

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

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, 1996

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

CARDIOVASCULAR DYNAMICS, 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: (714) 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 7, 1997, was approximately \$52,715,000 (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 7, 1997, approximately 9,080,902 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 1997 Annual Meeting of Stockholders to be held on May 19, 1997 are incorporated by reference into Part III.

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PART I

ITEM 1. BUSINESS

CardioVascular Dynamics, Inc. ("CVD" or the "Company") designs, develops, manufactures and markets catheters used to treat certain vascular diseases. The Company's catheters are used in conjunction with angioplasty and other interventional procedures such as vascular stenting and drug delivery. The Company's proprietary Focus and Multiple Microporous Membrane ("M(3)") technologies enable physicians to deliver therapeutic radial force, stents, drugs or contrast media accurately and effectively to the treatment site, and also allow the perfusion of blood during an interventional procedure. The Company believes that the combination of these technologies on a multiple-purpose catheter enables physicians to effectively perform challenging interventional procedures, resulting in improved treatment outcomes and lower costs. The Company has eleven issued U.S. patents covering certain aspects of its catheter technologies.

CVD has utilized its core proprietary technologies to develop catheters that provide clinical and cost benefits in the treatment of vascular diseases. The Company's catheters are designed to address three principal challenges facing cardiologists: restenosis of a treated vessel, chronic total occlusions and acute reclosure of a vessel during or soon after a procedure. 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. These characteristics allow a single balloon to expand to multiple diameters, enabling the physician to perform interventional procedures in vessels of varying diameters and anatomical locations. The Company's proprietary M(3) technology combines multiple membranes of polymeric balloon material to form a single balloon that enables the accurate delivery of drugs or contrast agents to the lesion or thrombus site. The M(3) technology can also be utilized to provide perfusion of blood during an interventional procedure. The Company believes that the Focus and M(3) technologies may enable physicians to cost-effectively treat vascular diseases by reducing the cost of those procedures which require more than one catheter.

FORWARD-LOOKING STATEMENTS

Certain statements contained in this Annual Report on Form 10-K, including, without limitation, statements containing the words "believes," "anticipates," "estimates," "expects" and words of similar import, constitute "forward-looking statements" within the meaning of Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Given these uncertainties, prospective investors are cautioned not to place undue reliance on such forward-looking statements. The Company disclaims any obligation to update any such factors or to publicly announce the result of any revisions to any of the forward-looking statements contained or incorporated by reference herein to reflect any events or developments.

PRODUCTS

Catheter Products

The Company has utilized its Focus and M(3) technologies to develop catheter products that address the challenges physicians experience in treating vascular diseases. These technologies are available in various combinations on a

multiple-purpose catheter, thereby enabling physicians to cost-effectively treat vascular disease. The Company's products are designed to be low profile (small, uninflated diameter), enabling cardiologists to advance them along narrow vessels, and flexible and trackable, enabling cardiologists to advance and control them accurately within the vasculature.

The following table lists CVD's currently marketed products:

| PRODUCTS | INTENDED APPLICATIONS | U.S. REGULATORY STATUS | FIRST COMMERCIAL SALE |
|---------------------------|---|-------------------------|-----------------------|
| Focus Catheters | | | |
| ARC | | | |
| Over-the-wire design..... | PTCA (i.e. balloon angioplasty in coronary arteries) | PMA Supplement Approved | Q3 1996 |
| CAT/CAT 15 | | | |
| Rail design..... | PTCA or Stent Delivery(2) | N/A(1) | Q1 1995 |
| FACT/FACT 15 | | | |
| Over-the-wire design..... | PTCA or Stent Delivery(2) | Approved | Q1 1996 |
| Lynx F/X | | | |
| Rail Design..... | PTCA or Stent Delivery(2) | N/A(1) | Q1 1997 |
| Focus | | | |
| Over-the-wire design..... | PTA (i.e. balloon angioplasty in peripheral arteries) | 510(k) Clearance | Q3 1995 |
| M3 Catheters | | | |
| Bullett Hi-Flo | | | |
| Over-the-wire design..... | Total Occlusion Drug Delivery (coronary) | 510(k) Clearance | Q2 1996 |
| Bullett F/X | | | |
| Rail design..... | Total Occlusion Drug Delivery (coronary) | 510(k) Clearance | Q2 1996 |
| Periflow Small Vessel | | | |
| Over-the-wire design..... | PTA/Drug Delivery | 510(k) Clearance | Q1 1996 |
| DART Stent..... | Coronary Stenting | N/A (1) | Q1 1997 |
| Enforcer Stent..... | Coronary Stenting | N/A (1) | Q1 1997 |

(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 the Company to obtain a PMA supplement approval. The Company is not currently seeking such approval.

Focus Catheters. The Company's Focus products have a catheter balloon that has an adjustable, larger center diameter and smaller, fixed, distal and proximal diameters. This characteristic provides increased utility in a variety of therapeutic treatments and anatomical locations. Existing uniform diameter catheters require cardiologists to use multiple balloons to treat vessels of varying diameters, resulting in unnecessary costs. In addition, the Focus catheters may 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.

M3 Catheters. The Company's M(3) catheters offer cardiologists the ability to deliver drugs or contrast media to the treatment site accurately and enable the perfusion of blood during angioplasty procedures. These capabilities may be combined on an interventional catheter to provide cardiologists the functionality of multiple catheters, in a single, cost-effective device. The accurate delivery of drugs to the treatment site may enhance the effectiveness of these pharmacological agents and may reduce the quantity of drug required to achieve an acceptable outcome. Drugs are utilized by cardiologists to reduce the occurrence of restenosis and acute reclosure, and to dissolve blood clots. Typically, therapeutic drug delivery is accomplished by means of an intravenous

injection, a method that requires larger amounts of drug than is clinically required because the drug is diffused throughout the body. The Company's M(3) technology enables cardiologists to deliver drugs directly to the treatment site through a catheter's lumen, or interior channel. While CVD's M(3) site-specific drug delivery catheters are currently marketed internationally, they can only be used in the United States to

administer drugs specifically approved by the FDA for administration by such catheters. The multiple lumens of the catheter may also be used to deliver contrast media for angiographic viewing when advancing the catheter along a totally occluded vessel. Traditional catheters must be removed to inject contrast media into a total occlusion. Finally, the M3 technology can be utilized to provide perfusion of blood during an interventional procedure. This perfusion capability allows the balloon to be inflated for longer durations and reduces the number of inflations and deflations required in certain procedures, and may increase the clinical effectiveness of the treatment.

Vascular Access Products

The Company's vascular access products utilize patented technology to provide rapid, accurate access to the body's vascular system for guidewire and catheter entry. The principal current product, called the SmartNeedle, was acquired from ACS and is based on Doppler ultrasound technology. a miniaturized ultrasound chip is placed at the tip of a disposable ultrasonic probe which is then placed inside a conventional vascular access needle. The probe is then connected to a separate reusable monitor. Once placed in the body as a part of the access needle, the Doppler chip emits an audible signal which enables the physician to more accurately determine whether or not the needle resides in the proper location within the intended arterial or venous lumen. Once positioned properly, the probe is removed, leaving the conventional access needle in place within the artery or vein. Since introduction, the SmartNeedle's primary use has been in interventional cardiology and radiology procedures.

NEW PRODUCT DEVELOPMENT

The Company focuses its research and development efforts on utilizing the Company's proprietary processes and patented technologies to develop cost-effective products that address existing and emerging clinical demands. The Company's strategy is to refine its existing technologies and to enhance the performance of its existing product offerings, including efforts to make its Focus and M3 products lower profile, more flexible and trackable, and operable at a broader range of inflation pressures. In addition, the Company is developing additional products utilizing combinations of its technologies that may provide cardiologists greater therapeutic applicability in a single device. The Company is also in the process of developing unique catheter designs intended to provide enhanced delivery of therapeutic radial force and pharmacological agents. The Company will be required to seek FDA approval for any new product and it is expected that some of these products will be subject to the PMA process. The Company's current new product development efforts are summarized in the table below.

| PRODUCTS | INTENDED APPLICATIONS | U.S. REGULATORY STATUS |
|------------------------------|---|------------------------|
| Focus Catheters | | |
| Lynx | | |
| Over-the-wire design..... | PTCA or Stent Delivery | PMA Supplement Filed |
| Facilitated Force..... | Controlled Plaque Incision and PTCA | Development Stage |
| Vascular Stent | | |
| IDI Stent..... | Peripheral Vascular Stent | Development Stage |
| M3 Catheters | | |
| Transport (1)..... | PTCA/Drug Delivery | Development Stage |
| Periflow Large-Vessel..... | PTA/Drug Delivery | 510(k) Clearance |
| MicroMembrane Radiation..... | Delivery of Radioactive Materials for Restenosis Prevention | Development Stage |
| MAC I (2)..... | Perfusion/PTCA | Development Stage |
| MAC II..... | Perfusion/Drug Delivery | Development Stage |
| MAC III..... | Perfusion/PTCA/Drug Delivery | Development Stage |
| PD Access..... | Vascular Access | 510(k) Filed |

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(1) Licensed to SCIMED. See "--Strategic Relationships."

(2) Licensed to ACS. See "--Strategic Relationships."

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The M3 technology is being utilized in various experimental clinical programs to administer the site-specific delivery of therapeutic agents following angioplasty or stent delivery for the purpose of reducing or eliminating restenosis. The Company is also using M3 technology in its MicroMembrane Radiation Therapy development program for restenosis prevention. This program is evaluating CVD's M3 technology to more accurately deliver radioactive substances specifically to the treatment site.

TECHNOLOGY

The Company has developed proprietary material manufacturing processes that it has utilized to develop patented interventional catheters. 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. The Company's Focus technology bonds a membrane between compliant and non-compliant materials, resulting in a balloon with a large center diameter and smaller, fixed 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. The Focus capability enables cardiologists to deliver stents or therapeutic radial force accurately to the treatment site, while minimizing the force applied to adjacent tissue. Conventional uniform diameter catheters may damage healthy vessel sections, as these sections receive as much radial force as do the diseased sites. It is widely believed that vessel wall damage may lead to acute reclosure of the vessel or restenosis.

The Company's M3 technology creates a membrane by applying mechanical and radiation treatment to standard polymeric balloon material during the extrusion process. Microporous holes are then drilled in the resulting material by proprietary mechanical or laser drilling processes. CVD's M3 technology enables blood to flow through a coil lumen or inner shaft of the catheter, allowing perfusion to the distal vessels (those beyond the treatment site) during angioplasty or drug delivery. Prior to inflation, the balloon acts as a shaft for the distal portion of the catheter. Once the balloon is inflated, the cardiologist advances a coil into and through the inner lumen of the inflated balloon. The coil supports the balloon during balloon angioplasty or drug delivery and facilitates the perfusion of the distal vessels. The M3 technology enables the Company to combine balloon angioplasty and perfusion capabilities on a single catheter in a profile comparable to standard balloon angioplasty catheters without perfusion capability. The Company believes that the M3 technology also enables it to combine PTCA and perfusion capabilities on a single catheter with a lower profile than any currently marketed catheter with similar capabilities.

The Company's IDI subsidiary, which was acquired in October 1996, utilizes patented technology in the development of medical stents for the treatment of patients with vascular disease caused by aneurysms or atherosclerosis. IDI is developing a compact, self-expanding metallic stent with a micro-porous surface for use as either a stent or a stent graft. By selecting metal foil of the proper thickness and tensile strength, and heat-treating it in the proper shape, the Company 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. There can be no assurance that IDI will successfully complete the development of any products or that any such products will receive any required regulatory approvals.

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 the Company has licensed to third parties, all of the Company's products are produced in its facilities in Irvine, California. The Company fabricates certain proprietary components, then

assembles, inspects, tests and packages all components into finished products. By designing and assembling its catheter products, the Company believes it is better able to control quality and costs, limit third-party access to its proprietary technology, and manage manufacturing process enhancements and new product introductions. In addition, the Company 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 are currently performed by single vendors. While the Company believes that there

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are other vendors available to perform these processes, an interruption of performance by any of these vendors could have a material adverse effect on the Company's ability to manufacture its products until a new source of supply were qualified and, as a result, could have an adverse effect on the Company's business, financial condition and results of operations.

The Company's success will depend in part upon its ability to manufacture its products in compliance with ISO 9001, the FDA's GMP regulations, CDHS licensing and other regulatory requirements, in sufficient quantities and on a timely basis, while maintaining product quality and acceptable manufacturing costs. The Company began manufacturing certain of its products at its facilities in July 1995. The Company also introduced a significant number of new products in 1996. Accordingly, the Company has very limited experience in manufacturing its products. In addition, on July 15, 1996, the Company entered into co-distribution agreements with Medtronic which granted Medtronic certain non-exclusive rights to distribute the Company's FACT, CAT and ARC catheters. Under the terms of these agreements, if the Company is unable to meet its delivery obligations with respect to the purchased catheters, up to 60% of the Company's manufacturing capacity will be devoted to manufacturing such catheters for Medtronic. The Company has undergone and expects to continue to undergo regular GMP inspections in connection with the manufacture of its products at the Company's facilities. The Company's success will depend, among other things, upon its ability to efficiently manage the simultaneous manufacture of different products and to integrate the manufacture of new products with existing products. There can be no assurance that the Company 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. The Company's failure to successfully commence the manufacturing of these new products, or to increase production volumes of new and existing products in a timely manner, would materially adversely affect the Company'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, GMP regulations, CDHS or other regulatory requirements could have a material adverse effect on the Company's business, financial condition and results of operations. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations--Risk Factors--Limited Manufacturing Experience."

MARKETING AND SALES

The Company's products are sold in the United States and international markets, principally Europe and Japan. However, certain of the Company's products are not available in each market due to regulatory and intellectual property restrictions. The Company currently sells its products through a combination of strategic partners, medical device distributors and eighteen direct sales personnel. The Company is a party to three agreements for the U.S. distribution of products incorporating its Focus and M3 technologies. CVD also has distribution agreements with 25 companies covering 41 countries outside the United States and Japan. CVD currently distributes certain products in Japan through an exclusive distribution agreement with Fukuda. Sales of the Company's products through Fukuda accounted for 18% and 15% of the Company's total product sales in 1995 and 1996, respectively. The Company recently informed Fukuda of its decision to terminate the existing Fukuda agreement. The Company expects that Fukuda will continue to distribute its products at least through 1997. The Company is currently negotiating with several distributors, including Fukuda, regarding a new distribution agreement for the Japanese market. In addition, sales to Johnson & Johnson International Systems, Inc. accounted for 12% of total product sales in 1995 and sales to Medtronics accounted for 22% of total product sales in 1996. The Company intends to expand its sales and marketing capability and to distribute selected new products through strategic partnerships. See "Item 7. Management's Discussion and Analysis of Financial

Condition and Results of Operations--Risk Factors--Limited Marketing and Sales Resources; Dependence Upon Strategic Relationships."

In 1994, 1995 and 1996, total export sales were \$970,000, \$2,054,000 and \$3,514,000, respectively, or approximately 83%, 59% and 42% respectively, of total product sales. In 1994, 1995 and 1996 sales to Europe accounted for \$255,000, \$1,179,000 and \$1,614,000, respectively; sales to Japan represented \$715,000, \$744,000 and \$1,240,000, respectively; and sales to Latin America represented \$0, \$131,000 and \$243,000, respectively. The Company expects to continue to derive significant revenue from international sales and

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therefore a significant portion of the Company'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 the Company's ability to deliver products on a competitive and timely basis. Future imposition of, or significant increases in the level of, customs duties, export quotas or other trade restrictions, could have an adverse effect on the Company's business, financial condition and results of operations. In foreign countries, the Company'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 the Company. See Note 1 of Notes to Consolidated Financial Statements. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations--Risk Factors--Dependence Upon International Sales."

POST-MARKETING CLINICAL STUDIES

The Company has completed the clinical trials required for FDA approval of those products which are marketed in the United States. In addition to those trials, the Company is also sponsoring a controlled, randomized, multicenter clinical study in the United States to continue to evaluate the clinical and economic value of its core technologies. Data from this study is being accumulated and analyzed to support the marketing of the Company's current products.

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

A second study is comparing the Focus PTCA catheter with conventional PTCA catheters. The Focus Lesion Expansion Optimizes Results Study ("FLEXOR Study") will evaluate the efficacy of Focus technology in improving clinical results following angioplasty procedures. Success will be measured based on the ability of Focus technology to improve the minimal lumen diameter ("MLD") of the arterial opening, to increase safety and to reduce the number of catheters necessary for PTCA procedures. Results will be interpreted in light of any procedure-related vascular complications, restenosis and occurrences of other major clinical adverse cardiac events. 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 was commenced in the fourth quarter of 1996. Completion is expected in 1997.

Certain of the Company's products which utilize Focus technology have received FDA approval for PTCA and PTA indications. However, none of these products has received FDA approval for use in stent delivery. An investigator-controlled study is currently testing the Company'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 is expected to be completed in 1997.

The Company also intends to sponsor additional studies from time to time to assess the value of, and to expand clinical indications of, its existing and new technologies. The Company is planning a clinical study to expand the clinical uses of its Focus technology catheters to include balloon dilatation of previously deployed stents in order to properly implant the stent in the arterial wall of small coronary vessels. This study will include approximately 100 patients and is expected to be completed in 1997.

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STRATEGIC RELATIONSHIPS

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

Advanced CardioVascular Systems, Inc. In January 1995, the Company entered into a license agreement with ACS. The parties subsequently confirmed their understanding with respect to certain matters in a second agreement dated March 4, 1996 (collectively, the "ACS Agreements"). Under the ACS Agreements, the Company acquired certain rights to ACS' SmartNeedle technology, subject to the payment of certain royalties. ACS was granted the option to acquire the exclusive worldwide rights to certain CVD perfusion technology, which ACS exercised on February 14, 1996. As a result, ACS has an exclusive worldwide right to develop, manufacture and market the Company's MAC I product line. In exchange for this technology, ACS is obligated to make milestone and minimum annual royalty payments to CVD, and also has certain obligations to develop and market the technology. In addition, in the event that CVD develops a product which combines coronary balloon angioplasty, perfusion and drug delivery technology on the same catheter, ACS will have certain rights to license such product. The ACS Agreements may be terminated upon 60 days notice in the event of a breach by the other party, subject to the breaching party's right to cure, or by ACS upon 30 days notice without cause.

SCIMED Life Systems, Inc. The Company has entered into a Stock Purchase and Technology License Agreement, dated September 10, 1994, with SCIMED (the "SCIMED Agreement"). Pursuant to the SCIMED Agreement, SCIMED purchased a 19% equity position in the Company. SCIMED was also granted an exclusive worldwide license to certain combined site-specific drug delivery and coronary angioplasty technology, including the Company's Transport products, for use in the cardiovascular field in exchange for license and royalty fees. The SCIMED Agreement also requires CVD to provide certain technical assistance and to perform additional research and development relating to the licensed technology in exchange for fees and reimbursement of expenses. In the event that CVD's SCIMED-funded research and development efforts result in improvements to the licensed technology, SCIMED will have an exclusive worldwide license to the technology in the cardiovascular field and a non-exclusive license outside the cardiovascular field, both of which are subject to the payment of royalties. The SCIMED Agreement may be terminated in the event of breach on 90 days notice by the non-breaching party (or on 30 days notice in certain limited circumstances) or by SCIMED upon 180 days notice.

Fukuda Denshi Co., Ltd. The Company entered into a Distribution Agreement, dated May 28, 1993, with Fukuda Denshi Co., Ltd. (the "Fukuda Agreement"), whereby Fukuda served as CVD's exclusive distributor for certain of the Company's products in Japan. In exchange for this exclusive distributorship, Fukuda paid a fee to CVD in addition to payments owing upon the purchase of the products. Fukuda also agreed to undertake all necessary clinical trials to obtain approval from Japanese regulatory authorities for the sale of the products in Japan. Fukuda's purchases under the Fukuda Agreement are subject to certain minimum requirements. The initial term of the Fukuda Agreement expires on May 31, 1998, subject to a five-year extension. The Fukuda Agreement may also be terminated in the event of breach upon 90 days notice by the non-breaching party. In July 1995 and May 1996, the distribution agreement with Fukuda was amended to grant Fukuda exclusive distribution rights to additional CVD products. Under these amendments, the Company received \$750,000 which converted into the right to receive 62,500 shares of Common Stock upon the consummation of the Company's initial public offering on June 19, 1996. Fukuda received these

shares on November 29, 1996. The Company recently informed Fukuda of its decision to terminate the existing Fukuda Agreement. The Company expects that Fukuda will continue to distribute its products at least through 1997. The Company is currently negotiating with several distributors, including Fukuda, regarding a new distribution agreement for the Japanese market.

Endosonics Corporation. The Company has entered into a license agreement with Endosonics Corporation ("EndoSonics"), dated December 22, 1995 (the "EndoSonics Agreement"), pursuant to which CVD granted EndoSonics the non-exclusive, royalty-free right to CVD's Focus technology for the development and sale of a combined Focus/Ultrasound product. In exchange, CVD received the non-exclusive, royalty-free

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right to submit PMA supplement applications utilizing an EndoSonics PMA as a reference and to manufacture and distribute CVD products as a supplement to the EndoSonics PMA. 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 the event of termination, the Company would be prohibited from submitting new PMA supplements referencing the EndoSonics PMA and would be required to seek independent FDA approval for such products, which would have a material adverse effect on the Company's business, financial condition and results of operations. In addition, in March of 1996, EndoSonics purchased 400,000 shares of CVD's Series B Preferred Stock for a purchase price of \$8,000,000, that converted into 800,000 shares of Common Stock upon the consummation of the Company's initial public offering on June 19, 1996.

Medtronic, Inc. On July 15, 1996, the Company entered into co-distribution agreements with Medtronic, providing for the co-distribution of the Company's FACT, CAT and ARC balloon angioplasty catheters. Under the terms of these agreements, Medtronic will purchase a minimum number of angioplasty catheters manufactured by the Company for distribution worldwide for a period of up to three years. If the Company is unable to meet its delivery obligations regarding the purchased catheters, up to 60% of the Company's manufacturing capacity will be devoted to manufacturing such catheters for Medtronic. Specific products to be distributed by Medtronic will differ in individual country markets. The initial term of the Medtronic agreements is for a period of three years from the date of first delivery of a product. The agreements may be terminated in the event of breach upon notice by the nonbreaching party, subject to the breaching party's right to cure.

PATENTS AND PROPRIETARY INFORMATION

The Company'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. The Company has eleven issued U.S. patents covering certain aspects of its catheter technology and licenses, and additional patents relating to the vascular access and IDI stent technology. No assurance can be given that any issued patents will provide competitive advantages for the Company's products, or that they will not be challenged or circumvented by competitors.

The interventional cardiovascular market in general and the balloon angioplasty catheter market (including the type of catheters offered by CVD) in particular have been characterized by substantial litigation regarding patent and other intellectual property rights. There can be no assurance that the Company's products do not infringe such patents or rights. During 1996, the Company received a notice of potential trademark infringement regarding the Company's use of the term "focal" in connection with the Company's balloon angioplasty catheter. CVD entered into an agreement which prohibits the Company from using this term. The Company has since ceased any use thereof. In the event that any such third-parties assert claims against the Company for patent infringement and such patents are upheld as valid and enforceable, the Company 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 the Company or that the Company 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 adequately

protect the Company's intellectual property rights abroad. The Company 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 the Company's trade secrets or proprietary technology will not otherwise become known or be independently developed by competitors in such a manner that the Company has no practical recourse. Litigation may be necessary to defend against claims of infringement or invalidity, to enforce patents issued to the Company 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,

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the Company and its officers, which would have a material adverse effect on its business, financial condition and results of operations. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations--Risk Factors--Reliance on Patents and Proprietary Technology; Risk of Patent Infringement."

COMPETITION

The Company believes 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. The Company believes it competes favorably with respect to the foregoing factors. The Company also believes that its competitive position is dependent upon its ability to continue to develop innovative new catheter technologies and obtain rapid regulatory approval.

Competition in the market for devices used in the treatment of cardiovascular and peripheral vascular disease is intense, and is expected to increase. The interventional cardiology market is characterized by rapid technological innovation and change, and the Company's products could be rendered obsolete as a result of future innovations. The Company's catheters and other products under development compete or will compete with catheters marketed by a number of manufacturers, including ACS, SCIMED, JJIS and Cordis Corporation, subsidiaries of Johnson & Johnson, Medtronic, Inc., C.R. Bard, Inc. and Schneider USA, a subsidiary of Pfizer, Inc. Such companies have significantly greater financial, management and other resources, established market positions, and significantly larger sales and marketing organizations than does the Company. The Company also faces competition from manufacturers of other catheter-based atherectomy devices, vascular stents and pharmaceutical products intended to treat vascular disease. In addition, the Company believes that many of the purchasers and potential purchasers of the Company's products prefer to purchase catheter products from a single source. Accordingly, many of the Company's competitors, because of their size and range of product offerings, have a competitive advantage over the Company. There can be no assurance that the Company's competitors will not succeed in developing or marketing technologies and products that are more clinically effective or cost effective than any that are being marketed or developed by the Company, or that such competitors will not succeed in obtaining regulatory approval for introducing or commercializing any such products prior to the Company. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations--Risk Factors--Significant Competition."

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. 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 the Company'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 the Company's ability to sell its products on a profitable basis. Failure by hospitals and other users of the Company's products to obtain reimbursement from third-party payors, or changes in government and private third-party payors' policies toward reimbursement for procedures employing the Company's products, would have a material adverse effect on the Company's business, financial condition and results of operations. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations--Risk Factors--Limitations on Third-Party Reimbursement."

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GOVERNMENT REGULATION

The manufacturing and marketing of the Company's products are subject to extensive and rigorous government regulation in the United States and in other countries. The Company believes that its success will be significantly dependent upon commercial sales of improved versions of its catheter products. The Company will not be able to market these new products in the United States unless and until the Company 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 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 the Company'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 the Company's products, it could act to withdraw approval or clearances of those products or request that the Company present additional data. Any such actions would have a material adverse effect on the Company's business, financial condition and results of operations.

If substantial equivalence cannot be established, or if the FDA determines that the device or the particular application for the device requires a more rigorous review to assure safety and effectiveness, the FDA will require that the manufacturer submit a PMA application that 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. It is expected that certain of the Company's products under development will be subject to this PMA process. The Company currently has a non-exclusive, royalty-free right to submit PMA supplement applications utilizing an EndoSonics PMA as a reference and to manufacture and distribute CVD products as a supplement to the EndoSonics PMA. This agreement may be terminated in the event of breach upon 60 days notice by the non-breaching party, subject to the breaching party's right to cure. In the event of termination, the Company would be prohibited from submitting new PMA supplements referencing the EndoSonics PMA and would be required to seek independent FDA approval for any such products, which would have a material adverse effect on the Company's business, financial condition and results of operations.

The Company is also 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, the Company is inspected on a routine basis by both the FDA and the CDHS for compliance with GMP regulations. These regulations require that the Company manufacture its products and maintain related documentation in a prescribed manner with respect to manufacturing, testing and control activities. The Company has also undergone and expects to continue to undergo regular GMP inspections in connection with the manufacture of its products at the Company's facilities. Further, the Company is required to comply with various FDA requirements for labeling. The Medical Device Reporting laws and regulations require that the Company provide 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. CVD 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 the Company 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 the Company's products. Delays in

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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 the Company's business, financial condition and results of operations.

The Company is also 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 accurately predicted. Failure to comply with regulatory requirements could have a material adverse effect on the Company's business, financial condition and results of operations.

International sales of the Company's products are subject to the registration requirements of each country. The regulatory review process varies from country to country and may in some cases require the submission of clinical data. The Company 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 that require a PMA but are not yet approved domestically. The European Union has promulgated rules which require that medical products receive by mid-1998 the right to affix the CE mark, an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. Failure to receive the right to affix the CE mark will prevent the Company from selling its products in member countries of the European Union, which would have a material adverse effect on the Company's business, financial condition and results of operations.

PRODUCT LIABILITY

The Company faces the risk of financial exposure to product liability claims. The Company'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. The Company is currently covered under a product liability insurance policy with coverage limits of \$2.0 million per occurrence and \$2.0 million per year in the aggregate. There can be no assurance that the Company's product liability insurance is adequate or that such insurance coverage will remain available at acceptable costs. There can be no assurance that the Company will not incur significant product liability claims in the future. A successful claim brought against the Company in excess of its insurance coverage could have a material adverse effect on the Company's business, financial condition and results of operations. Additionally, adverse product liability actions could negatively affect the reputation and sales of the Company's products and the Company's ability to obtain and maintain regulatory approval for its products and substantially divert the time and effort of management away from the Company's operations.

EMPLOYEES

As of December 31, 1996, the Company had 160 employees, including 106 in manufacturing, 19 in research, development and regulatory affairs, 26 in sales and marketing and 9 in administration. The Company believes that the success of

its business will depend, in part, on its ability to attract and retain qualified personnel. The Company believes it has good relations with its employees.

ITEM 2. PROPERTIES

PROPERTIES

Currently, the Company leases facilities aggregating approximately 33,000 square feet in Irvine, California under lease agreements which expire beginning in 1998. The Company believes that its facilities are adequate to meet its requirements through mid-1998.

ITEM 3. LEGAL PROCEEDINGS

None.

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

None.

EXECUTIVE OFFICERS OF THE REGISTRANT

The executive officers and key employees of the Company, and their ages as of February 14, 1997, are as follows:

| NAME | AGE | POSITION |
|---------------------------|-----|---|
| Michael R. Henson..... | 51 | President, Chief Executive Officer and Chairman of the Board of Directors |
| Dana P. Nickell..... | 47 | Vice President, Finance and Administration, Chief Financial Officer and Secretary |
| Harold A. Heitzmann..... | 49 | Vice President, Research, Development and Engineering |
| Jeffrey F. O'Donnell..... | 37 | Vice President, Sales and Marketing |
| Jeffrey H. Thiel..... | 41 | Vice President, Operations |
| Bart R. Navarro..... | 51 | Director of Research and Development |
| Claire K. Walker..... | 50 | Director of Clinical Affairs |
| George F. Kick..... | 51 | Business Manager, Peripheral Products |
| Blair W. Breyne..... | 38 | Director of International Market Development |
| Robert J. Imdieke..... | 43 | Manager, Quality Assurance |

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 as President and Chief Executive Officer in February 1995. Prior to joining CVD, Mr. Henson served as the Chief Executive Officer of EndoSonics from 1988 to February 1995. He was appointed Chairman of the Board of Directors of EndoSonics in February 1993. Between April 1983 and February 1988, Mr. Henson served as President and Chief Executive Officer of Trimedyn, Inc., a manufacturer of medical lasers and catheters. Prior to joining Trimedyn 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.

Dana P. Nickell joined the Company as Vice President, Finance and Administration and Chief Financial Officer in December 1995 and was appointed Secretary in May 1996. Prior to joining CVD he was Chief Financial Officer of Innerspace Inc., a medical device manufacturer which filed for bankruptcy protection in 1995, from May 1994 to April 1995. From August 1993 until April 1994, Mr. Nickell served as Chief Financial Officer of Masimo Corporation, a developer of pulse oximeter technology. Between November 1988 and June 1993, Mr. Nickell was Chief Financial Officer and Vice President, Finance, Administration and Business Development of EndoSonics. He also served as Secretary of EndoSonics from January 1990 to August 1992. Mr. Nickell is a Certified Public Accountant.

Harold A. Heitzmann, Ph.D., joined the Company as Vice President, Research, Development and Engineering in March 1997. From September 1995 to February 1997, Dr. Heitzmann was Vice President, Catheter Development for Cardiac Pathways. From September 1991 to April 1995, Dr. Heitzmann was Director of Engineering at Innerspace, Inc., a medical device company. From 1983 to September 1991, Dr. Heitzmann held various engineering management positions with Baxter Healthcare Corporation, most recently as Director of Advanced Cardiology Projects.

Jeffrey F. O'Donnell has served as Vice President, Sales & Marketing at the Company since November 1995. Prior to joining CVD, Mr. O'Donnell served as President and Vice President of Marketing and Business Development of Kensey Nash Corporation, a medical device manufacturer, from January 1994 to May 1995. From 1988 to 1994 Mr. O'Donnell held various sales and regional management positions at ACS. Prior to

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working at ACS, Mr. O'Donnell held senior sales and marketing positions with Boston Scientific and Johnson & Johnson.

Jeffrey H. Thiel has served as Vice President, Operations since October 1996. Prior to joining CVD, 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 Operation Management positions with St. Jude Medical.

Bart R. Navarro joined the Company in February 1995 as Director of Manufacturing. In January 1997, he became Director of Research and Development. From September 1989 to February 1995, Mr. Navarro served as Director of Manufacturing for Eclipse Surgical Technologies, Inc. From March 1985 to September 1989, Mr. Navarro served as Manager of Manufacturing for MCM Laboratories, Inc., a medical device manufacturer. From June 1981 to March 1985, Mr. Navarro served as a Process Engineer for Manufacturing for ACS.

Claire K. Walker has served as Director of Clinical Affairs of the Company since November 1994. From May 1992 to November 1994, Ms. Walker provided clinical marketing consulting services to CVD. 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. From July 1981 to August 1988, Ms. Walker was employed by ACS as a clinical specialist and from 1984 through 1988 worked as a direct sales representative. Ms. Walker also worked as a cardiovascular catheterization laboratory nurse.

George F. Kick joined the Company in March 1995 and served as Director of U.S. Marketing until December 1995 when he became the Business Manager, Peripheral Products. From January 1992 to March 1995, Mr. Kick worked as a consultant and project manager at NeuroNavigational, a medical device manufacturer, developing minimally invasive vascular surgical systems for arterial bypass in the leg. From February 1979 to December 1991, he served as President of Dynamic Concepts, a cardiovascular distribution company, representing Trimedyne, Telectronics, CryoLife and other high tech start-up companies.

Blair W. Breyne joined the Company in January 1994 and has served as Director of International Market Development for the Company since January 1995. From January 1994 through December 1994, Ms. Breyne served as Manager of International Market Development. Prior to joining the Company, Ms. Breyne was employed by EndoSonics from May 1990 through December 1993 as Manager and National Manager of Sales and Clinical Applications.

Robert J. Imdieke joined the Company as Manager of Quality Assurance in January 1995. Prior to joining CVD, Mr. Imdieke served as Manager, Quality Assurance at Imagyn Medical, Inc. from June 1991 to January 1995. From December 1989 until February 1991, he served as Quality Control Supervisor at Advanced Interventional Systems. Mr. Imdieke also served as Quality Assurance Manager at Trimedyne, Inc. from November 1984 through May 1989.

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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 "CCVD". 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 1996 | | |
| Second Quarter..... | \$12 3/4 | \$10 1/2 |
| Third Quarter..... | 17 1/2 | 10 1/4 |
| Fourth Quarter..... | 17 1/2 | 9 5/8 |

On March 6, 1997, the closing sale price of the Common Stock as reported on the Nasdaq National Market was \$10.63 per share. As of February 14, 1997, there were approximately 98 holders of record of the Common Stock.

DIVIDEND POLICY

The Company has not paid dividends since its inception. 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.

| | PERIOD FROM MARCH 16, 1992 (DATE OF INCEPTION TO) DECEMBER 31, 1992 ----- | YEAR ENDED DECEMBER 31, ----- | | | |
|--|---|--|-----------|------------|------------|
| | | 1993 (1) | 1994 | 1995 | 1996 |
| | | ----- (IN THOUSANDS, EXCEPT PER SHARE DATA) | | | |
| Consolidated Statements of Operations Data: | | | | | |
| Revenue: | | | | | |
| Sales..... | \$ -- | \$ 126 | \$ 1,169 | \$ 3,462 | \$ 8,384 |
| License fee and other from related party..... | -- | -- | 1,000 | -- | 150 |
| Contract..... | -- | -- | 220 | 641 | 200 |
| | ----- | ----- | ----- | ----- | ----- |
| Total revenue..... | -- | 126 | 2,389 | 4,103 | 8,734 |
| Costs and expenses: | | | | | |
| Cost of sales..... | -- | 79 | 848 | 2,051 | 4,111 |
| Charge for acquired in-process research and development (2).... | -- | 2,001 | -- | 488 | 2,133 |
| Research and development..... | 294 | 734 | 1,228 | 1,683 | 3,582 |
| Marketing and sales..... | -- | 94 | 748 | 1,526 | 3,358 |
| General and administrative..... | 29 | 96 | 587 | 1,331 | 1,548 |
| | ----- | ----- | ----- | ----- | ----- |
| Total operating costs and expenses..... | 323 | 3,004 | 3,411 | 7,079 | 14,732 |
| | ----- | ----- | ----- | ----- | ----- |
| Loss from operations..... | (323) | (2,878) | (1,022) | (2,976) | (5,998) |
| Other income..... | 10 | 29 | 51 | 102 | 1,374 |
| | ----- | ----- | ----- | ----- | ----- |
| Net loss..... | \$ (313) | \$ (2,849) | \$ (971) | \$ (2,874) | \$ (4,624) |
| | ===== | ===== | ===== | ===== | ===== |
| Net loss per share (pro forma through June 1996) (3)..... | | | \$ (0.25) | \$ (0.65) | \$ (0.65) |
| | | | ===== | ===== | ===== |
| Shares used in computing net loss per share (pro forma through June 1996) (3)..... | | | 3,876 | 4,441 | 7,141 |

| | DECEMBER 31, | | | | |
|--|----------------|----------|----------|------------|-----------|
| | 1992 | 1993 | 1994 | 1995 | 1996 |
| | (IN THOUSANDS) | | | | |
| Consolidated Balance Sheets Data: | | | | | |
| Cash and cash equivalents..... | \$ 650 | \$ 547 | \$ 3,379 | \$ 1,568 | \$ 17,192 |
| Marketable securities available for sale.... | -- | -- | -- | -- | 25,733 |
| Working capital (deficit)..... | 583 | (75) | 1,366 | (774) | 46,142 |
| Total assets..... | 678 | 690 | 4,340 | 4,002 | 50,084 |
| Convertible obligation..... | -- | -- | -- | 750 | -- |
| Accumulated (deficit)..... | (313) | (2,580) | (3,551) | (6,425) | (11,049) |
| Total stockholders' equity (net capital deficiency)..... | \$ 607 | \$ (241) | \$ 1,288 | \$ (1,098) | \$ 47,623 |

- (1) The period from March 16, 1992 (inception) to December 31, 1992 and the period from January 1, 1993 to June 9, 1993 reflect the operations of the predecessor to the Company. See Note 1 to Consolidated Financial 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 total of the purchase price for Intraluminal Devices, Inc. and the associated acquisition expenses for the year ended December 31, 1996. See Notes 1 and 2 of Notes to Consolidated Financial Statements.
- (3) See Note 1 of Notes to Consolidated Financial Statements for information regarding the calculation of net loss per share.

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

This Annual Report on Form 10-K contains forward-looking statements which involve risks and uncertainties. The Company's actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in "Risk Factors" beginning on page 19.

OVERVIEW

CVD designs, develops, manufactures and markets catheters used to treat certain vascular diseases. The Company's patented catheters utilize its Focus and M3 technologies to deliver therapeutic radial pressure, stents, drugs or contrast media and improved blood flow during angioplasty and stent placement procedures. To date, the majority of the Company's revenue has been derived from sales of its angioplasty and angioplasty-related catheters.

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 CVD in exchange for \$0.5 million in cash. Pursuant to an Agreement and Plan of Reorganization between EndoSonics and CVD signed on June 9, 1993, EndoSonics acquired all of the outstanding capital stock of CVD 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 CVD's assets and liabilities. Accordingly, the purchase price paid by EndoSonics has been allocated to CVD's identifiable assets and liabilities, including \$2.0 million to acquired in-process research and development, which was immediately expensed, as no CVD 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 CVD 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 CVD'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 initial public offering.

In September 1994, CVD and SCIMED entered into a Stock Purchase and Technology License Agreement to develop and license CVD's patented combination balloon angioplasty/site-specific drug delivery technology (the Transport product line) for use in the coronary vessels. Through December 31, 1996 the Company had received in the aggregate approximately \$2.2 million in license fees, research and development funding and technical assistance from SCIMED under this agreement. SCIMED also purchased a 19% equity position in the Company for a purchase price of \$2.5 million. See "Item 1. Business Strategic Relationships."

In January 1995, the Company and ACS entered into an agreement pursuant to which the Company 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 CVD perfusion 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 CVD, and also has certain obligations to develop and market the perfusion technology. Through December 31, 1996 the Company had received approximately \$0.35 million in milestone payments under the ACS Agreements. See "Item 1. Business -- Strategic Relationships."

The Company currently sells its products through a combination of medical device distributors and a limited number of direct sales personnel. The Company is a party to three agreements for the U.S. distribution of products incorporating its Focus and M3 technologies. CVD currently distributes certain products in Japan through an exclusive distribution agreement with Fukuda. The Company recently informed Fukuda of its decision to terminate the existing Fukuda agreement. The Company expects that Fukuda will continue to distribute its products at least through 1997. The Company is currently negotiating with several distributors, including Fukuda, regarding a new distribution agreement for the Japanese market. CVD also has distribution agreements with 25 companies covering 41 countries outside the United States and Japan. See "Item 1. Business--Strategic Relationships."

On July 15, 1996, CVD and Medtronic, Inc. entered into agreements providing for the co-distribution by Medtronic of the Company's balloon angioplasty catheters. These catheters employ the Company's patented Focus Technology. Under the agreements, Medtronic will purchase a minimum number of angioplasty catheters manufactured by the Company for distribution worldwide for a period of up to three years. If the Company is unable to meet its delivery obligations with respect to the purchased catheters, up to 60% of the Company's manufacturing capacity will be devoted to manufacturing such catheters for Medtronic. Specific products to be distributed by Medtronic will differ in individual country markets. The Company will continue to sell Focus Technology products through its own direct and indirect sales force network. These products are currently sold under the names, FACT, CAT and ARC. See "Item 1. Business--Strategic Relationships."

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RESULTS OF OPERATIONS

Years Ended December 31, 1995 and December 31, 1996

Sales Revenue. Sales revenue increased to \$8.4 million in 1996 from \$3.5 million in 1995, representing an increase of 140%. The increase resulted from increased sales of the Company's Focus catheters, and the introduction of new 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 relationship with Fukuda accounted for 22% and 15%, respectively, of total product sales in 1996.

License Fee and Other Revenue. License fee and other revenue increased to \$0.2 million in 1996 from \$0.0 million in 1995. This increase resulted from revenues from a license agreement with ACS. See "Item 1. Business--Strategic Relationships."

Contract Revenue. Contract Revenue was \$0.2 million in 1996 and \$0.6 million in 1995. This decrease stemmed from reduced technology development and other support from SCIMED. See "Item 1. Business--Strategic Relationships."

Cost of Sales. Cost of sales increased to \$4.1 million in 1996 from \$2.1 million in 1995. This increase resulted primarily from increased manufacturing volumes related to increased product sales. In July 1995, the Company transferred its product manufacturing from EndoSonics' facility to the Company's facility in Irvine, California.

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 inprocess 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.

Research and Development. Research and development increased to \$3.6 million in 1996 compared to \$1.7 million in 1995, representing an increase of 112%. This increase resulted primarily from expenditures on the development of vascular access and Focus technology products. The Company believes it must maintain a substantial commitment to research and development to remain competitive and expects expenditures related to research and development to increase.

Marketing and Sales. Marketing and sales expenses increased to \$3.4 million in 1996 from \$1.5 million in 1995, representing an increase of 127%. 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 FACT and ARC catheters. The Company expects to expand and expects expenses associated with these activities to increase in the future as it expands.

General and administrative. General and administrative expenses increased to \$1.5 million in 1996 from \$1.3 million in 1995, representing an increase of 15%. The added costs were primarily due to additions in administrative staff and the added costs of operating as a public company.

Other Income. Other income, principally interest income, increased to \$1.3 million in 1996 from \$0.1 million in 1995. The increase resulted from the investment of the net proceeds of the Company's initial public offering which amounted to approximately \$42.8 million.

Years Ended December 31, 1994 and December 31, 1995

Sales Revenue. Sales revenue increased to \$3.5 million in 1995 from \$1.2 million in 1994, representing an increase of 196%. Sales revenue in 1994 resulted primarily from sales of the Company's Transport products, which were subsequently licensed to SCIMED in 1995. The Company no longer receives sales revenue for the Transport. Sales revenue in 1995 was due to sales of the Company's CAT catheter, which was introduced in the first quarter of 1995, and sales of the SmartNeedle vascular access products beginning in the second quarter of 1995. Sales of products in Japan through the Company's exclusive distribution relationship with

Fukuda accounted for 18% of the Company's revenue in 1995. In addition, sales to JJIS accounted for 12% of the Company's revenue in 1995.

License Fee and Other Revenue. License fee and other revenue decreased to \$0.0 million in 1995 from \$1.0 million in 1994. License fee and other revenue represents amounts earned under the aforementioned agreement with SCIMED. Future revenue under this agreement will be derived primarily from royalties earned on SCIMED's sales of the Transport.

Contract Revenue. Contract revenue was \$0.6 million in 1995 and \$0.2 million in 1994. Contract revenue was earned under the aforementioned agreement with SCIMED.

Cost of Sales. Cost of sales increased to \$2.1 million in 1995 from \$0.8 million in 1994, representing an increase of 142%. This increase resulted primarily from increased manufacturing volumes related to increased product sales. In July 1995, the Company transferred its product manufacturing from EndoSonic's facility to the Company's facility in Irvine, California.

Charge for Acquired In-process Research and Development. The Company incurred a charge of \$0.5 million in 1995 in connection with the 1995 payment by EndoSonic of additional consideration related to the original acquisition by EndoSonic of CVD stock. This portion of the excess of the purchase price of CVD 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 CVD was in the development stage and had not yet received regulatory approval for any of its products at the time of the acquisition.

Research and Development. Research and development expenses increased to \$1.7 million in 1995 compared to \$1.2 million in 1994, representing an increase of 37%. This increase was due primarily to increased expenditures related to development of the Company's Focus and M3 technology products. These expenses also increased due to clinical trials and studies related to the Focus technology products. The Company believes that it must maintain a substantial commitment to research and development to remain competitive and expects expenditures related to research and development to increase.

Marketing and Sales. Marketing and sales expenses increased to \$1.5 million in 1995 from \$0.7 million in 1994, representing an increase of 104%. This increase resulted from the development and expansion of the Company's U.S. sales organization and marketing expenses related to the product launch of the SmartNeedle products. The Company expects to expand its marketing and sales force and expects expenses associated with marketing and sales to increase in the future.

General and Administrative. General and administrative expenses increased to \$1.3 million in 1995 from \$0.6 million in 1994, representing an increase of 127%. This increase resulted from expenses incurred as the Company commenced operations as an independent entity, rather than as a division of EndoSonic, and included the addition of a full-time Chief Executive Officer, increased legal and accounting expenses, increased support staff and increased travel expenses.

Other Income. Total other income remained relatively constant in 1995 from 1994.

The Company has experienced an operating loss for each of the last three years and expects to continue to incur operating losses through at least 1997. CVD's results of operations have varied significantly from quarter to quarter. Quarterly operating results will 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 fullscale 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.

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, 1996, 1995 and 1994, the Company's net cash used in operating activities was \$6.2 million, \$2.1 million and \$1.5 million, respectively. These increases were primarily due to funding of operating losses and the charges for acquired in-process research and development.

On December 31, 1996, CVD had cash, cash equivalents and marketable securities available for sale of \$42.9 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 1997. CVD'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

History of Operating Losses; Anticipated Future Losses; Future Capital Requirements. The Company was founded in 1992 and has experienced annual operating losses since its inception. Its net loss was \$1.0 million, \$2.9 million and \$4.6 million in 1994, 1995 and 1996, respectively. The Company's accumulated deficit at December 31, 1996 was \$11.0 million. The Company expects to continue to incur operating losses through at least 1997 and there can be no assurance that the Company will ever be able to achieve or sustain profitability in the future. The Company expects to incur substantially increased costs related to, among other things, clinical testing, product development, manufacturing scaleup and sales and marketing activities. The Company anticipates that its existing capital resources will be sufficient to fund its operations through 1997. The Company's future capital requirements will depend on many factors, including its research and development programs, the scope and results of clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in obtaining and enforcing patents or any litigation by third parties regarding intellectual property, the status of competitive products, the establishment and scale-up of manufacturing capacity, the establishment of sales and marketing capabilities, the establishment of collaborative relationships with other parties and costs related to the acquisition of new technologies and product development. The Company may require additional funds to finance these activities and for working capital requirements. The Company may seek such funds through financings, including private or public equity or debt offerings and collaborative arrangements with corporate partners. There can be no assurance that funds will be raised on favorable terms, if 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 relinquish rights to certain technologies, product candidates or products that the Company would not otherwise relinquish.

Dependence Upon New Products; Rapid Technological Change; Risk of Obsolescence. The medical device industry generally, and the interventional catheter market in particular, are characterized by rapid technological change, changing customer needs, and frequent new product introductions. As a result, the useful lives of both the technology and products for the treatment of cardiovascular and peripheral vascular diseases are limited, in some instances to as little as twelve months. The Company's future success will depend upon its ability to develop, manufacture and introduce new products that address the needs of its customers. There can be no assurance that the Company will be successful in developing and marketing new products that achieve market acceptance or that the Company will not experience difficulties that could delay or prevent the successful development, introduction and marketing of new products. In addition, there can be no assurance that the Company's existing products will not be rendered obsolete as a result of technological developments or that the products that the Company has under development will not be rendered obsolete prior to the introduction of such products. See "Item 1. Business--Products."

Limited Sales to Date; Uncertainty of Market Acceptance. The Company's catheters are used in conjunction with angioplasty and other intravascular procedures such as vascular stenting and drug delivery. Although the Company has received regulatory clearance for a total of fifty-two products, only twenty-nine of such products have been marketed. Of those products which have been marketed, many have been marketed only in limited quantities or in certain markets, or are allowed to be marketed only in certain countries. In addition, while interventional catheters are widely used technologies, the Company's catheter designs are relatively new. The commercial success of the Company's products will depend upon their acceptance by the medical community as useful, cost-effective components of interventional cardiovascular and peripheral vascular procedures, including the acceptance by the medical community of stents and the availability and acceptance of therapeutic drugs for use in interventional procedures. The Company currently relies upon relationships with certain prominent doctors and researchers in the medical community to promote the uses and acceptance of its approved products. There can be no assurance that the Company will be able to maintain such relationships or establish additional relationships in the future. The erosion or loss of any such relationship could detrimentally affect the market acceptance of the Company's products. Failure of the Company's products to achieve such market acceptance would have a material adverse effect on the Company's business, financial condition and results of operations. See "Item 1. Business--Products."

Fluctuations in Quarterly Operating Results. CVD's results of operations have varied significantly from quarter to quarter. The Company has experienced an operating loss for each of the last five years. Quarterly operating results will 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 fluctuating 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.

Reliance on Patents and Proprietary Technology; Risk of Patent Infringement. While the Company owns certain issued and allowed U.S. patents and has additional U.S. and foreign patent applications pending, there can be no assurance that the Company's patent applications will issue as patents or that any issued patents will provide competitive advantages for the Company's products or will not be successfully challenged or circumvented by its competitors. The interventional cardiovascular and peripheral vascular markets in general and the market for balloon angioplasty catheters (including the type of catheters offered by CVD) in particular has been characterized by substantial litigation regarding patent and other intellectual property

rights. There can be no assurance that the Company's products do not infringe such patents or rights. During 1996, the Company received a notice of potential trademark infringement regarding the Company's use of the term "focal" in connection with the Company's balloon angioplasty technology and entered into an agreement which prohibits the Company from using this term. The Company has since ceased any use thereof. In the event that any parties assert claims against the Company for patent infringement and such patents are upheld as valid and enforceable, the Company 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 the Company or that the Company 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 adequately protect the Company's intellectual property rights abroad. The Company 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 the Company's trade secrets or proprietary technology will not otherwise become known or be independently developed by competitors in such a manner that the Company has no practical recourse. Litigation may be necessary to defend against claims of infringement or invalidity, to enforce patents issued to the Company or to protect trade secrets, and 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, the Company and its officers, which could have a material adverse effect on the Company's business, financial condition and results of operations. See "Item 1. Business--Patents and Proprietary Information."

Significant Competition. Competition in the market for devices used in the treatment of cardiovascular and peripheral vascular disease is intense, and is expected to increase. The interventional cardiology market is characterized by rapid technological innovation and change, and the Company's products could be rendered obsolete as a result of future innovations. The Company's catheters and other products under development compete or will compete with products marketed by a number of manufacturers, including Advanced Cardiovascular Systems, Inc., a subsidiary of Guidant Corporation ("ACS"), SCIMED Life Systems, Inc., a subsidiary of Boston Scientific Corporation ("SCIMED"), Johnson & Johnson Interventional Systems ("JJIS") and Cordis Corporation, subsidiaries of Johnson & Johnson, Medtronic, Inc., C.R. Bard, Inc. and Schneider USA, a subsidiary of Pfizer, Inc. Such companies have significantly greater financial, management and other resources, established market positions, and significantly larger sales and marketing organizations than does the Company. The Company also faces competition from manufacturers of other catheter-based devices, vascular stents and pharmaceutical products intended to treat vascular disease. In addition, the Company believes that many of the customers and potential customers of the Company's products prefer to purchase catheter products from a single source. Accordingly, many of the Company's competitors, because of their size and range of product offerings, have a competitive advantage over the Company. There can be no assurance that the Company's competitors will not succeed in developing or marketing technologies or products that are more clinically effective or cost effective than any that are being marketed or developed by the Company, or that such competitors will not succeed in obtaining regulatory approval for introducing or commercializing any such products prior to the Company. See "Item 1. Business--Competition."

Limited Manufacturing Experience. The Company's success will depend in part on its ability to manufacture its products in compliance with ISO 9001, the FDA's Good Manufacturing Practices ("GMP") regulations, 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. The Company began manufacturing certain of its products at its facilities in July 1995. The Company also introduced a significant number of new products in 1996. Accordingly, the Company has very limited experience in manufacturing its products. In addition, on July 15, 1996, the Company entered into co-distribution agreements with Medtronic, Inc. ("Medtronic") which granted Medtronic certain non-exclusive rights to distribute the Company's FACT, CAT and ARC catheters. Under the terms of these agreements, if the Company is unable to meet its delivery obligations with respect to the purchased catheters,

up to 60% of the Company's manufacturing capacity will be devoted to manufacturing such catheters for Medtronic. The Company has undergone and expects to continue to undergo regular GMP inspections in connection with the manufacture of its products at the Company's facilities. The Company's success will depend, among other things, on its ability to efficiently manage the simultaneous manufacture of different products and to integrate the manufacture of new products with existing products. There can be no assurance that the Company 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. The Company's failure to successfully commence the manufacturing of these new products, or to increase production volumes of new or existing products in a timely manner, would materially adversely affect the Company's business, financial condition and results of operations. Failure to increase production volumes in a timely or cost-effective manner or to achieve or maintain compliance with ISO 9001, GMP regulations, CDHS licensing or other regulatory requirements could have a material adverse effect on the Company's business, financial condition and results of operations.

The Company purchases many standard and custom built components from independent suppliers and subcontracts certain manufacturing processes from independent vendors. Most of these components and processes are available from more than one vendor. However, certain manufacturing processes are currently performed by single vendors. An interruption of performance by any of these vendors could have a material adverse effect on the Company's ability to manufacture its products until a new source of supply was qualified and, as a result, could have an adverse effect on the Company's business, financial condition and results of operations. See "Item 1. Business--Manufacturing" and "Item 1. Business--Government Regulation."

Potential Inability to Manage Growth. Prior to June 1996, the Company historically relied on EndoSonic to perform certain activities on its behalf, including manufacturing, financial, regulatory and administrative functions. Since July 1995, CVD has conducted its manufacturing operations at its facilities in Irvine and also currently performs the financial, regulatory and administrative functions previously performed by EndoSonic. Accordingly, the Company has experienced a period of significant expansion of its operations that has placed a significant strain upon its management systems and resources. The Company has recently implemented a number of new financial and management controls, reporting systems and procedures. In addition, the Company has recently hired a significant number of employees and plans to further increase its total head count. The Company also plans to expand the geographic scope of its customer base and operations. This expansion has resulted and will continue to result in substantial demands on the Company's management resources. The Company's ability to manage future expansion of its operations will require the Company to continue to improve its financial and management controls, reporting systems and procedures on a timely basis and to expand, train and manage its employee work force. There can be no assurance that the Company will be able to do so successfully. The failure to do so would have a material adverse effect on the Company's business, financial condition and results of operations.

Government Regulation. The manufacturing and marketing of the Company's products are subject to extensive and rigorous government regulation in the United States and in other countries. The Company believes that its success will be significantly dependent upon commercial sales of improved versions of its catheter products. The Company will not be able to market these new products in the United States unless and until the Company 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 ("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 ("510(k)"). All of the 510(k) clearances received for the Company'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 the Company's products, it could act to withdraw approval or clearances of those products or request that the Company

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

If substantial equivalence cannot be established, or if the FDA determines that the device or the particular application for the device requires a more rigorous review to assure safety and effectiveness, the FDA will require that the manufacturer submit a PMA application that 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. It is expected that certain of the Company's products under development will be subject to this PMA process. The Company currently has a non-exclusive, royalty-free right to submit PMA supplement applications utilizing an EndoSonics PMA as a reference and to manufacture and distribute CVD products as a supplement to the EndoSonics PMA. This agreement may be terminated in the event of breach upon 60 days notice by the non-breaching party, subject to the breaching party's right to cure. In the event of termination, the Company would be prohibited from submitting new PMA supplements referencing the EndoSonics PMA and would be required to seek independent FDA approval for any such products, which would have a material adverse effect on the Company's business, financial condition and results of operations.

The Company is also 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, the Company is inspected on a routine basis by both the FDA and the CDHS for compliance with GMP regulations. These regulations require that the Company manufacture its products and maintain related documentation in a prescribed manner with respect to manufacturing, testing and control activities. The Company has also undergone and expects to continue to undergo regular GMP inspections in connection with the manufacture of its products at the Company's facilities. Further, the Company is required to comply with various FDA requirements for labeling. The Medical Device Reporting laws and regulations require that the Company provide 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. CVD 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 the Company 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 the Company'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 the Company's business, financial condition and results of operations.

The Company is also 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 accurately predicted. Failure to comply with regulatory requirements could have a material adverse effect on the Company's business, financial condition and results of operations. See "Item 1. Business--Products" and "Item 1. Business--Government Regulation."

International sales of the Company's products are subject to the registration requirements of each country. The regulatory review process varies from country to country and may in some cases require the submission of clinical data. The Company 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 that require a PMA but are not yet approved domestically. The European Union has promulgated rules which require that medical products receive by mid-1998 the right to affix the CE mark, an international symbol of

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adherence to quality assurance standards and compliance with applicable European medical device directives. Failure to receive the right to affix the CE mark will prevent the Company from selling its products in member countries of the European Union, which would have a material adverse effect on the Company's business, financial condition and results of operations.

Limited Marketing and Sales Resources; Dependence Upon Strategic Relationships. CVD intends to rely primarily on certain strategic relationships, medical device distributors and its direct sales organization to distribute its products. The Company's ability to distribute its products successfully depends in part on the marketing capabilities of its strategic partners. In recent years 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, such as the Company, to effectively distribute their products without a relationship with one or more of the major suppliers. The Company is currently marketing certain of its products through licensing agreements with SCIMED and ACS and through co-distribution agreements with Medtronic. In addition, Fukuda Denshi Company, Ltd. ("Fukuda") is currently the Company's exclusive distributor in Japan for certain of the Company's products. Fukuda is also responsible for obtaining regulatory approval for the Company's products in Japan. The Company recently informed Fukuda of its decision to terminate the existing Fukuda agreement. The Company expects that Fukuda will continue to distribute its products at least through 1997. The Company is currently negotiating with several distributors, including Fukuda, regarding a new distribution agreement for the Japanese market. The Company's revenue from its distributor relationships is dependent upon the efforts made by such parties and there can be no assurance that such efforts will be successful. There can be no assurance that the Company will be able to maintain or expand its relationships with its strategic partners or to replace its strategic partners in the event any such relationship were terminated. In the event of such a termination, the Company's ability to distribute its products would be materially adversely affected, which would have a material adverse effect on the Company's business, financial condition and results of operations.

CVD currently has a limited marketing and sales staff. The Company intends to expand its direct sales force to market the Company's products expansion. However, there can be no assurance that CVD will successfully expand its direct sales and marketing organization, or that if expanded, such organization will be able to effectively distribute CVD's products. If CVD is unable to achieve distribution of its products through its direct sales organization, the Company's business, financial condition and results of operations would be materially adversely affected.

The Company also has product development relationships with SCIMED and ACS. SCIMED currently funds certain research and development efforts undertaken by CVD in the area of combined drug delivery and coronary angioplasty. ACS conducts development work on the Company's perfusion technology. If CVD is unable to maintain its relationships with these or future strategic partners its product development efforts could be materially adversely affected, which would materially adversely affect the Company's business, financial condition and results of operations. See "Item 1. Business--Marketing and Sales" and "Item 1. Business--Strategic Relationships."

Dependence Upon International Sales. The Company derives, and expects to continue to derive, a significant portion of its revenue from international sales. In 1994, 1995 and 1996, the Company's international sales were \$1.0 million, \$2.1 million and \$3.5 million, respectively, or 83%, 59% and 42%, respectively, of product sales. The Company expects to continue to derive significant revenue from international sales and therefore a significant portion of the Company'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 the Company's ability to deliver products on a competitive and timely basis. Future imposition of, or significant increases in the level of, customs duties, import quotas or other trade restrictions, could have an adverse effect on the Company's business, financial condition and results of operation. In foreign countries, the Company's products are subject to governmental review and certification. The regulation of medical devices, particularly in the European Union, continues to expand and there can be no assurance that new laws or regulations will

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not have an adverse effect on the Company's business, financial condition and results of operations. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations."

Limitations on 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. Health Care Financing 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 the Company'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 the Company's ability to sell its products on a profitable basis. In addition, reimbursement may be denied if the product use is not in accordance with approved FDA labeling. Failure by hospitals and other users of the Company's products to obtain reimbursement from third-party payors, or changes in government and private third-party payors' policies toward reimbursement for procedures employing the Company's products, would have a material adverse effect on the Company's business, financial condition and results of operations. See "Item 1. Business--Third-Party Reimbursement."

Control by Existing Stockholder; Limitations on Pooling-of-Interests Accounting in Merger Transactions, prior to the anticipated distribution discussed below. EndoSonics currently owns approximately 45% of the Company's outstanding Common Stock. As a result, EndoSonics is able to elect at least two members to the Company's five person board of directors and has the ability to effectively control the Company and influence its affairs and the conduct of its business. Such concentration of ownership may have the effect of delaying, deferring or preventing a change in control of the Company. In accordance with applicable accounting standards, the Company is prohibited from accounting for a merger transaction, of or by the Company, as a pooling-of-interests for a period of two years following June 25, 1996, the date on which EndoSonics ceased to control 50% of the outstanding voting Common Stock of the Company. As a result, any business combination consummated prior to the expiration of such period would have to be accounted for using the purchase method. Under the purchase method, the excess of the purchase price over the net book value of the assets acquired would be amortized to expense, which could result in a significant negative impact on the acquiror's results of operations and, therefore, reduce the attractiveness of, or the price paid in, a particular acquisition transaction.

On January 27, 1997, EndoSonics announced that in connection with the acquisition of Cardiometrics, Inc. ("Cardiometrics") by EndoSonics pursuant to an Agreement and Plan of Reorganization, dated as of January 26, 1997, among EndoSonics, River Acquisition Corporation, a wholly-owned subsidiary of EndoSonics, and Cardiometrics, shares of the Company's Common Stock held by EndoSonics would be distributed to the former stockholders, warrant holders and option holders of Cardiometrics. After such distribution, EndoSonics is expected to own approximately 22% of the Company's outstanding Common Stock. On the same date, EndoSonics also announced that the EndoSonics Board of Directors had approved a dividend distribution of one CVD share for every 25

EndoSonics shares. The distribution is expected to take place in the second half of 1997 to EndoSonics stockholders then of record. The exact record date and date of distribution have not yet been determined.

Potential Product Liability; Limited Insurance. The Company faces the risk of financial exposure to product liability claims. The Company'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. The Company is currently covered under a product liability insurance policy with coverage limits of \$2.0 million per occurrence and \$2.0 million per year in the aggregate. There can be no assurance that the Company's product liability insurance is adequate or that such insurance coverage will remain available at acceptable costs. There can be no assurance that the Company will not incur significant product liability claims in the future. A successful claim brought against

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the Company in excess of its insurance coverage could have a material adverse effect on the Company's business, financial condition and results of operations. Additionally, adverse product liability actions could negatively affect the reputation and sales of the Company's products and the Company's ability to obtain and maintain regulatory approval for its products and substantially divert the time and effort of management away from the Company's operations.

Volatility of Stock Price. Since the Company's initial public offering in June 1996, the price of the Company's Common Stock has fluctuated significantly. The Company believes that factors such as variations in quarterly results of operations, any future litigation involving the Company, announcements of technological innovations or new products by the Company or its competitors, governmental regulatory action, other developments or disputes with respect to proprietary rights, general trends in the industry and overall market conditions, and other factors, could cause the price of the Company's Common Stock to fluctuate, perhaps substantially. In addition, in recent years the stock market in general, and the market for small capitalization stocks in particular, has experienced extreme price fluctuations which have often been unrelated to the operating performance of affected companies. Such fluctuations could adversely affect the market price of the Company's Common Stock.

Effect of Certain Charter Provisions; Anti-takeover Effects of Certificate of Incorporation, Bylaws and Delaware Law. The Company's Board of Directors has the authority to issue up to 5,000,000 shares of Preferred Stock and to determine the price, rights, preferences, privileges and restrictions, including voting rights, of those shares without any further vote or action by the stockholders. The rights of the holders of Common Stock will be subject to, and may be adversely affected by, the rights of the holders of any Preferred Stock that may be issued in the future. The issuance of Preferred Stock could have the effect of making it more difficult for a third party to acquire a majority of the outstanding voting stock of the Company. In addition, the Company is subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which will prohibit the Company from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. The application of Section 203 also could have the effect of delaying or preventing a change of control of the Company. Further, certain provisions of the Company's Certificate of Incorporation and Bylaws and of Delaware law could delay or make more difficult a merger, tender offer or proxy contest involving the Company, which could adversely affect the market price of the Company's Common Stock.

Absence of Dividends. The Company has never paid any cash dividends on the Common Stock and does not anticipate paying any cash dividends on the Common Stock in the foreseeable future.

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.

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

Not applicable.

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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 shareholders for the Annual Meeting to be held on or about May 19, 1997. 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 shareholders for the Annual Meeting to be held on or about May 19, 1997.

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 shareholders for the Annual Meeting to be held on or about May 19, 1997.

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 shareholders for the Annual Meeting to be held on or about May 19, 1997.

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, 1995 and 1996
 - Consolidated Statements of Operations for the years ended December 31, 1994, 1995 and 1996
 - Consolidated Statements of Stockholders' Equity for the years ended December 31, 1994, 1995 and 1996
 - Consolidated Statements of Cash Flows for the years ended December 31, 1994, 1995 and 1996
 - Notes to Consolidated Financial Statements

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. No reports on Form 8-K were filed during the last quarter of the fiscal year covered by this Annual Report on Form 10-K.

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(c) Exhibits.

- 1.1(1) Form of Underwriting Agreement.
- 2.1(3) Agreement and Plan of Reorganization dated as of June 9, 1993 among EndoSonic Corporation ("EndoSonic"), EndoSonic Acquisition Corporation and CardioVascular Dynamics, Inc. ("CVD").
- 2.2(3) First Amendment dated as of June 30, 1993 to the Agreement and Plan of Reorganization among EndoSonic, EndoSonic Acquisition Corporation and CVD.
- 2.3(5) Agreement and Plan of Reorganization by and among CardioVascular Dynamics, Inc., IDI Acquisition Corporation and Intraluminal Devices, Inc. ("IDI") dated as of October 2, 1996.

- 3.1(3) Certificate of Incorporation.
- 3.2(3) Amended Bylaws.
- 4.1(1) Specimen Certificate of Common Stock.
- 10.1(3) Form of Indemnification Agreement to be 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 CVD.
- 10.5(3) Stock Purchase Option Agreement dated June 5, 1992, by and between EndoSonic and CVD.
- 10.6(3)* Japanese Distribution Agreement dated May 28, 1993, as amended on October 27, 1994 and July 17, 1995, (the "Japanese Distribution Agreements") by and between CVD and Fukuda Denshi Co., Ltd. ("Fukuda")
- 10.7(3)* Stock Purchase and Technology License Agreement dated September 10, 1994, as amended on September 29, 1995, by and among EndoSonic, CVD and SCIMED Life Systems, Inc. ("SCIMED").
- 10.8(3) Waiver and Grant of Warrant dated June 30, 1995 by and between SCIMED, CVD and Endosonics.
- 10.9(3)* License Agreement dated January 15, 1995 by and between CVD and Advanced CardioVascular Systems, Inc. ("ACS").
- 10.10(3)* License Agreement dated March 4, 1996 by and between CVD and ACS.
- 10.11(3) Series B Stock Purchase Agreement dated March 29, 1996 by and between CVD and EndoSonic.
- 10.12(3) License Agreement dated December 22, 1995 by and between CVD and EndoSonic.
- 10.13(1) Form of Stockholder Agreement with EndoSonic.
- 10.14(1) Form of Tax Allocation Agreement with EndoSonic.
- 10.15(3) Industrial Lease dated February 23, 1995 by and between the Irvine Company and CVD.
- 10.16(1) Waiver and Grant of Warrant dated May 2, 1996 by and between SCIMED, CVD and EndoSonic.
- 10.17(2) Amendment to Japanese Distribution Agreements dated May 13, 1996 by and between CVD and Fukuda.
- 10.18(4)* Supply Agreement dated July 15, 1996 by and between CVD and Medtronic, Inc.
- 10.19(4)* OEM Agreement dated July 15, 1996 by and between CVD and Medtronic, Inc.
- 10.20 License Agreement dated February 6, 1997 by and between CVD and EndoSonic.

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- 23.1 Consent of Ernst & Young LLP, Independent Auditors.
- 24.1 Power of Attorney. (Reference is made to page 31 of this Annual Report on Form 10-K.)
- 27.1 Financial Data Schedule.

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* Confidential treatment requested.

- (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.

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.

CARDIOVASCULAR DYNAMICS, INC.

Date: March 21, 1997

/S/ MICHAEL R. HENSON

By:

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

/S/ DANA P. NICKELL

By:

 Dana P. Nickell
 Vice President, Finance and
 Administration,
 Chief Financial Officer and
 Secretary
 (Principal Financial and
 Accounting Officer)

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 Dana P. Nickell, 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) | President, Chief Executive Officer (Principal Executive Officer) and Chairman | March 21, 1997 |
| /S/ DANA P. NICKELL ----- (Dana P. Nickell) | Vice President, Finance and Administration, Chief Financial Officer and Secretary (Principal Financial and Accounting Officer) | March 21, 1997 |
| /s/ William G. Davis ----- (William G. Davis) | Director | March 21, 1997 |
| /s/ Mitchell Dann ----- (Mitchell Dann) | Director | March 21, 1997 |
| /S/ GERARD VON HOFFMAN ----- (Gerard von Hoffman) | Director | March 21, 1997 |
| /S/ EDWARD M. LEONARD ----- (Edward M. Leonard) | Director and Assistant Secretary | March 21, 1997 |

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REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

The Board of Directors and Shareholders
CardioVascular Dynamics, Inc.

We have audited the accompanying consolidated balance sheets of CardioVascular Dynamics, Inc. and subsidiary as of December 31, 1995 and 1996, 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, 1996. Our audits also included the financial statement schedule listed in the Index at Item 14(a)2. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit 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 audit provides 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 CardioVascular Dynamics, Inc. and subsidiary at December 31, 1995 and 1996, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 1996, 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
January 30, 1997

CARDIOVASCULAR DYNAMICS, INC.

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

| | DECEMBER 31, | |
|--|--------------|-----------|
| | 1995 | 1996 |
| | ----- | ----- |
| Assets | | |
| Current Assets: | | |
| Cash and cash equivalents..... | \$ 1,568 | \$ 17,192 |
| Marketable securities available-for-sale..... | -- | 25,733 |
| Accounts receivable, net of allowance for doubtful accounts of \$180 and \$377, respectively..... | 1,117 | 2,268 |
| Other accounts receivable..... | -- | 320 |
| Inventories..... | 754 | 2,899 |
| Other current assets..... | 58 | 162 |
| | ----- | ----- |
| Total current assets..... | 3,497 | 48,574 |
| Property and Equipment: | | |
| Furniture and equipment..... | 357 | 1,161 |
| Leasehold improvements..... | 174 | 310 |
| | ----- | ----- |
| | 531 | 1,471 |
| Less accumulated depreciation and amortization..... | (107) | (289) |
| | ----- | ----- |
| Net property and equipment..... | 424 | 1,182 |
| Notes receivable from officers..... | -- | 325 |
| | ----- | ----- |
| Other assets..... | 81 | 3 |
| | ----- | ----- |
| Total assets..... | \$ 4,002 | \$ 50,084 |
| | ===== | ===== |
| Liabilities and Stockholders' Equity (net capital deficiency) | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses..... | \$ 1,684 | \$ 2,382 |
| Payable to Parent..... | 2,537 | -- |
| Deferred distributorship fee revenue, current portion..... | 50 | 50 |
| | ----- | ----- |
| Total current liabilities..... | 4,271 | 2,432 |
| Deferred distributorship fee revenue..... | 79 | 29 |
| Convertible obligation..... | 750 | -- |
| Commitments | | |
| Stockholders' equity (net capital deficiency): | | |
| Convertible Preferred Stock, \$.001 par value; aggregate liquidation preference of \$13,160,000 as of December 31, 1995; 7,560,000 shares authorized, 2,000,000 and no shares issued and outstanding as of December 31, 1995 and 1996, respectively..... | 2 | -- |
| Common Stock, \$.001 par value; 30,000,000 shares authorized, no shares and 9,004,000 shares issued or outstanding at December 31, 1995 and 1996, respectively..... | -- | 9 |
| Additional paid-in capital..... | 5,670 | 58,869 |
| Deferred compensation..... | (345) | (376) |
| Accumulated deficit..... | (6,425) | (11,049) |
| Unrealized gain on available-for-sale securities..... | -- | 170 |
| | ----- | ----- |
| Total stockholders' equity (net capital deficiency)..... | (1,098) | 47,623 |
| | ----- | ----- |
| Total liabilities and stockholders' equity (net capital deficiency)..... | \$ 4,002 | \$ 50,084 |
| | ===== | ===== |

See accompanying notes.

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CARDIOVASCULAR DYNAMICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

| | | | | | | | | | |
|--|-------------|-------|-----------|------|-----------|----------|-------------|-------|-----------|
| options..... | -- | -- | -- | -- | 345 | (345) | -- | -- | -- |
| Net loss..... | -- | -- | -- | -- | -- | -- | (2,874) | -- | (2,874) |
| Balance at December 31, 1995..... | 2,000,000 | 2 | -- | -- | 5,670 | (345) | (6,425) | -- | (1,098) |
| Sale of Preferred Stock to EndoSonics..... | 400,000 | -- | -- | -- | 8,000 | -- | -- | -- | 8,000 |
| Conversion of Preferred Stock..... | (2,400,000) | (2) | 4,800,000 | 5 | (3) | -- | -- | -- | -- |
| Exercise of Common Stock Options.... | -- | -- | 139,000 | -- | 138 | -- | -- | -- | 138 |
| Initial Public Offering of Common Stock..... | -- | -- | 3,910,000 | 4 | 42,764 | -- | -- | -- | 42,768 |
| Deferred compensation resulting from grant of options..... | -- | -- | -- | -- | 150 | (150) | -- | -- | -- |
| Amortization of deferred compensation..... | -- | -- | -- | -- | -- | 119 | -- | -- | 119 |
| Acquisition of Intraluminal Devices, Inc..... | -- | -- | 93,000 | -- | 1,400 | -- | -- | -- | 1,400 |
| Conversion of \$750,000 debt by Fukuda Denshi.... | -- | -- | 62,000 | -- | 750 | -- | -- | -- | 750 |
| Net loss..... | -- | -- | -- | -- | -- | -- | (4,624) | -- | (4,624) |
| Unrealized gain on investments..... | -- | -- | -- | -- | -- | -- | -- | 170 | 170 |
| Balance at December 31, 1996..... | -- | \$ -- | 9,004,000 | \$ 9 | \$ 58,869 | \$ (376) | \$ (11,049) | \$170 | \$ 47,623 |

See accompanying notes.

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CARDIOVASCULAR DYNAMICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)

| | YEAR ENDED DECEMBER 31, | | |
|---|-------------------------|------------|------------|
| | 1994 | 1995 | 1996 |
| Operating activities | | | |
| Net loss..... | \$ (971) | \$ (2,874) | \$ (4,624) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization..... | 18 | 74 | 182 |
| Amortization of deferred compensation..... | -- | -- | 119 |
| Bad debt expense..... | -- | 249 | 221 |
| Charge for acquired in-process research and development..... | -- | 488 | 1,400 |
| Net changes in: | | | |
| Trade accounts receivable, net..... | (662) | (639) | (1,372) |
| Receivable from related parties..... | (125) | 125 | -- |
| Inventories..... | (14) | (704) | (2,145) |
| Other assets..... | -- | (135) | (671) |
| Accounts payable and accrued expenses..... | 273 | 1,369 | 698 |
| Deferred distributor fee revenue..... | (50) | (54) | (50) |
| Net cash used in operating activities..... | (1,531) | (2,101) | (6,242) |
| Investing activities: | | | |
| Purchase of available-for-sale securities..... | -- | -- | (25,563) |
| Capital expenditures for furniture, fixtures and equipment..... | (35) | (443) | (940) |
| Net cash used in investing activities..... | (35) | (443) | (26,503) |
| Financing activities: | | | |
| Proceeds from issuance of convertible obligation..... | -- | 750 | -- |
| Proceeds from sale of Common Stock..... | 2,500 | -- | 42,768 |
| Proceeds from exercise of stock options..... | -- | -- | 138 |
| Proceeds from sale of Preferred Stock to Parent..... | -- | -- | 8,000 |
| Payable to Parent, net..... | 1,898 | (17) | (2,537) |
| Net cash provided by financing activities..... | 4,398 | 733 | 48,369 |

| | | | |
|---|---------|----------|----------|
| Net increase (decrease) in cash..... | 2,832 | (1,811) | 15,624 |
| Cash and cash equivalents, beginning of period..... | 547 | 3,379 | 1,568 |
| | ----- | ----- | ----- |
| Cash and cash equivalents, end of period..... | \$3,379 | \$ 1,568 | \$17,192 |
| | ===== | ===== | ===== |
| Supplemental disclosure of non-cash financing activities: | | | |
| Common stock issued upon the acquisition of Intraluminal Devices, Inc., Note 2..... | -- | -- | \$ 1,400 |
| Conversion of Debentures to Common Stock, Note 5..... | -- | -- | 750 |

See accompanying notes.

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CARDIOVASCULAR DYNAMICS, 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

CardioVascular Dynamics, Inc. (the "Predecessor") was incorporated on March 16, 1992 in the State of California. The Predecessor, and its successor corporation discussed below, develops, manufactures and markets proprietary therapeutic catheters used to treat certain vascular diseases.

In June 1992, EndoSonics Corporation ("EndoSonics") acquired a 40% preferred interest in the Predecessor. EndoSonics, a Delaware corporation, develops, manufactures, and markets intravascular ultrasound imaging systems and diagnostic, therapeutic and imaging catheters for the treatment of coronary and peripheral vascular disease.

In June 1993, EndoSonics acquired all of the remaining Preferred and Common Stock of the Predecessor. The acquisition was accomplished through a merger between the Predecessor and EndoSonics Acquisition Corp., a wholly owned subsidiary of EndoSonics (which then changed its name to CardioVascular Dynamics, Inc.) (hereinafter referred to as "CVD" or the "Company").

The acquisition by EndoSonics resulted in a new basis for the CVD assets and liabilities. Accordingly, the purchase price paid by EndoSonics has been allocated to the identifiable assets and liabilities, including in-process research and development, which was immediately expensed as no CVD products had received regulatory approval and the technology did not have identifiable alternative uses. The amount by which the purchase price exceeded the Predecessor's net book value has been reflected as paid-in capital in the accompanying financial statements. Pursuant to the terms of the original merger agreement, in June 1995 EndoSonics issued an additional 50,000 shares of its Common Stock to the former shareholders of the Predecessor. The fair market value of such shares of \$488 has been reflected in the accompanying financial statements as an additional charge for acquired in-process technology.

Subsequent to the acquisition, EndoSonics began performing certain services for CVD (see Note 4), including general management, accounting, cash management, and other administrative and engineering services. The amounts charged to CVD for such services have been determined based on proportional cost allocations and have been agreed to by the management of CVD and EndoSonics. In the opinion of CVD's management, the allocation methods used are reasonable. Such allocations, however, are not necessarily indicative of costs that would have been incurred had CVD continued to operate independent of EndoSonics. No formal agreement currently exists which specifies the nature of services to be provided by EndoSonics to CVD, or the charges for such services. Therefore, amounts are not necessarily indicative of the future charges to be incurred by CVD.

In 1994 and 1996, the Board of Directors of CVD approved a 16,200-for-1 and a 2-for-1 Common Stock split, respectively, which have been reflected retroactively for all periods in the accompanying financial statements.

On June 19, 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. CVD 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.

In October 1996, CVD acquired 100% of the common stock of Intraluminal Device, Inc. ("IDI") in exchange for CVD common stock valued at \$1.4 million. The acquisition was accomplished through the formation of IDI Acquisition, Inc., a wholly-owned subsidiary of CVD, and the merging of IDI into IDI Acquisition, Inc. (See Note 2).

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CARDIOVASCULAR DYNAMICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

The consolidated financial statements for December 31, 1996 include the accounts of the Company and its subsidiary. Intercompany transactions have been eliminated.

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 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 shareholders' 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.

LONG-LIVED ASSETS

In March 1995, Statement of Financial Accounting Standards (SFAS) No. 121, "Accounting for the Impairment of Long-lived Assets to be Disposed of," was issued. SFAS No. 121 requires that long-lived assets and certain identifiable intangibles to be held and used or disposed of by an entity be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. During 1996, the Company adopted this statement and determined that no impairment loss need be recognized for the applicable assets.

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 medical device distributors worldwide. The Company performs ongoing credit evaluations of its customers' financial condition and

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CARDIOVASCULAR DYNAMICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

generally does not require collateral from customers. Management believes that an adequate allowance for doubtful accounts has been provided.

During 1994, 1995, and 1996 product sales to Fukuda Denshi Co., Ltd., ("Fukuda"), the Company's Japanese distributor (see Note 5), comprised 61%, 18% and 14% of total revenue. Accounts receivable from Fukuda represented 15% and 1% of net accounts receivable at December 31, 1995 and 1996, respectively.

Product sales to Medtronic, Inc. ("Medtronic") accounted for 21% of total revenues during 1996. At December 31, 1996, 27% of accounts receivable were due from Medtronic. One other customer comprised 12% of revenues for the year ended December 31, 1995 and 14% of accounts receivable at December 31, 1995.

EXPORT SALES

The Company had export sales by region as follows:

| | YEAR ENDED DECEMBER 31, | | |
|--------------------|-------------------------|---------|---------|
| | 1994 | 1995 | 1996 |
| Europe..... | \$255 | \$1,179 | \$1,614 |
| Japan..... | 715 | 744 | 1,240 |
| Latin America..... | -- | 131 | 243 |
| Other..... | -- | -- | 417 |
| | ----- | ----- | ----- |
| | \$970 | \$2,054 | \$3,514 |
| | ===== | ===== | ===== |

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.

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 FASB Statement No. 123, "Accounting for Stock-Based Compensation," requires use of option valuation models that were not developed for use in valuing employee stock options. Under APB 25, because the exercise price of the Company's employee stock options equals the market price of the underlying stock on the date of grant, no compensation expense is recognized.

Pro forma information regarding net income and earnings per share is required by Statement 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 opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

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CARDIOVASCULAR DYNAMICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

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%; a dividend yield of 0%; volatility of the expected market price of the Company's common stock of 0.475; and a weighted-average expected life of the options of 3.5 years.

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, 1995 and 1996 follows:

| | 1995 | 1996 |
|-----------------------------------|------------|------------|
| | ----- | ----- |
| Pro forma net loss..... | \$ (2,905) | \$ (5,170) |
| Pro forma net loss per share..... | \$ (0.65) | \$ (0.72) |

Because Statement 123 is applicable only to options granted subsequent to December 31, 1994, its pro forma effect will not be fully reflected until 1997.

Income Taxes

From June 1993 until June 1996, the Company's results of operations have been included in consolidated tax returns filed by EndoSonics. 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 CVD.

Net Loss Per Share

Pro forma net loss per share is computed using the weighted average number of shares of Common Stock, convertible Preferred Stock (using the as-if-converted method) and Common Stock issuable upon conversion of the Convertible Obligation, outstanding. Common equivalent shares from stock options and warrants are not included as the effect is anti-dilutive, except that in accordance with Securities and Exchange Commission Staff Accounting Bulletins, common equivalents shares issued by the Company at prices substantially below the anticipated initial public offering price during the period beginning one year prior to the proposed public offering have been included in the calculation as if they were outstanding for all periods presented (using the treasury stock method and the estimated initial public offering price).

For periods subsequent to the Company's initial public offering in June 1996, the Company's net loss per share has been calculated based on the weighted average number of common and dilutive common equivalent shares outstanding. Common stock equivalents that are anti-dilutive are excluded from the calculation.

RECLASSIFICATIONS

To conform with the 1996 financial statement presentation, certain reclassifications have been made to the 1995 and 1994 financial statements.

2. ACQUISITION OF INTRALUMINAL DEVICES, INC.

On October 16, 1996, the Company acquired all of the outstanding shares of IDI in exchange for approximately 93,000 shares of CVD common stock valued at \$1.4 million. 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 \$0.7 million were expensed as acquired in-process research and development.

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CARDIOVASCULAR DYNAMICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

The following table reflects unaudited pro forma combined results of operations of the Company and IDI on the basis that the acquisition had taken place and the related charge, noted above, was recorded at the beginning of 1996 as IDI operations were not material to the Company's operations prior to 1996:

| | 1996 |
|---------------------------------|----------|
| | ----- |
| Revenues..... | \$ 8,734 |
| Net loss..... | (4,820) |
| Net loss per common share..... | (0.67) |
| Shares used in computation..... | 7,214 |

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 acquisition been consummated at the beginning of 1996 or of future operations of the combined companies under the ownership and management of the Company.

3. SCIMED LIFE SYSTEMS, INC.

In September 1994, CVD and EndoSonics entered into a Stock Purchase and Technology License Agreement with SCIMED Life Systems, Inc. ("SCIMED"). SCIMED acquired a 19% interest in CVD in exchange for \$2,500 in cash.

CVD 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 CVD in exchange for a \$1,000 license fee that was paid in 1994. SCIMED will pay royalties to CVD on sales of the Transport and other products which use this patented technology. CVD 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. The warrant expires in September 1997.

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.

SCIMED also paid CVD \$220, \$641 and \$200 in 1994, 1995 and 1996, respectively, on a cost reimbursement basis to fund continuing development of the technology and for other support. Additionally, the Company recorded \$43 in product sales to SCIMED during 1994 (none in 1995 or 1996).

4. RELATED PARTY TRANSACTIONS

The following is a summary of significant transactions between CVD and EndoSonics:

- During 1994 and a portion of 1995, EndoSonics manufactured certain of the Company's catheter products at cost plus a mark-up of 30%. Total purchases from EndoSonics during 1994 and 1995 amounted to \$843 and \$172,

respectively. In addition, during 1994 EndoSonics performed certain billing and collection services for CVD in return for a fee per invoice which aggregated to \$10.

- Prior to the Company's initial public offering in June 1996, certain EndoSonics corporate expenses, primarily related to executive management time, accounting, cash management, and other administrative and engineering services, have been allocated to the Company. Total expenses allocated were \$290, \$340, and \$156 for the years ended December 31, 1994, 1995 and 1996, respectively.

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CARDIOVASCULAR DYNAMICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

No interest expense has been charged on the net payable due to EndoSonics. The following is an analysis of the payable to EndoSonics:

| | YEAR ENDED DECEMBER 31, | | |
|---|----------------------------|---------|---------|
| | 1994 | 1995 | 1996 |
| Beginning balance..... | \$ 656 | \$2,554 | \$2,537 |
| Inventory purchases..... | 843 | 172 | -- |
| Corporate cost allocations..... | 300 | 340 | 156 |
| Cash disbursements made by EndoSonics on behalf of CVD..... | 1,730 | 312 | -- |
| Cash collections made by EndoSonics on behalf of CVD..... | (318) | (700) | -- |
| Cash payments to EndoSonics..... | (549) | -- | (2,693) |
| Cash disbursements made by CVD on behalf of EndoSonics and other..... | (108) | (141) | -- |
| Ending balance..... | \$2,554 | \$2,537 | \$ -- |
| Average balance during period..... | \$1,750 | \$2,551 | \$1,974 |

In connection with the initial public offering, CVD and EndoSonics entered into a Tax Allocation Agreement that provides, among other things, for (i) the allocation of tax liabilities and adjustments thereto as between the business of the Company and other businesses conducted by EndoSonics and its affiliates related to periods in which the Company is includable in consolidated federal income tax returns filed by EndoSonics, (ii) the allocation of responsibility for filing tax returns and (iii) the conduct of and responsibility for taxes owed in connection with tax audits and various related matters.

EndoSonics and CVD entered into a Stockholder Agreement providing that all transactions between the Company and EndoSonics or any affiliate of EndoSonics must be approved by a special committee of CVD's Board of Directors comprised of two directors who are not officers, directors, employees or affiliates of EndoSonics. The provisions of this agreement became effective upon the consummation of the initial public offering and will terminate on the earlier of seven years from the date of the agreement or on the date EndoSonics beneficially owns less than 25% of CVD's Common Stock.

(See Notes 5 and 11)

5. AGREEMENTS WITH FUKUDA

The Company has executed a distribution agreement with Fukuda. The agreement provides Fukuda with exclusive distribution rights relative to certain of the Company's products in Japan for periods extending through May 1999, which may be extended at the option of the parties. Distribution fee revenue received from Fukuda are deferred and are being recognized as revenue over the initial periods covered by the respective agreements.

In July 1995 and May 1996, the distribution agreement with Fukuda was amended. In exchange for the exclusive distribution rights to additional CVD 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. The Company has accounted for this as a convertible obligation payable as of December 31, 1995. In November, 1996, Fukuda exercised the conversion feature of said obligation. The Company recently informed Fukuda of its decision to terminate the existing distribution agreement. The Company expects that Fukuda will continue to distribute its products at least through 1997. The Company is currently negotiating with several distributors, including Fukuda, regarding a new distribution agreement for the Japanese market.

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CARDIOVASCULAR DYNAMICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

6. LICENSE AGREEMENTS

In January 1995 the Company entered into a license agreement with Advanced CardioVascular Systems, Inc. ("ACS") under which the Company acquired the exclusive worldwide rights to ACS' SmartNeedle technology. The Company assumed responsibility for manufacturing the product in 1996, subject to the payment of royalties. ACS was granted an option, which was exercised in February 1996, to obtain exclusive worldwide rights to certain CVD perfusion technology. In exchange for the perfusion technology, ACS is obligated to make milestone and minimum royalty payments to CVD, and also has certain obligations to develop and market the perfusion technology. An initial milestone of \$150 was earned in the year ended December 31, 1996.

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

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 classified as current assets and available-for-sale at December 31, 1996:

| | COST | GROSS UNREALIZED HOLDING (LOSSES) GAINS | FAIR |
|---|----------|---|----------|
| | ----- | ----- | ----- |
| U.S. Treasury and other agencies debt securities..... | \$10,000 | \$ (19) | \$ 9,981 |
| Corporate debt securities..... | \$15,563 | 189 | 15,752 |
| | \$25,563 | \$ 170 | \$25,733 |
| | ===== | ===== | ===== |

All short-term investments at December 31, 1996 were due within one year.

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, | |
|--------------|-------|
| ----- | ----- |
| 1995 | 1996 |
| ----- | ----- |

| | | |
|----------------------|--------|---------|
| Raw materials..... | \$ 162 | \$1,015 |
| Work in process..... | 330 | 510 |
| Finished goods..... | 262 | 1,374 |
| | ----- | ----- |
| | \$ 754 | \$2,899 |
| | ===== | ===== |

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CARDIOVASCULAR DYNAMICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

| | DECEMBER 31, | |
|---|--------------|---------|
| | 1995 | 1996 |
| | ----- | ----- |
| Accounts payable..... | \$ 962 | \$ 750 |
| Accrued payroll and related expenses..... | 352 | 1,040 |
| Accrued warranty..... | 113 | 29 |
| Other accrued expenses..... | 257 | 563 |
| | ----- | ----- |
| | \$1,684 | \$2,382 |
| | ===== | ===== |

10. COMMITMENTS

Operating Leases

The Company leases its administrative, research and manufacturing facilities and certain equipment under longterm, noncancelable 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:

| | |
|-----------|-------|
| 1997..... | \$392 |
| 1998..... | 354 |
| 1999..... | 178 |
| 2000..... | 57 |
| | ---- |
| | \$981 |
| | ===== |

Rental expense charged to operations for all operating leases during the years ended December 31, 1994, 1995 and 1996, was approximately \$60, \$171 and \$365, respectively.

11. STOCKHOLDERS' EQUITY

Preferred Stock

In February 1995, every two shares of the Company's outstanding Common Stock was exchanged for one share of Series A Preferred Stock with a liquidation preference of \$6.58 per share. 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 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. Under the terms of the 1996 Plan, 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, as determined by the Board of Directors. The Company has authorized 1,200,000 shares of Common Stock for issuance under the 1996 Plan. The options granted under the 1996

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CARDIOVASCULAR DYNAMICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

Plan 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.

| | OPTION PRICE PER SHARE | NUMBER OF SHARES |
|------------------------------------|---------------------------|---------------------|
| | ----- | ----- |
| Balanced at January 1, 1994..... | | -- |
| Granted..... | \$ 1.00 | 464,000 |
| Exercised..... | | -- |
| Forfeited..... | | -- |
| Cancelled..... | | -- |
| | ----- | ----- |
| Balanced at December 31, 1994..... | \$ 1.00 | 464,000 |
| Granted..... | \$1.00 to \$ 1.50 | 493,000 |
| Exercised..... | | -- |
| Forfeited..... | | -- |
| Cancelled..... | | -- |
| | ----- | ----- |
| Balanced at December 31, 1995..... | \$1.00 to \$ 1.50 | 957,000 |
| Granted..... | \$2.50 to \$13.25 | 319,000 |
| 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 | 1,118,525 |
| | ===== | ===== |

No options had been exercised and 125,000 options were exercisable at December 31, 1995. As of December 31, 1996, 253,525 options were exercisable.

During 1995, the Company recorded deferred compensation of approximately \$345 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 \$150 of deferred compensation was recorded during the year ended December 31, 1996. Deferred compensation is being amortized over the vesting period of the related options. \$119 of deferred compensation was amortized in the year ended December 31, 1996.

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.

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CARDIOVASCULAR DYNAMICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

12. INCOME TAXES

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

| | 1995 | | 1996 | |
|---|----------|-------|----------|-------|
| | FEDERAL | STATE | FEDERAL | STATE |
| Net operating loss carryforward..... | \$ 1,322 | \$ 60 | \$ 1,792 | \$ 44 |
| Accrued expenses..... | 20 | 3 | 456 | 78 |
| Research and development credits..... | 97 | 25 | 256 | 144 |
| Bad debt reserve..... | 63 | 11 | 132 | 23 |
| Depreciation..... | -- | -- | 52 | 9 |
| Inventory write-downs..... | 73 | 13 | 51 | 9 |
| Capitalized research and development..... | -- | 150 | -- | 276 |
| Deferred revenue..... | 45 | 8 | 28 | 5 |
| Other..... | -- | -- | 47 | 57 |
| Gross deferred tax assets..... | 1,620 | 270 | 2,814 | 645 |
| Valuation allowance..... | (1,620) | (270) | (2,814) | (645) |
| Total deferred tax assets..... | -- | -- | -- | -- |
| Net deferred tax assets..... | \$ -- | \$ -- | \$ -- | \$ -- |

The valuation allowance increased by \$1,569 and \$1,072 in 1996 and 1995, 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, 1996, the Company has net operating loss carryforwards for federal and state income tax purposes of approximately \$5,120,000 and \$740,000, respectively, which expire in the years 1997 through 2010. In addition, the Company has research and development tax credits for federal and state income tax purposes of approximately \$256,000 and \$144,000, respectively, which expire in the years 2008 through 2010.

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.

13. 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 1995 and 1996.

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CARDIOVASCULAR DYNAMICS, INC.

SCHEDULE II -- VALUATION AND QUALIFYING ACCOUNTS
YEARS ENDED DECEMBER 31, 1996, 1995 AND 1994
(IN THOUSANDS)

| COLUMN A ----- DESCRIPTION ----- | COLUMN B | COLUMN C | | COLUMN D ----- DEDUCTIONS ----- | COLUMN E ----- BALANCE AT END OF PERIOD ----- |
|---|--|-------------------------------------|---------------------------------|--|--|
| | BALANCE AT BEGINNING OF PERIOD | CHARGES TO COSTS AND EXPENSES | CHARGED TO OTHER ACCOUNTS | | |
| Year ended December 31, 1996 | | | | | |
| Allowance for doubtful accounts..... | \$180 | \$221 | \$ -- | \$(24) | \$377 |
| Accrued warranty expenses..... | \$113 | \$ -- | \$ -- | \$(84) | \$ 29 |
| Year ended December 31, 1995 | | | | | |
| Allowance for doubtful accounts..... | \$ 85 | \$ 95 | \$ -- | \$ -- | \$180 |
| Accrued warranty expenses..... | \$ 20 | \$ 93 | \$ -- | \$ -- | \$113 |
| Year ended December 31, 1994 | | | | | |
| Allowance for doubtful accounts..... | \$ -- | \$ 85 | \$ -- | \$ -- | \$ 85 |
| Accrued warranty expenses..... | \$ -- | \$ 20 | \$ -- | \$ -- | \$ 20 |

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EXHIBIT INDEX

| EXHIBIT | DESCRIPTION |
|-----------|---|
| 1.1(1) | Form of Underwriting Agreement..... |
| 2.1(3) | Agreement and Plan of Reorganization dated as of June 9, 1993 among EndoSonic Corporation ("EndoSonic"), EndoSonic Acquisition Corporation and CardioVascular Dynamics, Inc. ("CVD")..... |
| 2.2(3) | First Amendment dated as of June 30, 1993 to the Agreement and Plan of Reorganization among EndoSonic, EndoSonic Acquisition Corporation and CVD..... |
| 2.3(5) | Agreement and Plan of Reorganization by and among CardioVascular Dynamics, Inc., IDI Acquisition Corporation and Intraluminal Devices, Inc. ("IDI") dated as of October 2, 1996..... |
| 3.1(3) | Certificate of Incorporation..... |
| 3.2(3) | Amended Bylaws..... |
| 4.1(1) | Specimen Certificate of Common Stock..... |
| 10.1(3) | Form of Indemnification Agreement to be 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 CVD..... |
| 10.5(3) | Stock Purchase Option Agreement dated June 5, 1992, by and between EndoSonic and CVD..... |
| 10.6(3)* | Japanese Distribution Agreement dated May 28, 1993, as amended on October 27, 1994 and July 17, 1995, (the "Japanese Distribution Agreements") by and between CVD and Fukuda Denshi Co., Ltd. ("Fukuda")..... |
| 10.7(3)* | Stock Purchase and Technology License Agreement dated September 10, 1994, as amended on September 29, 1995, by and among EndoSonic, CVD and SCIMED Life Systems, Inc. ("SCIMED")..... |
| 10.8(3) | Waiver and Grant of Warrant dated June 30, 1995 by and between SCIMED, CVD and Endosonics..... |
| 10.9(3)* | License Agreement dated January 15, 1995 by and between CVD and Advanced CardioVascular Systems, Inc. ("ACS")..... |
| 10.10(3)* | License Agreement dated March 4, 1996 by and between CVD and ACS..... |
| 10.11(3) | Series B Stock Purchase Agreement dated March 29, 1996 by and between CVD and EndoSonic..... |
| 10.12(3) | License Agreement dated December 22, 1995 by and between CVD and EndoSonic..... |
| 10.13(1) | Form of Stockholder Agreement with EndoSonic..... |
| 10.14(1) | Form of Tax Allocation Agreement with EndoSonic..... |
| 10.15(3) | Industrial Lease dated February 23, 1995 by and between the Irvine Company and CVD..... |
| 10.16(1) | Waiver and Grant of Warrant dated May 2, 1996 by and between SCIMED, CVD and Endosonics..... |
| 10.17(2) | Amendment to Japanese Distribution Agreements dated May 13, 1996 by and |

| | |
|-----------|--|
| | between CVD and Fukuda..... |
| 10.18(4)* | Supply Agreement dated July 15, 1996 by and between CVD and Medtronic, Inc..... |
| 10.19(4)* | OEM Agreement dated July 15, 1996 by and between CVD and Medtronic, Inc.... |
| 10.20 | License Agreement dated February 6, 1997 by and between CVD and EndoSonics..... |
| 23.1 | Consent of Ernst & Young LLP, Independent Auditors..... |
| 24.1 | Power of Attorney (Reference is made to page 35 of this Annual Report on Form 10-K)..... |
| 27.1 | Financial Data Schedule..... |

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* Confidential treatment requested.

- (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.

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LICENSE AGREEMENT

THIS LICENSE AGREEMENT (the "Agreement") is effective as of this 6th day of February, 1997 (the "Effective Date"), by and between Endosonics Corporation, a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 2870 Kilgore Road, Rancho Cordova, California 95670 ("Endosonics") and Cardiovascular Dynamics, Inc., a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 13844 Alton Parkway, Suite 140, Irvine, California 92718 ("CVD").

WHEREAS, CVD is the owner of the entire right, title and interest in and to the Licensed Patents set forth in Exhibit A;

WHEREAS, CVD has developed various catheter products using proprietary technology covered by the Licensed Patents;

WHEREAS, Endosonics is desirous of acquiring a non-exclusive license to the Licensed Materials (as defined below) which shall include a limited exclusive license to make, have made, use, sell and have sold catheter products developed by Endosonics using the Licensed Materials;

WHEREAS, CVD is desirous of acquiring a non-exclusive license to use Endosonics PMA Number P910031 (the "Endosonics PMA"), to reference, use and rely upon information in the Endosonics PMA in order to enable CVD to file for and obtain PMA approval for the Focus Catheters from the U.S. Food and Drug Administration ("FDA"); and

WHEREAS, the parties are willing to grant such licenses upon the terms and subject to the conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the foregoing and other mutual covenants, terms and conditions hereinafter expressed, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

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ARTICLE I

DEFINITIONS

1.1 "LICENSED PATENTS" shall mean the patents set forth in Exhibit A attached hereto and incorporated herein by this reference, and any and all divisions, continuations-in-part, reissues, renewals, or extensions thereof.

1.2 "FOCUS CATHETERS" shall mean all catheter products combining CVD Focus Technology on the same catheter with an Endosonics transducer developed by Endosonics pursuant to this Agreement using the Licensed Patents and/or CVD Focus Technology.

1.3 "CVD FOCUS TECHNOLOGY" shall mean all CVD inventions (whether or not patentable), ideas, knowhow, trade secrets, processes and other technical information necessary or useful in manufacturing the Focus Catheters (including without limitation the Specifications (as defined below)) that CVD (i) owns or controls as of the Effective Date or (ii) acquires or develops during the term of this Agreement.

1.4 "LICENSED MATERIALS" shall mean the Licensed Patents associated with CVD Focus Technology.

1.5 "ENDOSONICS TRANSDUCER" shall mean the Endosonics ultrasound transducer product(s) set forth in Exhibit B attached hereto and incorporated herein by this reference.

1.6 "SPECIFICATIONS" shall mean the specifications for Focus Catheter products developed by CVD using or incorporating the Licensed Materials.

ARTICLE II

LICENSE GRANT

2.1 Subject to the terms and conditions of this Agreement, CVD hereby grants to Endosonics (i) a non-exclusive, worldwide, fully paid-up, royalty-free right and license to practice under the Licensed Patents and to use the CVD Focus Technology to make, have made and use the Focus Catheters, (ii) an exclusive, worldwide, fully paid-up, royalty-free right and license to market, sell or otherwise distribute the Focus Catheters only as bundled on the same catheter device with an Endosonics Transducer. Upon execution of this Agreement, CVD shall transfer a copy of all existing Licensed Materials to Endosonics.

2.2 Subject to the terms and conditions of this Agreement, Endosonics hereby grants to CVD a nonexclusive, worldwide, fully paid-up, royalty-free right and license to reference, use, and rely upon information in the Endosonics PMA in order to enable CVD to file for and obtain PMA approval, as evidenced by a separate CVD PMA number on file at the FDA, for the coronary balloon dilatation catheters from the FDA. CVD shall use, reference, or rely upon the Endosonics PMA for the limited purpose of obtaining FDA approval of a unique PMA which will be in CVD's name and shall not be a PMA supplement to Endosonics' PMA.

2.3 Subject to the terms and conditions of this Agreement, Endosonics shall furnish to CVD a complete copy of all manufacturing information in the Endosonics PMA applicable to CVD's manufacture of CVD coronary balloon dilatation products.

2.4 Subject to the provisions of this Agreement, Endosonics is authorized to improve, modify, correct and enhance the Licensed Materials as it may deem appropriate, and Endosonics shall exclusively control, and own all right, title and interest in and to, the resulting improvement, modification, correction or enhancement including, without limitation, any patent rights available with respect thereto, any trade secrets pertaining thereto and any copyrights subsisting therein as derivative works, but only to the extent that the same shall be separate and clearly distinguishable from the underlying work. Nothing in this Section 2.4 is intended to modify Endosonics' limited rights to market, sell or otherwise distribute Focus Catheters only as bundled on the same catheter with an Endosonics Transducer, as defined in Section 2.1 of this Agreement.

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ARTICLE III

REPORTS AND EXPENSE REIMBURSEMENT

3.1 Should Endosonics incur any out-of-pocket expenses to assist CVD in executing Sections 2.2 or 2.3 of this Agreement, CVD shall reimburse Endosonics for such out-of-pocket expenses up to a maximum of One Thousand Dollars (\$1,000.00). If such out-of-pocket expenses exceed One Thousand Dollars (\$1,000.00), Endosonics shall request CVD's prior written approval prior to incurring such expenses.

3.2 Should CVD incur any out-of-pocket expenses to assist Endosonics in executing Section 2.1 of this Agreement, Endosonics shall reimburse CVD for such out-of-pocket expenses up to a maximum of One Thousand Dollars (\$1,000.00). If such expenses exceed One Thousand Dollars (\$1,000.00), CVD shall request Endosonics' prior written approval prior to incurring such expenses.

ARTICLE IV

OWNERSHIP

4.1 CVD Rights. As between the parties and subject to the rights granted to Endosonics under this Agreement, all right, title and interest in and to the Licensed Materials (including, without limitation, all patent rights, copyrights, trade secret rights and other proprietary rights) is and shall remain in CVD.

4.2 Endosonics' Rights to Endosonics' PMA. Subject to the rights granted to CVD under Section 2.2 of this Agreement, all right, title and interest in and to the information contained in the Endosonics PMA (including, without limitation, all patent rights, copyrights, trade secret rights and other

proprietary rights) shall remain in Endosonics.

ARTICLE V

PATENT AND REGULATORY MATTERS

5.1 Patent Enforcement. During the term of this Agreement, CVD shall diligently maintain, protect and enforce the Licensed Patents, which shall include taking all necessary action to prevent and terminate any third party infringement of the Licensed Patents. CVD shall have no responsibility to maintain, protect and enforce any technology or patents resulting from any modifications to the Licensed Materials.

5.2 Domestic Regulatory Matters; CVD PMA Submission. Endosonics shall cooperate fully with CVD in preparing regulatory filings associated with CVD's submission of a PMA for all current Focus Catheter products and shall prepare and execute promptly all documents or instruments necessary to enable CVD to make such regulatory filings and to obtain FDA approval of the PMA, including, without limitation:

(a) a signed, written statement from Endosonics to the FDA that authorizes CVD and the FDA to reference, use, and reply upon the Endosonics PMA in seeking approval for a PMA for CVD's Focus Catheter products; and

(b) a statement signed by both CVD and Endosonics confirming that Endosonics has furnished CVD with a complete copy of all manufacturing information in the Endosonics PMA applicable to CVD's manufacture of the Focus Catheter products.

5.3 Domestic Regulatory Matters; Annual Reporting Requirements. CVD shall cooperate fully with Endosonics in preparing regulatory filings associated with Endosonics submission of PMA reports required by the FDA, including but not limited to Annual Reports. CVD shall disclose to Endosonics all changes to any product distributed under the Endosonics PMA, whether considered significant or not, and whether undertaken before or after initial product introduction, no later than August 15 of each calendar year. CVD's obligations under this Section shall terminate upon abandonment of Endosonics' PMA approvals for CVD distributed products. A final report of all changes as described above shall be submitted to Endosonics fifteen (15) days following such abandonment.

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5.4 Domestic Regulatory Matters; Distribution of CVD Product under Endosonics' PMA. CVD will cease to distribute CVD Focus products which were approved under Endosonics' PMA following approval by the FDA of CVD's original PMA Application, or twelve (12) months after execution of this Agreement, whichever occurs first. No new applications shall be made under Endosonics' PMA following execution of this Agreement.

5.5 Foreign Regulatory Matters. Endosonics shall obtain and maintain all applicable approvals and registrations for the Catheters in any country into which Endosonics shall distribute the Focus Catheters and CVD shall render all necessary assistance to enable Endosonics to accomplish the foregoing.

ARTICLE VI

REPRESENTATIONS AND WARRANTIES OF CVD

6.1 Title. CVD represents and warrants that, to the best of its knowledge, it has complete title to the Licensed Materials, free from any liens or encumbrances, and that, to the best of its knowledge, the use of, or practice under, the Licensed Materials in the United States and its territories will not infringe the intellectual property rights of any third party.

6.2 Validity. CVD represents and warrants that, to the best of its knowledge, the Licensed Patents are valid and enforceable and that, to the best of its knowledge, there are no third party infringers of the Licensed Materials.

ARTICLE VII

CONFIDENTIALITY

Each party agrees that all inventions, processes, materials, chemicals,

reagents, know-how and ideas and all other business, technical and financial information it obtains from the other are the confidential property of the disclosing party ("Proprietary Information" of the disclosing party). Except as expressly allowed in this Agreement, the receiving party will hold in confidence and not use or disclose any Proprietary Information of the disclosing party and shall similarly bind its employees in writing. The receiving party shall not be obligated under this Article VII with respect to information that:

- (i) is or has become readily publicly available through no fault of the receiving party or its employees or agents; or
- (ii) is received from a third party lawfully in possession of such information and lawfully empowered to disclose such information and provided the receiving party abides by all restrictions imposed by such third party; or
- (iii) was rightfully in the possession of the receiving party prior to its disclosure by the other party provided the receiving party abides by all restrictions imposed on its possession of such information; or
- (iv) was independently developed by employees or consultants of the receiving party without access to such Proprietary Information; or
- (v) is required by order of a government agency or court of competent jurisdiction to be disclosed.

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ARTICLE VIII

INDEMNIFICATION

CVD agrees to indemnify Endosonics from, for, and against any loss, cost, damages, liability or expense (including reasonable attorney's fees) arising out of any claim ("Claim") brought by third parties (i) alleging that the manufacture, use or sale of a Focus Catheter infringes any third party rights or (ii) relating to any breach of the warranties set forth in Article VI above (collectively, "Damages"); provided, however, that CVD's indemnification obligations hereunder shall not apply to the extent (and only to the extent) that such Damages result from (i) Endosonics's use or distribution of technology and materials other than the Licensed Materials or (ii) modifications, improvements, corrections or enhancements made by Endosonics to the Licensed Materials. Endosonics agrees to indemnify CVD from, for, and against Damages incurred by CVD that are excluded from CVD's indemnification obligations pursuant to the foregoing sentence. In the event of a Claim, the party seeking indemnification hereunder shall promptly notify the indemnifying party of such Claim, shall allow the indemnifying party to have sole defense of such Claim and shall cooperate and render reasonable assistance upon the request, and at the expense, of the indemnifying party.

ARTICLE IX

DISCLAIMERS AND LIMITATION OF LIABILITY

9.1 EXCEPT FOR THE WARRANTIES EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTIES WITH RESPECT TO THE TECHNOLOGY OR MATERIALS THAT IT PROVIDES TO THE OTHER PARTY UNDER THIS AGREEMENT AND EACH PARTY HEREBY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING ALL WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

9.2 NEITHER PARTY WILL BE LIABLE TO THE OTHER (I) WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY FOR ANY SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES OR (II) FOR LOST PROFITS OR DATA.

ARTICLE X

TERM AND TERMINATION

10.1 This Agreement shall commence as of the Effective Date, and shall continue in force (unless terminated earlier in accordance with this Article X) until the last of the Licensed Patents expires and any PMA or regulatory approvals obtained through the use of Endosonics' PMA are abandoned, or the last

of the Licensed Patents is ruled invalid or unenforceable in a final decision by a court of competent jurisdiction or by the United States Patent and Trademark Office.

10.2 This Agreement and all licenses granted hereunder may be terminated by either party immediately if the other party breaches a material term or provision of this Agreement and fails to cure such breach within sixty (60) days after written notice from the non-breaching party.

10.3 This Agreement also may be terminated by either party, at its option, upon written notice to the other party, (i) upon the institution by the other party of insolvency, receivership or bankruptcy proceedings or any similar proceedings for the settlement of its debts, or (ii) upon the institution of such proceedings against the other party, which are not dismissed or otherwise resolved in such party's favor within sixty (60) days thereafter.

10.4 The following Articles shall survive termination of this Agreement: I, IV, VI, VII, VIII, IX and XI, along with this Section 10.4. Except in the case of termination by CVD pursuant to Section 10.2 above, the licenses granted to Endosonics under Section 2.1 of this Agreement shall also survive termination of this Agreement. In the event this Agreement is terminated by CVD pursuant to Section 10.2 above, Endosonics

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shall have the right thereafter to sell completed Focus Catheters then on hand, in the process of being manufactured or as otherwise needed to meet its then-existing supply obligations. Except in the case of termination by Endosonics pursuant to Section 10.2 above, the licenses granted to CVD under Sections 2.2 of this Agreement shall also survive termination of this Agreement. In the event this Agreement is terminated by Endosonics pursuant to Section 10.2 above, the licenses granted to CVD under Sections 2.2 of this Agreement shall continue thereafter only as necessary to sell completed CVD products then on hand, in the process of being manufactured or to meet CVD's then-existing supply obligations.

ARTICLE XI

MISCELLANEOUS

11.1 Assignment. This Agreement shall be binding upon and inure to the benefit of the parties hereto, their respective subsidiaries, successors and permitted assigns. Either party may freely assign this Agreement to an acquiror of all or substantially all of its stock, business or assets relating to this Agreement (whether by merger, acquisition or otherwise).

11.2 Notices. All notices given by either party under the terms of this Agreement shall be in writing and personally delivered, sent by certified mail (return receipt requested) or by commercial overnight courier service to a party's address as set forth in the initial paragraph of this Agreement. Notices shall be effective five (5) days after mailing or upon actual receipt, whichever is sooner. Either party may change the person to whom, or address to which, notice should be directed by giving written notice thereof.

11.3 Entire Agreement. This Agreement constitutes the entire agreement and understanding between the parties and supersedes the December 22, 1995 License Agreement between the parties in its entirety, and all other previous or contemporaneous communications, memoranda, understandings or agreements, either oral or written, between the parties with respect to the subject matter hereof.

11.4 Governing Law. This Agreement shall be governed by and interpreted in accordance with the laws of the State of California without regard to the conflicts of laws provisions thereof. The sole jurisdiction and venue for actions related to the subject matter hereof shall be the California state and U.S. federal courts having within their jurisdiction the location of Endosonics's principal place of business. Both parties consent to the jurisdiction of such courts and agree that process may be served in the manner provided herein for giving of notices or otherwise as allowed by California state or U.S. federal law. In any action or proceeding to enforce rights under this Agreement, the prevailing party shall be entitled to recover costs and attorneys' fees.

11.5 Headings. Headings and captions are for convenience only and are not

to be used in the interpretation of this Agreement.

11.6 Severability. If any provision of this Agreement is held by a court of competent jurisdiction to be illegal, invalid or unenforceable, that provision shall be limited or eliminated to the minimum extent necessary so that this Agreement shall otherwise remain in full force and effect and enforceable.

11.7 Relationship of Parties. The parties hereto expressly understand and agree that for the purposes of this Agreement the other is an independent contractor in the performance of each and every part of this Agreement and is solely responsible for all of its employees and agents and its labor costs and expenses arising in connection therewith. This Agreement in no way creates a partnership, joint venture or agency relationship between the parties and neither party shall have the right or authority to bind the other in any way as a result of this Agreement.

11.8 Amendment and Waiver. Except as otherwise expressly provided herein, any provision of this Agreement may be amended and the observance of any provision of this Agreement may be waived (either generally or in any particular instance and either retroactively or prospectively) only with the written consent of the parties. The failure of either party to enforce its rights under this Agreement at any time for any period shall not be construed as a waiver of such rights.

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IN WITNESS WHEREOF, each party has caused this Agreement to be executed by its duly authorized representative as of the day and year first above written.

ENDOSONICS CORPORATION

By:

Title:

CARDIOVASCULAR DYNAMICS, INC.

By:

Title:

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EXHIBIT A

LICENSED PATENTS

- - U.S. Patent No. 5,470,313
- - U.S. Patent App. No. 08/201935
- - EPO Patent App. No. 94119841.8

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EXHIBIT B

ENDOSONICS TRANSDUCER

CONSENT OF ERNST & YOUNG, LLP, INDEPENDENT AUDITORS

We consent to the incorporation by reference in the Registration Statement (Form S-1 No. 333-15901) of CardioVascular Dynamics, Inc. and in the related Prospectus of our report dated January 30, 1997, with respect to the consolidated financial statements and schedules of CardioVascular Dynamics, Inc. and subsidiary included in this Annual Report (Form 10-K) for the year ended December 31, 1996.

/s/ ERNST & YOUNG LLP

Orange County, California
March 21, 1997

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