement") is made and entered into as of \_\_\_\_\_, 1999 by and between RADIANCE MEDICAL SYSTEMS, INC., a Delaware corporation (the "Company"), and Jeffrey Thiel, an individual (the "Executive").

## R E C I T A L

The Company desires to employ Executive in the capacity hereinafter stated, and the Executive desires to enter into the employ of the Company in that capacity pursuant to the terms and conditions set forth herein.

## A G R E E M E N T

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements set forth herein, the Company and the Executive, intending to be legally bound, hereby agree as follows:

1. EMPLOYMENT. The Company hereby agrees to employ the Executive as the Executive Vice President, Operations of the Company, reporting to the Chief Executive Officer ("CEO") of the Company, and the Executive accepts such employment and agrees to devote substantially all his business time and efforts and skills on such reasonable duties as shall be assigned to him by the Company commensurate with such position.

2. TERM. The initial term of the Executive's employment hereunder shall commence \_\_\_\_\_, 1999 ("Effective Date") and shall be for a period of two (2) years, and shall automatically extend for successive one year periods following the initial term unless either party delivers written notice to the other no later than sixty (60) days prior to the end of the second anniversary of the Effective Date or any successive anniversary of the Effective Date, as the case may be, of intent not to renew. Executive's employment is subject to earlier termination as hereafter specified.

## 3. POSITION AND DUTIES.

3.1 SERVICE WITH THE COMPANY. During the term of this Agreement, the Executive agrees to perform such reasonable duties and on such basis as shall be assigned to him from time to time by the CEO; such duties, however, to be commensurate with the Executive's position as Executive Vice President, Operations of the Company. In particular, and without limitation, such duties shall include, within the guidelines set by the CEO, setting up long-range strategic plans, guidance of day-to-day operations of the Company, preparing operating budgets for presentation to the CEO, and implementation of operating plans as approved by the CEO.

3.2 NO CONFLICTING DUTIES. Except as provided in Exhibit A hereto, during the term hereof, the Executive shall not serve as an officer, director, employee, consultant or advisor to any other business; provided, however, that the Executive may serve as a director of another corporation so long as (i) such corporation does not compete, directly or indirectly, with the Company or any of its Affiliates for such products as defined as "Competitive Products" in Exhibit B

attached to this Agreement, and (ii) such services do not adversely affect Executive's ability to perform his duties under this Agreement, unless such other service is approved by the CEO or Board of Directors of the Company. For purposes of this Agreement, the term "Affiliate" means any corporation, association or other business entity of which more than 50% of the total voting power of shares of stock entitled to vote in the election of directors, managers or trustees thereof is at the time owned or controlled by the Company. Notwithstanding the foregoing, nothing contained herein shall prevent Executive from making and expending any time of passive personal investments and/or expending reasonable amounts of time for educational and charitable activities. Except as provided in Exhibit A hereto, the Executive confirms that he is under

no contractual commitment inconsistent with his obligations set forth in this Agreement.

#### 4. COMPENSATION.

4.1 BASE SALARY. As compensation for all services to be rendered by the Executive under this Agreement, the Company shall pay to the Executive a base salary of \$153,846 ("Base Salary"), which shall be paid on a regular basis in accordance with the Company's normal payroll procedures and policies. The amount of the Base Salary shall be reviewed by the Compensation Committee of the Board of Directors, which may annually increase Executive's Base Salary in amounts consistent with industry practices as determined in its sole discretion. Executive's performance, the performance of the Company and such other factors as the Compensation Committee of the Board of Directors deem appropriate shall also be considered.

4.2 INCENTIVE COMPENSATION PLANS. In addition to the Base Salary, Executive shall be eligible to participate in management incentive compensation plans approved by the Company's Board of Directors, such participation to be on terms similar to those afforded to other management employees holding positions with the Company. In addition to the Base Salary, the Executive shall be entitled to earn up to twenty percent (20%) of his Base Salary as incentive compensation. All amounts to which the Executive may be entitled under any incentive compensation plans shall be subject to the provisions, rules and regulations of any such plan which apply to other management employees.

4.3 PARTICIPATION IN BENEFIT PLANS. During the term of this Agreement, Executive shall be entitled to participate in all employee benefit plans, profit-sharing, stock options, vacation and other perquisite plans and programs for which key employees of the Company are generally eligible. The Executive's participation in any such plan or program shall be subject to the provisions, rules and regulations thereof that are generally available to all participants thereon, provided, however, in no event shall Executive's benefits be less than the benefits described in Exhibit C.

4.4 EXPENSES. In accordance with the Company's policies established from time to time, the Company will pay or reimburse the Executive for all reasonable and necessary out-of-pocket expenses incurred by him in the performance of his duties under this Agreement, provided that Executive submits appropriate vouchers and expense reports substantiating the amount thereof and the business purposes for which such expenses were incurred.

4.5 ACCELERATION OF OPTIONS. Notwithstanding any provisions of the Company's option or stock incentive plan, or of the Executive's stock option or restricted stock agreements, in

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the event of a "Corporate Transaction" or "Change of Control," as defined below, during the period of the Executive's employment hereunder; all of the Executive's stock options shall vest in full and all rights of the company to repurchase restricted stock of the Executive shall terminate. For purposes hereof, "Change in Control" shall mean a change in ownership or control of the Company effected through either of the following transactions:

(i) the acquisition, directly or indirectly, by any person or related group of persons (other than the Company or a person that directly or indirectly controls, is controlled by, or is under common control with, the Company), of beneficial ownership (within the meaning of Rule 13d-3 of the 1934 Act) of securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities pursuant to a tender or exchange offer made directly to the Company's stockholders which the Board does not recommend such stockholders to accept, or

(ii) a change in the composition of the Board over a period of thirty-six (36) consecutive months or less such that a majority of the Board members ceases, by reason of one or more contested elections for Board membership, to be comprised of individuals who either (A) have been Board members continuously since the beginning of such period or (B) have been elected or nominated for election as Board members during such period by at least a majority of the Board members described in clause (A) who were still in office at the time the Board

approved such election or nomination.

"Corporate Transaction" shall mean either of the following stockholder-approved transactions to which the Company is a party:

(i) a merger or consolidation in which securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities are transferred to a person or persons different from the persons holding those securities immediately prior to such transaction; or

(ii) the sale, transfer or other disposition of all or substantially all of the Company's assets in complete liquidation or dissolution of the Company.

#### 5. TERMINATION.

5.1 TERMINATION BY THE COMPANY FOR CAUSE. Any of the following acts or omissions shall constitute grounds for the Company to terminate the Executive's employment pursuant to this Agreement for "cause":

(a) Willful misconduct by Executive causing material harm to the Company but only if Executive shall not have discontinued such misconduct within 30 days after receiving written notice from the Company describing the misconduct and stating that the Company will consider the continuation of such misconduct as cause for termination of this Agreement.

(b) Any material act or omission by the Executive involving gross negligence in the performance of the Executive's duties to, or material deviation from any of the policies or directives of, the Company, other than a deviation taken in good faith by the Executive for the benefit of the Company;

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(c) Any illegal act by the Executive which materially and adversely affects the business of the Company or any felony committed by Executive, as evidenced by conviction thereof, provided that the Company may suspend the Executive with pay while any allegation of such illegal or felonious act is investigated.

Termination by the Company for cause shall be accomplished by written notice to the Executive and shall be preceded by a written notice providing a reasonable opportunity for the Executive to correct his conduct.

5.2 TERMINATION FOR DEATH OR DISABILITY. In addition to termination for cause pursuant to Section 5.1 hereof, the Executive's employment pursuant to this Agreement shall be immediately terminated without notice by the Company (i) upon the death of the Executive or (ii) upon the Executive becoming totally disabled. For purposes of this Agreement, the term "totally disabled" means an inability of Executive, due to a physical or mental illness, injury or impairment, to perform a substantial portion of his duties for a period of one hundred eighty (180) or more consecutive days, as determined by a competent physician selected by the Company's Board of Directors and reasonably agreed to by the Executive, following such one hundred eighty (180) day period.

5.3 TERMINATION FOR GOOD REASON. Executive's employment pursuant to this Agreement may be terminated by the Executive for "good reason" if the Executive voluntarily terminates his employment as a result of any of the following:

(a) Without the Executive's prior written consent, a reduction in his then current Base Salary;

(b) Without Executive's prior written consent, a relocation of the Executive's place of employment outside of Orange County, California;

(c) Resignation as a result of unlawful discrimination, as evidenced by a final court order;

(d) A reduction in duties and responsibilities which results in the Executive no longer having duties customary for an Executive Vice President, Operations; or

(e) The Company materially breaches any provision of this Agreement.

5.4 TERMINATION WITHOUT CAUSE. The Company may terminate this Agreement, and the employment of the Executive under this Agreement, without cause at any time upon at least thirty (30) days prior written notice to the Executive.

5.5 PAYMENTS UPON REMOVAL OR TERMINATION. If during the term of this Agreement, the Executive resigns for one of the reasons stated in Section 5.3, or the Company terminates the Executive's service, except as provided in Sections 5.1 or 5.2 hereof, the Executive shall be entitled to the following compensation: (i) the portion of his then current Base Salary which has accrued through his date of termination, (ii) any payments for unused vacation and reimbursement expenses, which are due, accrued or payable at the date of Executive's termination, (iii) severance payment in an amount (the "Severance Amount") equal to Executive's then-current Base Salary, payable for the remainder of the Term; and (iv) all of Executive's options to purchase shares of the Company's common stock and restricted stock shall accelerate and automatically vest by one additional year, and such options shall otherwise be exercisable in accordance with their terms.

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All payments required to be made by the Company to the Executive pursuant to this Section 5.5 shall be paid on a regular basis in accordance with the Company's normal payroll procedures and policies, including, without limitation, the Severance Amount which shall be paid at such times and in such amounts consistent with the Company's normal payroll procedures and policies over the number of months immediately succeeding the date of termination that is equal to the number of months of Base Salary payable as the Severance Amount. If the Company terminates the Executive's employment pursuant to Sections 5.1 or 5.2, or if the Executive voluntarily resigns (except as provided in Section 5.3), then the Executive shall be entitled to only the compensation set forth in items (i) and (ii) or the first paragraph of this Section 5.5.

To the extent that any or all of the payments and benefits provided for in this Agreement constitute "parachute payments" within the meaning of Section 280G of the Internal Revenue Code (the "Code") and, but for this paragraph, would be subject to the excise tax imposed by Section 4999 of the Code, then at the Executive's election:

(A) the Executive shall receive all such payments and benefits the Executive is entitled to receive hereunder, and any liability for taxes pursuant to the above shall be the liability solely of the Executive; or

(B) the aggregate amount of such payments and benefits shall be reduced such that the present value thereof (as determined under the Code and applicable regulations) is equal to 2.99 times the Executive's "base amount" (as defined in the Code).

The determination of any reduction or increase of any payment or benefits under this paragraph 5 pursuant to the foregoing provision shall be made by a nationally recognized public accounting firm chosen by the Company in good faith, and such determination shall be conclusive and binding on the Company and the Executive.

6. ASSIGNMENT. This Agreement shall not be assignable, in whole or in part, by either party without the written consent of the other party, except that the Company may, without the consent of the Executive, assign its rights and obligations under this Agreement to an Affiliate or to any corporation, firm or other business entity (i) with or into which the Company may merge or consolidate, or (ii) to which the Company may sell or transfer all or substantially all of its assets. After any such assignment by the Company, the Company shall be discharged from all further liability hereunder and such assignee shall thereafter be deemed to be the Company for the purposes of all provisions of this Agreement including this Section 6.

7. SUCCESSORS. This Agreement shall inure to the benefit of and be enforceable by the Executive's personal and legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees. If the Executive should die while any amounts are still payable to him hereunder, all

such amounts, unless otherwise provided herein, shall be paid in accordance with the terms of this Agreement to the Executive's devisee, legatee, or other designee or, if there be no such designee, to the Executive's estate.

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#### 8. MISCELLANEOUS.

8.1 GOVERNING LAW. This Agreement is made under and shall be governed by and construed in accordance with the laws of the State of California.

8.2 PRIOR AGREEMENTS. This Agreement contains the entire agreement of the parties relating to the subject matter hereof and supersedes all prior agreements and understanding with respect to such subject matter, and the parties hereto have made no agreements, representations or warranties relating to the subject matter of this Agreement which are not set forth herein.

8.3 ARBITRATION. In the event of any controversy, claim or dispute between the parties hereto arising out of or relating to this Agreement, the matter shall be determined by arbitration, which shall take place in Orange County, California, under the rules of the American Arbitration Association. The arbitrator shall be a retired Superior Court judge mutually agreeable to the parties and if the parties cannot agree such person shall be chosen in accordance with the rules of the American Arbitration Association. The arbitrator shall be bound by applicable legal precedent in reaching his or her decision. Any judgment upon such award may be entered in any court having jurisdiction thereof. Any decision or award of such arbitrator shall be final and binding upon the parties and shall not be appealable. The parties hereby consent to the jurisdiction of such arbitrator and of any court having jurisdiction to enter judgment upon and enforce any action taken by such arbitrator. The fees payable to the American Arbitration Association and the arbitrator shall be paid by the Company.

8.4 WITHHOLDING TAXES. The Company may withhold from any salary and benefits payable under this Agreement all federal, state, city or other taxes or amounts as shall be required to be withheld pursuant to any law or governmental regulation or ruling.

8.5 AMENDMENTS. No amendment or modification of this Agreement shall be deemed effective unless made in writing signed by the parties hereto.

8.6 NO WAIVER. No term or condition of this Agreement shall be deemed to have been waived nor shall there be any estoppel to enforce any provisions of this Agreement, except by a statement in writing signed by the party against whom enforcement of the waiver or estoppel is sought. Any written waiver shall not be deemed a continuing waiver unless specifically stated, shall operate only as to the specific term or condition waived and shall not constitute a waiver of such term or condition for the future or as to any act other than that specifically waived.

8.7 SEVERABILITY. To the extent any provision of this Agreement shall be invalid or unenforceable, it shall be considered deleted herefrom and the remainder of such provision and of this Agreement shall be unaffected and shall continue in full force and effect.

8.8 COUNTERPART EXECUTION. This Agreement may be executed by facsimile and in counterparts, each of which shall be deemed an original and all of which when taken together shall constitute but one and the same instrument.

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8.9 ATTORNEYS FEES. Should any legal action or arbitration be required to resolve any dispute over the meaning or enforceability of this Agreement or to enforce the terms of this Agreement, the prevailing party shall be entitled to recover its or his reasonable attorneys fees and costs incurred in such action, in addition to any other relief to which that party may be entitled.

8.10 NOTICES. Any notice required or permitted to be given hereunder shall be in writing and may be personally served or sent by United States Mail, and shall be deemed to have been given when personally served or two days after having been deposited in the United States Mail, registered mail, return receipt

requested, with first class postage prepaid and properly addressed as follows:

If to Executive: Jeffrey Thiel  
8 Thornapple  
Laguna Niguel, CA 92677

If to the Company: Radiance Medical Systems, Inc.  
13700 Alton Parkway, Suite 160  
Irvine, CA 92618  
Attn: Chief Executive Officer

9.11 PROPRIETARY INFORMATION AND INVENTIONS AGREEMENT. Executive agrees to sign the Company's standard form of employee proprietary information and inventions agreement.

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IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year set forth above.

"COMPANY"  
RADIANCE MEDICAL SYSTEMS, INC.,  
a Delaware corporation

By: \_\_\_\_\_  
Its: \_\_\_\_\_

"EXECUTIVE"

\_\_\_\_\_  
Jeffrey Thiel

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Exhibit A

Jeffrey Thiel Board of Director Memberships

None.

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Exhibit B

"Competitive Products"

1. PTCA Catheters
2. Conventional Coronary Stents - Without Drug Delivery
3. Conventional Coronary Stents - with Radiation
4. Coronary and Peripheral Vascular Radiation Catheters

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Exhibit C

J. Thiel Benefits

--Health Insurance  
--Dental Insurance  
--Long Term Disability Insurance  
--Prescription Drug Insurance  
--401K Program Participation  
--Employee Stock Purchase Program Participation  
--Paid Company Holidays  
--Paid vacation per company policy

## EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the "Agreement") is made and entered into as of \_\_\_\_\_, 1999 by and between RADIANCE MEDICAL SYSTEMS, INC., a Delaware corporation (the "Company"), and Claire Walker, an individual (the "Executive").

## R E C I T A L

The Company desires to employ Executive in the capacity hereinafter stated, and the Executive desires to enter into the employ of the Company in that capacity pursuant to the terms and conditions set forth herein.

## A G R E E M E N T

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements set forth herein, the Company and the Executive, intending to be legally bound, hereby agree as follows:

1. EMPLOYMENT. The Company hereby agrees to employ the Executive as the Vice President, Clinical Affairs of the Company, reporting to the Chief Executive Officer ("CEO") of the Company, and the Executive accepts such employment and agrees to devote substantially all her business time and efforts and skills on such reasonable duties as shall be assigned to her by the Company commensurate with such position.

2. TERM. The initial term of the Executive's employment hereunder shall commence \_\_\_\_\_, 1999 ("Effective Date") and shall be for a period of two (2) years, and shall automatically extend for successive one year periods following the initial term unless either party delivers written notice to the other no later than sixty (60) days prior to the end of the second anniversary of the Effective Date or any successive anniversary of the Effective Date, as the case may be, of intent not to renew. Executive's employment is subject to earlier termination as hereafter specified.

## 3. POSITION AND DUTIES.

3.1 SERVICE WITH THE COMPANY. During the term of this Agreement, the Executive agrees to perform such reasonable duties and on such basis as shall be assigned to her from time to time by the CEO; such duties, however, to be commensurate with the Executive's position as Executive Vice President, Clinical Affairs of the Company. In particular, and without limitation, such duties shall include, within the guidelines set by the CEO, designing, implementing and monitoring clinical studies on the Company's products, \_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_.

3.2 NO CONFLICTING DUTIES. Except as provided in Exhibit A hereto, during the term hereof, the Executive shall not serve as an officer, director, employee, consultant or advisor to any other business; provided, however, that the Executive may serve as a director of another corporation so long as (i) such corporation does not compete, directly or indirectly, with the Company or any of its Affiliates for such products as defined as "Competitive Products" in Exhibit B attached to this Agreement, and (ii) such services do not adversely affect Executive's ability to

perform her duties under this Agreement, unless such other service is approved by the CEO or Board of Directors of the Company. For purposes of this Agreement, the term "Affiliate" means any corporation, association or other business entity of which more than 50% of the total voting power of shares of stock entitled to vote in the election of directors, managers or trustees thereof is at the time owned or controlled by the Company. Notwithstanding the foregoing, nothing contained herein shall prevent Executive from making and expending any time of passive personal investments and/or expending reasonable amounts of time for educational and charitable activities. Except as provided in Exhibit A hereto, the Executive confirms that she is under no contractual commitment inconsistent with her obligations set forth in this Agreement.

#### 4. COMPENSATION.

4.1 BASE SALARY. As compensation for all services to be rendered by the Executive under this Agreement, the Company shall pay to the Executive a base salary of \$138,180 ("Base Salary"), which shall be paid on a regular basis in accordance with the Company's normal payroll procedures and policies. The amount of the Base Salary shall be reviewed by the Compensation Committee of the Board of Directors, which may annually increase Executive's Base Salary in amounts consistent with industry practices as determined in its sole discretion. Executive's performance, the performance of the Company and such other factors as the Compensation Committee of the Board of Directors deem appropriate shall also be considered.

4.2 INCENTIVE COMPENSATION PLANS. In addition to the Base Salary, Executive shall be eligible to participate in management incentive compensation plans approved by the Company's Board of Directors, such participation to be on terms similar to those afforded to other management employees holding positions with the Company. In addition to the Base Salary, the Executive shall be entitled to earn up to twenty percent (20%) of her Base Salary as incentive compensation. All amounts to which the Executive may be entitled under any incentive compensation plans shall be subject to the provisions, rules and regulations of any such plan which apply to other management employees.

4.3 PARTICIPATION IN BENEFIT PLANS. During the term of this Agreement, Executive shall be entitled to participate in all employee benefit plans, profit-sharing, stock options, vacation and other perquisite plans and programs for which key employees of the Company are generally eligible. The Executive's participation in any such plan or program shall be subject to the provisions, rules and regulations thereof that are generally available to all participants thereon, provided, however, in no event shall Executive's benefits be less than the benefits described in Exhibit C.

4.4 EXPENSES. In accordance with the Company's policies established from time to time, the Company will pay or reimburse the Executive for all reasonable and necessary out-of-pocket expenses incurred by her in the performance of her duties under this Agreement, provided that Executive submits appropriate vouchers and expense reports substantiating the amount thereof and the business purposes for which such expenses were incurred.

4.5 ACCELERATION OF OPTIONS. Notwithstanding any provisions of the Company's option or stock incentive plan, or of the Executive's stock option or restricted stock agreements, in the event of a "Corporate Transaction" or "Change of Control," as defined below, during the period

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of the Executive's employment hereunder; all of the Executive's stock options shall vest in full and all rights of the company to repurchase restricted stock of the Executive shall terminate. For purposes hereof, "Change in Control" shall mean a change in ownership or control of the Company effected through either of the following transactions:

(i) the acquisition, directly or indirectly, by any person or related group of persons (other than the Company or a person that directly or indirectly controls, is controlled by, or is under common control with, the Company), of beneficial ownership (within the meaning of Rule 13d-3 of the 1934 Act) of securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities pursuant to a tender or exchange offer made directly to the Company's stockholders which the Board does not recommend such stockholders to accept, or

(ii) a change in the composition of the Board over a period of thirty-six (36) consecutive months or less such that a majority of the Board members ceases, by reason of one or more contested elections for Board membership, to be comprised of individuals who either (A) have been Board members continuously since the beginning of such period or (B) have been elected or nominated for election as Board members during such period by at least a majority of the Board members described in clause (A) who were still in office at the time the Board approved such election or nomination.

"Corporate Transaction" shall mean either of the following stockholder-approved transactions to which the Company is a party:

(i) a merger or consolidation in which securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities are transferred to a person or persons different from the persons holding those securities immediately prior to such transaction; or

(ii) the sale, transfer or other disposition of all or substantially all of the Company's assets in complete liquidation or dissolution of the Company.

#### 5. TERMINATION.

5.1 TERMINATION BY THE COMPANY FOR CAUSE. Any of the following acts or omissions shall constitute grounds for the Company to terminate the Executive's employment pursuant to this Agreement for "cause":

(a) Willful misconduct by Executive causing material harm to the Company but only if Executive shall not have discontinued such misconduct within 30 days after receiving written notice from the Company describing the misconduct and stating that the Company will consider the continuation of such misconduct as cause for termination of this Agreement.

(b) Any material act or omission by the Executive involving gross negligence in the performance of the Executive's duties to, or material deviation from any of the policies or directives of, the Company, other than a deviation taken in good faith by the Executive for the benefit of the Company;

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(c) Any illegal act by the Executive which materially and adversely affects the business of the Company or any felony committed by Executive, as evidenced by conviction thereof, provided that the Company may suspend the Executive with pay while any allegation of such illegal or felonious act is investigated.

Termination by the Company for cause shall be accomplished by written notice to the Executive and shall be preceded by a written notice providing a reasonable opportunity for the Executive to correct her conduct.

5.2 TERMINATION FOR DEATH OR DISABILITY. In addition to termination for cause pursuant to Section 5.1 hereof, the Executive's employment pursuant to this Agreement shall be immediately terminated without notice by the Company (i) upon the death of the Executive or (ii) upon the Executive becoming totally disabled. For purposes of this Agreement, the term "totally disabled" means an inability of Executive, due to a physical or mental illness, injury or impairment, to perform a substantial portion of her duties for a period of one hundred eighty (180) or more consecutive days, as determined by a competent physician selected by the Company's Board of Directors and reasonably agreed to by the Executive, following such one hundred eighty (180) day period.

5.3 TERMINATION FOR GOOD REASON. Executive's employment pursuant to this Agreement may be terminated by the Executive for "good reason" if the Executive voluntarily terminates her employment as a result of any of the following:

(a) Without the Executive's prior written consent, a reduction in her then current Base Salary;

(b) Without Executive's prior written consent, a relocation of the Executive's place of employment outside of Orange County, California;

(c) Resignation as a result of unlawful discrimination, as evidenced by a final court order;

(d) A reduction in duties and responsibilities which results in the Executive no longer having duties customary for a Vice President, Clinical Affairs; or

(e) The Company materially breaches any provision of this

Agreement.

5.4 TERMINATION WITHOUT CAUSE. The Company may terminate this Agreement, and the employment of the Executive under this Agreement, without cause at any time upon at least thirty (30) days prior written notice to the Executive.

5.5 PAYMENTS UPON REMOVAL OR TERMINATION. If during the term of this Agreement, the Executive resigns for one of the reasons stated in Section 5.3, or the Company terminates the Executive's service, except as provided in Sections 5.1 or 5.2 hereof, the Executive shall be entitled to the following compensation: (i) the portion of her then current Base Salary which has accrued through her date of termination, (ii) any payments for unused vacation and reimbursement expenses, which are due, accrued or payable at the date of Executive's termination, (iii) severance payment in an amount (the "Severance Amount") equal to Executive's then-current

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Base Salary, payable for the remainder of the Term; and (iv) all of Executive's options to purchase shares of the Company's common stock and restricted stock shall accelerate and automatically vest by one additional year, and such options shall otherwise be exercisable in accordance with their terms.

All payments required to be made by the Company to the Executive pursuant to this Section 5.5 shall be paid on a regular basis in accordance with the Company's normal payroll procedures and policies, including, without limitation, the Severance Amount which shall be paid at such times and in such amounts consistent with the Company's normal payroll procedures and policies over the number of months immediately succeeding the date of termination that is equal to the number of months of Base Salary payable as the Severance Amount. If the Company terminates the Executive's employment pursuant to Sections 5.1 or 5.2, or if the Executive voluntarily resigns (except as provided in Section 5.3), then the Executive shall be entitled to only the compensation set forth in items (i) and (ii) or the first paragraph of this Section 5.5.

To the extent that any or all of the payments and benefits provided for in this Agreement constitute "parachute payments" within the meaning of Section 280G of the Internal Revenue Code (the "Code") and, but for this paragraph, would be subject to the excise tax imposed by Section 4999 of the Code, then at the Executive's election:

(A) the Executive shall receive all such payments and benefits the Executive is entitled to receive hereunder, and any liability for taxes pursuant to the above shall be the liability solely of the Executive; or

(B) the aggregate amount of such payments and benefits shall be reduced such that the present value thereof (as determined under the Code and applicable regulations) is equal to 2.99 times the Executive's "base amount" (as defined in the Code).

The determination of any reduction or increase of any payment or benefits under this paragraph 5 pursuant to the foregoing provision shall be made by a nationally recognized public accounting firm chosen by the Company in good faith, and such determination shall be conclusive and binding on the Company and the Executive.

6. ASSIGNMENT. This Agreement shall not be assignable, in whole or in part, by either party without the written consent of the other party, except that the Company may, without the consent of the Executive, assign its rights and obligations under this Agreement to an Affiliate or to any corporation, firm or other business entity (i) with or into which the Company may merge or consolidate, or (ii) to which the Company may sell or transfer all or substantially all of its assets. After any such assignment by the Company, the Company shall be discharged from all further liability hereunder and such assignee shall thereafter be deemed to be the Company for the purposes of all provisions of this Agreement including this Section 6.

7. SUCCESSORS. This Agreement shall inure to the benefit of and be enforceable by the Executive's personal and legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees. If the

Executive should die while any amounts are still payable to her hereunder, all such amounts, unless otherwise provided herein, shall be paid in accordance with the terms of this Agreement to the Executive's devisee, legatee, or other designee or, if there be no such designee, to the Executive's estate.

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#### 8. MISCELLANEOUS.

8.1 GOVERNING LAW. This Agreement is made under and shall be governed by and construed in accordance with the laws of the State of California.

8.2 PRIOR AGREEMENTS. This Agreement contains the entire agreement of the parties relating to the subject matter hereof and supersedes all prior agreements and understanding with respect to such subject matter, and the parties hereto have made no agreements, representations or warranties relating to the subject matter of this Agreement which are not set forth herein.

8.3 ARBITRATION. In the event of any controversy, claim or dispute between the parties hereto arising out of or relating to this Agreement, the matter shall be determined by arbitration, which shall take place in Orange County, California, under the rules of the American Arbitration Association. The arbitrator shall be a retired Superior Court judge mutually agreeable to the parties and if the parties cannot agree such person shall be chosen in accordance with the rules of the American Arbitration Association. The arbitrator shall be bound by applicable legal precedent in reaching his or her decision. Any judgment upon such award may be entered in any court having jurisdiction thereof. Any decision or award of such arbitrator shall be final and binding upon the parties and shall not be appealable. The parties hereby consent to the jurisdiction of such arbitrator and of any court having jurisdiction to enter judgment upon and enforce any action taken by such arbitrator. The fees payable to the American Arbitration Association and the arbitrator shall be paid by the Company.

8.4 WITHHOLDING TAXES. The Company may withhold from any salary and benefits payable under this Agreement all federal, state, city or other taxes or amounts as shall be required to be withheld pursuant to any law or governmental regulation or ruling.

8.5 AMENDMENTS. No amendment or modification of this Agreement shall be deemed effective unless made in writing signed by the parties hereto.

8.6 NO WAIVER. No term or condition of this Agreement shall be deemed to have been waived nor shall there be any estoppel to enforce any provisions of this Agreement, except by a statement in writing signed by the party against whom enforcement of the waiver or estoppel is sought. Any written waiver shall not be deemed a continuing waiver unless specifically stated, shall operate only as to the specific term or condition waived and shall not constitute a waiver of such term or condition for the future or as to any act other than that specifically waived.

8.7 SEVERABILITY. To the extent any provision of this Agreement shall be invalid or unenforceable, it shall be considered deleted herefrom and the remainder of such provision and of this Agreement shall be unaffected and shall continue in full force and effect.

8.8 COUNTERPART EXECUTION. This Agreement may be executed by facsimile and in counterparts, each of which shall be deemed an original and all of which when taken together shall constitute but one and the same instrument.

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8.9 ATTORNEYS FEES. Should any legal action or arbitration be required to resolve any dispute over the meaning or enforceability of this Agreement or to enforce the terms of this Agreement, the prevailing party shall be entitled to recover its or her reasonable attorneys fees and costs incurred in such action, in addition to any other relief to which that party may be entitled.

8.10 NOTICES. Any notice required or permitted to be given hereunder shall be in writing and may be personally served or sent by United States Mail,

and shall be deemed to have been given when personally served or two days after having been deposited in the United States Mail, registered mail, return receipt requested, with first class postage prepaid and properly addressed as follows:

If to Executive: Claire Walker  
787 Balboa Avenue  
Laguna Beach, CA 92651

If to the Company: Radiance Medical Systems, Inc.  
13700 Alton Parkway, Suite 160  
Irvine, CA 92618  
Attn: Chief Executive Officer

9.11 PROPRIETARY INFORMATION AND INVENTIONS AGREEMENT. Executive agrees to sign the Company's standard form of employee proprietary information and inventions agreement.

8

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year set forth above.

"COMPANY"  
RADIANCE MEDICAL SYSTEMS, INC.,  
a Delaware corporation

By: \_\_\_\_\_  
Its: \_\_\_\_\_

"EXECUTIVE"

\_\_\_\_\_  
Claire Walker

9

Exhibit A

Claire Walker Board of Director Memberships

None.

10

Exhibit B

"Competitive Products"

1. PTCA Catheters
2. Conventional Coronary Stents - Without Drug Delivery
3. Conventional Coronary Stents - with Radiation
4. Coronary and Peripheral Vascular Radiation Catheters

11

Exhibit C

C. Walker Benefits

- Health Insurance
- Dental Insurance
- Long Term Disability Insurance
- Prescription Drug Insurance
- 401K Program Participation
- Employee Stock Purchase Program Participation
- Paid Company Holidays
- Paid vacation per company policy

List of Subsidiaries

1. CVD/RMS Acquisition Corp., a Delaware corporation.
2. CVD GmbH, a German corporation.
3. IDI Acquisition Corporation, a Delaware corporation.

## CONSENT OF ERNST &amp; YOUNG LLP, INDEPENDENT AUDITORS

We consent to the incorporation by reference in the Registration Statements on Form S-8 No. 333-07959, No. 333-42161 and No. 333-72531 and the Registration Statements on Form S-3 No. 333-35343, No. 333-33997, No. 333-71053, and No. 333-59305 of our report dated February 18, 1999, with respect to the consolidated financial statements and schedule of Radiance Medical Systems, Inc. and subsidiaries included in this Annual Report (Form 10-K) for the year ended December 31, 1998.

/s/ ERNST & YOUNG LLP

Orange County, California  
March XX , 1999

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