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FORM 10-K

SECURITIES AND EXCHANGE COMMISSION
Washington, D. C. 20549

(Mark One)

[X] 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 0-26992

CARDIOVASCULAR DIAGNOSTICS, INC.
(Exact name of registrant as specified in its charter)

NORTH CAROLINA	56-1493744
(State or other jurisdiction of incorporation or organization	(I.R.S. Employer Identification No.)

5301 Departure Drive, Raleigh, North Carolina 27616
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: 919-954-9871

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

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

Common Stock ($.001 Par Value)
(Title of class)

Indicate by check mark whether the registrant (1) has filed all reports

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of 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 based upon $5.50 per share, the closing price of the Common Stock on March 21, 1997, on the NASDAQ National Market System, was approximately $29,615,146 as of such date. Shares of Common Stock held by each officer and director and by each person who owns 10% 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 may not be conclusive for other purposes.

As of March 21, 1997, the registrant had outstanding 6,716,186 shares of Common Stock ($.001 par value).

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company's Proxy Statement for the 1997 Annual Meeting of Shareholders are incorporated herein by reference into Part III.

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Statements in this Annual Report on Form 10-K that are not descriptions of historical facts are forward-looking statements that are subject to risks and uncertainties. Actual results could differ materially from those currently anticipated due to a number of factors, including those set forth herein and in the Company's other filings with the Securities and Exchange Commission, and including, in particular, risks relating to uncertainties regarding market acceptance of the Company's products, government regulation, new product development, healthcare reform, third-party reimbursement and competition.

PART I

Item 1. BUSINESS.

Cardiovascular Diagnostics, Inc., a North Carolina corporation (the "Company" or the "Registrant"), develops, manufactures and markets a proprietary cardiovascular diagnostic test system that provides rapid and accurate evaluation of hemostasis at the point of patient care. The Company believes that its Thrombolytic Assessment System ("TAS") is the only stat, or "as soon as possible", point-of-care system capable of monitoring both the coagulation (formation) and lysis (dissolution) of blood clots. Such monitoring provides information which is critical in administering anticoagulant and thrombolytic (clot-dissolving) drugs, which are used in the treatment of heart attacks and strokes and in a variety of other medical procedures.

Evaluation of hemostasis is an integral part of patient diagnosis and treatment for a wide variety of medical conditions. Hemostatic test results must be provided quickly because a majority of the drugs used to regulate clotting are cleared rapidly from the body, and these drugs must be closely monitored to maintain drug levels within a safe treatment range. The Company believes that generally, hospital central and stat laboratories, which currently provide the majority of such testing, cannot provide timely information to clinicians regarding coagulation, and thrombolytic and other drug monitoring. Any delay in providing such information can be a problem since the physician is likely to leave the patient area during this time, which may result in a further delay in diagnosis and treatment. The Company believes that TAS can provide information regarding coagulation as well as thrombolytic and other drug monitoring on a timely basis, thus permitting quicker diagnosis and therapeutic intervention, which will improve hemostatic therapy and the quality of patient care. The Company believes that this improvement may facilitate quicker transfers out of expensive critical care settings, reduce the overall length of hospital stays, reduce expenditures for laboratory equipment and its associated maintenance and labor, and reduce the unnecessary use, and therefore the overall cost, of pharmaceuticals. In addition, point-of-care testing can save hospitals money by reducing the numerous steps, paperwork and personnel involved in collecting, transporting, documenting and processing blood samples.

The Company currently sells its TAS analyzer and a menu of six tests in the United States. Four of these tests, the Prothrombin Time ("PT"), the PT One, the Activated Partial Thromboplastin Time ("APTT") and the Heparin Management ("HMT") tests (which monitor oral anticoagulant therapy, low level intravenous anticoagulant therapy and high level intravenous anticoagulant therapy, respectively), have received Food and Drug Administration ("FDA") clearance under Section 510(k) of the Food, Drug and Cosmetic Act (the "FDC Act"), and are currently sold for commercial use. The other two tests, the SK Panel and Lysis Onset Time ("LOT") tests (which are used in conjunction with the administration

of thrombolytic or clot-dissolution drugs such as Tissue Plasminogen Activator ("t-PA"), streptokinase and urokinase), are currently sold in the U.S. "for investigational use only", pending further FDA review and clearance. The SK Panel, which consists of three tests that the Company

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intends to sell separately in the future, assists physicians in anticipating possible complications of thrombolytic therapy by screening patients for resistance to streptokinase. The LOT test may be used during the administration of any thrombolytic drug to detect the establishment of the lytic state, after which additional administration of the drug may no longer be efficacious. The Company believes that the SK Panel and LOT test will be useful diagnostic tools for managed-care hospitals, especially those operating under contracts which may capitate per procedure charges, because healthcare providers can optimize thrombolytic therapy, providing for better, more cost-effective patient care. The Company currently sells the TAS analyzer and all six of these tests for commercial use in Europe.

The TAS technology allows for further expansion of the Company's menu of tests. The Company plans to introduce new tests in 1997 in certain European markets. Tests under development include three tests for heparin management (Heparin Response Test ("HRT"), Heparin Neutralizing Test ("HNT") and the Protamine Sulfate Titration ("PMT")), and two tests for anticoagulants other than heparin (the Anti-Xa and Thrombin Inhibitor Management/Ecarin Clotting Time ("TIM/ECT")). The Company intends to submit notifications for each of these tests to the FDA for U.S. marketing clearance under Section 510(k) of the FDC Act at or about the time of its European market launches. In addition, the Company is pursuing strategic corporate alliances in order to increase the installed base of TAS analyzers and to further accelerate development and expansion of the applications of TAS.

On October 31, 1993, the Company acquired Coeur Laboratories, Inc. ("Coeur"), which manufactures and sells a line of disposable power injection syringes used for cardiology and radiology procedures, as well as a line of manifolds used in custom angiographic procedure kits. The Company acquired Coeur in order to gain access to Coeur's management and infrastructure, its positive annual cash flow and its manufacturing facility. The Company believes that the acquisition of Coeur has accelerated the commercialization of TAS.

Industry Overview

The practice of laboratory medicine has changed dramatically over the last 30 years, with new technology continuously evolving in response to the physician's demand for information. This demand for information is particularly acute in blood testing, where access to timely and accurate results is critical to effective patient care. Initially, hospital blood analysis was performed in multiple small laboratories that typically used time-consuming manual techniques. The accuracy of tests performed under these conditions varied considerably depending upon, among other factors, the skill of the laboratory personnel. The advent of automated blood testing, first introduced in the mid-1960's, allowed for centralization and standardization of laboratory tests. With improved access to blood analysis, physicians began to use laboratory tests as a primary diagnostic tool and consequently demanded more tests and faster results. In an effort to meet this demand, some hospitals established decentralized stat laboratories nearer the patient. These laboratories typically rely on technology designed for efficiency in a high-volume centralized department. The Company believes that reliance on this technology makes stat laboratories inadequate and expensive, creating a need for new technology suitable for use at the point of patient care.

Recent advances in technology allow many blood tests to be performed at the point of patient care, where the physician can most effectively use test results. Portable, easy-to-use analyzers designed to perform blood analysis rapidly and accurately are emerging as a solution to current healthcare demands. While speed is important in point-of-care testing, accuracy is critical. Since point-of-care testing is typically performed by operators who lack any special laboratory skills or training, the more error-proof the testing system, from sample collection through archiving of the test result, the more reliable the system will prove to be. By design, most point-of-care tests require limited materials and minimum labor. Point-of-care test systems

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must also comply with the Clinical Laboratory Improvement Amendment of 1988 ("CLIA") regulations. See "--Government Regulation--CLIA".

Point-of-care devices are being developed for four major types of blood testing--blood gas, chemistry, hematology and hemostasis. The Company's technology focuses on hemostasis testing, which consists of the monitoring of coagulation and thrombolytic drugs. Based upon market research conducted by IMS America ("IMS"), the Company estimates that in 1992 U.S. hospitals conducted over 300 million PT and aPTT tests, two anticoagulant tests currently marketed by the Company. The Company believes that very few of such tests were conducted at the point of patient care because of the limited availability at that time of accurate point-of-care hemostasis testing.

Access to timely and accurate coagulation test results must be provided quickly because a majority of the drugs used to regulate clotting are cleared rapidly from the body and these drugs must be closely monitored to maintain drug levels within a safe treatment range. Coagulation testing presents special challenges in achieving test accuracy, because blood begins to coagulate as soon as it leaves the body, and therefore any delay in performing a coagulation test may lead to a less accurate test result. For this reason, coagulation testing is an ideal area for point-of-care testing.

The increased use over the past few years of thrombolytic drugs, which dissolve clots, in the treatment of heart attacks and strokes has increased the need for rapid thrombolytic test results, which can be provided by point-of-care testing. Prior to development of the Company's products, there were no point-of-care thrombolytic test systems available. Current laboratory tests capable of monitoring thrombolysis take 45 minutes to two hours to perform and therefore do not provide results during the critical early minutes of therapy, during which the patient is likely to derive the most benefit from appropriate doses of the drug. The ability to inform the physician of the presence of inhibitors to specific thrombolytic drugs and to monitor clot dissolution within minutes provides objective information upon which the healthcare provider can base a decision regarding optimal and cost-effective use of thrombolytic drugs such as t-PA, streptokinase and urokinase.

TAS Benefits

The Company believes that the TAS analyzer and test cards enhance the physician's ability to obtain accurate hemostasis testing results quickly at the point of patient care. TAS will permit the timely initiation or alteration of patient therapy and assist in the monitoring of patient response to therapy, thereby providing the potential for substantial improvement in the quality of patient care and for reduced overall healthcare costs. Benefits of the Company's TAS point-of-care system include:

- Accuracy and Precision. Clinical trials indicate that TAS's accuracy and precision are comparable to that of conventional laboratory equipment. TAS reduces opportunities for error by eliminating many of the steps involved in laboratory blood analysis, including transportation of the blood sample, its preparation for testing and the reporting of test results.

- Rapid Test Results. TAS typically provides test results in under three minutes, which allows the healthcare provider to diagnose more quickly and accurately a patient's condition, as well as begin treatment, change treatment or monitor the patient's response to ongoing therapy.

- Cost-Effectiveness. The Company believes that in addition to being competitive with the cost of laboratory testing on a test-by-test basis, TAS also may facilitate quicker transfers out of expensive critical care settings, reduce the overall length of hospital stays, reduce expenditures for laboratory equipment and associated maintenance

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and labor, and reduce the unnecessary use, and therefore the overall cost, of pharmaceuticals.

- Ease of Use. TAS requires only a single drop of unprocessed blood, and no specialized laboratory training to operate. It can be used by any healthcare provider at the point of patient care. The TAS analyzer automatically controls all functions of the system, eliminating the need for highly specialized skills to perform the analysis and interpret the results.

- Compliance with Current CLIA Regulations. Features of the TAS analyzer that were designed to meet CLIA regulations include internal quality control, operator access codes, patient identification, data storage, printer interface and battery operation. The Company believes that TAS complies with current CLIA regulations.

Strategy

The Company's goal is to become the leading manufacturer and marketer of cost-effective point-of-care test systems for coagulation and thrombolytic drug monitoring and to establish TAS as the standard of care for coagulation and thrombolytic drug monitoring at the point of patient care. The Company intends to achieve this goal through the following strategies:

Broadening Sales and Marketing Efforts. In October 1996, the Company entered into a five-year North American distribution arrangement with Dade International ("Dade"). The Company has independent distributors in various countries, including the United Kingdom, Italy, Belgium, Germany, Austria, The Netherlands, Scandinavia, Israel, New Zealand and Australia.

Targeting Acute Care Facilities. The Company is directing its initial marketing efforts toward integrated healthcare networks ("IHN's") and large hospitals' central and stat laboratories, as well as acute care sites within such hospitals. The Company believes that these targeted customers are the most likely to make initial TAS purchases due to their high demand for the benefits of point-of-care testing. The Company also believes that once TAS's utility is demonstrated, additional sites within hospitals will be more likely to purchase TAS products.

Promoting Hospital and Physician Acceptance. The Company is seeking to gain broad acceptance of its products by hospitals and physicians through the dissemination of scientific, clinical and patient outcome data on its products. The Company's initial marketing efforts are targeted to directors of hospital central laboratories and cardiovascular specialists.

Expanding Technology Applications. The Company is seeking to expand the applications of TAS through development of additional tests, including heparin management tests, new anticoagulant tests and general screening tests. The Company is also developing complementary products such as quality control tests and data collection and analysis equipment.

Entering into Strategic Alliances. The Company is pursuing strategic corporate alliances with pharmaceutical and other companies. The Company believes that such strategic corporate alliances would increase the installed base of TAS analyzers and further accelerate the development and expansion of the applications of TAS.

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Technology

The Company's core technology relating to both the TAS analyzer and test cards is currently protected by three U.S. patents and 28 corresponding international patents. The TAS card technology combines a mixture of dry reagents and paramagnetic iron oxide particles ("PIOP") that is contained within the card's reaction chamber. The test card has the approximate dimensions and half the thickness of a standard credit card. Blood samples are introduced into this reagent/particle mixture, dissolving the dry reagent and freeing the magnetic particles to move within the card's chamber. When the oscillating magnetic field is generated by the TAS analyzer, the magnetic particles within the TAS card's reaction chamber move in response to the magnetic field. An optical sensor within the TAS analyzer monitors the motion of the magnetic particles without touching the blood sample. When movement diminishes to a predetermined amplitude, the TAS system determines that a clot has been formed.

Conversely, the same technology is used to measure the time required for a clot to dissolve. The Company's technology permits the measurement of clot dissolution by introducing a sample of blood to a mixture of magnetic particles and reagents including a clot-forming chemical, thereby inducing a clot. The system then measures the amount of time required for the induced clot to dissolve. The Company believes that TAS is the only point-of-care system capable of monitoring both coagulation and dissolution of clots. Furthermore, an additional benefit to the Company is the flexibility of the TAS technology, which allows for further expansion of the Company's menu of tests, since new tests can be developed by using different reagents in the test cards.

Products

Thrombolytic Assessment System (TAS)

The Company's Thrombolytic Assessment System, or TAS, consists of a proprietary portable analyzer and proprietary, disposable test cards. The Company's TAS analyzer and test cards are designed to work effectively in a decentralized testing environment where they are used by healthcare personnel

who need not have received formal central laboratory training. The current list price for the TAS analyzer is $5,000 and for individual test cards is between $6.00 and $30.00, depending on the test. All of these prices are subject to discounts for purchases in volume. The Company's products are able to provide point-of-care testing, which can save valuable time in obtaining test results, is more convenient to the healthcare professional than laboratory testing and allows for more efficient treatment of patients. The Company believes that TAS complies with current CLIA regulations. However, there is no formal CLIA approval process for specific devices other than the classification process, pursuant to which the TAS tests have been categorized as "moderate complexity" tests. Furthermore, the CLIA regulations affecting use of the TAS analyzer are subject to ongoing implementation, interpretation and revision. See "--Government Regulation--CLIA."

Analyzer/System Operation

The TAS analyzer weighs approximately four pounds and is about the size of the typical office telephone. The TAS analyzer has a four-line LCD display screen, which is driven by software to prompt the technician to input the user and patient ID numbers, sample type, and timing of application of the blood sample.

TAS can test unprocessed whole blood or plasma. Whole blood is obtained through venipuncture by drawing blood from a patient, often into a tube containing sodium citrate, which stabilizes the blood prior to testing. The process of citrating blood requires no special training or skill, and can be done at the point of patient care by the same person who performs the TAS

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test, without adding any time to the process. Plasma, which is typically used in laboratory testing, is whole blood which has had various cellular components removed through spinning in a centrifuge for 10 to 15 minutes.

To operate TAS, a test card is swiped through the magnetic strip reader of the analyzer, which automatically initiates quality controls and begins to elicit information from the operator through a series of prompts outlining the operating procedure for the specific test to be performed. The test card is then inserted into the TAS analyzer. A single drop of unprocessed citrated whole blood or plasma is then placed into the reaction chamber of the card, which already contains the appropriate mixture of dry reagents and PIOP for the test being performed. Typically within three minutes, the screen on the TAS analyzer displays a numerical test result, which is comparable to the result which would be achieved in a central laboratory using traditional testing procedures. The portable analyzer has been designed with a memory capability, may be connected to a printer, and with a software upgrade may be connected to the hospital's patient information system. The internal memory of the TAS analyzer allows for the storage of up to 1,000 individual test results and has an alphanumeric keypad that allows for the input of up to a 20-character patient identification code. Additionally, the keypad provides for coded entry so only authorized personnel can gain access to the system. The TAS analyzer can operate either on wall current or on an internal rechargeable battery.

Test Cards

Currently the TAS analyzer is capable of performing a variety of coagulation and thrombolytic assessment tests, including the aPTT, PT, HMT, SK Panel and LOT tests. The following table describes the tests that the Company is currently selling:

<TABLE>
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TEST	TYPE	PRINCIPAL APPLICATION	STATUS
<S>	<C>	<C>	<C>
Coagulation			
aPTT	Baseline/monitoring	Monitors low heparin levels	510(k) clearance received. Sold commercially in U.S. and Europe.
PT	Baseline/monitoring	Monitors oral anticoagulants	510(k) clearance received. Sold commercially in U.S. and Europe.
PT One	Baseline/monitoring	Monitors oral anticoagulants with greater sensitivity	510(k) clearance received. Sold commercially in U.S. and Europe.
HMT	Heparin management	Monitors high heparin levels	510(k) clearance received. Sold commercially in U.S. and Europe.

Thrombolysis

SK Panel*	Pre-therapy screen	Resistance to streptokinase	Extended clinical trials required for 510(k) clearance. Sold commercially in Europe and for investigational use only in U.S.
LOT	Thrombolytic drug monitoring	Monitors establishment of lytic state	Extended clinical trials required for 510(k) clearance. Sold commercially in Europe and for investigational use only in U.S.

</TABLE>

* Consists of three tests that the Company intends to sell separately in the future.

The aPTT test is a coagulation screening test which may be used in conjunction with the PT to provide a global assessment of a patient's ability to form a clot. In addition, the aPTT test is used to monitor heparin, an injectable anticoagulant. Hospitals routinely use heparin as the initial treatment for patients with a clot, including patients suffering from

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heart attacks or strokes. Heparin also prevents clots from forming in patients undergoing procedures involving particular risks of clotting, such as angioplasties, angiograms, open heart surgeries, dialyses and certain other surgeries. Heparin must be closely monitored to assure adequate anticoagulation without increasing the risk of developing a bleeding complication. Time is particularly important when monitoring heparin, since the drug affects a patient's coagulation system within minutes.

The PT test is a general screening test that is used to assess a patient's baseline hemostatic function or to monitor the use of warfarin, an oral anticoagulant. Although they are both anticoagulants, heparin and warfarin work in different ways and require different tests to monitor their functions. Warfarin is widely used for long-term treatment in patients who have previously developed clots, including after heart attacks, in order to inhibit coagulation and reduce the risk of developing additional clots. A physician uses the PT test to monitor and maintain drug levels within a safe treatment range; that is, too little warfarin will not prevent a new clot from developing, but too much of the drug may result in a bleeding complication.

The Company manufactures and markets two different types of PT test cards, a general purpose PT test card routinely used in the United States, and the PT One, which uses a more sensitive scale of measurement. The PT One is currently the preferred test for all indications in Europe and is rapidly becoming more popular in the United States.

aPTT tests are incapable of monitoring high levels of heparin. Therefore, the Company developed its HMT for monitoring patients requiring high dose heparin therapy during procedures such as open heart surgeries or dialyses. For example, during the course of an open heart surgery, the patient's blood may be tested as many as four to six times to assure an adequate heparin effect. The Company believes that its HMT is a more effective test than the Activated Clotting Time test ("ACT") currently used for procedures requiring high dose heparin therapy. Unlike ACT, HMT is not sensitive to changes in blood temperature or dilution, such as typically occur during open heart surgery. Clinical trials also indicate that HMT more closely correlates with a precise but time-consuming laboratory measurement of heparin concentration than does ACT. Finally, the Company believes that HMT is easier to perform and is less prone to operator error than ACT.

The SK Panel is designed to assess a patient's response to one of the most commonly used thrombolytic drugs, streptokinase. Since approximately 10% of patients may develop neutralizing antibodies or inhibitors to streptokinase (which prevent the drug from being effective), physicians often use the more expensive thrombolytic drug, t-PA, rather than risk ineffective therapy with streptokinase. The SK Panel provides the physician with objective information on which to base a decision regarding the choice of thrombolytic drug. The SK Panel consists of three test cards, which the Company intends to market separately in the future. Two of the cards are designed to test the patient's response to low and high levels of streptokinase. The third card, which contains the Lytic Control test, is designed to identify possible defects in a patient's fibrinolytic system that may interfere with all thrombolytic drugs.

The LOT test is designed to monitor a patient's response to any of the currently used thrombolytic drugs, including streptokinase, t-PA and urokinase. The LOT test is used during the administration of any thrombolytic drug to detect the establishment of the lytic state, after which additional administration of the drug may no longer be efficacious. Before the Company

developed the LOT test, there was no rapid, precise method for monitoring the effects of thrombolytic therapy. With the information provided by the LOT test, healthcare providers can optimize thrombolytic therapy, providing for better, more cost-effective patient care.

The Company is currently studying the feasibility of or developing several new tests to expand the menu for the TAS Analyzer. The Company is studying or developing four new tests to complement the aPTT and HMT in a

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complete heparin monitoring package. The Company's Heparin Response Test ("HRT") will be used to determine rapidly an individual's response to heparin, since patients differ widely in their responses to this drug. If HRT indicates that a patient may be resistant to the effect of heparin, adjunct therapy or another anticoagulant may be chosen. One reason for this resistance may be a deficiency of the natural anticoagulant, antithrombin ("AT"), which is required in order for heparin to achieve its full effect. The Company is developing an AT test to identify patients with this particular heparin defect. The Heparin Neutralization Test ("HNT") will monitor patients who have received heparin to determine if they have an underlying coagulation defect that may increase their risk of bleeding. The Protamine Sulfate Management Test ("PMT") will determine whether protamine sulfate has neutralized the heparin in a patient's blood at the end of surgery or if a patient develops a bleeding complication while on heparin. The Company also intends to develop an additional piece of equipment, known as ACCENT, to collect and analyze data derived from the Company's heparin monitoring tests.

The Low-range Heparin Management Test ("LHMT") card currently under development by the Company is intended to monitor the levels of heparin used during certain surgical procedures, including angioplasty and cardiac surgery on pediatric patients.

The Company is studying or developing two tests that will be used in connection with new anticoagulant drugs entering the market. The Thrombin Inhibitor Management/Ecarin Clotting Time ("TIM/ECT") test is designed to monitor the effect of a new class of anticoagulant drugs, "antithrombins" such as hirudin or argatroban. Likewise, the Company's Anti-Xa test will be used to monitor low molecular weight heparin, a more purified form of heparin that cannot be monitored by the aPTT. In addition, the Anti-Xa test can determine full length heparin concentration and it may be used in combination with the aPTT and HMT to more precisely determine a patient's response to heparin.

The Company's Ancrod test is a new test under development that will allow a physician to monitor a patient's level of Ancrod, a new drug for the treatment of stroke.

The Company is also developing, or preparing for field trials of, versions of certain of its test cards, including PT and HMT, which would allow testing of noncitrated, as well as citrated, blood. In addition, the Company is developing PT and aPTT test cards calibrated to the reagents of its new North American distributor, Dade. See "--Sales and Marketing".

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The following table describes certain of the Company's tests currently undergoing initial feasibility study or development (including field trials):

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TEST	TYPE	PRINCIPAL APPLICATION	STATUS
<S>	<C>	<C>	<C>
HRT	Heparin management	Predicts response to heparin	Initial development completed; field trials in progress.
AT	Heparin management	Required heparin co-factor	Feasibility determination in progress.
HNT	Heparin management	Predicts problems after heparin neutralization	Initial development completed; field trials in progress.

PMT	Heparin management	Specifies amount of protamine sulfate to neutralize heparin	Initial development completed; field trials in progress.
LHMT	Heparin management	Low-range heparin management	Initial development completed; field trials in progress.
(TIM) ECT	New anticoagulant drug monitoring	Thrombin inhibitor management	Initial development completed; field trials in progress.
Anti-Xa	New anticoagulant drug monitoring	Monitors low molecular weight heparin	Feasibility determination in progress.
Ancrod	New stroke drug monitoring	Monitors new treatment for stroke	Feasibility determined; development initiated.

</TABLE>

Quality Control Products

The Company also develops and manufactures single-use "crush-vial" controls for each test card. These controls perform quality assurance at the point of care. In addition, the Company is developing Electronic Quality Control ("EQC") cards to test analyzer function.

Sales and Marketing

The Company commenced marketing TAS products commercially in May 1995. As of December 31, 1996, the Company had sold 287 TAS analyzers in the United States to a total of 60 hospitals and 252 analyzers in Europe. These analyzers and certain of the Company's test cards are currently being used in ten different departments in those hospitals.

In April 1995, the Company entered into a purchasing agreement with Voluntary Hospitals of America ("VHA"), a 1,000-member hospital alliance. VHA's Technology Development Program had previously identified the Company as a technically innovative company producing new products that will benefit VHA member hospitals. The Company was selected by VHA as the vendor of choice for point-of-care hemostasis testing after investigating available technologies. The Company was selected for this VHA program because of the improved patient care and potential cost savings resulting from use of TAS in monitoring anticoagulant drugs and in selecting and monitoring thrombolytic drugs. Under the program, VHA will provide marketing support for the Company products and has produced marketing and training videotapes for TAS, promotional brochures and technical white papers. In exchange for such services, the Company has agreed to provide VHA member hospitals with priority in receiving TAS products, as well as "most favored customer" pricing on TAS products. In addition, the Company will pay rebates to VHA on sales to VHA member hospitals.

In 1996, the Company focused its sales and marketing efforts on hospitals with over 200 or more beds through its direct sales force. The Company employed eight experienced technical sales staff and a laboratory trained technical service group of five. Utilizing this group the Company

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achieved its goal of gaining recognition for its technology and initiated over 170 clinical evaluations.

In October 1996, the Company signed an exclusive, five-year development and distribution agreement with Dade, a world leader in coagulation reagent sales, with its share of the U.S. reagent market estimated at over 50%. An anticipated advantage of this agreement is that the Company's TAS technology may be used to calibrate test results to Dade products, with the anticipated standardized testing solutions being more attractive to customers. Under the Company's agreement with Dade, Dade has the right to distribute TAS technology under a joint Dade/Cardiovascular Diagnostics, Inc. label to hospitals and non-hospital laboratories. The PT and aPTT tests will be sold exclusively by Dade in the United States, Canada, Mexico and certain Latin American countries. In addition, Dade intends to cooperate in, and fund development of, additional tests for distribution.

The Company continues to consider additional distribution channels in the United States, including joint ventures with strategically positioned corporate partners. To the extent that specialized test capabilities are developed, the Company may consider joint development and subsequent co-marketing agreements with corporate partners in the pharmaceutical industry.

During 1996, the Company also entered into collaborative agreements with Bayer Corporation and Knoll AG for development of tests for anti-thrombin and thrombin inhibitor drugs, respectively. These test cards are currently involved in the field and clinical trials associated with these therapeutic

compounds. The Company's strategy with respect to these and other potential specialty tests is to be the only company capable of monitoring certain next generation drugs at the site of administration. The Company expects to continue to attempt to enter into new collaboration agreements with major pharmaceutical companies in 1997.

The Company also markets TAS products in Europe and elsewhere. The advantages of marketing TAS in Europe include the presence of a large number of physicians and scientists who are recognized experts in the areas of hematology and cardiology. These physicians and scientists publish extensively on new technologies and tend to be early adopters of the latest technical innovations. In Europe, the Company's strategy is to sell primarily through independent distributors, although it may in the future enter into strategic European distribution agreements like the agreement with Dade. The Company has entered into agreements with an independent distributor in each of the United Kingdom, Italy, Belgium, Germany, Austria, The Netherlands, Scandinavia, Israel, New Zealand and Australia. Selection criteria for Company distributors include: an interventional cardiology and point-of-care focus; synergistic other product offerings; a dedicated sales force; and technical sales orientation. The Company provides its distributors' personnel with a comprehensive, three-day training course at its headquarters in Raleigh, North Carolina. Monthly reports are obtained from each distributor detailing results of evaluations, completed sales and a three-month rolling sales forecast. Formal distributor meetings are held on a quarterly basis to review sales and marketing progress. Distributor relationships are reviewed annually before extension of the distribution agreement.

The commercial success of the Company's products will depend upon their acceptance by the medical community and third-party payors as useful and cost-effective. Market acceptance will depend upon several factors, including the establishment of the utility and cost-effectiveness of the Company's tests, the receipt of regulatory clearances in the United States and elsewhere and the availability of third-party reimbursement. The availability of point- of-care hemostasis test systems has been limited to date, so the Company, by selling point-of-care hemostasis test products, is targeting an essentially new market. Diagnostic tests similar to those developed by the Company are generally performed by a central laboratory at a hospital or clinic. The approval of the purchase of diagnostic equipment by a hospital is generally

controlled by its central laboratory. The Company expects there will be resistance by central laboratories to yield control of tests they have previously performed. The Company will also have to demonstrate to physicians that its diagnostic products perform as intended, meaning that the level of accuracy and precision attained by the Company's products must be comparable to test results achieved by central laboratory systems. Failure of the Company's products to achieve market acceptance would have a material adverse effect on the Company.

The Company is substantially dependent upon Dade for marketing and distribution in North America. There can be no assurance that the Company will be able to build an adequate sales and marketing staff, that establishing such a sales and marketing staff will be cost-effective, or that Dade's or the Company's direct sales and marketing efforts will be successful. The loss of one or more of the Company's foreign distributors or the inability to enter into agreements with new distributors to sell TAS products in additional countries could have a material adverse effect on the Company. There can be no assurance that the Company or its distributors will be successful in marketing or selling the Company's products.

Clinical Evaluations

In the ongoing effort to support released as well as developmental products, clinical trials and evaluations have escalated in activity. During 1996, over 170 hospitals throughout the United States initiated clinical evaluations using the PT, aPTT or HMT test cards. The purpose of these evaluations was to allow the hospitals to use the system in a clinical setting over an extended period to confirm the TAS accuracy, precision, speed and ease of use. Similar evaluations have been accomplished in Europe through the network of individual country distributors; these evaluations have included the SK and LOT test cards as well as the PT, aPTT and HMT. Where applicable, the TAS data is compared to existing systems and methodologies and the clinical utility is established by the institution. Evaluations of this type are intended to provide the institution with the necessary documentation to support routine use of the TAS.

In 1996, the activities surrounding formal clinical trials sponsored and funded by the Company were reorganized and realigned to more closely support the product priorities and Company objectives. As a part of this process, clear clinical trial objectives and the expected outcome or benefit have been established. Formal trials being initiated by the Company must comply with the

objective of FDA submission or provide the Company with pertinent clinical data which ultimately results in presentation and publication of the data. Clinical sites and studies are screened and the sites are involved in the development and design of the study protocol. Studies and data are monitored by the Company in order to ensure that when completed, the trial will meet with the study objectives.

The coordination and monitoring of clinical trial activity is being addressed in the United States as well as Europe. In an attempt to assist with this effort in Europe, the Company has established a European Scientific Advisory Board which is comprised of cardiologists, anesthesiologists and laboratory based coagulation clinicians. This board has recommended that the Company endorse multi-center coordinated trials which concentrate on TAS technology as compared to existing methods. Initially, proposed studies include HMT, aPTT, SK and LOT tests and would involve multiple sites in different countries utilizing a defined specific protocol. By involving multiple sites in a coordinated trial, the power of the study is enhanced and the endorsement of TAS technology is more widespread. Similar efforts are being pursued in the United States, with clinical sites being carefully selected and studies being closely coordinated.

In addition, multiple research trials are being conducted for new test cards and controls. These studies are primarily being accomplished in

established reference laboratories where there is a collaborative research agreement between the Company and the institution. This type of situation provides the Company with a controlled external testing environment where confidentiality is maintained and exposure is minimal. Initial field testing is performed in these sites as well as data collection for 510(k) submissions.

In 1997, CVDI intends to continue to initiate trials and obtain clinical data which demonstrate clinical utility, support product claims and quantify the advantages of rapid testing in terms of patient outcome and cost savings. More than 20 studies are planned over the course of the year, with the objective being to provide the Company and the marketplace with pertinent clinical evaluations and publications. These clinical trials are critical to the ultimate success of the Company.

Research and Development

The Company has a research and development staff consisting of eight people, four of whom have Ph.D's in related fields. Continuing research and development is focused on expanding the menu of tests. See "--Products--Test Cards".

During fiscal 1994, fiscal 1995 and fiscal 1996, the Company's research and development expenses were approximately $1,882,000, $1,801,000 and $2,230,000, respectively. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations--Results of Operations".

Competition

The medical diagnostic testing industry is characterized by rapidly evolving technology and intense competition. TAS competes in the coagulation and hematology testing market with manufacturers providing testing equipment to central and stat laboratories of hospitals, since such laboratories currently perform a substantial portion of such testing, and with other point-of-care coagulation and hematology test system manufacturers. Laboratories provide the same tests performed by TAS; however, these laboratory tests generally require the use of skilled technicians and complex, expensive equipment. The Company believes that TAS offers several advantages over these laboratory-based instruments, including faster results, ease-of-use, reduced opportunity for error and cost-effectiveness.

The Company has several competitors, including Boehringer Mannheim Corporation ("BMC"), International Technidyne Corporation ("ITC") and Medtronic, that manufacture and market point-of-care coagulation and hematology test systems. ITC, in particular, has a large installed base of systems, which it has been selling for approximately 20 years. Despite the fact that the Company believes that TAS competes favorably with these systems, ITC's installed base could give it a competitive advantage. Although the market for point-of-care coagulation and hematology test systems is in its early stages of development, the Company believes that potential customers will base their purchasing decisions upon a combination of factors, including accuracy and precision, speed, cost-effectiveness, ease-of-use and compliance with CLIA guidelines.

If the Company introduces additional blood tests beyond its initial coagulation and hematology tests, it will compete with numerous companies that market similar products to hospitals for use in laboratories and at the point of patient care. Other manufacturers and academic institutions may be conducting

research and development with respect to blood testing technologies and other companies may in the future engage in research and development activities regarding products competitive with those of the Company. Many of the companies in the medical technology industry, including those listed above, have substantially greater capital resources, research and development staffs, sales and manufacturing capabilities and manufacturing facilities than the Company. Such entities may be developing or could in the future attempt to develop additional products competitive with TAS. Many of these companies

also have substantially greater experience than the Company in research and development, obtaining regulatory clearances, manufacturing and marketing, and may therefore represent significant competition for the Company. There can be no assurance that the Company's competitors will not succeed in developing or marketing technologies and products that will be more effective or less expensive than those being marketed by the Company or that would render the Company's technology and products obsolete or noncompetitive.

Patents and Other Intellectual Property

The Company pursues patent applications to provide protection from competitors. This strategy includes evaluating and seeking patent protection both for inventions most likely to be used in the Company's products and for those inventions most likely to be used by others as competing alternatives. Three U.S. and 28 corresponding international patents have issued to the Company covering various aspects of the TAS technology. The Company has filed, and is pursuing, a number of additional U.S. and international patent applications.

The Company's success will depend in part on its ability to enforce its patents, to preserve its trade secrets and to operate without infringing the proprietary rights of third parties. The Company's ability to protect its proprietary position is also in part dependent on the issuance of additional patents on current and future applications. The validity and breadth of claims covered in medical technology patents involve complex legal and factual questions. No assurance can be given that any patent applications will be issued, that the scope of any patent protection will exclude competitors or provide competitive advantages to the Company, that any of the Company's patents will be held valid if subsequently challenged or that others will not claim rights in or ownership to the patents and other proprietary rights held by the Company. Furthermore, there can be no assurance that others have not developed or will not develop similar products, duplicate any of the Company's products or design around the Company's patents. In addition, others may hold or receive patents or file patent applications which contain claims having a scope that covers products developed by the Company. In the event that any relevant claims of third-party patents are upheld as valid and enforceable, the Company could be prevented from practicing the subject matter claimed in such patents or could be required to obtain licenses from the patent owners of each of such patents or to redesign its products or processes to avoid infringement. There can be no assurance that such licenses would be available or, if available, would be 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.

The Company also relies upon unpatented trade secrets to protect its proprietary technology. In particular, the Company believes that its custom-designed automated test card production line embodies proprietary Company process technology. No assurance can be given that others will not independently develop or otherwise acquire equivalent technology or otherwise gain access to the Company's proprietary technology or that the Company can ultimately protect meaningful rights to such unpatented proprietary technology.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. In March 1997, the Company filed a lawsuit against BMC alleging, among other things, misappropriation of trade secrets. See "Item 3. Legal Proceedings". This and any other litigation, which would result in substantial cost to and diversion of effort by the Company, may be necessary to enforce patents issued to the Company, to protect trade secrets or know-how owned by the Company, to defend the Company against claimed infringement of the rights of Biotrack or others or to determine the ownership, scope or validity of the proprietary rights of the Company and others. An adverse determination in any such litigation could subject the Company to significant liability to third parties, could require the Company to seek licenses from third parties, which

licenses may not be available or, if available, may not be on terms acceptable to the Company; and ultimately could prevent the Company from manufacturing, selling or using its products, any of which could have a material adverse effect on the Company.

Licenses

BMC License

In June 1989, the Company entered into a License Agreement with BMC (as subsequently amended in September 1995, the "BMC License"), pursuant to which the Company granted BMC exclusive rights to manufacture and sell aPTT and PT test products under the Company's patent applications throughout the world, except for certain Asian countries. Under the terms of the BMC License, the Company regained certain rights to manufacture and sell such products in 1993, when the Company paid BMC $1,000 after BMC declined to license the SK Panel. In September 1995, the Company and BMC amended the BMC License to terminate the royalty and milestone payment obligations of BMC to the Company effective June 30, 1995, and to clarify that the Company can sell aPTT and PT tests for use on an analyzer that is also capable of analyzing a thrombolytic test. The TAS analyzer is capable of analyzing aPTT, PT and thrombolytic tests, and the Company does not intend to introduce an analyzer capable of analyzing aPTT or PT tests that is not also capable of analyzing a thrombolytic test. As a result of this amendment, the Company and BMC each have rights to sell aPTT and PT test products under the Company's patent applications throughout the world, except for certain Asian countries. During the year ended October 31, 1993, the Company received a fee from the licensee of $750,000 for the licensee introducing the licensed product to market. The Company received royalty payments of $88,841 under this agreement during the year ended December 31, 1994 and $61,596 during the year ended December 31, 1995. BMC's obligation to pay royalties and any future milestone payments under the BMC license terminated as of the end of the second quarter of 1995.

Tokuyama Soda License

In October 1988, the Company entered into a License Agreement with Tokuyama Soda Company, Ltd. ("Tokuyama") pursuant to which the Company granted Tokuyama exclusive rights to manufacture and sell PT and aPTT tests and analyzers in certain Asian countries (the "Tokuyama License"). The Tokuyama License requires that the Company negotiate in good faith with Tokuyama for 90 days prior to marketing or licensing in these Asian nations any new products that the Company develops related to the licensed tests or analyzer technology.

In 1988 and 1989, Tokuyama paid the Company an aggregate license fee of $1,080,000 pursuant to the Tokuyama License. In addition, until the earlier of October 2004 or the expiration of the last Japanese patent covering the licensed technology, Tokuyama must pay the Company royalties based on Tokuyama's net sales of licensed products, subject to annual minimums through September 2000. The Company can terminate the Tokuyama License if Tokuyama fails to make a required payment or report (or makes a false report), or if Tokuyama voluntarily ceases the manufacture and sale of licensed products for 12 months, and if, in any such case, Tokuyama fails to remedy such default within 60 days after notice thereof from the Company.

In December 1995, the Company and Tokuyama amended the Tokuyama License, to, among other things, provide the Company with the right to market PT and aPTT tests and analyzers in an Asian country (other than Japan, Taiwan and South Korea) if Tokuyama has not attained annual net sales of $250,000 in the country by June 30, 1996 (or within 12 months of the time when export to such country becomes authorized). In the event the Company exercises this right, it and Tokuyama may both market in the country and must each pay royalties to the other. The amendment also provides that the Company owns all rights outside Asia to Tokuyama improvements to the Company's technology, and must

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pay royalties to Tokuyama based on Company net sales of products incorporating such improvements.

The Company received royalty payments under this agreement of $46,450, $63,176 and $32,835 using the years ended December 31, 1994, 1995 and 1996, respectively.

Manufacturing

The Company operates a manufacturing facility in Raleigh, North Carolina to assemble TAS analyzers. Vendors currently provide all molded parts, mechanical components and printed circuit boards. The Company assembles the components and provides final mechanical, electrical and chemistry testing of each analyzer. The Company believes that it has sufficient capacity to accommodate anticipated demand.

The Company also operates a proprietary automated test card production line at its Raleigh facility. This automated production line was custom-designed by the Company and built to its specifications. The Company believes that this production line embodies proprietary Company process technology. The line has been designed to allow for increased production as dictated by customer demand. Programs are currently in process to attempt to double manufacturing capacity from the current level of 22,000 cards per day.

The FDC Act requires the Company to manufacture its products in registered establishments and in accordance with GMP. The Company and Coeur are both registered as medical device manufacturers and are subject to periodic inspections by the FDA. The Company received ISO 9002 certification in 1996, and the Company and Coeur are further implementing requirements of the International Standards Organization ("ISO") at their manufacturing facilities.

To be successful, the Company must manufacture its products in compliance with regulatory requirements, in sufficient quantities and on a timely basis, while maintaining product quality and acceptable manufacturing costs. The Company has limited experience producing its products in large commercial quantities. There can be no assurance that the Company will be able to manufacture accurate and reliable products in large commercial quantities on a timely basis and at an acceptable cost.

Most of the raw materials and components used to manufacture the Company's TAS products are readily available. However, certain of these materials are obtained from a sole supplier or a limited group of suppliers. For example, the Company currently obtains the PIOP used in the TAS test cards from a single source, which is currently holding enough PIOP to produce the Company's test cards for at least the next ten years. The Company believes that, in the event of an interruption in the availability of PIOP from such supplier, the Company has enough PIOP at its facility to supply its needs until an alternative source could be procured. The Company generally does not maintain long-term agreements with any of its suppliers. The reliance on sole or limited suppliers and the failure to maintain long-term agreements with suppliers involves several risks, including the inability to obtain an adequate supply of required raw materials and components and reduced control over pricing, quality and timely delivery. Any interruption in supply could have a material adverse effect on the Company.

Government Regulation

FDA

The medical devices to be marketed and manufactured by the Company are subject to extensive regulation by the FDA. Pursuant to the FDC Act, the FDA regulates the clinical testing, manufacture, labeling, distribution and promotion of medical devices. Noncompliance with applicable requirements can result in, among other things, fines, injunctions, civil penalties, recall or

seizure of products, total or partial suspension of production, failure of the government to grant premarket clearance or premarket approval ("PMA") for devices, withdrawal of marketing approvals and criminal prosecution. The FDA also has the authority to request repair, replacement or refund of the cost of any device manufactured or distributed by the Company.

In the United States, medical devices are classified into one of three classes (Class I, II or III), on the basis of the controls deemed necessary by the FDA to reasonably assure their safety and effectiveness. Under the FDA regulations, Class I devices are subject to general controls (for example, labeling, premarket notification and adherence to GMPs) and Class II devices are subject to general and special controls (for example, performance standards, postmarket surveillance, patient registries, and FDA guidelines). Generally, Class III devices are those which must receive a PMA from the FDA to ensure their safety and effectiveness (for example, life-sustaining, life-supporting and implantable devices, or new devices which have not been found substantially equivalent to legally marketed devices).

Before a new device can be introduced into the market, the manufacturer must generally obtain marketing clearance through either a 510(k) notification (a "510(k)") or a PMA. Commercial distribution of a device for which a 510(k) is required can begin only after the FDA issues an order finding the device to be "substantially equivalent" to a predicate legally marketed Class I or II medical device, or to a Class III medical device for which the FDA has not required a PMA. The FDA has recently been requiring a more rigorous demonstration of substantial equivalence than in the past. It generally takes from four to 12 months from submission of a 510(k) to obtain a 510(k) clearance, but it may take longer. The FDA may determine that a proposed device is not substantially equivalent to a legally marketed device, or that additional information is needed before a substantial equivalence determination can be made. A request for

additional data may require that clinical studies of the device's safety and efficacy be performed. A "not substantially equivalent" determination or a request for additional information could delay the market introduction of new products that fall into this category and could have a material adverse effect on the Company's business, financial condition and results of operations. For any of the Company's products that are cleared through the 510(k) process, modifications or enhancements that could significantly affect the safety or efficacy of the device or that constitute a major change to the intended use of the device will require a new 510(k). If the FDA requires the Company to submit a new 510(k) for any modification to the device the Company may be prohibited from marketing the modified device until the 510(k) is cleared by the FDA.

The Company received 510(k) clearance to market its PT and aPTT test cards, along with a first generation analyzer, in 1988. In 1993, the Company received 510(k) clearance for the TAS analyzer to be marketed with PT and aPTT tests. The Company received 510(k) clearance in May 1995 to commercially market the HMT test. The Company submitted a 510(k) for its SK Panel in September 1993. This submission was withdrawn in October 1994, after consultation with the FDA, pending the conclusion of additional clinical evaluations of the SK Panel. The Company is currently working with the FDA to establish protocols for additional clinical evaluations. The Company intends to submit the data from those clinical trials to the FDA in a revised 510(k) for the SK Panel. There can be no assurance, however, that the additional clinical evaluations will satisfy the FDA's requirements, that market clearance will be forthcoming in a timely manner, if at all, or that the FDA will not require more extensive clinical evaluations, other information, or submission of a PMA. There can be no assurance that the Company will obtain 510(k) clearance on a timely basis, or at all, for any device for which it files a future 510(k).

The SK Panel and LOT tests are currently sold in the United States for investigational use only in connection with clinical evaluations of the safety and effectiveness of the products. Although clinical investigations of most devices are subject to the investigational device exemption ("IDE")

requirements, a clinical investigation is exempt from the IDE requirements provided the clinical investigation involves a noninvasive test, does not require an invasive sampling procedure that presents significant risk, does not introduce energy into a subject, and is not used as a diagnostic procedure without confirmation of the diagnosis by another medically established diagnostic product or procedure. Manufacturers must also establish distribution controls to assure that devices distributed for the purposes of conducting clinical investigations are used only for that purpose. Pursuant to FDA policy, manufacturers of devices labeled "for investigational use only" must establish a certification program under which investigational devices are distributed to or utilized only by individuals, laboratories or healthcare facilities that have provided the manufacturer with a written certification of compliance indicating that: the device will be used for investigational purposes only; results will not be used for diagnostic purposes without confirmation of the diagnosis under another medically established diagnostic device or procedure; all investigations will be conducted with approval from an institutional review board ("IRB"), using an IRB-approved study protocol, and patient informed consent; and the device will be labeled in accordance with the applicable labeling regulations. Failure of the Company or recipients of the Company's "investigational use only" products to comply with these requirements could result in enforcement action by the FDA that would adversely affect the Company's ability to conduct testing necessary to obtain market clearance and, consequently could have a material adverse effect on the Company.

The Company submitted a 510(k) for a new injector turret developed by Coeur for use in power injectors for angiographic procedures to the FDA in August 1995. The 510(k) was prepared by a high-level employee of the Company with regulatory affairs and quality assurance responsibilities. The 510(k) contained product information, including results from tests that were purportedly performed relating to physical measurements of the device. In September 1995, while the 510(k) was under review by the FDA, the FDA contacted the employee who prepared it and asked for additional information. After receiving the request, the employee informed senior Company management that no testing relating to physical measurements had been performed on the device and that the physical measurement test data submitted in the 510(k) were false. The employee acknowledged sole responsibility for creating and submitting the false data. Upon learning of the matter, the Company promptly withdrew the 510(k), suspended the responsible employee and initiated an internal investigation of the matter. Upon completion of the Company's detailed internal investigation, the Company had the matter investigated by an independent quality assurance organization and the Company's special FDA regulatory counsel. Based on the results of these investigations, the Company concluded that the employee had acted alone, that no pressure had been put on the employee to obtain clearance for this device and that there was no evidence that false data had been previously submitted to the FDA. As a result of this matter, the Company created a permanent Compliance Committee (which currently consists of three non-employee

directors of the Company) to report directly to the Board of Directors on regulatory compliance matters and to recommend regulatory procedures and safeguards to preclude the possibility of any such occurrences in the future. The Compliance Committee reviewed the results of the Company's internal investigation and the independent investigations of this matter. Based on the recommendations of the Compliance Committee, the Company accepted the resignation of the responsible employee. The Company also has advised the FDA of the matter and described the corrective actions the Company has taken. The Company believes that it has acted appropriately in connection with this matter, but there can be no assurance that the FDA will consider the Company's corrective actions to be sufficient. If the Company's corrective actions are not deemed sufficient by the FDA, possible consequences include civil money penalties against the Company and/or its officers (ranging from $1,000 to $500,000 per violation), temporarily withholding future 510(k) clearances and criminal prosecution. These actions, if taken by the FDA, could have a material adverse effect on the Company.

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A PMA application must be filed if a proposed device is not substantially equivalent to a legally marketed Class I or Class II device, or if it is a Class III device for which FDA has called for PMAs. A PMA application must be supported by valid scientific evidence which typically includes extensive data, including preclinical and clinical trial data, to demonstrate the safety and effectiveness of the device. In addition, the submission must include the proposed labeling, advertising literature and training methods (if required). FDA review of a PMA application generally takes one to two years from the date the PMA application is accepted for filing, but may take significantly longer. The review time is often significantly extended by the FDA asking for more information or clarification of information already provided in the submission. Toward the end of the PMA review process, the FDA generally will conduct an inspection of the manufacturer's facilities to ensure that the facilities are in compliance with applicable GMP requirements. If the FDA's evaluations are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions which must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter, authorizing commercial marketing of the device for certain indications. If the FDA's evaluations are not favorable, the FDA will deny approval of the PMA application or issue a "not approvable" letter. The FDA may also determine that additional clinical trials are necessary, in which case PMA approval may be delayed for several years while additional clinical trials are conducted and submitted in an amendment to the PMA. Modifications to a device that is the subject of an approved PMA, its labeling, or manufacturing process may require approval by the FDA of PMA supplements or new PMAs. The PMA process can be expensive, uncertain and lengthy and a number of devices for which FDA approval has been sought by other companies have never been approved for marketing. There can be no assurance that the Company will be able to obtain necessary regulatory approvals on a timely basis, or at all, and delays in receipt of or failure to receive such approvals, the loss of previously received approvals, or failure to comply with existing or future regulatory requirements would have a material adverse effect on the Company's business, financial condition and results of operations.

Any products manufactured or distributed by the Company pursuant to FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences with the use of the device. Device manufacturers are required to register their facilities and list their devices with the FDA, and are subject to periodic inspections by the FDA and certain state agencies. The FDC Act requires devices to be manufactured in accordance with Good Manufacturing Practice ("GMP") regulations which impose certain procedural and documentation requirements upon the Company with respect to manufacturing and quality assurance activities. The FDA has approved changes to the regulations which may increase the cost of complying with GMP requirements.

Labeling and promotion activities are subject to scrutiny by the FDA and in certain instances, by the Federal Trade Commission. The FDA actively enforces regulations prohibiting marketing of products for unapproved uses.

Regulations on Exported Products

Export of products that have market clearance from the FDA in the United States do not require FDA authorization. However, foreign countries often require an FDA certificate for products for export (a "CPE"). To obtain a CPE the device manufacturer must certify to FDA that the product has been granted clearance in the United States and that the manufacturing facilities appeared to be in compliance with GMPs at the time of the last FDA inspection. The FDA will refuse to issue a CPE if significant outstanding GMP violations exist.

Export of products subject to the 510(k) requirements, but not yet

cleared to market, are permitted without FDA authorization provided certain requirements are met. Unapproved products subject to the PMA requirements

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must be approved by the FDA for export. To obtain FDA export approvals certain requirements must be met and information must be provided to the FDA, including documentation demonstrating that the product is approved for import into the country to which it is to be exported and, in some instances, safety data from animal or human studies. There can be no assurance that the FDA will grant export approval when such approval is necessary, or that the countries to which the devices are to be exported will approve the devices for import.

The Company has obtained CPEs for the PT, PT One, aPTT and HMT tests and the TAS analyzer. Failure of the Company to obtain a CPE for the export of its products in the future could have a material adverse effect on the Company. Products which the Company exports that do not have premarket clearance in the United States include the SK Panel and LOT tests. The Company has made a determination that these products are subject to the 510(k) requirements and, consequently, has not requested FDA approval for the export of this device. However, there can be no assurance that the FDA would agree with the Company's determination that these products are subject to the 510(k) requirements and would not require the Company to obtain FDA export approval. Such a determination by the FDA may significantly delay and impair the Company's ability to continue exporting the SK Panel and LOT tests and could have a material adverse effect on the Company.

The introduction of the Company's test products in foreign markets will also subject the Company to foreign regulatory clearances, which may impose additional substantial costs and burdens. International sales of medical devices are subject to the regulatory requirements of each country. The regulatory review process varies from country to country. Many countries also impose product standards, packaging, requirements, labeling requirements and import restrictions on devices. In addition, each country has its own tariff regulations, duties and tax requirements. Approval by foreign government authorities is unpredictable and uncertain, and no assurance can be given that the necessary approvals or clearances will be granted on a timely basis or at all. Delays in receipt of, or a failure to receive, such approvals or clearances, or the loss of any previously received approvals or clearances, could have a material adverse effect on the Company.

CLIA

The Company's products are also subject to the requirements of CLIA. This law requires all laboratories, including those performing blood chemistry tests, to meet specified standards in the areas of personnel qualification, administration, participation in proficiency testing, patient test management, quality control, quality assurance and inspections. The regulations have established three levels of regulatory control based on test complexity - --"waived", "moderate complexity" and "high complexity". The PT and aPTT tests performed by TAS have been categorized by the FDA and the Centers for Disease Control and Prevention (the "CDC") as moderate complexity tests. There can be no assurance that these tests will not be recategorized, or that other tests performed by the TAS will not be categorized as high complexity tests or that such a categorization will not have a material adverse effect on the Company. Furthermore, there can be no assurance that regulations under and future administrative interpretations of CLIA will not have an adverse impact on the potential market for the Company's products.

Laboratories that perform either moderate or high complexity tests must meet certain standards, with the major difference in requirements being quality control and personnel standards. Quality control standards for moderate complexity tests (not modified by laboratories) are being implemented in stages, while laboratories performing high complexity and modified moderate complexity tests currently must meet all of the quality control requirements. Personnel standards for high complexity tests require that personnel have more education and experience than personnel conducting moderate complexity tests. All laboratories performing moderately complex or highly complex tests are required to obtain either a registration certificate or certification of

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accreditation from the Health Care Financing Administration. With certain specified exceptions, each site for laboratory testing must file a separate application and separately meet all CLIA requirements. Multiple laboratory sites

within a hospital located at contiguous buildings on the same campus and under common direction may file a single application. As a result of the CLIA requirements, hospitals may be discouraged from expanding point-of-care testing. Because CLIA certification must be obtained by laboratories, the Company does not possess sufficient data to make a determination as to the cost of certification to a laboratory or the potential inhibiting effect of CLIA certification on the purchase of the Company's products by laboratories.

Other Regulations

Company and its products are also subject to a variety of state and local laws and regulations in those states or localities where its products are or will be marketed. Any applicable state or local laws or regulations may hinder the Company's ability to market its products in those states or localities. Use of the Company's products will also be subject to inspection, quality control, quality assurance, proficiency testing, documentation and safety reporting standards pursuant to the Joint Commission on Accreditation of Healthcare Organizations. Various states and municipalities may also have similar regulations.

Manufacturers are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. There can be no assurance that the Company will not be required to incur significant costs to comply with such laws and regulations now or in the future or that such laws or regulations will not have a material adverse effect upon the Company.

Changes in existing requirements or adoption of new requirements or policies could adversely affect the ability of the Company to comply with regulatory requirements. Failure to comply with regulatory requirements could have a material adverse effect on the Company. There can be no assurance that the Company will not be required to incur significant costs to comply with laws and regulations in the future or that laws or regulations will not have a material adverse effect upon the Company.

Reimbursement

The Company's ability to commercialize its products successfully depends in part on the extent to which reimbursement for the cost of such products and related treatment will be available from government health administration authorities (such as the Health Care Financing Administration (the "HCFA")), which determines Medicare reimbursement levels), private health insurers and other organizations ("Payors"). Payors are increasingly challenging the prices of medical products and services. Payors may deny reimbursement if they determine that a prescribed device has not received appropriate FDA or other governmental regulatory clearances, is not used in accordance with cost-effective treatment methods, or is experimental, unnecessary or inappropriate. Also, the trend towards managed healthcare in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of healthcare services and products, as well as legislative proposals to reform healthcare or reduce government insurance programs, may result in customers demanding lower prices for the Company's TAS products. The cost containment measures that healthcare providers are instituting and the impact of any healthcare reform could have an adverse effect on the Company's ability to sell its products and may have a material adverse effect on the Company.

Effective October 1991, HCFA adopted new regulations providing for the inclusion of capital-related costs in the prospective payment system, under which providers are reimbursed on a per-discharge basis at fixed rates unrelated to actual costs, based on diagnostic related groups. Under this

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system of reimbursement, equipment costs generally will not be reimbursed separately, but rather, will be included in a single, fixed-rate, per-patient reimbursement. These regulations are being phased in over a 10-year period, and, although the full implications of these regulations cannot yet be known, the Company believes that the new regulations will place more pressure on hospitals' operating margins, causing them to limit capital expenditures. These regulations could have an adverse effect on the Company's results of operations if hospitals decide to defer obtaining medical equipment as a result of any such limitation on their capital expenditures. The Company is unable to predict the effect on the Company, if any, additional government regulations, legislation or initiatives or changes by other Payors affecting reimbursement or other matters which may influence decisions to obtain medical equipment.

There can be no assurance that reimbursement in the United States or foreign countries will be available for any of the Company's products, or that if available it will not be decreased in the future, or that any reduction in reimbursement amounts will not reduce the demand for or the price of the

Company's products. The unavailability of third-party reimbursement or the inadequacy of the reimbursement for medical procedures using the Company's tests would have a material adverse effect on the Company. Moreover, the Company is unable to forecast what additional legislation or regulations, if any, relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulations would have on the Company.

Coeur's Business

On October 31, 1993, the Company acquired Coeur, which manufactures and sells a line of disposable power injection syringes used for cardiology and radiology procedures, as well as a line of manifolds used in custom angiographic procedure kits. The Company acquired Coeur in order to gain access to Coeur's management and infrastructure, its positive annual cashflow and its manufacturing facility. The Company believes that the acquisition of Coeur has accelerated the commercialization of TAS.

Because Coeur does not manufacture injectors and has no direct sales force, its primary customers for disposable syringes are injector manufacturers. The three principal injector manufacturers are Medrad (which is the market leader), Liebel-Flarsheim and E-Z-EM. Coeur's unique marketing position is a result of a patent that allows Coeur to manufacture an alternative to Medrad 200m1 syringes, which model represents approximately half of all disposable syringe sales. Because hospitals typically use more than one manufacturer's injector, salesmen must have a full line of syringes capable of fitting each type of injector. Liebel Flarsheim and E-Z-EM buy 200m1 syringes from Coeur, because Coeur's patent makes it the only current alternative source for Medrad 200m1 syringes. In addition, Coeur manufactures, on an OEM basis, all disposable syringes for E-Z-EM injectors. For the fiscal year ended December 31, 1996, E-Z-EM, Liebel-Flarsheim and Kimal Scientific Products Ltd. each represented more than 10%, and in total represented 77% of Coeur's net sales.

Coeur's other product line is manifolds, which historically have been sold to kit manufacturers as components for custom angiographic kits. Most kit components are commodity products and not proprietary. Management believes that future sales trends will be toward more standardization of angiographic kits. Additional competitors are expected to enter the custom kit market and pricing will become more competitive.

Since its acquisition by the Company in October 1993, Coeur has operated profitably and therefore helped fund the Company's activities related to its diagnostic products. While the Company does not expect to rely upon profits from Coeur to fund a significant portion of its operations, there can be no assurances that Coeur will remain profitable. Coeur's business is subject to various risks, including the limited market for its products, competition,

decreases in gross profits attributable to increases in the price of raw materials, technological obsolescence, uncertainty of protection of patents and other proprietary technology, reliance upon its distributors and a limited number of customers, and governmental regulation.

Product Liability and Insurance

The Company faces an inherent business risk of exposure to product liability claims in the event that the use of its products is alleged to have resulted in adverse effects. The Company maintains product liability insurance with coverage of up to $6 million per claim, with an annual aggregate policy limit of $7 million. There can be no assurance that liability claims will not exceed the coverage limits of such policies or that such insurance will continue to be available on commercially acceptable terms, or at all. Consequently, product liability claims could have a material adverse effect on the company's business, financial condition and results of operations.

Employees

The Company had 83 employees as of December 31, 1996. Eight employees are engaged in research and development, 44 in manufacturing and quality control, 10 in engineering, 11 in sales/marketing and 10 in finance/administration. Many of the Company's executive and technical personnel have had experience with biomedical diagnostics companies. None of the Company's employees are covered by a collective bargaining agreement and the Company believes that employee relations are good.

The Company's success depends to a significant extent upon a number of key management and technical personnel. Although the Company maintains key man life insurance policies on three of its executive officers, the loss of the services of one or more of these executive officers or other key employees could have a material adverse effect on the Company's business, financial condition and results of operations. The Company also believes that its future success

will depend in large part upon its ability to attract and retain highly skilled technical, management and sales and marketing personnel. Competition for such personnel is intense, and there can be no assurance that the Company will be successful in attracting and retaining such personnel. The Company's failure to attract, hire and retain these personnel would have a material adverse effect on the Company.

Factors Affecting Operating Results and Stock Price

The Company's revenues and operating results may vary significantly from quarter to quarter as a result of a number of factors, including the volume and timing of sales, customer purchasing patterns and the timing of new product introductions by the Company or its competitors. A substantial number of outstanding shares of Common Stock will become eligible for future sale in the public market at various times. Sales of substantial amounts of such shares in the public market could adversely affect the market price of the Common Stock. The stock market has from time to time experienced extreme price and volume fluctuations, particularly in the high technology sector, which have often been unrelated to the operating performance of particular companies. In addition, factors such as announcements of technological innovations or new products by the Company or its competitors or third parties, as well as market conditions in the medical diagnostic device or point-of-care blood testing industries, may have a significant impact on the market price of the Company's Common Stock.

Item 2. PROPERTIES.

The Company's principal corporate offices are located at 5301 Departure Drive, Raleigh, North Carolina 27616. The Company occupies approximately

55,000 square feet of development, production and administration space at that location pursuant to a facility lease that runs through January 2001.

The Company believes that its facilities are adequate for its current needs and that suitable additional space will be available as required.

Item 3. LEGAL PROCEEDINGS.

In August 1992, Ciba Corning sent a letter to the Company stating it appeared that the Company infringed patents owned by Biotrack Inc., ("Biotrack") a wholly-owned subsidiary of Ciba Corning, and that the Company should cease any activity that infringed the patents. In September 1992, the Company responded that it believes that it is not infringing Biotrack's patents and that its issued U.S. patents protect all of its products which are currently cleared by the FDA or in clinical trials. Since September 1992, BMC has acquired Biotrack, and the Company has had no further contact with Biotrack or its parent concerning this matter until March 1996, when BMC sent another letter to the Company alleging infringement. The Company intends to defend itself vigorously in connection with these allegations.

In March 1997, the Company filed suit in Raleigh, North Carolina in U.S. District court charging BMC with misappropriation of the Company's trade secrets by improper disclosure, breach of contract, breach of fiduciary duty, unfair and deceptive trade practices and constructive fraud. In addition, the Company has requested a declaratory judgment that neither the products nor activities of the Company infringe U.S. Patents purportedly owned by BMC. The complaint alleges that this unauthorized disclosure of the Company's trade secrets is (i) a breach of the license agreement between BMC and the Company, (ii) a breach of the fiduciary duty owed by BMC to CVDI, (iii) constructive fraud, (iv) a misappropriation of the Company's trade secrets in violation of North Carolina's Trade Secrets Act, and (v) constitutes unfair trade practices in violation of the North Carolina Unfair Trade Practices Act. The complaint further requests the court to declare that the Company's blood assay products and activities do not infringe either of two U.S. Patents held by BMC, in response to a letter to the Company from BMC asserting that the Company is infringing these patents. The Company is requesting an award of substantial actual and punitive damages due to the unauthorized disclosure of the Company's trade secrets, which could be tripled due to violation of the North Carolina Unfair Trade Practices Act and is seeking to obtain ownership of the patents and patent applications worldwide that contain the Company trade secret information.

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

No matters were submitted to a vote of security holders during the fourth quarter ended December 31, 1996.

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Executive Officers of the Company

The following sets forth information with respect to all the executive officers of the Company, including their names, ages, positions with the Company and business experience during the last five years, as of March 31, 1997.

John P. Funkhouser, age 43, was elected President, Chief Executive Officer and a director of the Company in October 1993 upon the Company's acquisition of Coeur. Since February 1992, Mr. Funkhouser has also served as President and Chief Executive Officer of Coeur. Before his employment with Coeur, Mr. Funkhouser was a General Partner with Hillcrest Group, a venture capital firm, and worked for over nine years in managing venture capital portfolio companies. In 1991, CSVa, Inc., a venture capital portfolio company of which Mr. Funkhouser was a director, filed a petition for bankruptcy. Mr. Funkhouser holds a B.A. from Princeton University and an M.B.A. from the University of Virginia.

B. Denise Hobbs, age 45, was elected Vice President of Finance and Administration in February 1997. Since October 1993, she has also served as Treasurer and Secretary of the Company. From October 1993 until May 1996, Ms. Hobbs was also Director of Finance and Administration of the Company. Since 1991, she has also served as Coeur's Controller and Secretary. For over three years prior to joining Coeur, Ms. Hobbs was the Controller for the Virginia Municipal League. Ms. Hobbs holds an M.S. in Accounting and Finance from Virginia Commonwealth University.

Jonathon Lawrie, Ph.D., age 46, was elected Managing Director, Europe and Chief Scientific Officer in 1994. From January 1992 until 1994, Dr. Lawrie served as President and a director of the Company. Prior to joining the Company, Dr. Lawrie was Director of Development of Roche Diagnostic Systems for over two years. Dr. Lawrie holds an M.S. and a Ph.D. in Microbiology and Immunology from the University of Washington.

Michael D. Riddle, age 43, was elected Vice President of Sales and Marketing in January 1995. Prior to joining the Company, Mr. Riddle was employed by American Home Products for more than five years in various positions, most recently Vice President of Sales and Marketing for its subsidiary, Sherwood Medical Devices. Mr. Riddle holds an A.I.M.L.T. from Bromley College of Technology (Kent, United Kingdom).

Wayne J. Scroggins, age 48, was elected Executive Vice President and Chief Operating Officer of the Company in May 1996. Before joining the Company, Mr. Scroggins spent the past 24 years in operational and financial positions of increasing responsibility with the domestic and international tobacco subsidiaries of RJR Nabisco, Inc. and with R.J. Reynolds Industries, Inc. Mr. Scroggins is a Certified Public Accountant and holds a B.A. in Accounting and Finance from Lewis University.

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PART II

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

(a) Price Range of Common Stock

The Company's Common stock trades on the Nasdaq National Market under the symbol "CVDI". The following sets forth the quarterly high and low sales prices for the fiscal year ended December 31, 1996 as reported by Nasdaq. These prices are based on quotations between dealers, which do not reflect retail mark-up, mark-down or commissions, and do not necessarily represent actual transactions.

	High	Low
Fiscal Year Ended December 31, 1996		
January 1, 1996 through March 31, 1996	$11-5/8	$9-1/2

April 1, 1996 through June 30, 1996	11-1/2	7-1/2
July 1, 1996 through September 30, 1996	8-1/4	4-1/4
October 1, 1996 through December 31, 1996	6-3/4	3-3/4

(b) Approximate Number of Equity Security Holders

As of December 31, 1996, the number of record holders of the Company's Common Stock was 250, and the Company believes that the number of beneficial owners was approximately 1,500.

(c) Dividends

The Company has never paid a cash dividend on its Common Stock and anticipates that for the foreseeable future any earnings will be retained for use in its business and, accordingly, does not anticipate the payment of cash dividends.

Recent Sales of Unregistered Securities

Since December 31, 1995, the Company has issued and sold the following unregistered securities:

1. From January 1, 1996 through December 31, 1996, the Company issued options to purchase an aggregate of 109,000 shares of Common Stock to employees and consultants of the Company.

Item 6. SELECTED FINANCIAL DATA.

The selected financial data presented below summarizes certain financial data and should be read in conjunction with the more detailed financial statements of the Company and the notes thereto which have been audited by Coopers & Lybrand L.L.P., independent accountants, whose report thereon is included elsewhere in this Annual Report on Form 10-K along with said financial statements. See "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business".

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CARDIOVASCULAR DIAGNOSTICS, INC. AND SUBSIDIARIES
Selected Consolidated Financial Data
(In thousands, except per share data)

<TABLE>
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	Year Ended December 31,			Two Month Period Ended December 31,	Year Ended October 31,	
RESULTS OF OPERATIONS	1996	1995	1994	1993	1993	1992
<S>	<C>	<C>	<C>	<C>	<C>	<C>
Net sales	$6,411	$5,199	$4,695	$738	$ ---	$ ---
Cost of goods sold	5,257	4,268	3,021	570	---	---
Gross profit	1,154	931	1,674	168	---	---
Operating expenses:						
Research and development	2,300	1,801	1,882	283	2,085	1,317
General and administrative	2,933	2,191	1,441	357	1,051	675
Sales and marketing	1,896	1,278	453	33	256	---
Total operating expenses	7,129	5,270	3,776	673	3,392	1,992
Other income, net	906	469	365	32	1,050	325
Provision for income taxes	(52)	(82)	(91)	(4)	---	---
Net loss	($5,121)	($3,952)	($1,828)	($477)	($2,342)	($1,667)
Net loss per share	($0.78)	($0.74)	($0.35)	($0.10)	($0.65)	($0.54)
Weighted Average Shares Outstanding	6,566	5,323	5,179	4,600	3,626	3,116

	As of December 31,			As of October 31,	
FINANCIAL CONDITION	1996	1995	1994	1993	1992
Cash and cash equivalents	$2,716	$16,237	$3,206	$626	$604
Total assets	18,351	23,986	8,328	5,468	1,817

Long term debt, excluding current portion	67	499	269	330	42
Total liabilities	683	2,176	901	1,346	283
Accumulated deficit	(15,940)	(10,819)	(6,867)	(4,562)	(2,220)
Shareholders' equity	$17,668	$21,810	$7,428	$4,422	$1,534

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Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION.

This discussion contains forward-looking information. The actual results might differ materially from those projected in the forward-looking statements for various reasons, including the possibility of pressure from managed care hospitals to decrease prices, the availability of products from vendors, the timing of orders from customers, the ability to determine proper inventory levels and the possibility of competition entering the point-of-care hemostasis monitoring market. Additional information concerning factors that could cause actual results to materially differ from those in the forward-looking statements is contained herein and in the Company's other SEC filings, including under the heading "Risk Factors" in the company's initial public offering prospectus, copies of which are available upon request.

Cardiovascular Diagnostics, Inc. ("CVDI" or the "Company") is located in Raleigh, North Carolina, within a 55,000 square foot facility housing office space, research labs and manufacturing clean rooms. CVDI develops, manufactures and markets the Thrombolytic Assessment System ("TAS"), a proprietary cardiovascular diagnostic test system that provides rapid and accurate evaluation of hemostasis at the point of patient care. CVDI has a European subsidiary, Cardiovascular Diagnostics Europe, BV ("CDE"), located in Amsterdam, Holland, which serves as a sales and distribution office for TAS products sold in Europe. CVDI's other subsidiary, Coeur Laboratories, Inc. ("Coeur"), located within the Raleigh facility, assembles and sells disposable power injection syringes used for cardiology and radiology procedures, as well as a line of manifolds sold in custom angiographic procedure kits.

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Through November 1995, CVDI's operations were funded primarily through private sales of equity securities, National Institutes of Health Small Business Innovative Research ("NIH SBIR") grants, license fees, equipment lease lines and profits from Coeur. In December 1995, the Company completed its initial public offering, selling 2.2 million shares with net proceeds to the Company of $17.7 million.

During 1996 the Company had 10 sales people covering the major metropolitan areas across the United States and nine distributors selling into 13 countries, compared to three sales people in the U.S. and two distributors in Europe at the beginning of 1995. The laboratory response to CVDI's technology was largely positive, as the Company's sales force initiated more than 170 hospital evaluations of TAS during 1996. However, throughout 1996, individual hospitals continued to consolidate into integrated health networks, ("IHN"). This consolidation delayed many pending decisions to adopt the new technology provided by CVDI's TAS, and created a demand for standardized test results from one hospital to another. CVDI offers a technological breakthrough capable of providing rapid diagnostic test results standardized to the central laboratory tests. CVDI signed a North American distribution agreement with DADE International ("Dade"), the world's largest reagent manufacturer. This represents a milestone event for CVDI, since Dade and CVDI together have the ability to provide IHNs a total standardized hemostasis solution from less time sensitive testing to immediate "stat" testing.

The TAS is a flexible technology platform which allows CVDI to develop tests to monitor drug therapy. To capitalize on this ability, CVDI has signed collaboration agreements with Knoll AG and Bayer Corporation to monitor the effects of new drugs under development in clinical trials. This is a new era for diagnostic and pharmaceutical companies to team together to introduce more powerful drugs for specific indications.

CVDI's strategy is to eventually offer a continuum of drug monitoring for cardiac patients throughout their hospital stay, and later, for patients who must continue using anticoagulant therapy in an outpatient format. This strategy will enable CVDI to establish the TAS technology as the gold standard of coagulation care.

RESULTS OF OPERATIONS

Sales for the year ended December 31, 1996 increased 23% to $6.4 million compared to a year earlier. The $1.2 million increase in sales was attributable to higher TAS product sales, $1.8 million in fiscal 1996 as compared to $600,000 in fiscal 1995. All sales in fiscal 1994 were derived from Coeur. The gross profit margin for fiscal 1996 was 18%, unchanged from fiscal 1995. The gross profit margin declined in 1995 to 18% from 36% in fiscal 1994 as 1995 TAS product sales were insufficient to recover production start-up and associated

overhead expenses of TAS product production. TAS analyzer sales in fiscal 1996 totaled 395 (214 analyzers in the U.S. and 181 in Europe). Since the TAS was brought to market in 1995, 539 analyzers have been sold, 287 in the U.S. and 252 to distributors in Europe. The Company signed a North American distribution agreement with DADE International ("Dade") in October, 1996. This agreement should enable CVDI to penetrate the U.S. market as TAS products will be sold by DADE.

The Company's research and development expenses relate primarily to its TAS products. Research and development expenses for 1996 were $2.3 million, or 28% greater than 1995, due to increased clinical trials expenses for expansion of the TAS test card menu. The research and development expenses for fiscal year 1995 were slightly less than fiscal 1994 as a result of the redirection of the company from the development stage to commercialization. Research and development expenses for 1997 are expected to increase as the company initiates additional clinical trials for new test cards under development.

The Company's general and administration expenses rose $742,000, or 34%, from fiscal 1995 to fiscal 1996. Principal factors contributing to the increase were additional staffing, the full year effect of public company related expenses, such as investor relations and director and officer liability insurance, and an 11,000 square feet increase of facility space. In fiscal 1995 the Company's general and administrative expenses increased 52% from fiscal 1994. Unearned compensation related to the vesting of options upon the consummation of the initial public offering in December 1995 accounted for $383,000 or 51% of this increase. Staffing and associated office expenses for the Amsterdam facility and an increase in allowance for doubtful accounts accounted for the balance of this year to year increase.

Sales and marketing expenses increased approximately $617,000 from fiscal 1995 to 1996. This increase reflected the addition of seven sales people and the associated travel expenses, as well as increased marketing and advertising expenses. The increase of approximately $825,000 from

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fiscal 1994 to fiscal 1995 was a result of staffing the European office, establishing a warranty reserve for TAS products and associated travel expenses for the market launch of TAS in 1995. Sales marketing and advertising expenses are expected to decrease in 1997 due to the Dade distribution agreement which was signed in October 1996.

The net loss for the year ended December 31, 1996 was $5.1, million or $0.78 per share, compared to a net loss of $4.0 million, or $0.74 per share, in 1995. The additional loss of $1.1 million was a result of increased operating expenses from fiscal 1995 to fiscal 1996 of $1.8 million which was partially offset by increased interest income of $523,000 and $223,000 of higher gross profits.. The net loss for fiscal 1995 was $0.74 per share compared to a loss of $0.35 per share in 1994. The $0.74 loss per share in 1995 was due to $0.60 per share of operating losses and $0.14 per share of charges for reserves and compensation expense. In fiscal 1995, CVDI increased the allowance for doubtful accounts as a result of delinquent foreign receivables and established a reserve for obsolete inventory recognizing the one-year life for test cards.

The Company recorded an unearned compensation expense of $427,000 in fiscal 1995, the amount by which the deemed fair value of the Common Stock exceeded the exercise price of certain options as of the date of grant. Such compensation is expensed as the options vest. For the year ended December 31, 1995, $383,000 of such compensation was expensed. The compensation expense for the year ended December 31, 1996 was $11,000. The Company expects to continue to recognize the remaining compensation expense at a rate of $11,000 per year in 1997 through 1999.

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 1996 CVDI had cash and cash equivalents and short term investments of $8.7 million and working capital of $11.6 million, as compared to $16.2 million and $16.8 million, respectively, at December 31, 1995.

Capital expenditures for 1996 were $1.4 million, primarily for additional automated TAS test card production equipment and lease-hold improvements. Accordingly, depreciation expense increased $113,000, or 21%, from 1995 to 1996. CVDI expects capital expenditures to be approximately $700,000 for 1997, none of which is currently subject to contracts or commitments. These expenditures are likely to include additional manufacturing and production equipment, furniture and fixtures, computers and engineering equipment. In addition the Company has contractual obligations with vendors to purchase approximately $1.0 million of raw materials during 1997. Management believes that its existing capital resources and the cash flows from operations will be adequate to satisfy its planned capital requirements through at least 1998.

CVDI's European subsidiary, CDE, makes expenditures in Dutch guilders. There is some currency risk when translating financial statements from guilders to dollars, however, sales invoicing and remittances are completed in dollars. Therefore, any currency translation adjustments are non-cash items.
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FACTORS THAT MAY AFFECT FUTURE RESULTS

A number of uncertainties exist that may affect the Company's future operating results and stock price, including managed care, FDA regulations and other regulatory guidelines affecting the Company. The market price of the Common Stock could be subject to significant fluctuations in response to variations in the Company's quarterly operating results as well as other factors which may be unrelated to the Company's performance. The stock market in recent years has experienced extreme price and volume fluctuations that often have been unrelated or disproportionate to the operating performance of and announcements concerning public companies. Such broad fluctuations may adversely affect the market price of the Company's Common Stock. Securities of issuers having relatively limited capitalization or securities recently issued in an initial public offering are particularly susceptible to volatility based on short-term trading strategies of certain investors.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

See Index to Consolidated Financial Statements on page F-1.

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

Not applicable.

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PART III

Certain information required by Part III is omitted from this report because the Registrant will file a definitive proxy statement for its 1997 Annual Meeting of Shareholders (the "Proxy Statement") within 120 days after the end of its fiscal year pursuant to Regulation 14A promulgated under the Securities Exchange Act of 1934, as amended, and the information included therein is incorporated herein by reference to the extent provided below.

Item 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

The information required by Item 10 of Form 10-K concerning the Registrant's executive officers is set forth under the heading "Executive Officers of the Company" located at the end of Part I of this Form 10-K.

The other information required by Item 10 of Form 10-K is incorporated by reference to the information under the headings "Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement.

Item 11. EXECUTIVE COMPENSATION.

The information required by Item 11 of Form 10-K is incorporated by reference to the information under the heading "Proposal No. 1--Election of Directors--Information Concerning the Board of Directors and Its Committees", "Other Information--Compensation of Executive Officers", "--Compensation of Directors", "--Report of the Compensation Committee on Executive Compensation", "--Compensation Committee Interlocks and Insider Participation", and "--Performance Graph" in the Proxy Statement.

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

The information required by Item 12 of Form 10-K is incorporated by reference to the information under the heading "Other Information--Principal Shareholders" in the Proxy Statement.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

The information required by Item 13 of Form 10-K is incorporated by reference to the information under the heading "Other Information--Certain Transactions" in the Proxy Statement.

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PART IV

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

(a) The following Financial Statements, Financial Statement Schedules and Exhibits are filed as part of this report or incorporated herein by reference:

(1) Financial Statements.

See Index to Consolidated Financial Statements on page F-1.

(2) Financial Statement Schedules.

Schedule II, Valuation and Qualifying Accounts, is found on page S-1 of this Form 10-K.

All other schedules for which provision is made in Regulation S-X are not required under the related instructions, are inapplicable, or the required information is given in the financial statements, including the notes thereto and, therefore, have been omitted.

(3) Exhibits Filed.

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Exhibit Number	Description
<S>	<C>
3.1 (a)	Articles of Incorporation, as currently in effect.
3.3 (a)	Bylaws.
4.1 (a)	Form of Common Stock certificate.
10.1 (a)*	License Agreement with Boehringer Mannheim Corporation, dated June 21, 1989, as amended September 28, 1995.
10.2 (a)*	License Agreement with Tokuyama Soda Company, Ltd., dated October 6, 1988.
10.3 (a)	Form of International Distributor Agreement.
10.4 (a)*	Purchasing Agreement with VHA Inc., dated April 1, 1995.
10.5	(a) Lease Agreement dated November 21, 1990 relating to 5301 Departure Drive, Raleigh, as amended.
10.6 (a)	Contract of Lease for Industrial Property, Service Agreement and Addendum, dated effective as of January 1, 1995 (The Netherlands).
10.7 (a)	Amended and Restated Registration Rights Agreement, dated December 16, 1994, as amended August 31, 1995.
10.8 (a)	1994 Stock Plan, as amended.
10.9 (a)	1995 Stock Plan, as amended.
10.10 (a)*	License Agreement with Duke University, dated January 22, 1993.
10.11 (a)*	Agreement between Coeur and E-Z-EM, Inc., dated March 24, 1995.
10.12 (a)	Financial Assistance Agreement with North Carolina Biotechnology Center, dated January 7, 1994.
10.13 (a)	Equipment Lease Agreements with Centura Bank, dated March 15, 1993.
10.14 (a)	Equipment Finance Line with Phoenix Growth Capital Corp., dated May 5, 1995.
10.15 (a)	Master Equipment Lease Agreement with Venture Lending & Leasing, Inc., dated June 2, 1995.

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10.16 (a)	Loan Agreements with Max Edward Bolene, d/b/a Carolina Financial Services, Inc., as amended.
10.17 (a)	Security Agreement and Commercial Notes between Coeur and Centura Bank, dated September 21,

		1995.
	10.18 (b)*	Amendment Agreement, dated December 14, 1995, to License Agreement with Tokuyama Soda Company, Ltd.
	10.19 (c)*	Distribution Agreement, dated October 18, 1996, with Dade International.
	10.20*	Patent Sublicense Agreement, dated December 1, 1996, with Knoll AG.
	10.21	Development Agreement, dated August 21, 1996, with Bayer Corporation.
	21.1 (a)	List of Subsidiaries.
	27.1	Financial Data Schedule.

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* Confidential treatment requested.

(a) Incorporated herein by reference to the identically-numbered exhibits to the Registrant's Registration Statement on Form S-1 (Registration No. 33-98078) initially filed October 12, 1995, as amended.

(b) Incorporated herein by reference to the identically-numbered exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1995.

(c) Incorporated herein by reference to the identically-numbered exhibit to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.

(b) Forms 8-K. No Current Reports on Form 8-K were filed by the Registrant during the fourth quarter of the fiscal year ended December 31, 1996.

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CARDIOVASCULAR DIAGNOSTICS, INC.

AND SUBSIDIARIES

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REPORT OF INDEPENDENT ACCOUNTANTS

The Board of Directors and Shareholders

Cardiovascular Diagnostics, Inc.

We have audited the accompanying consolidated balance sheets of Cardiovascular Diagnostics, Inc. and subsidiaries as of December 31, 1996 and 1995, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 1996. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with generally accepted auditing standards. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting

the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Cardiovascular Diagnostics, Inc. and subsidiaries as of December 31, 1996 and 1995, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 1996 in conformity with generally accepted accounting principles.

/s/ COOPERS & LYBRAND

Raleigh, North Carolina

February 20, 1997

<PAGE>

CARDIOVASCULAR DIAGNOSTICS, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

December 31, 1996 and 1995

<TABLE>
<CAPTION>

ASSETS	1996	1995
<S>	<C>	<C>
Current assets:		
Cash and cash equivalents	$ 2,716,242	$16,237,132
Short term investments, held-to-maturity	5,973,405	--
Receivables:		
Trade, net of allowance for doubtful accounts of $5,000 in 1996 and $40,395 in 1995	906,491	762,756
Other	385,073	40,430
Total receivables	1,291,564	803,186
Inventories	2,018,798	1,304,851
Other current assets	198,111	159,401
Total current assets	12,198,120	18,504,570
Property and equipment, net	4,236,128	3,495,821
Intangible assets, net	1,700,560	1,810,466
Other noncurrent assets	216,547	175,183
	$ 18,351,355	$ 23,986,040
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 377,314	$ 953,293
Accrued expenses	219,634	387,081
Current portion of long-term debt	--	282,566
Current portion of capital lease obligations	19,082	53,772
Total current liabilities	616,030	1,676,712
Long-term debt, less current portion	50,000	456,612
Capital lease obligations, less current portion	16,987	38,086
Deferred gain on sale-leaseback	--	4,247
Total noncurrent liabilities	66,987	498,945
Total liabilities	683,017	2,175,657
Commitments and contingencies (Notes 8, 13 and 14)		
Shareholders' equity:		
Preferred stock, $.001 par value; authorized 1,000,000 shares - Series A participating preferred stock, voting; designated 696,000 shares at December 31, 1996 and 1995; no shares issued or outstanding at December 31, 1996 and 1995		
Common stock, $.001 par value; authorized 10,000,000 shares; 6,663,986 and 6,447,562 issued and outstanding at December 31, 1996 and 1995, respectively	6,664	6,447
Additional paid-in capital	33,682,330	32,672,438
Cumulative translation adjustments	(48,078)	(5,568)
Accumulated deficit	(15,939,578)	(10,818,934)
Unearned compensation	(33,000)	(44,000)
Total shareholders' equity	17,668,338	21,810,383
	$ 18,351,355	$ 23,986,040

</TABLE>

The accompanying notes are an integral part of the consolidated financial statements.

<PAGE>

CARDIOVASCULAR DIAGNOSTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

for the years ended December 31, 1996, 1995 and 1994

<TABLE>
<CAPTION>

	1996	1995	1994
<S>	<C>	<C>	<C>
Net sales	$ 6,411,519	$ 5,198,950	$ 4,695,488
Cost of sales:			
Materials and labor	3,121,439	2,744,932	2,105,605
Overhead	2,135,605	1,523,296	915,585
Total cost of sales	5,257,044	4,268,228	3,021,190
Gross profit	1,154,475	930,722	1,674,298
Operating expenses:			
General and administrative	2,933,016	2,191,036	1,441,070
Sales and marketing	1,895,492	1,278,139	453,152
Research and development	2,300,462	1,800,936	1,881,778
Total operating expenses	7,128,970	5,270,111	3,776,000
Loss from operations	(5,974,495)	(4,339,389)	(2,101,702)
Other income (expense):			
Interest expense	(16,317)	(59,550)	(48,471)
Interest income	634,989	111,536	28,930
Grant income	254,204	292,534	249,523
License fee and royalty income	32,835	124,772	135,291
Other income, net	905,711	469,292	365,273
Loss before income taxes	(5,068,784)	(3,870,097)	(1,736,429)
Provision for income taxes	(51,860)	(82,136)	(91,250)
Net loss	$(5,120,644)	$(3,952,233)	$ (1,827,679)
Net loss per share	$ (0.78)	$ (0.74)	$ (0.35)
Weighted average number of common shares and common share equivalents	6,566,134	5,323,239	5,178,526

</TABLE>

The accompanying notes are an integral part of the consolidated financial statements.

<PAGE>

CARDIOVASCULAR DIAGNOSTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Shareholders' Equity

for the years ended December 31, 1996, 1995 and 1994

<TABLE>
<CAPTION>

	Series A Participating Preferred Stock	Common Stock	Additional Paid-In Capital	Cumulative Translation Adjustments	Accumulated Deficit
<S>	<C>	<C>	<C>	<C>	<C>
Balances at December 31, 1993		$2,828	$ 8,681,479		$ (5,039,022)
Issuance of 612,638 shares of common stock at $4.9377 per share, net of issuance costs		613	2,722,706		
Issuance of 4,088 shares of common stock at $.395 per share		4	1,611		
Issuance of 11,855 shares of common stock at $.5925 per share		11	7,014		
Issuance of 482,372 shares of Series A preferred stock at $6.25 per share, net of issuance costs	$ 482		2,878,361		
Net loss for the year ended December 31, 1994					(1,827,679)

Translation adjustment				$ (557)	
Balances at December 31, 1994	482	3,456	14,291,171	(557)	(6,866,701)
Issuance of 210,900 shares of Series A preferred stock at $6.25 per share, net of issuance costs	211		1,278,595		
Issuance of 3,671 shares of common stock at $0.59 per share		4	2,171		
Issuance of 1,265 shares of common stock at $0.5056 per share		1	639		
Issuance of 15,189 shares of common stock at $0.3950 per share		15	5,985		
Unearned compensation related to common stock options			426,638		
Amortization of unearned compensation					
Conversion of 693,272 shares of Series A participating preferred stock to 877,530 shares of common stock	(693)	877	(184)		
Issuance of 393,904 shares of common stock for liquidation preference		394	(394)		
Issuance of 1,700,000 shares of common stock at $11.00 per share, net of issuance costs		1,700	16,667,817		
Net loss for the year ended December 31, 1995					(3,952,233)
Translation adjustment				(5,011)	
Balances at December 31, 1995	--	6,447	32,672,438	(5,568)	(10,818,934)
Issuance of 100,000 shares of common stock at $11.00 per share, net of issuance costs		100	990,595		
Issuance of 39,148 shares of common stock at $0.79 per share		39	30,887		
Issuance of 7,593 shares of common stock at $0.59 per share		8	4,472		
Issuance of 79,767 shares of common stock at $0.395 per share		80	31,428		
Repurchase of 10,000 shares of common stock at $4.75 per share		(10)	(47,490)		
Amortization of unearned compensation					
Net loss for the year ended December 31, 1996					(5,120,644)
Translation adjustment				(42,510)	
Balance at December 31, 1996	$ --	$ 6,664	$ 33,682,330	$(48,078)	$(15,939,578)

</TABLE>

<TABLE>
<CAPTION>

	Unearned Compensation	Total Shareholders' Equity
<S>	<C>	<C>
Balances at December 31, 1993		$ 3,645,285
Issuance of 612,638 shares of common stock at $4.9377 per share, net of issuance costs		2,723,319
Issuance of 4,088 shares of common stock at $.395 per share		1,615
Issuance of 11,855 shares of common stock at $.5925 per share		7,025
Issuance of 482,372 shares of Series A preferred stock at $6.25 per share, net of issuance costs		2,878,843
Net loss for the year ended December 31, 1994		(1,827,679)
Translation adjustment		(557)
Balances at December 31, 1994		7,427,851
Issuance of 210,900 shares Series A preferred stock at $6.25 per share, net of issuance costs		1,278,806
Issuance of 3,671 shares of common stock at $0.59 per share		2,175
Issuance of 1,265 shares of common stock at $0.5056 per share		640
Issuance of 15,189 shares of common stock at $0.3950 per share		6,000
Unearned compensation related to common stock options	$ (426,638)	
Amortization of unearned compensation	382,638	382,638
Conversion of 693,272 shares of Series A participating preferred stock to 877,530 shares of common stock		
Issuance of 393,904 shares of common stock for liquidation preference Issuance of 1,700,000 shares of common stock at $11.00 per share, net of issuance costs		16,669,517
Net loss for the year ended December 31, 1995		(3,952,233)
Translation adjustment		(5,011)
Balances at December 31, 1995	(44,000)	21,810,383
Issuance of 100,000 shares of common stock at $11.00 per share, net of issuance costs		990,695

Issuance of 39,148 shares of common stock at $0.79 per share			30,926
Issuance of 7,593 shares of common stock at $0.59 per share			4,480
Issuance of 79,767 shares of common stock at $0.395 per share			31,508
Repurchase of 10,000 shares of common stock at $4.75 per share			(47,500)
Amortization of unearned compensation		11,000	11,000
Net loss for the year ended December 31, 1996			(5,120,644)
Translation adjustment			(42,510)
Balance at December 31, 1996		$(33,000)	$17,668,338

</TABLE>

The accompanying notes are on integral part of the consolidated financial statements.

<PAGE>

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CARDIOVASCULAR DIAGNOSTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

for the years ended December 31, 1996, 1995 and 1994

<TABLE>
<CAPTION>

	1996	1995	1994
<S>	<C>	<C>	<C>
Cash flows from operating activities:			
Net loss	$ (5,120,644)	$ (3,952,233)	$ (1,827,679)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	663,809	550,342	391,011
Amortization of intangible assets	203,479	213,805	216,688
Amortization of discount on investments, net	(285,509)	--	--
Amortization of deferred gain on sale-leaseback	(4,247)	(16,999)	(17,000)
Provision for warranties	--	50,000	--
Provision for doubtful accounts	--	40,395	12,000
Amortization of unearned compensation	11,000	382,638	--
Provision for inventory obsolescence	40,000	82,000	--
Loss (gain) on disposal of fixed assets	(3,192)	2,989	28,948
Provision for deferred income taxes	--	7,573	91,250
Change in assets and liabilities:			
Receivables	(488,378)	(271,020)	71,403
Inventories	(753,947)	(601,293)	(196,800)
Other assets	(80,074)	(142,392)	(128,474)
Accounts payable and accrued expenses	(743,426)	931,054	(223,028)
Deferred revenue and gains		(25,000)	25,000
Net cash used in operating activities	(6,561,129)	(2,748,141)	(1,556,681)
Cash flows from investing activities:			
Purchases of property and equipment	(1,417,977)	(2,343,157)	(978,767)
Proceeds from sales of property and equipment	23,532		
Costs incurred to obtain patents	(93,573)	(144,763)	(26,374)
Refunds of deposits	--	--	1,358
Purchases of short-term investments, held to maturity	(10,687,896)	--	--
Proceeds from maturities of investments	5,000,000	--	--
Net cash used in investing activities	(7,175,914)	(2,487,920)	(1,003,783)

</TABLE>

(Continued)

<PAGE>

CARDIOVASCULAR DIAGNOSTICS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows (Continued)

for the years ended December 31, 1996, 1995 and 1994

<TABLE>
<CAPTION>

	1996		1995		1994	
<S>	<C>	<C>	<C>	<C>	<C>	<C>
Cash flows from financing activities:						
Proceeds from issuance of long-term debt						
Principal payments on long-term debt and capital lease obligations		--		500,000		15,325
		(751,446)		(185,020)		(125,275)
Purchase of treasury stock		(47,500)		--		--
Net proceeds from issuance of stock		1,057,609		17,957,138		5,610,802
Net cash provided by financing activities		258,663		18,272,118		5,500,852
Effect of exchange rates on cash		(42,510)		(5,011)		(557)
Net increase (decrease) in cash equivalents and cash equivalents		(13,520,890)		13,031,046		2,939,831
Cash and cash equivalents at beginning of year		16,237,132		3,206,086		266,255
Cash and cash equivalents at end of year		$ 2,716,242		$ 16,237,132		$ 3,206,086
Supplemental disclosures of cash flow information:						
Cash paid during the year for interest expense		$ 11,589		$ 59,968		$ 49,805
Cash received during the year for interest income		$ 473,288		$ 103,078		$ 28,930
Cash paid during the year for income taxes		$ 76,724		$ 88,700		--
Supplemental disclosure of noncash investing and financing activities:						
Capital lease and debt obligations incurred for equipment		$ 6,479		$ 21,095		$ 76,148
Debt retired by discounts on products sold						$ 49,126

</TABLE>

The accompanying notes are an integral part of the consolidated financial statements.

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CARDIOVASCULAR DIAGNOSTICS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization

Cardiovascular Diagnostics, Inc. (the "Company") develops, manufactures and markets a proprietary cardiovascular diagnostic test system that provides rapid and accurate evaluation of hemostasis at the point of patient care. The Company has two wholly-owned subsidiaries, Coeur Laboratories, Inc. ("Coeur") and Cardiovascular Diagnostics Europe, BV ("CDE"). Coeur manufactures and sells a line of disposable power injection syringes used for cardiology and radiology procedures, as well as a line of manifolds used in custom angiographic procedure kits. CDE, a Dutch company, distributes the Company's products in Europe.

In December 1995, the Company completed an initial public offering ("IPO") of 1,700,000 new shares of $.001 par value common stock. The offering price per share was $11.00, resulting in gross proceeds of $18.7 million. Net of underwriting discount and offering expenses, the Company received approximately $16.7 million.

In January 1996, the underwriters of the Company's IPO purchased an additional 100,000 shares of the Company's common stock under the terms of an option to purchase additional shares to cover over-allotments. The Company received net proceeds of approximately $991,000 from the sale of these shares.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents.

Investments

Investments are accounted for in accordance with Statement of Financial Accounting Standards No. 115 (SFAS No. 115), "Accounting for Certain Investments in Debt and Equity Securities." This statement requires certain securities to be classified into three categories:

(a) Securities Held-to-Maturity - Debt securities that the entity has the positive intent and ability to hold to maturity are reported at amortized cost.

(b) Trading Securities - Debt and equity securities that are bought and held principally for the purpose of selling in the near term are reported at fair value, with unrealized gains and losses included in earnings.

(c) Securities Available-for-Sale - Debt and equity securities not classified as either securities held to maturity or trading securities are reported at fair value, with unrealized gains and losses excluded from earnings and reported as a separate component of stockholders' equity.

<PAGE>

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Investments (continued)

The Company has the intent and ability to hold all investments at December 31, 1996 until maturity.

Inventories

Inventories are stated at the lower of standard cost (which approximates cost on a first-in, first-out basis) or market.

Property and Equipment

Property and equipment are stated at cost and are depreciated using the straight-line method over the estimated useful lives of the respective assets, which range from three to seven years. Leasehold improvements are amortized over the shorter of the estimated useful lives of the improvements, or the term of the facility lease.

Expenditures for repairs and maintenance are charged to expense as incurred. The costs of major renewals and betterments are capitalized and depreciated over their estimated useful lives. Upon disposition, the cost and related accumulated depreciation of property and equipment are removed from the accounts and any resulting gain or loss is reflected in operations.

Intangible Assets

Excess of cost over fair value of net assets acquired ("goodwill") resulted from the acquisition of Coeur and is being amortized over ten years using the straight-line method. Organization costs were incurred in connection with the formation of CDE and are being amortized over five years. Patents are amortized using the straight-line method over their estimated useful lives (13 to 17 years). Periods of amortization are evaluated periodically to determine whether later events and circumstances warrant revised estimates of useful lives.

At each balance sheet date, the Company evaluates the recoverability of unamortized goodwill based upon expectations of nondiscounted cash flows and operating income of Coeur. Impairments, if any, would be recognized in operating results if a permanent diminution in value were to occur.

Convertible Debt

Convertible debt is recorded as a liability until converted into common stock, at which time it is recorded as equity.

Revenue and Income Recognition Policies

Revenue from the sale of products is recorded at the time the goods are shipped or when title passes. Income under license agreements is recorded upon the achievement of certain milestones contained in these agreements. Income from research grants is recognized when amounts are expended for the specific purpose stated in the grant.

<PAGE>

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Income Taxes

Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

Loss Per Common Share

Historical loss per common share is computed by dividing net loss by the weighted average number of common shares and common share equivalents outstanding during the period. Pursuant to the Securities and Exchange Commission Staff Accounting Bulletins, Series A preferred shares that automatically converted into common shares upon the effective date of the IPO, 393,904 additional shares of common stock that were issued to holders of Series A preferred stock upon the closing of the IPO, as discussed in Note 9, and stock options issued to employees during the 12 months immediately preceding the IPO, have been included in the calculation as if they were outstanding for all periods presented (using the treasury stock method and the IPO price of $11.00 per share).

Stock Options

On January 1, 1996 the Company adopted Statement of Financial Accounting Standards No. 123, "Accounting for Stock Based Compensation" (SFAS No. 123). As permitted by SFAS No. 123, the Company has chosen to continue to apply APB Opinion No. 25 "Accounting for Stock issued to Employees" (APB No. 25) and related interpretations in accounting for its stock plans. Had compensation cost for the Company's plans been determined based on the fair value at the grant dates for awards under the plans consistent with the method of SFAS 123, the impact on the Company's net loss and net loss per share would not have been material.

Fair Value of Financial Instruments

The following methods and assumptions were used by the Company's management in estimating fair values for financial instruments.

Short-Term Investments, Held-to-Maturity

The fair values of the Company's short-term investments have been based upon quoted market prices.

<PAGE>

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Long-Term Debt

Market values of debt issues were estimated based upon prevailing market interest rates at December 31, 1996 for debt issues with similar characteristics.

A summary of significant financial instruments at December 31, 1996 is as follows:

	Market Value	Carrying Value	Location of Details
Short-term investments, held to maturity	$5,979,680	$5,973,405	Note 2
Long-term debt	$ 49,623	$ 50,00	Note 7

Use of Estimates in the Preparation of the Financial Statements

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 and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates.

Recent Accounting Pronouncements

In February 1997, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards ("SFAS") No. 128, "Earnings Per Share." SFAS 128 is designed to improve the earnings per share information provided in financial statements by simplifying the existing computational guidelines, revising the disclosure requirements, and increasing comparability of earnings per share data on an international basis. This pronouncement is effective for periods beginning after December 15, 1997, and is not expected to have a material impact on the Company's financial statements.

2. SHORT-TERM INVESTMENTS

At December 31, 1996 the Company classified investment securities in the consolidated financial statements according to management's intent. Investment securities at December 31, 1996 are summarized as follows:

<TABLE>
<CAPTION>

		Gross Realized		
	Amortized Cost	Gains	Losses	Estimated Market Value
<S>	<C>	<C>	<C>	<C>

Held-to-maturity:

U.S. Treasury obligations	$ 5,973,405	6,275	$ -	$ 5,979,680

</TABLE>

<PAGE>

3. INVENTORIES

Inventories at December 31, 1996 and 1995 consisted of the following:

	1996	1995
Raw materials	$ 1,431,534	$ 975,686
Finished goods	587,264	329,165
	$ 2,018,798	$ 1,304,851

4. PROPERTY AND EQUIPMENT

Property and equipment at December 31, 1996 and 1995 consisted of the following:

	1996	1995
Molds and equipment	$4,709,870	$4,014,533
Furniture, fixtures and EDP equipment	711,993	519,154
Leasehold improvements	1,040,093	774,912
Equipment under capital leases	390,691	387,569
Automobiles	16,222	32,645
	6,868,869	5,728,813
Less accumulated depreciation and amortization	2,632,741	2,232,992
	$4,236,128	$3,495,821

5. INTANGIBLE ASSETS

Intangible assets at December 31, 1996 and 1995 consisted of the following:

	1996	1995
Excess of cost over fair value of net assets acquired	$1,802,506	$1,802,506
Patents	478,338	382,687
Other	85,123	87,201
	2,365,967	2,272,394
Less accumulated amortization	665,407	461,928
	$1,700,560	$1,810,466

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6. RESEARCH AND DEVELOPMENT GRANTS

The Company has recognized income related to National Institutes of Health Small Business Innovation Research grant awards as follows:

<TABLE>
<CAPTION>

	1996	1995	1994
<S>	<C>	<C>	<C>
Phase II grant award of $500,000 for research related to research of a rapid fibrinogen assay			$ 13,735
Phase I grant award of $487,269 for research related to thrombolytic drug research		$ 8,587	235,788
Phase II grant award of $315,041 for research related to thromobolytic drug research		114,500	
Phase I grant award of $75,000 for research related to rapid monitoring of antithrombin agents		75,000	
Grant award of $100,000 for research related to a rapid immunoassay for acute myacardial injury detection	$ 10,466	94,447	
Phase II grant award of $541,383 for research related to rapid monitoring of antithrombin agents	243,738		
	$254,204	$292,534	$249,523

</TABLE>

7. LONG-TERM DEBT

Long-term debt as of December 31, 1996 and 1995 consisted of the following:

<TABLE>
<CAPTION>

	Fair Value 1996	1996	1995
<S>	<C>	<C>	<C>
Convertible financial assistance agreement (see below)	$ 49,623	$ 50,000	$ 50,000
15.0% note payable due February 1, 1995, collateralized by subordinated claims to all assets			85,000
12% note payable due May 3, 1996, collateralized by certain inventories			110,000
Bank notes payable repaid in 1996			494,178
$	49,623	50,000	739,178
Current portion of long-term debt			(282,566)
Long-term debt, excluding current portion		$ 50,000	$ 456,612

</TABLE>

In January 1994, the Company received a $50,000 loan pursuant to a financial assistance agreement to fund research. The funds were used only for direct costs related to the approved project. The $50,000, plus interest at 7.5% per annum, is due in January 1999. The loan, at the request of the lender, can be converted at any time into common stock based on an exercise price of $5.33 per share, subject to adjustment for stock splits, stock dividends, combinations and other similar events. Accrued but unpaid interest is not convertible into common stock. This agreement includes certain covenants relating to, among other things, use of funds and maintenance of a significant presence in the State of North Carolina for a period of five years. Management believes the Company was in compliance with all of these covenants at December 31, 1996 and 1995. 12

<PAGE>

8. LEASES

The Company leases its office space under a noncancelable operating lease agreement. In January 1995, the lease term was extended from 1996 to 2001. In addition, the Company leases certain equipment under various capital and

operating lease agreements. Equipment held under capital leases as of December 31, 1996 and 1995 was $390,691 and $387,569, respectively, and the related accumulated amortization was $345,105 and $292,533, respectively. Rent expense related to operating leases totaled $416,635, $317,334, and $191,654 for the years ended December 31, 1996, 1995 and 1994, respectively.

Future minimum lease payments as of December 31, 1996 are as follows:

Year ending December 31,	Capital Leases	Operating Leases
1997	$21,617	$ 428,520
1998	17,400	357,392
1999	1,030	372,443
2000	--	382,630
2001		44,911
Total minimum lease payments	40,047	1,585,896
Imputed interest (rates 8.00% to 9.24%)	(3,978)	
Present value of minimum lease payments	36,069	
Less current maturities	19,082	
Long-term capital lease obligations	$16,987	

9. SHAREHOLDERS' EQUITY

Authorized Shares

In November 1995 the Company amended its Articles of Incorporation to increase the number of authorized shares of common stock to 10,000,000.

Common Stock

In January and February 1994, the Company raised $2,723,319, net of issuance costs, in a private placement of 612,638 shares of its common stock at $4.94 per share.

In December 1994, the Company raised $2,878,843, net of issuance costs, in a private placement of 482,372 shares of its Series A participating preferred stock at $6.25 per share.

In January 1995, the Company raised $1,278,806, net of issuance costs, in a private placement of 210,900 shares of Series A participating preferred stock at $6.25 per share.

<PAGE>

9. SHAREHOLDERS' EQUITY (Continued)

Common Stock (Continued)

The authorized and designated Series A preferred stock outstanding prior to the closing of the IPO had rights, preferences and privileges related to liquidation, dividends, voting and conversion. Upon the closing of the IPO, each share of Series A preferred stock was converted into the number of common shares as was determined by dividing $6.25 by the Series A conversion price ($4.94 at the closing of the IPO), resulting in 877,530 shares of common stock. Upon closing of the Company's IPO, in addition to the shares issued upon conversion, the holders of the Series A preferred stock were issued the number of shares of common stock as was determined by dividing the Series A Preferential Amount ($4.94) by the price per share of common stock in the public offering. Based upon the IPO price of $11.00 per share, the holders of the Series A preferred stock were issued an additional 393,904 shares of common stock, representing fair value of $4,332,948. The issuance of these shares has been recorded at par value with a corresponding reduction in additional paid-in capital. As of December 31, 1996 and 1995, no shares of preferred stock were outstanding and none of the 1,000,000 authorized shares were designated. The Company's Board of Directors is authorized, without further shareholder action, to issue preferred stock in one or more series and to fix the voting rights, liquidation preferences, dividend rights, repurchase rights, conversion rights, redemption rights and terms, including sinking fund provisions, and certain other rights and preferences, of the preferred stock. Although there is no current intention to do so, the Board of Directors of the Company may, without shareholder approval, issue shares of a class or series of preferred stock with voting and conversion rights which could adversely affect the voting power or dividend rights of the holders of common stock and may have the effect of delaying, deferring or preventing a change in control of the Company.

Stock Warrants

At December 31, 1994, 6,567 warrants at exercise prices ranging from $0.5056 to $9.0182 per share were outstanding. In conjunction with the 1995 common stock offering, the Company issued warrants for the purchase of 15,189 shares of common stock at $0.3950 per share. In September 1995, 16,455 warrants were

exercised, and, upon the closing of the IPO, 1,504 warrants expired, leaving 3,797 warrants with an exercise price of $4.9377 per share outstanding. In 1996, the remaining 3,797 warrants expired.

Stock Options

The Company has a stock option plan (the "Plan") whereby nonqualified stock options are granted to key employees. Under the terms of the Plan, options to purchase common stock are granted at a price determined by the Board of Directors. These options may be exercised during specified future periods and generally expire ten years from date of grant.

<PAGE>

9. SHAREHOLDERS' EQUITY (Continued)

Stock Options (Continued)

During the year ended December 31, 1994, a stock option plan (the "1994 Plan") was established to purchase common stock. Options granted under the 1994 Plan generally vest over four years. Certain options granted to date under the 1994 Plan also provided for acceleration of vesting upon the achievement by the Company of certain milestones and became fully vested by their terms upon the closing of the IPO. During the year ended December 31, 1995, the exercise price of these options was reduced to $0.79. Also during the year ended December 31, 1995, the Company granted options to purchase 55,694 shares of the Company's common stock at an exercise price of $0.79 which vest over four years.

During 1995, the Company recorded unearned compensation of $426,638, which represented the amount by which the deemed fair value of the Company's common stock exceeded the exercise price on the date of grant. During 1995, $382,638 of the unearned compensation was recorded as compensation expense, which represented the expense related to the options that became fully vested upon the closing of the IPO. The remaining unearned compensation is being amortized to compensation expense over the vesting period, which is generally four years. During 1996, $11,000 of this expense was recognized.

In November 1995 the shareholders of the Company approved, effective upon completion of the IPO, the adoption of the Company's 1995 Stock Plan (the "1995 Plan"). The 1995 Plan reserves 238,150 shares of the Company's common stock for issuance to employees, consultants and directors of the Company. Options granted under the 1995 Plan generally vest over four years and have a term of 10 years.

A summary of the status of the Company's Plans as of December 31, 1996, 1995 and 1994, and changes during the years ending on those dates is presented below:

<TABLE>
<CAPTION>

	1996		1995		1994	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
<S>	<C>	<C>	<C>	<C>	<C>	<C>
Outstanding at beginning of year	865,000	$3.58	601,192		225,154	
Granted	109,000	$4.50	271,984		490,506	
Exercised	(126,508)	$0.73	(3,670)		(22,114)	
Forfeited	(89,696)	$0.58	(4,506)		(92,354)	
Outstanding at end of year	757,796	$2.44	865,000	$3.58	601,192	$0.72
Options exercisable at year-end	451,558		593,016		74,619	

</TABLE>

<PAGE>

9. SHAREHOLDERS' EQUITY (Continued)

The following table summarizes information about the Plan's stock options at December 31, 1996:

<TABLE>
<CAPTION>

Options Outstanding				Options Exercisabld	
Range of	Number Outstanding	Weighted Average Remaining Contractual	Weighted Average Exercise	Number Excersibale	Weighted Average Exercise

Exercise Prices	at 12/31/96	Life	Price	at 12/31/96	Price
<S>	<C>	<C>	<C>	<C>	<C>
$0.40 - $0.79	432,506	8.1 years	$ 0.78	390,736	$0.78
$4.50 - $12.10	325,290	9.2 years	$ 4.64	60,822	$5.25
	757,796			451,558	

</TABLE>

10. SIGNIFICANT CUSTOMERS AND CONCENTRATION OF CREDIT RISK

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents, short-term investments and accounts receivable. The Company places its temporary cash in accounts with federally insured depository institutions. At December 31, 1996 the Company had a majority of its cash invested in one financial institution. The Company's short-term investments consist of obligations of the U.S. Treasury. Concentrations of credit risk with respect to trade receivables exist due to the Company's small customer base. Periodic credit evaluations of customers' financial condition are performed and generally no collateral is required. The Company establishes reserves for expected credit losses and such losses, in the aggregate, have not exceeded management's expectations.

During the years ended December 31, 1996, 1995 and 1994 there were sales to three Coeur customers that exceeded 10% of net sales. Sales to these customers were: 1996 - customer A, $2,192,778 (34%), customer B, $748,280 (12%) and customer C, $671,188 (10%); 1995 - customer A, $2,095,548 (40%), customer B, $790,132 (15%) and customer C, $632,781(12%); 1994 - customer A, $2,269,012 (48%), customer B, $712,155 (15%) and customer C, $733,138(16%).

The Company operates in a single industry segment, providing medical diagnostic and imaging products.

The Company has operations in two geographic regions, the United States and Europe. The geographic areas are, to a significant degree, interdependent with respect to research, product supply and business expertise. Sales between geographic areas are generally priced to recover cost plus appropriate mark-up for profit. The Company began its European operations in 1994 and revenues from its foreign operations did not exceed 10% of its consolidated revenues in 1994 or 1995. During 1996, revenues from foreign operations were approximately $725,000, substantially all of which were from customers in Europe and the United Kingdom. In addition, the Company's identifiable assets of its foreign operations are less than 10% of its consolidated total assets.

<PAGE>

10. SIGNIFICANT CUSTOMERS AND CONCENTRATION OF CREDIT RISK (Continued)

The Company generated revenue from export sales as follows:

	1996	1995	1994
United Kingdom	$ 957,980	$ 850,311	$ 976,918
Other	684,728	650,633	616,422
Total export sales	$1,642,708	$1,500,944	$1,593,340

11. LICENSE AGREEMENTS

The Company entered into a license agreement with Tokuyama Soda Company, Ltd. ("TS"), as amended in December 1995, pursuant to which the Company granted TS exclusive rights to manufacture and sell PT and aPTT tests and analyzers in certain Asian countries. The Company received royalty payments under this agreement of $32,835, $63,176 and $46,450 during the years ended December 31 1996, 1995 and 1994, respectively.

Additionally, the Company had a license agreement with Boehringer Mannheim Corporation. The Company received royalty payments under this agreement of $61,596 and $88,841 during the years ended December 31, 1995 and 1994, respectively. All obligations under this license agreement were terminated effective June 30, 1995.

12. INCOME TAXES

Income tax expense consisted entirely of current state taxes of $51,860, $82,136

and $91,250 for the years ended December 31, 1996, 1995 and 1994, respectively.

A reconciliation of expected income tax at the statutory Federal rate of 34% with the actual income tax expense for the years ended December 31, 1996, 1995 and 1994 is as follows:

<TABLE>
<CAPTION>

	1996	1995	1994
<S>	<C>	<C>	<C>
Expected income tax benefit at statutory rate	$(1,706,576)	$(1,315,832)	$ (590,386)
State tax provision (benefit)	(114,326)	(25,373)	19,105
Goodwill amortization	62,830	62,985	66,811
Compensation paid with incentive stock options	3,740	130,097	
Other	16,192	157,259	34,720
Change in valuation allowance and June 30, 1995, respectively	1,790,000	1,073,000	561,000
Net income tax provision	$ 51,860	$ 82,136	$ 91,250

</TABLE>

<PAGE>

12. INCOME TAXES (Continued)

The components of the net deferred tax assets and net deferred tax liabilities as of December 31, 1996 and 1995 were as follows:

	1996	1995
Deferred tax assets:		
Accrued expenses	$ 17,000	
Other	28,000	$ 38,000
Alternative minimum tax credits	9,000	9,000
Net operating loss carryforward	6,446,000	4,591,000
Research and development credits	229,000	229,000
Foreign tax credits	35,000	35,000
Total gross deferred tax assets	6,764,000	4,902,000
Valuation allowance	(6,536,000)	(4,746,000)
Net deferred tax assets	228,000	156,000
Deferred tax liabilities:		
Patents	160,000	130,000
Fixed assets	68,000	26,000
Total gross deferred tax liabilities	228,000	156,000
Net deferred taxes	$ -	$ -

At December 31, 1996 and 1995, the Company had approximately $16,089,000 and $11,349,000, respectively, of combined net operating losses, $229,000 of research and development tax credits, $35,000 of foreign tax credits, and $9,000 of alternative minimum tax credits available to offset future federal income taxes. These carryforwards expire in 2002 through 2010 if not utilized. At December 31, 1996 and 1995, for state income tax purposes, the Company had combined net operating loss carryforwards of approximately $12,020,782 and $8,977,000, respectively. These carryforwards expire in 1997 through 2001 if not utilized. To the extent that Coeur's net operating losses incurred through 1994 (approximately $2,000,000 at December 31, 1996) are utilized in the future, the benefit will reduce the excess of cost over fair value of net assets acquired.

Due to the Company's and Coeur's history of operating losses and uncertainty regarding future operations, management has determined that a valuation allowance equal to the amount of net deferred tax assets is required.

As a result of changes in ownership, as defined by Internal Revenue Code Section 382, Coeur's losses through 1994 and the Company's consolidated losses through January 1995 will be subject to an annual limitation of $175,000 and $482,000, respectively.

An additional change in ownership occurred in 1996 in connection with the Company's IPO which subjects the losses incurred since January 1995 to an incremental annual limitation of $1,954,000 per year.

13. CONTINGENCIES

The Company is subject to certain legal proceedings and claims arising in the ordinary course of business. It is management's opinion that the disposition of these matters will not have a material adverse effect on the consolidated financial position, results of operations or liquidity of the Company.

<PAGE>

14. COMMITMENTS

The Company has several agreements to sell its products to customers at fixed prices. Management does not anticipate any losses resulting from these commitments.

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CARDIOVASCULAR DIAGNOSTICS, INC.
SCHEDULE II - VALUATION AND QUALIFYING ACCOUNTS
for the years ended December 31, 1996, 1995 and 1994

<TABLE>
<CAPTION>

<S>	<C> Balance at Beginning of Period	<C> Charged to Costs and Expenses	<C> Deductions	<C> Balance at End of Period
Year Ended December 31, 1996				
Deducted from asset accounts:				
Accounts Receivable Reserves (a)	$ 40,395	$ 0	$ 35,395 (f)	$ 5,000
Inventory Reserves (b)	$ 82,000	$ 40,000	$ 73,744 (e)	$ 48,256
Added to liability accounts:				
Warranty Reserves (c)	$ 50,000	$ 0	$ 6,155 (d)	$ 43,845
Year Ended December 31, 1995				
Deducted from asset accounts:				
Accounts Receivable Reserves (a)	$ 0	$ 40,395	$ 0	$ 40,395
Inventory Reserves (b)	$ 0	$ 152,578	$ 70,578 (e)	$ 82,000
Added to liability accounts:				
Warranty Reserves (c)	$ 0	$ 50,000	$ 0	$ 50,000
Year Ended December 31, 1994				
Deducted from asset accounts:				
Accounts Receivable Reserves (a)	$ 0	$ 12,000	$ 12,000 (f)	$ 0

</TABLE>

(a) Represents an allowance for both product returns and doubtful accounts. Activity represents doubtful accounts only. Revenues have been reduced directly for product returns.
(b) Represents an allowance for excess and aging inventory and lower of cost or market adjustments.
(c) Represents an allowance for estimated costs to be incurred under warranty obligations.
(d) Represents costs incurred to fulfill warranty claims.
(e) Represents inventory items written down to lower of cost or market.
(f) Represents uncollectible accounts written off.

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REPORT OF INDEPENDENT ACCOUNTANTS

To the Board of Directors and Shareholders
Cardiovascular Diagnostics, Inc.

Our report on the consolidated financial statements of Cardiovascular Diagnostics, Inc. and subsidiaries is included on page F-2 of this Form 10-K. In connection with our audits of such financial statements, we have also audited the related financial statement schedule, Schedule II - Valuation and Qualifying Accounts, including on page S-1 of this Form 10-K.

In our opinion, the consolidated financial statement schedule referred to above, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information required to be included therein.

/s/ COOPERS & LYBRAND
Raleigh, North Carolina
February 20, 1997

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SIGNATURE

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 DIAGNOSTICS, INC.

Date: March 26, 1997 By: /s/ John P. Funkhouser
John P. Funkhouser,
President

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

<TABLE>
<CAPTION>

Signature	Title	Date
<S>	<C>	<C>
/s/John P. Funkhouser John P. Funkhouser	President and Director (Principal Executive Officer)	March 26, 1997
/s/ B. Denise Hobbs B. Denise Hobbs	Treasurer and Vice President of Finance and Administration (Principal Financial and Accounting Officer)	March 26, 1997
/s/ Dennis J. Dougherty Dennis J. Dougherty	Director	March 26, 1997
William A. Hawkins	Director	March __, 1997
/s/ John K. Pirotte John K. Pirotte	Director	March 26, 1997
/s/ Stephen R. Puckett Stephen R. Puckett	Director	March 25, 1997
/s/ Philip R. Tracy Philip R. Tracy	Director	March 26, 1997
Paul W. Wiles	Director	March __, 1997

</TABLE>

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<TYPE>EX-10
<SEQUENCE>2
<DESCRIPTION>EXHIBIT 10.20
<TEXT>

<PAGE>

PATENT SUBLICENSE AGREEMENT

THIS PATENT SUBLICENSE AGREEMENT (this "Agreement"), effective as of December 9, 1996 (the "Effective Date"), is made and entered into by and between CARDIOVASCULAR DIAGNOSTICS, INC., a North Carolina corporation with principal offices at 5301 Departure Drive, Raleigh, North Carolina ("CDI") and KNOLL AG, a corporation organized under the laws of the Federal Republic of Germany with principal offices at Knollstrasse, 6700 Ludwigshafen, Federal Republic of Germany ("Knoll").

WHEREAS, Knoll owns or controls by exclusive worldwide license certain "Patent Rights" (as later defined herein) pursuant to the terms of a License Agreement with Max-Planck- Gesellschaft (the "MPG License Agreement") a copy of which is attached hereto as Exhibit A and Knoll has the right to grant sublicenses thereunder;

WHEREAS, CDI desires to use the Patent Rights in commercial applications; and

WHEREAS, Knoll is willing to grant, and CDI desires to obtain, an exclusive sublicense under the MPG License Agreement in accordance with the terms and conditions set forth herein.

NOW, THEREFORE, the parties hereto agree as follows:

SECTION 1

DEFINITIONS

For the purposes of this Agreement, the following words and phrases shall have the following meanings:

1.1 "Product" shall mean the technology covered by the Patent Rights included in a CDI test card or other CDI product and a wet-chemistry based technology as described in Knoll's validation report VR-HPA-02.

1.2 "Net Sales" shall mean the aggregate invoiced sales price received by CDI from its customers (including distributors) on Sales, less any amounts, to the extent such amounts are included in the invoiced sales price, for: (a) actual allowances for damages and returned goods; (b) quantity and trade discounts actually allow and taken; (c) transportation shipping and handling costs and insurance; (d) sales, excise, turnover, value-added and other similar direct taxes, and (e) customs duties.

1.3 "Patent Rights" shall mean all inventions and know-how (patented, patentable or non-patentable) and any and all intellectual property rights of Knoll, either existing as of the Effective Date or subsequent thereto, relating to a test known as

*[ ] CONFIDENTIAL TREATMENT REQUESTED; CERTAIN INFORMATION OMITTED AND FILED SEPARATELY WITH THE SEC.

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an ecarin clotting time test, as further described by illustration on Exhibit B, and methods and procedures for use of such device, including without limitation all matters described, claimed or covered by (i) United States and foreign patents listed on Exhibit C; (ii) United States and foreign patent applications; (iii) any additions, continuations, continuations- in-part, divisionals, reissues or extensions based on any of the foregoing patents or patent applications; (iv) any patent or intellectual property rights obtained from any of the foregoing patent applications; and (v) any trade secrets, know how and other intellectual property rights relating to the above to the extent Knoll has access to and control of any such Rights.

1.4 "Sale" shall mean any sale, transfer or other disposition to a third party of technology covered by the Patent Rights which technology is included as a component or portion of a Product.

SECTION 2

GRANT OF RIGHTS

2.1 Grant. Subject to the terms and conditions of this Agreement, Knoll hereby grants to CDI a perpetual, exclusive, worldwide, royalty-bearing

sublicense, including the right to grant additional sublicenses, under the Patent Rights to develop, make, have made, use, have used, modify, have modified, sell and have sold the Products. Sublicenses granted by CDI to third parties shall include terms and conditions substantially similar to terms and conditions contained therein and shall be subject to the approval by Knoll which shall not be unreasonably withheld. In addition, this sublicense, and any sublicenses granted by CDI, shall terminate simultaneously with the termination of the MPG License Agreement and any sublicenses granted by CDI shall terminate simultaneously with the termination of this Agreement.

2.2 Subcontracts. The following shall not be deemed to be sublicenses hereunder: (a) appointment of a third party (including, but not limited to, a distributor) to market, sell, use or otherwise dispose of Products; (b) subcontracting of a third party to develop Products; or (c) subcontracting of a third party to manufacture Products.

2.3 Sales of Products. The exclusive worldwide license granted by Knoll shall include but not be limited to, a license to sell Products to CDI's customers and to convey to any CDI customer rights to use and resell the Products sold to such customers by CDI.

2.4 Delivery. Promptly after the Effective Date and thereafter upon reasonable notice, Knoll shall deliver to CDI all data, documentation and other physical embodiments of the Patent Rights to the extent that Knoll has access to and control of any

such materials, together with all cooperation, assistance and access to data reasonably requested by CDI including but not limited to visits by CDI personnel to Knoll facilities. In addition, Knoll shall provide CDI with access to all of its available data which CDI may require in connection with the validation and registration of the Product.

SECTION 3

GRANT OF RIGHTS

CDI has the obligation to exclusively purchase its requirements of ecarin standard reagent from Pentapharm until December 31, 1998 at conditions to be agreed upon. Based on an agreement between Knoll and Pentapharm dated February 15, 1996.

SECTION 4

CONSIDERATION

4.1 Royalties. In consideration for the license granted to CDI herein, CDI shall pay to Knoll royalties equal to:

4.1.1 [ ] (of which [ ] remunerates the patent rights and [ ] remunerates the Know-How of Knoll) for its Net- Sales in countries in which a patent has been filed or granted and for its export from such countries to countries without patent protection; and

4.1.2 [ ] of Net-Sales in countries where the product is manufactured and sold by CDI or sublicensees and in which no patent is filed or granted, but only as long as the product is the only product in the market based on or related to the licensed technology, but in no case longer than the validity of the US patent.

4.2 No Multiple or Cumulative Royalties. CDI shall have no obligation to pay to Knoll multiple royalties because a Product, or the manufacture, use or sale of a Product is or shall be covered in any country by more than one patent or patent application licensed under this Agreement. In addition, the two (2) royalty rates provided in Section 4.1 are mutually exclusive of one another and are not cumulative; only one of such two rates shall apply to a given Sale. In no event shall royalties payable to Knoll on any Sale exceed [ ] percent [ ] of Net Sales attributed to such Sale.

4.3 Combination Product Royalties. In the event a Product is sold in combination with other components whose manufacture, use or sale by an unlicensed party would not constitute an infringement of the Patent Rights ("Combination Product"), Net Sales for the purpose of determining royalties payments shall be calculated by multiplying the actual net receipts attributed to the Combination Product by the fraction A/B, where A is the

*[ ] CONFIDENTIAL TREATMENT REQUESTED; CERTAIN INFORMATION OMITTED AND FILED SEPARATELY WITH THE SEC.

invoiced sales price of the Product sold separately and B is the invoiced sales price of the Combination Product. In the event that no separate sales of such

Product are made by CDI, Net Sales for determining royalties payments on the Combination Product shall be calculated by reasonably allocating the actual net receipts attributed to the Combination Product between the Product and the other components, based upon the fair value of the components.

4.4 Term of Royalties Obligation.

4.4.1 The obligation of CDI to pay to Knoll royalties pursuant to section 4.1.1 or 4.1.2 shall commence upon the receipt of revenue from the first sale. Upon (i) expiration of the patent in a country or (ii) if the patent in a country has been determined invalid or unenforceable by a competent court or administrative body provident that such determination is final and unappealed or unappealable or (iii) the parties agree that a patent is no longer valid or (iv) upon expiration of the term mentioned in section 4.1.2, CDI shall have no further obligation to pay the [ ] royalty to Knoll, but will continue to pay to Knoll the [ ] Know-How royalty as long as the product is sold anywhere in the world.

4.5 Payments of Sublicensees. In case CDI receives from its sublicensees a down payment or other form of remuneration made in connection with the grant of sublicense rights and not for work to be performed by CDI, and except for royalties, CDI shall transfer [ ] of such payment to Knoll.

SECTION 5

ROYALTY PAYMENTS AND ACCOUNTING

5.1 Royalty Statement and Payments. Within sixty (60) days after the end of each calendar quarter during the term of this Agreement, CDI shall deliver to Knoll:

5.1.1 A statement showing the basis for the royalty payment due for such quarter, including but not limited to: (i) the number of Sales during the reporting period; (ii) the invoiced sales price for all Sales during the reporting period; (iii) the total Net Sales during the reporting period; and (iv) any royalties due Knoll pursuant to Section 4 for the reporting period. In the event that no royalty is due for any calendar quarter during the term of this Agreement, CDI shall so report; and

5.1.2 Payment in United States dollars of the amount of royalties due Knoll based on CDI's statement required under Section 5.1.1.

5.2 Audit Rights. Knoll shall be entitled to retain, at Knoll's expense, an independent accounting firm acceptable to CDI

*[ ] CONFIDENTIAL TREATMENT REQUESTED; CERTAIN INFORMATION OMITTED AND FILED SEPARATELY WITH THE SEC.

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to conduct one (1) audit per calendar year of CDI's books and records of account for payments made within twelve (12) months of such audit, regarding royalties payable to Knoll for the sole purpose of verifying the accuracy of such payments, such audit to be conducted during CDI's normal business hours and after ten (10) days written notice. The accounting firm shall report to Knoll only whether there is a royalty underpayment and, if so, the amount thereof. In the event such accounting firm reports to Knoll that there is a royalty underpayment, CDI shall promptly remit to Knoll all amounts due, including interest on such underpayment from the date due until paid at the prime rate of interest quoted in the Wall Street Journal for such period plus [ ] percent [ ]. If the results of such audit indicate that CDI has under paid its royalty obligation by [ ] percent [ ] or more for any 12 month period examined, CDI shall bear the expense of such audit.

SECTION 6

REPRESENTATIONS, WARRANTIES AND INDEMNIFICATION

6.1 Representations and Warranties.

6.1.1 Knoll represents and warrants that: (i) Knoll is the sole and exclusive owner or licensor with right to sublicense the Patent Rights; (ii) Knoll has not previously granted, and will not grant to any third party during the term of this Agreement, any rights under the Patent Rights; and (iii) Knoll has full power, right and authority to grant the rights and licenses granted in this Agreement.

6.1.2 CDI represents and warrants that CDI has full power, right and authority to enter into and carry out its obligations under this Agreement.

6.2 Limitation. EXCEPT FOR THE EXPRESS WARRANTIES IN THIS SECTION 6, KNOLL MAKES NO WARRANTIES FOR THE PATENT RIGHTS OR PRODUCTS, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, STATUTORY OR OTHERWISE, AND KNOLL SPECIFICALLY DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY OR WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.

6.3 Indemnification.

6.3.1 Knoll hereby agrees to defend and indemnify CDI against, and hold CDI harmless from, any loss, cost, liability or expense (including court costs and reasonable fees of attorneys and other professionals) arising out of or in connection with a breach of Knoll's representations and warranties in Section 6.1.1 above, provided that: (i) Knoll shall have sole control of such defense provided, however, if Knoll fails to take control, CDI shall have the right but not the obligation to do so, and (ii) CDI shall provide notice promptly

*[ ] CONFIDENTIAL TREATMENT REQUESTED; CERTAIN INFORMATION OMITTED AND FILED SEPARATELY WITH THE SEC.

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to Knoll of any actual or threatened claim of which CDI becomes aware. In the event of any such claim, CDI shall provide Knoll, at Knoll's expense, information and assistance as Knoll may reasonably request for purposes of defense.

6.3.2 CDI hereby agrees to defend and indemnify Knoll against, and hold Knoll harmless from, any loss, cost, liability or expense (including court costs and reasonable fees of attorneys and other professionals) arising out of or in connection with CDI's Manufacture, use or sale of the Products, excluding claims covered by Section 6.3.1 above; provided that: (i) CDI shall have sole control of such defense and (ii) Knoll shall provide notice promptly to CDI of any actual or threatened claim of which Knoll becomes aware.

SECTION 7

CONFIDENTIALITY

7.1 General. Except as otherwise expressly provided in this Agreement, each party shall hold in strict confidence and not use or disclose to any third party (other than employees, consultants and advisors who are similarly bound in writing) any product, technical, manufacturing, process, marketing, financial, business or other information, ideas or know-how identified in writing as confidential ("Confidential Information") of or used by the other party; provided, however, that Confidential Information of a party shall not include:

7.1.1 Information which at the time of disclosure was previously known to the receiving party as demonstrated by written records;

7.1.2 Information which at the time of disclosure is published or otherwise generally available to the public; or

7.1.3 Information which, after disclosure by the other party, is published or otherwise becomes generally available to the public through no breach of this Agreement by the receiving party.

7.2 Exceptions. A party may disclose Confidential Information of the other:

7.2.1 In connection with the order of a court or other governmental body; provided, however, that written notice is provided promptly to the other party to enable the other party to seek a protective order or otherwise prevent disclosure of such information;

7.2.2 As required by or in compliance with laws or regulations; provided, however, that written notice is provided promptly to the other party to enable the other party to seek a

<PAGE>

protective order or otherwise prevent disclosure of such information;

7.2.3 In confidence, to accountants, banks and financing sources and their advisors; or

7.2.4 In confidence, in connection with a merger or acquisition or proposed merger or acquisition, or the like.

7.3 Terms of this Agreement. CDI and Knoll agree to not disclose the financial terms or conditions of this Agreement to any third party without the prior written consent of the other party, except as may be required by law. Each party shall use reasonable efforts to provide the other party with five (5) days advance notice of any disclosure required by law where the disclosure could have an adverse impact on the rights of a party hereunder.

7.4 Remedies. Any breach of the restrictions contained in this Section 7 is a breach of this Agreement which will cause irreparable harm to the non-breaching party entitling such non- breaching party to injunctive relief in

addition to all legal remedies.

SECTION 8

PATENT PROSECUTION, ENFORCEMENT AND DEFENSE

8.1 Patent Prosecution.

8.1.1 Knoll shall bear the principal responsibility for and shall file and prosecute all patent applications and maintain all patents within the Patent Rights in the United States of America and in foreign countries; provided, however, that Knoll shall consult with CDI before initiating or ceasing any filing within the Patent Rights. Knoll shall keep CDI reasonably informed of the status of the patents and applications within the Patent Rights. In the event that Knoll elects to not file any patent application or ceases prosecution of any patent application or maintenance of any patent within the Patent Rights, Knoll shall inform CDI in due time, and CDI shall have the right, but not an obligation, to file such patent applications, prosecute such patent application or maintain such patent within the Patent Rights.

8.1.2 Payment of all costs and expenses relating to the filing, prosecution, and maintenance of the Patent Rights in the United States and in foreign jurisdictions after the Effective Date shall be the responsibility of Knoll, provided that upon reimbursement of such costs and expenses to Knoll by CDI, CDI may then deduct such amounts from the amounts owing to Knoll under Section 4. Notwithstanding the above, CDI shall not be obligated to reimburse Knoll costs and expenses relating to

the filing or prosecution of any patent application or maintenance of any patent within the Patent Rights in countries where CDI reasonably objects to such filing, prosecution or maintenance. In any country where CDI fails to reimburse Knoll fees and costs relating to filing or prosecution of a patent application or maintenance of a patent within the Patent Rights, CDI's rights and license under this Agreement in such country shall terminate six (6) months after receipt by CDI of the initial request by Knoll for reimbursement where the reimbursement is made by CDI within such six (6) month period. Reimbursement due Knoll pursuant to this Section 8.1.2 shall be paid by CDI within thirty days (30) (but not later than one hundred eighty (180) days) of CDI's receipt of Knoll's itemized invoice.

8.2 Patent Enforcement. During the term of this Agreement, CDI shall notify Knoll promptly in writing of any alleged infringement by a third party of the Patent Rights exclusively licensed to CDI under this Agreement, and provide Knoll any available evidence thereof. In the event that Knoll fails to cause any infringement to terminate, or fails to initiate suit or action to abate any infringement, within ninety (90) days after receipt of CDI's written notice of such infringement, or in the event that Knoll discontinues the prosecution of any such suit or action after commencement thereof, CDI may, effective as of the date of such failure or discontinuance, at CDI's sole option, implement any or all of the following rights and remedies:

8.2.1 Withhold an amount equal to the difference between the royalty due to Knoll hereunder and the royalty payable by Knoll under the MPG License Agreement during the period from the commencement of such infringement until such infringement is terminated by court judgment or otherwise; and

8.2.2 Initiate and prosecute, or continue prosecution of, at CDI's own cost and expense, any such suit or action, in which event upon CDI's request, Knoll shall make available to CDI all information in Knoll's possession and provide CDI with assistance reasonably necessary to permit CDI to bring and prosecute, or continue prosecution of, such suit or action. CDI shall be entitled to retain for CDI any recovery realized as a result of a suit, action or other proceeding initiated and prosecuted by CDI to enforce the Patent Rights without obligation to Knoll.

8.3 Patent Defense. During the term of this Agreement, CDI shall notify Knoll promptly in writing of any claim asserted against CDI by any third party alleging infringement of any patent owned by such third party in connection with CDI's manufacture, use or sale of Products. Notwithstanding anything herein to the contrary, if, during the term of this Agreement, the manufacture, use or sale of Products by CDI under any issued and valid patent within the Patent Rights would infringe any patent owned by a third party, CDI shall have the right to deduct

from the royalties payable to Knoll under Section 4 an amount equal to the difference between the royalty due hereunder and the royalty payable by Knoll

under the MPG License Agreement.

8.4 Cooperation. In any suit, action or other proceeding in connection with enforcement and/or defense of the Patent Rights, Knoll and CDI shall cooperate fully, and upon the request and, at the expense of the party initiating and prosecuting such suit, action or other proceeding, the other party shall make available to such party at reasonable times and under appropriate conditions all relevant personnel, records, papers, information, samples, specimens and other similar materials in such other party's possession.

SECTION 9

TERM AND TERMINATION

9.1 Term. The term of this agreement shall commence on the effective date and shall continue in full force and effect as long as CDI or its sublicensees manufacture and market the product anywhere in the world, unless terminated prior to such date pursuant to this section 9.

9.2 Termination for Cause. Either party shall have the right to terminate this Agreement following any material breach or default in performance under this Agreement by the other party upon thirty (30) days prior written notice by certified mail to the breaching party specifying the nature of the breach or default. Unless the breaching party has cured the breach or default prior to the expiration of such thirty (30) day period, or such breaching party has initiated good faith efforts to cure any such breach which the party is unable to cure within such thirty-day period, and during the period that such efforts continue no termination may be declared, the non-breaching party, at its sole option, may terminate this Agreement upon written notice to the breaching party. Termination of this Agreement shall become effective upon receipt of such notice by the breaching party. Knoll shall have the right to terminate this agreement forthwith by giving six (6) months previous notice in case CDI is not actively pursuing to sell one/or the other technology-based product (wet/or dry chemistry) within eighteen (18) months after approval of the first direct thrombin inhibitor in North America or the EC, unless such failure is due to regulatory problems beyond the control of CDI.

9.3 Effect of Termination. In case Knoll terminates this agreement forthwith according to section 9.2 CDI shall transfer to Knoll or a third party designated by Knoll all product registrations and shall be entitled to sell remaining stock of the product during a term of six months after the expiration of the agreement unless Knoll or a third party designated by Knoll purchases such stock at CDI's cost price.

9.4 Survival. The following sections shall survive expiration or termination of this Agreement for any reason: Sections 5, 6, 7 and 10.

SECTION 10

GENERAL PROVISIONS

10.1 Development. The parties acknowledge that the technology underlying the Patent Rights requires additional development on the part of CDI. CDI acknowledges that it shall bear all development risk and cost associated with the development and commercialization of the Product. CDI shall use commercially reasonable efforts to exploit the Product where such exploitation is commercially feasible to do so. Consequently, CDI will use commercially reasonable efforts to file product registrations in the countries in which direct thrombin inhibitors are approved or under clinical development provided, however, CDI shall have [ ] months to complete such filing subsequent to the date that CDI and Knoll agree that CDI is in receipt of all data relating to the drug necessary to complete CDI's registration for the country where the drug approval has been granted.

CDI and Knoll acknowledge that CDI may have tactical, technical or economic reasons for not completing any such filing and CDI shall provide Knoll notice of any such reasons within a reasonable period of time after any such decision is made by CDI.

In the event that CDI does not have a tactical, technical or economic reason for failing to complete a filing in a country where Knoll has revised PEG-hirudin drug approval, the parties shall negotiate in good faith with respect to each such country.

CDI shall provide Knoll with a semi-annual written report of its product development activities, product registration activities and business development activities relating to the product, to the extent such disclosures are permitted under any nondisclosure agreements entered into by CDI with its collaborating, strategic or other corporate partners. CDI and Knoll shall

cooperate with one another in the registration process, and CDI may request Knoll to attend regulatory meetings with governmental regulatory agencies.

10.2 Further Assurance. During the term of this Agreement, and at any time or from time to time on and after the Effective Date, Knoll shall at the request of CDI: (i) deliver to CDI such records, data or other documents consistent with the provisions of this Agreement, (ii) execute, and deliver or cause to be delivered, all such assignments, consents, documents or further instruments of transfer or license, and (iii) take or cause to be taken all such other actions, as CDI may reasonably deem

*[ ] CONFIDENTIAL TREATMENT REQUESTED; CERTAIN INFORMATION OMITTED AND FILED SEPARATELY WITH THE SEC.

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necessary or desirable in order for CDI to obtain the full benefits of this Agreement and the transactions contemplated hereby.

10.3 Governing Law. This Agreement shall be governed by, and construed and interpreted in accordance with, the laws of the Federal Republic of Germany, without reference to conflict of laws principles or statutory rule of arbitration.

10.4 Arbitration. All disputes arising in connection with this Agreement shall be settled according to the Rules of Conciliation and Arbitration of the Zurich Chamber of Commerce. If such settlement cannot be achieved the dispute shall be submitted to the arbitration Court of the Zurich Chamber of Commerce for final decision according to the aforesaid Rules of Conciliation and Arbitration.

10.5 Force Majeure. Neither party shall be liable for any loss, damage or penalty resulting from delays or failures in performance resulting from acts of God and other causes beyond its control. Each party agrees to notify the other promptly of any circumstance delaying its performance and to resume performance as soon thereafter as is reasonably practicable.

10.6 Assignment. The parties agree that their rights and obligations under this Agreement may not be transferred or assigned to a third party without the prior written consent of the other party hereto. Notwithstanding the foregoing, CDI may transfer or assign its rights and obligations under this Agreement to a successor to all or substantially all of its business or assets relating to this Agreement whether by sale, merger, operation of law or otherwise.

10.7 Limitation of Liability. IN NO EVENT WILL EITHER PARTY BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT DAMAGES ARISING IN ANY WAY OUT OF THIS AGREEMENT, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY. THIS LIMITATION WILL APPLY EVEN IF THE OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

10.8 No Third Party Beneficiaries. Knoll and CDI intend that only Knoll and CDI will benefit from, and are entitled to enforce the provisions of, this Agreement and that no third party beneficiary is intended under this Agreement.

10.9 Modifications. No modification to this Agreement, nor any waiver of any rights, shall be effective unless assented to in writing by the party to be charged and the waiver of any breach or default shall not constitute a waiver of any other right hereunder or any subsequent breach or default.

10.10 Notices. Any required notices hereunder shall be given in writing at the address of each party set forth above, or to such other address as either party may substitute by written

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notice to the other in the manner contemplated herein, and shall be deemed served when delivered or, if delivery is not accomplished by reason or some fault of the addressee, when tendered.

10.11 Descriptive Headings. The headings of the several sections of this Agreement are intended for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.

10.12 Entire Agreement. This Agreement constitutes the entire and exclusive Agreement between the parties hereto with respect to the subject matter hereof, and supersedes and cancels all previous registrations, agreements, commitment and writings in respect thereof.

10.13 Severability. In the event that any provision of this Agreement becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement shall continue in full force and effect without said provision; provided that no such severability shall be effective if

it materially changes the economic benefit of this Agreement to either Knoll or CDI. In the event that any provision of this Agreement becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, and severability of such provision would materially change the economic benefit of this Agreement to either Knoll or CDI, Knoll and CDI shall modify such provision in accordance with Section 10.8 to obtain a legal, enforceable and valid provision and provide an economic benefit to Knoll and CDI that most nearly effects Knoll's and CDI's intent in entering into this Agreement.

10.14 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument.

[The next page is the signature page]

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IN WITNESS WHEREOF, the undersigned are duly authorized to execute this Agreement on behalf of Knoll and CDI as applicable.

KNOLL AG	CARDIOVASCULAR DIAGNOSTICS, INC.
By:_____	By:_____
Print Name:_____	Print Name:_____
Title:_____	Title:_____

SS1-CORP-7695-1-43868.7

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BAYER CORPORATION - CARDIOVASCULAR DIAGNOSTICS, INC.
DEVELOPMENT AGREEMENT

This Development Agreement is made this 21st day of August, 1996 ("Effective Date") among Cardiovascular Diagnostics, Inc., a North Carolina corporation with its principal place of business located at 5301 Departure Drive, Raleigh, North Carolina 27604 (the "Company") and Bayer Corporation, an Indiana corporation with a principal place of business at 400 Morgan Lane, West Haven, Connecticut 06516 ("Bayer").

WHEREAS, the Company has developed or is developing proprietary blood test systems, consisting of analyzers and test cards (collectively, the "Products"), including a test designed to measure the amount of the natural anticoagulant Antithrombin III ("ATIII") in whole blood (the "ATIII Product"), the ATIII-specific test cards not yet being approved for marketing by the USFDA;

WHEREAS Bayer is engaged in clinical trials of its Antithrombin III drug (Thrombate III(TM)) at Cincinnati Children' s Hospital under the supervision of investigators Drs. Chris Morris and Richard Brilli, wherein the investigators monitor levels of ATIII by submitting whole blood samples to chromogenic assay;

WHEREAS the Company and Bayer desire to collaborate in the approval of the ATIII Product by allowing the Company access to the clinical trials and samples of whole blood having high or low ATIII levels and data from the chromogenic assay tests that establish those high and low levels, the data to be included in a 510K Medical Device Registration application to the USFDA;

NOW THEREFORE, in consideration of the promises and the obligations of the

parties set forth below and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Development. The company shall complete development of its ATIII Product in accordance with the specifications provided to Bayer on Exhibit A hereto. In order to facilitate such development, Bayer shall provide the Company with access to and data from Bayer' s clinical studies regarding ThrombateIII, and such other consulting, assistance and information as the Company requests from time to time. The Company agrees that it will supply, at its expense, the Products and the ATIII Product for and during the course of Bayer's clinical trials and prior to 510K approval of the ATIII Product. It is currently anticipated by the parties that such development with respect to the test card shall be substantially complete on or before September 30, 1996, and that such development with respect to the related software shall be substantially complete on or before November 30, 1996. In the event that all such development is not substantially complete by November 30, 1996, either party may terminate this Agreement by written notice to the other at its address set forth above.

2. Baver Clinical Trials. As soon as possible following substantial completion of development under Section 1 hereof, Bayer may commence clinical trials of Bayer's Thrombate III product

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(the "Clinical Trials"). Bayer hereby agrees to purchase analyzers and ATIII Products from the Company, and the Company agrees to sell analyzers and ATIII Products to Bayer, on the terms set forth on Exhibit B hereto, in amounts sufficient to satisfy the requirements of the Clinical Trials for products of that nature. The Parties agree that Bayer's obligation to purchase the Products and ATIII Products is contingent upon the Company receiving final approval of the related 510K application from the USFDA.

3. Right of First Refusal. The Company grants to Bayer a First Right of Refusal (`'Right") to exclusively co-market and co-promote world-wide its Products/ATIII Product together with Bayer's Thrombate III product. Marketing and promotion shall include those commercial activities normally required to bring to the attention of a potential customer the beneficial features, use and availability of the Products/ATIII Product through the Company, but shall not include distribution of, of the taking of orders for, the Product/ATIII Products. The Right must be exercised within two (2) months after notification from the Company of approval of the Product's 510K application, or the Right shall expire. Exercise of the Right shall be by written notification to the Company. The parties shall separately negotiate in good faith the essential terms and conditions of the exclusive co-marketing/co-promotion agreement. Failure to either reach agreement on the essential terms and conditions, or failure by Bayer to negotiate in good faith towards such an agreement, within six (6) months of the exercise of the Right, shall terminate the Right.

4. Other Product Purchases. If, during the term of this Agreement, Bayer orders from the Company any Products that have at that time been approved or cleared by the FDA for commercial marketing in the United States, the Company shall sell those Products to Bayer, subject to the Company 's then standard terms and conditions, at the prices reflected on Exhibit C hereto. Promptly after a Product not listed on Exhibit C as of the date hereof receives such FDA approval or clearance, the Company shall add it to Exhibit C and send a copy of the revised Exhibit C to Bayer.

5. Warranties: Limitation of Liability. The Company represents and warrants that the Products at the time of shipment to Bayer or Bayer's designee hereunder shall be free from defects in material and workmanship and will conform to the specifications as found in their respective package inserts. THESE WAPRANTIES ARE EXPRESSLY IN LEU OF ANY AND ALL WARRANTES, EXPRESS OR IMPLED.

THE COMPANY'S LIABILITY ARISING OUT OF THIS AGREEMENT AND/OR DEVELOPMENT AND/OR SALE OF THE PRODUCTS SHALL BE LIMITED TO THE AMOUNT PAID BY BAYER TO THE COMPANY FOR THE PRODUCTS. IN NO EVENT SHALL THE COMPANY BE LIABLE FOR COSTS OF PROCUREMENT OF SUBSTITUTE GOODS BY ANYONE. IN NO EVENT SHALL THE COMPANY BE LIABLE TO BAYER OR ANY OTHER PARTY FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL OR INDIRECT DAMAGES, HOWEVER CAUSED, ON ANY THEORY OF LIABILITY, WHETHER OR NOT THE COMPANY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

6. Governing Law; Assignment; Modification. This agreement shall be governed by the laws of the State of North Carolina, without regard to conflict of laws principles. Neither this Agreement, nor any obligations hereunder may be assigned or otherwise transferred by either party hereto. This Agreement may only be modified by a written instrument signed by each party.

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7. Compliance with Laws. The Company shall manufacture the Products and operate its facilities in compliance with all laws of the United States applicable to the operation of its business generally and to the manufacture of Products under this Agreement.

8. Confidentiality: Proprietary; Information. The parties agree that during the term of this Agreement and any extensions thereto and for a period of five (5) years thereafter, all material and/or information which is transferred hereunder

and which is marked "Confidential" (or if oral, is reduced to writing within 30 days of such transfer and marked "Confidential") shall be held in confidence by the receiving party, and shall not be disclosed to any third party without the prior written consent of the originating party. The terms of this paragraph shall not apply to any material or information which:

(a) is or becomes generally available to the public by any means other than the receiving party's breach of its obligations; or

(b) is obtained non-confidentially from a third party who had the legal right to disclose same; or

(b) was in the prior possession of the receiving party, as evidenced by written records.

The parties agree that during the term of this Agreement, both will not disclose any information which is confidential or proprietary to any third party.

9. Term Termination. This Agreement shall expire three (3) years from the Effective Date, unless otherwise extended by mutual written consent of the Parties. Notwithstanding anything contained herein to the contrary, either party shall have the right to terminate this Agreement due to a material breach by the other party, which breach is not cured within 30 days after notice thereof. The provisions of Sections 6, 8 and 9 hereof shall survive any termination of this Agreement. Furthermore, termination shall not relieve either party of obligations incurred prior to the termination.

10. Entire Agreement. This Agreement, including all exhibits hereto, sets forth the entire agreement and understanding of the parties relating to the subject matter hereof and merges all prior discussions between them.

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11. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed to be an original and all of which together shall constitute one instrument.

12. Partial Invalidity. If any provision of this Agreement is held to be invalid, then the remaining provisions shall nevertheless remain in full force and effect. The parties agree to renegotiate in good faith any term held invalid and to be bound by the mutually agreed substitute provision.

IN WITNESS WHEREOF, the parties have executed this Development Agreement as of the date first written above.

CARDIOVASCULAR DIAGNOSTICS, INC.	BAYER CORPORATION
By: /s/ John P. Funkhouser	By: /s/ Eugene Simonalle
Name: John P. Funkhouser	Name: Eugene Simonalle
Title: President	Title: Assistant Secretary
Date: 8/21/96	Date: 21 Aug. '96

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