

SECURITIES AND EXCHANGE COMMISSION

FORM 10-K

Annual report pursuant to section 13 and 15(d)

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FILER

CARDIOVASCULAR DIAGNOSTICS INC /NC/

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FORM 10-K
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549

(Mark One)

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934. For the fiscal year ended December 31, 1998 OR
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934. For the transition period from _____ to _____

Commission file number 0-25133

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

NORTH CAROLINA 56-2098302
(State or other jurisdiction of (I.R.S. Employer
incorporation or organization) 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)

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

The aggregate market value of the voting stock held by non-affiliates of the registrant based upon \$3.75 per share, the closing price of the Common Stock on March 22, 1999, on the NASDAQ National Market System, was approximately \$27,954,000 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 22, 1999, the registrant had outstanding 7,454,490 shares of Common Stock (\$.001 par value).

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DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company's Proxy Statement for the 1999 Annual Meeting of Shareholders are incorporated herein by reference into Part III.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

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 under the heading "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations -- Factors That May Affect Future Results" and elsewhere, as well as in the Company's other filings with the Securities and Exchange Commission (the "SEC"), and including, in particular, risks relating to new product development, uncertainties regarding market acceptance of the

PART I

Item 1. BUSINESS

PharmaNetics, Inc. (the "Company") is a North Carolina holding company incorporated in July 1998 as the parent company of Cardiovascular Diagnostics, Inc. ("CVDI"). CVDI develops, manufactures and markets rapid turnaround diagnostics to assess blood clot formation and dissolution. CVDI's products are a proprietary cardiovascular analyzer and dry chemistry tests (known as the "Thrombolytic Assessment System" or "TAS") that provide, at the point of patient care, rapid accurate evaluation of hemostasis. CVDI is also establishing itself in the emerging field of theranostics or rapid near-patient testing in which the diagnostic results may influence treatment decisions. Current tests and tests under development are used in the treatment of angina, heart attack, stroke, deep vein thrombosis and pulmonary and arterial emboli. CVDI's wholly owned subsidiary, Coeur Laboratories, Inc. ("Coeur"), manufactures and sells a line of disposable power injection syringes used for cardiology and radiology procedures.

CVDI believes that the TAS is the only stat, or "as soon as possible", point-of-care system capable of monitoring 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 a variety of medical procedures. 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 an effective treatment range. CVDI 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 of diagnosis and treatment. CVDI believes that the TAS can provide information regarding coagulation as well as thrombolytic and other drug

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monitoring on a timely basis, thus permitting quicker diagnosis and therapeutic intervention, which will improve hemostatic therapy and the quality of patient care. CVDI 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 reduce the unnecessary use of pharmaceuticals. In addition, point-of-care testing can reduce hospitals' costs by reducing the numerous steps, paperwork and personnel used in collecting, transporting, documenting and processing blood samples.

The Company currently sells domestically and internationally its TAS analyzer and a menu of tests and controls. Five of these tests, the Prothrombin Time ("PT"), PT non-citrated ("PTNC"), the PT One, the activated Partial Thromboplastin Time ("aPTT") and the Heparin Management test ("HMT"), (which monitors oral anticoagulant therapy, low level intravenous anticoagulant therapy and high level intravenous anticoagulant therapy), 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. Three other tests, the Lysis Onset Time ("LOT"), Ecarin Clotting Time ("ECT") and a modified ecarin clotting time test have been sold "for investigational use only", pending FDA review and clearance.

During 1993, CVDI acquired Coeur, which manufactures and sells a line of disposable power injection syringes used for cardiology and radiology procedures. CVDI acquired Coeur in order to gain access to Coeur's management and infrastructure, its cash flow and its manufacturing facility. Each year since the acquisition, Coeur has generated revenue of between \$4.6 and \$4.7 million, as well as positive cash flow. The Company has used some of this cash to fund more rapid TAS research and development than would have been possible otherwise. Additionally, CVDI believes that the ability to make immediate use of Coeur's existing manufacturing facility and experienced management team enabled CVDI to develop its infrastructure more rapidly, thereby accelerating the commercialization of TAS.

INDUSTRY OVERVIEW

The practice of laboratory medicine continues to evolve 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 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. CVDI 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 routine 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

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to perform blood analysis rapidly and accurately are emerging as a solution to these 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 must also comply with the Clinical Laboratory Improvement Act of 1988 ("CLIA") regulations. See "-- Government Regulation --".

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. Non-anticoagulated blood begins to clot as soon as it leaves the body, therefore point-of-care coagulation testing is the only viable approach to get results and make necessary medical decisions.

TECHNOLOGY

The Company's core technology relating to both the TAS analyzer and test cards is currently protected by a number of U.S. and 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 CVDI 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

TAS ANALYZER

The TAS analyzer weighs approximately four pounds and is about the size of a typical office telephone. The TAS analyzer has a four-line LCD display, 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.

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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 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.

The analyzer and test cards are designed to work effectively in a decentralized testing environment where it is used by healthcare personnel who need not have received formal central laboratory training. 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, noncitrate or citrate, whole blood or plasma is then placed into the reaction chamber of the test 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 analyzer can operate either on wall current or on an internal rechargeable battery.

FDA APPROVED TEST CARDS

The following describes CVDI's test cards that have been approved by the FDA:

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 oral anticoagulants, such as warfarin. Warfarin is widely used in the United States for long-term treatment in patients who have previously developed clots, including after heart attacks, in order to inhibit coagulation to reduce the risk of developing additional clots. A physician uses the PT test to monitor and maintain drug levels within a safe treatment range; too little warfarin will not prevent a new clot from developing, but too much of the drug may result in a bleeding complication. CVDI manufactures and markets three different types of PT test cards, a general purpose PT test card routinely used in the United States, the PT One, which uses a more sensitive scale of measurement, and the PT-NC, which is used with finger stick samples. The PT One is currently the preferred test for all indications in Europe and is rapidly becoming popular in the United States.

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

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the initial treatment for patients with a clot, including patients suffering from heart attacks or strokes. Heparin also prevents clots from forming in patients undergoing procedures involving particular risks of clotting, such as, 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 intravenously administered drug affects a patient's coagulation system within minutes.

Generally, aPTT tests are incapable of monitoring high levels of heparin. Currently, the activated clotting time ("ACT") test and the HMT are used to monitor high levels of heparin. The Company developed and markets its HMT for monitoring patients requiring high dose heparin therapy during procedures such as open heart surgeries or dialysis. 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 ACT because it is easier to use and less prone to operator error. Also, unlike ACT, HMT is not sensitive to changes in blood temperature or dilution, such as typically occur during bypass surgery. The Company believes that HMT more closely correlates with a precise but time-consuming laboratory measurement of heparin concentration than does ACT. Finally, CVDI has under development the Low-range Heparin Management Test ("LHMT") card to be used to measure heparin levels in the therapeutic ranges desirable during cardiac catheterization.

TEST CARDS UNDER DEVELOPMENT

Continuing research and development is focused on expanding the current

menu of tests for the TAS analyzer. CVDI is currently developing the following new tests:

| Test ---- | Description ----- |
|----------------------------------|--|
| Heparin Management Panel ("HMP") | A complete heparin monitoring titration and neutralization package to complement the aPTT and HMT that includes a new analyzer known as Accent |
| Low Range Fibrinogen ("LRF") | Test to monitor the effects of anicrod, a fibrinogen lowering drug for the treatment of stroke under development at Knoll AG |
| Therapeutic Anticoagulant | Test for identifying potential treatment with investigational therapeutic anticoagulant under development by Eli Lilly and Company for patients with sepsis |
| Ecarin Clotting Time ("ECT") | Test to monitor direct thrombin inhibitors like hirudin, which is in development for use in patients treated for heart attack or prevention of deep vein thrombosis |
| Modified Ecarin Clotting Time | Test to allow the monitoring of an antithrombin drug |
| | under development at Astra AB |
| SK Panel | Test to assess response to streptokinase; provides a physician with information to assist in choosing the appropriate dose of the thrombolytic drug |
| Lysis Onset Time ("LOT") | Test to monitor a patient's lytic response to any thrombolytic drug used for the treatment of heart attack, stroke, or other thrombotic diseases |
| Anti Factor Xa | Test to monitor the anticoagulant effect of low molecular weight heparins and other anticoagulant drugs used for the treatment and prevention of thrombotic diseases |

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QUALITY CONTROL PRODUCTS

The Company also develops and manufactures single-use "crush-vial" controls for each test card. These controls allow quality assurance testing at the point of care. In addition, the Company has developed an Electronic Quality Control ("EQC") card used to test analyzer function.

SALES AND MARKETING

CVDI commenced marketing TAS products in May 1995. In the beginning, CVDI initiated a sales and marketing strategy with a direct sales force targeting hospitals with over 200 beds. Through this initiative CVDI achieved its goal of gaining recognition for its technology and was able to attract several strategic partners. As consolidation in the health care industry began to occur, the marketing focus was shifted to begin targeting major corporate

accounts and integrated health networks ("IHNS"). To accomplish this CVDI signed an exclusive development and distribution agreement with Dade International, Inc. ("Dade") in 1996 to market the PT and aPTT tests. As CVDI's primary distributor, Dade represented 15%, 17% and 3% of total Company sales in 1998, 1997 and 1996 respectively. In 1996, CVDI also entered into an agreement with Avecor Cardiovascular to distribute CVDI's Heparin Management Test ("HMT") to hospitals.

In August 1998, the agreements with Dade and Avecor were terminated effective December 1998, at which time Chiron Diagnostics Corporation ("Chiron Diagnostics") became CVDI's new distribution partner pursuant to the agreement discussed below. In November 1998, Bayer acquired Chiron Diagnostics and it became a part of Bayer Diagnostics. The Company believes Bayer's position as a global leader in diagnostics will make it a good partner.

In connection with the CVDI's termination of the Dade agreement, CVDI agreed to continue to supply for 3 years the cards currently sold to Dade's contracted customers.

In August 1998, CVDI signed a five-year global distribution agreement, subject to minimum annual sales, with Chiron Diagnostics

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to distribute CVDI's PT, aPTT, HMT and LHMT test cards. At that time, CVDI received an up-front investment of \$6 million from Chiron Diagnostics in exchange for 600,000 shares of common stock. As noted above, in November 1998, Bayer acquired Chiron Diagnostics and it became a part of Bayer Diagnostics. CVDI believes that Bayer Diagnostics has a strong global presence and that its shared strategy for expanding rapid diagnostic platforms into critical care settings and its considerable presence in these specialized areas of the hospital will lead to increased placements of TAS products. CVDI also believes that the TAS products are complementary with Bayer Diagnostics' leading market position in blood gas analysis. Bayer Diagnostics began marketing CVDI's products covered by the agreement in January 1999, following the termination of the distribution agreements with Dade and Avecor Cardiovascular. In addition, Bayer Diagnostics has the contingent right to distribute outside the U.S. certain test cards currently under development and a right of first refusal for distribution of these tests in the U.S.

Under the agreement signed in August 1998 with Chiron Diagnostics, now Bayer Diagnostics (the "Agreement"), Bayer Diagnostics agreed to purchase minimum quantities of CVDI's products covered by the Agreement during the term of the Agreement at pre-determined prices. The Agreement is renewable for successive five-year terms. CVDI has the right to terminate the Agreement if (1) Bayer Diagnostics does not meet annual or semiannual sales targets, (2) Bayer Diagnostics fails to make payments when due to the Company, and (3) a distributor appointed by Bayer Diagnostics sells products which are competitive with CVDI. Either party may terminate the Agreement upon the occurrence of any of the following: (1) the insolvency of the other party; (2) material breach of the Agreement by other party which is not cured; or (3) certain types of "change-in-control" transactions by the other party.

The Company also markets TAS products in Europe and other foreign countries. In Europe there are a large number of recognized experts in the fields of hematology and cardiology. Until the signing of the Agreement in August 1998, the Company's strategy had been to sell primarily through selected independent distributors. Certain distribution agreements remain in place in foreign countries and upon expiration of these agreements, Bayer Diagnostics will become CVDI's exclusive distributor in these territories.

To further the goal of establishing itself in the emerging field of theranostics, the Company has entered into a sub-license agreement with Knoll AG for the development of a test card for potential use in assisting treatment of unstable angina and has entered into collaborative agreements with Knoll AG and Eli Lilly and Company ("Eli Lilly") in which the Company is developing test cards for potential use in patient identification and monitoring of therapies being investigated for the treatment of ischemic stroke and sepsis. Under certain of these agreements, CVDI has agreed to develop and supply test cards and is entitled to receive development fees based upon the achievement of product milestones, such as the filing of a 510k application. Under each of these agreements, CVDI has granted the other party rights to purchase TAS products and test cards at pre-determined prices. Each of these agreements can be terminated by either party following the other party's failure to cure a material breach of the agreement. In relation to the development of the ECT card to monitor a thrombin inhibitor, CVDI has a worldwide exclusive sublicense from Knoll to make, use and sell the ECT test.

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Under a separate agreement, CVDI is developing the LRF card for use in patients treated with Ancrod, which is under development by Knoll AG for ischemic stroke. Further, the Company is developing a test to monitor a therapeutic anticoagulant under development at Eli Lilly for assisting treatment of patients with sepsis. Under this agreement, either party may terminate the agreement if Eli Lilly substantially ceases efforts with respect to its product's clinical trials. In addition, upon completion of certain phases of development contemplated by the agreement, Eli Lilly may terminate the agreement following its receipt of the applicable final study report for such phase. CVDI's intent is to enter into additional collaborations to expand the theranostic test card menu.

Coeur's products are marketed worldwide, primarily to power injector manufacturers and, to a lesser extent, end users who perform diagnostic procedures. There are three principal power injector manufacturers and Coeur manufactures disposable syringes, on an original equipment manufacturing ("OEM") basis, for two of these manufacturers, Liebel Flarsheim ("LF"), a wholly owned subsidiary of Mallinkrodt Group, Inc., and E-Z-EM. As a percentage of total Company sales in 1998, 1997, 1996, sales to LF represented 17%, 30% and 34%, respectively, and sales to E-Z-EM represented 21%, 18% and 10%, respectively.

The commercial success of the Company's products will depend upon their acceptance by the medical community and third-party payors as being 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 by selling point-of-care hemostasis test products, the Company 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 Bayer Diagnostics as its principal distributor for marketing and distribution of its products. There can be no assurance that Bayer Diagnostics will be successful in marketing or selling the Company's products or that the Company could build a cost-effective and adequate sales and marketing staff. The loss of one or more of the Company's 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.

COMPETITION

The medical diagnostic testing industry is characterized by rapidly evolving technology and intense competition. The currently marketed TAS menu competes in the coagulation and hematology testing market with

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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 some of 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.

CVDI has several competitors, including Roche Diagnostics (which acquired Boehringer Mannheim Corporation in 1998), 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 over 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, CVDI 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 CVDI 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 CVDI 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 CVDI'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 CVDI or that would render CVDI's technology and products obsolete or noncompetitive.

PATENTS AND OTHER INTELLECTUAL PROPERTY

The Company pursues patent applications to provide protection from competitors. A number of U.S. and corresponding international patents have been issued to CVDI covering various aspects of the TAS technology. These patents expire between 2004 and 2013. 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

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the issuance of additional patents on current and future applications. 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, others may have or will develop similar products, duplicate the Company's products or design around the Company's patents. If 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. Such licenses may not be available or, if available, could be on terms unacceptable to the Company.

The Company also relies upon unpatented trade secrets to protect its proprietary technology. In particular, CVDI believes that its custom-designed automated test card production line embodies proprietary process technology. Others may independently develop or otherwise acquire equivalent technology or otherwise gain access to CVDI's proprietary technology and CVDI may not ultimately be able to 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 Boehringer Mannheim Corporation alleging, among other things, misappropriation of trade secrets. See "Legal Proceedings."

LICENSES

TOKUYAMA SODA LICENSE

CVDI is a party to a License Agreement with Tokuyama Soda Company, Ltd. ("Tokuyama") pursuant to which CVDI granted Tokuyama exclusive rights to manufacture and sell PT and aPTT tests and analyzers in Myanmar, Brunei, Hong Kong, Indonesia, Japan, Malaysia, China, Philippines, Taiwan, South Korea, Singapore and Thailand (the "Tokuyama License"). The Tokuyama License requires that CVDI negotiate in good faith with Tokuyama for 90 days prior to marketing or licensing in these Asian nations any new products that CVDI develops related to the licensed tests or analyzer technology.

Until the earlier of October 2004 or the expiration of the last Japanese patent covering the licensed technology, Tokuyama must pay CVDI royalties based on Tokuyama's net sales of licensed products, subject to annual minimums through September 2000. CVDI 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 CVDI.

In December 1995, CVDI 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

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of the time when export to such country becomes authorized). In the event CVDI exercises this right, it and Tokuyama may both market in the country and must each pay royalties to the other. To date, CVDI has not exercised this right. The amendment also provides that CVDI owns all rights outside Asia to Tokuyama improvements to the CVDI's technology, and must pay royalties to Tokuyama based on CVDI net sales of products incorporating such improvements.

CVDI received royalty payments under this agreement of \$22,398, \$30,741 and \$32,835 during the years ended December 31, 1998, 1997 and 1996, respectively.

MANUFACTURING

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

CVDI also operates proprietary automated test card production equipment at its Raleigh facility. This automated production equipment was custom-designed by CVDI and built to its specifications. CVDI believes that this production machinery embodies proprietary process technology. The equipment has been designed to allow for increased production as dictated by customer demand. Current annual manufacturing capacity is approximately 10 million cards.

The FDC Act requires the Company to manufacture its products in registered establishments and in accordance with Good Manufacturing Practice ("GMP") now known as Quality System Regulations ("QSR"). CVDI and Coeur are both registered as medical device manufacturers and are subject to periodic inspections by the FDA. In addition, CVDI received ISO 9001 certification in 1997 and Coeur received ISO 9002 certification in 1998.

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. The Company may not 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 CVDI's TAS products are readily available. However, certain of these materials are obtained from a sole supplier or a limited group of suppliers. PIOP and some reagents used in the TAS test cards are obtained from single sources. However, CVDI maintains enough supply to produce test cards for an extended period of time. The Company believes that, in the event of an interruption in the availability of supplies, the Company has enough supply at its facility to fulfill its needs until an alternative source can be procured. The Company seeks to maintain long-term agreements with its suppliers when possible. The reliance on sole or limited suppliers and the inability 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.

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GOVERNMENT REGULATION

FDA

The medical devices 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,:

- o fines

- o injunction
- o civil penalties
- o recall or seizure of products
- o total or partial suspension of production
- o failure of the government to grant premarket clearance or premarket approval ("PMA") for devices
- o withdrawal of marketing approvals or
- o 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.

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 the more time-consuming PMA process. The Company believes that its products qualify for the 510(k) approval process. 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 medical device. The FDA has recently been requiring a more rigorous demonstration of substantial equivalence than in the past. It generally takes from four to twelve 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.

CVDI received 510(k) clearance to market its PT and aPTT test cards, along with a first generation analyzer, in 1988. In 1993, CVDI received 510(k) clearance for the current TAS analyzer to be marketed with PT and aPTT tests and received 510(k) clearance in May 1995 to commercially market the HMT test. CVDI received 510(k) clearance for PT, HMT and aPTT controls in 1996 and for PT-NC controls in 1997. CVDI 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

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additional clinical evaluations of the SK Panel. The SK Panel and LOT tests are currently available to be sold in Europe for investigational use only in connection with clinical evaluations of the safety and effectiveness of the products. In addition, CVDI submitted 510(k) applications for the LHMT test card in December 1997 and for the ECT test card in January 1998. In August 1998, the FDA notified CVDI that it would require additional data before commencing its review of the 510(k) applications for the LHMT and ECT test cards. The Company currently plans to resubmit each 510(k) after compiling the requested additional data. The Company may not 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.

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:

- o the device will be used for investigational purposes only
- o results will not be used for diagnostic purposes without confirmation of the diagnosis under another medically established diagnostic device or procedure
- o all investigations will be conducted with approval from an institutional review board ("IRB"), using an IRB-approved study protocol, and patient informed consent and
- o the device will be labeled in accordance with the applicable labeling regulations

Failure of CVDI or recipients of CVDI's "investigational use only" products to comply with these requirements could result in enforcement action by the FDA that would adversely affect CVDI's ability to conduct testing necessary to obtain market clearance and, consequently could have a material adverse effect

on the Company.

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 designed and manufactured in accordance with QSR regulations which impose certain procedural and documentation requirements upon the Company with respect to design, manufacturing and quality assurance activities. The FDA has approved changes to the regulations which will and have increased the cost of complying with QSR 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.

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REGULATIONS ON EXPORT

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 the FDA that the product has been granted clearance in the United States and that the manufacturing facilities appeared to be in compliance with QSRs at the time of the last FDA inspection. The FDA will refuse to issue a CPE if significant outstanding QSR 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 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.

CVDI 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, the LOT test and the ECT test. The Company believes that these products are subject to the 510(k) requirements and, consequently, has not requested FDA approval for export. However, there can be no assurance that the FDA would agree with the Company that a 510(k) is needed rather than a PMA. If the FDA disagreed, it could significantly delay and impair CVDI's ability to continue exporting the SK Panel, the LOT test and the ECT test and could have a material adverse effect on the Company.

FOREIGN REGULATIONS

Sales of the Company's test products outside the United States are also subject to foreign regulatory requirements that vary widely from country to country. These laws and regulations range from simple product registration requirements in some countries to complex clearance and production controls in others. As a result, the processes and time periods required to obtain foreign marketing approval may be longer or shorter than those necessary to obtain FDA approval. These differences may affect the efficiency and timeliness of international market introduction of the Company's products, and there can be no assurance that the Company will be able to obtain regulatory approvals or clearances for its products in foreign countries. 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.

In particular, in order to market the Company's products in the member countries of the European Union (the "EU"), the Company is required to comply with the European Medical Devices Directive ("MDD") and to obtain CE Mark certification for its Coeur products and for the TAS analyzer. The CE Mark denotes conformity with European standards for safety and allows certified devices to be placed on the market in all EU countries. Medical devices may not be sold in EU countries unless they

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display the CE Mark. All of the applicable Company's products marketed in Europe have obtained CE Mark certification. There can be no assurance that the Company will be successful in maintaining CE Mark certification of its products. The TAS Analyzer also must and does meet the requirements of the Electromagnetic Capability Directive. In Japan, the Company relies upon its collaborative partner, Tokuyama, to comply with applicable regulations regarding the product listing, manufacture and sale of products in that country. The Company believes that the Company's products are in compliance with applicable regulations in Japan. Failure to maintain CE Mark certification in Europe or to obtain or maintain other foreign regulatory approvals could have a material adverse effect on the Company's business, financial condition and results of operations.

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, aPTT and HMT 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 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.

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OTHER REGULATIONS

The 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.

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 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

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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, of 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

In October 1993, CVDI 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 200ml 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 200ml syringes from Coeur, because Coeur's patent makes it the only current alternative source for Medrad 200ml syringes. In addition, Coeur manufactures, on an OEM basis, all disposable syringes for E-Z-EM injectors. For the fiscal year ended December 31, 1998, E-Z-EM and Liebel-Flarsheim each represented more than 10%, and in total represented 73% 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. Manifold sales were 2%, 3% and 8% in 1998, 1997 and 1996 respectively of Coeur's net sales, and Coeur expects that manifold sales in 1999 will be minimal.

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Since its acquisition by CVDI, Coeur has operated profitably and therefore helped fund CVDI'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 \$11 million per claim, with an annual aggregate policy limit of \$12 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 76 employees as of December 31, 1998. Ten employees were engaged in research and development (6 of which have Ph D's and 1 has an M.D.), 41 in manufacturing and quality control, 10 in engineering, 6 in sales/marketing and 9 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 management and technical personnel, none of whom have employment agreements with the Company. Although the Company maintains a \$500,000 key man life insurance policy on its chief executive officer, the loss of the service of this officer 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.

ITEM 2. PROPERTIES

The Company's executive offices are located at 5301 Departure Drive, Raleigh, North Carolina 27616, and its telephone number is (919) 954-9871. 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

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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 U.S. District Court for the Eastern District of North Carolina, 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 requested a declaratory judgment that neither the products nor activities of the Company infringe U.S. patents purportedly owned by BMC. In April 1997, BMC answered the claims and submitted a patent infringement counterclaim against CVDI. Each party filed a motion for judgment on the pleadings with respect to all claims asserted by the other party. In November 1997, the Court issued a Judgment and Order granting CVDI's motion for judgment on the pleadings, holding that CVDI has a license, until June 21, 1999 or until the last of the patents expire, to the patents at issue. It dismissed all other claims of the parties. Both parties appealed and on February 1, 1999, the United States Court of Appeals for the Federal Circuit issued an opinion in which it affirmed the decision of the district court in all respects. While either party could petition for rehearing by the entire court, or could petition the United States Supreme Court to consider the case, it is management's opinion that the disposition of this matter will not have a material adverse effect on the consolidated financial position, results of operations or liquidity of the Company.

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

The Company held a special shareholders' meeting on December 2, 1998. The following is a description of the matters voted upon and approved at the meeting and the votes cast with respect to each matter.

- (a) An Agreement and Plan of Merger providing for the merger of Cardiovascular Diagnostics, Inc. with a wholly owned subsidiary of PharmaNetics, Inc., a North Carolina corporation organized for the purpose of becoming a holding company of Cardiovascular Diagnostics, Inc. pursuant to which all of Cardiovascular Diagnostics, Inc. shareholders became shareholders of PharmaNetics, Inc. on a share-for-share basis.

| Votes For | Votes Against | Votes Abstained |
|-----------|---------------|-----------------|
| 5,024,288 | 42,289 | 10,245 |

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- (b) A 350,000 share increase in the number of shares of Common Stock reserved for issuance under the Company's 1995 Stock Plan

| Votes For | Votes Against | Votes Abstained |
|-----------|---------------|-----------------|
| 6,251,691 | 563,879 | 25,770 |

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, 1999.

John P. Funkhouser, age 45, was elected President, Chief Executive Officer and a director of the Company in October 1993 upon the Company's acquisition of Coeur. In February 1998, Mr. Funkhouser was appointed Chairman of the Board of Directors of the Company. 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. Mr. Funkhouser holds a B.A. from Princeton University and an M.B.A. from the University of Virginia.

Dick D. Timmons II, age 53, was elected Vice President and Chief Operating Officer of the Company in January 1998. Since October 1997, Mr. Timmons had served as Vice President of Manufacturing of the Company. Before joining the Company, Mr. Timmons spent 22 years in operations and product development positions of increasing responsibility, with the Diagnostic Products Division of Abbott Laboratories and Johnson & Johnson. From 1994 until October 1997, he served as Director of Operations at Direct Access Diagnostics, an HIV testing service, and from 1988 until 1994, he was Director of Technology Transfer at Ortho Diagnostics Systems, a medical diagnostic test company. Mr. Timmons holds a B.S. in Industrial Engineering from Purdue University and an M.B.A. from Lake Forest School of Management.

Andras Gruber, M.D., age 45, joined the Company as its Vice President,

Chief Scientific and Medical Officer in November 1998. Prior to joining the Company, Dr. Gruber spent 4 years with Depotech Corporation in various positions, including Director of Medical Affairs. From 1986 to 1994, Dr. Gruber conducted biomedical research at the Scripps Research Institute. Dr. Gruber is a board certified internist with 7 years immediate patient care experience. Dr. Gruber holds an M.D. degree from Semmelweis Medical University in Budapest.

Michael D. Riddle, age 45, joined the Company as its 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).

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Peter J. Scott, age 50, joined the Company as its Vice President of Quality Assurance and Regulatory Affairs in October 1997. Prior to joining the Company, Mr. Scott was employed by Gaymar Industries Inc., a medical device company, for five years as Director of Quality Assurance and Regulatory Affairs. Mr. Scott holds a B.S. from Tusculum College and an M.B.A. from Mt. St. Mary's College, and is a Certified ASQ Quality Engineer.

Paul T. Storey, age 32, was elected Treasurer and Secretary in February 1998. Since December 1997, Mr. Storey has also served as Director of Finance of the Company. Prior to joining the Company, Mr. Storey was employed for more than eight years at KPMG Peat Marwick LLP, most recently as a senior manager. Mr. Storey is a Certified Public Accountant and holds a B.A. in Accounting from Furman University.

Part II

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

(a) Price Range of Common Stock

The common stock of the Company's subsidiary, Cardiovascular Diagnostics Inc., traded on the Nasdaq National Market under the symbol "CVDI" until the holding company reorganization effected on December 2, 1998 after which the Company's common stock began trading on the Nasdaq National Market under the symbol "PHAR". The following sets forth the quarterly high and low closing sales prices of the common stock of CVDI and the Company, as applicable, for the fiscal years ended December 31, 1998 and 1997 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, 1998 | | |
| January 1, 1998 through March 31, 1998 | \$ 9 | 6 3/8 |
| April 1, 1998 through June 30, 1998 | 8 1/2 | 5 |
| July 1, 1998 through September 30, 1998 | 7 3/4 | 4 7/8 |
| October 1, 1998 through December 31, 1998 | 7 3/4 | 3 5/8 |
| Fiscal year ended December 31, 1997 | | |
| January 1, 1997 through March 31, 1997 | \$ 5 3/4 | 3 1/2 |
| April 1, 1997 through June 30, 1997 | 8 1/4 | 4 5/8 |
| July 1, 1997 through September 30, 1997 | 9 3/8 | 5 3/4 |
| October 1, 1997 through December 31, 1997 | 9 1/8 | 4 1/2 |

(b) Approximate Number of Equity Security Holders

As of December 31, 1998, the number of record holders of the Company's Common Stock was approximately 200, and the Company believes that the number of beneficial owners was approximately 1,900.

(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.

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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 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".

PHARMANETICS, INC. AND SUBSIDIARIES

Selected Consolidated Financial Data (in thousands, except per share data)

<TABLE>

<CAPTION>

| | Year Ended December 31, | | | | |
|---|----------------------------|-------------|-------------|-------------|-------------|
| | <C> 1998 | <C> 1997 | <C> 1996 | <C> 1995 | <C> 1994 |
| <S> RESULTS OF OPERATIONS | | | | | |
| Net sales | \$ 8,790 | \$ 7,618 | \$ 6,411 | \$ 5,199 | \$ 4,695 |
| Cost of goods sold | 6,343 | 6,169 | 5,257 | 4,268 | 3,021 |
| Gross profit | 2,447 | 1,449 | 1,154 | 931 | 1,674 |
| Operating expenses: | | | | | |
| Research and development | 2,652 | 2,573 | 2,300 | 1,801 | 1,882 |
| General and administrative | 3,191 | 3,594 | 2,933 | 2,191 | 1,441 |
| Sales and marketing | 748 | 1,347 | 1,896 | 1,278 | 453 |
| Total operating expenses | 6,591 | 7,514 | 7,129 | 5,270 | 3,776 |
| Other income, net | 568 | 1,468 | 906 | 469 | 365 |
| Provision for income taxes | (67) | (82) | (52) | (82) | (91) |
| Net loss | (\$ 3,643) | (\$ 4,679) | (\$ 5,121) | (\$ 3,952) | (\$ 1,828) |
| Basic and diluted loss per common share | (\$ 0.52) | (\$ 0.70) | (\$ 0.78) | (\$ 0.74) | (\$ 0.35) |
| Weighted average shares outstanding | 7,007 | 6,722 | 6,566 | 5,323 | 5,179 |

As of December 31,

| | 1998 | 1997 | 1996 | 1995 | 1994 |
|---|-----------|-----------|-----------|-----------|----------|
| FINANCIAL CONDITION | | | | | |
| Cash and cash equivalents | \$ 3,998 | \$ 5,885 | \$ 2,716 | \$ 16,237 | \$ 3,206 |
| Short term investments | 3,703 | -- | 5,973 | -- | -- |
| Total assets | 18,693 | 17,685 | 18,351 | 23,986 | 8,328 |
| Long term debt, excluding current portion | 1,626 | 2,351 | 67 | 499 | 269 |
| Total liabilities | 2,949 | 4,492 | 683 | 2,176 | 901 |
| Accumulated deficit | (24,262) | (20,619) | (15,940) | (10,819) | (6,867) |
| Shareholders' equity | \$ 15,744 | \$ 13,193 | \$ 17,668 | \$ 21,810 | \$ 7,428 |

</TABLE>

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

This discussion contains forward-looking statements. The Company's actual results might differ materially from those projected in the forward-looking statements for various reasons, including development risks, 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 additional 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 (including under the heading " -- Factors That May Affect Future Results") and in the Company's other SEC filings, copies of which are available upon request.

CVDI 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's subsidiary, Coeur Laboratories, Inc. ("Coeur"), located within the Raleigh facility, assembles and sells disposable power injection syringes used for cardiology and radiology procedures.

The Company derives income from the following sources: TAS and Coeur product sales; grants; interest income; and development income recognized in connection with collaboration agreements. Coeur product sales in 1998, 1997 and 1996 represented 53%, 62% and 71%, respectively, of total Company sales.

During 1996, the Company had salespeople covering the major metropolitan

areas across the United States and nine distributors selling into 13 countries. Because of the speed and the ease of use of the TAS product and the high correlation between the testing results from CVDI's product with the testing results obtained by hospitals' central laboratories, the laboratory response to CVDI's technology was largely positive. However, since 1996, individual hospitals have continued to consolidate into IHNs, which delayed many pending decisions to adopt the new technology provided by 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. Given the consolidation in the hospital industry, CVDI determined that

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distribution arrangements, rather than a direct sales force, were needed to penetrate the market. In 1996, CVDI signed a North American distribution agreement with Dade, in 1997 CVDI signed additional distribution agreements in niche markets with Avecor Cardiovascular and Johnson & Johnson's Ortho Clinical Diagnostics S.p.A. in Italy, and in August 1998 CVDI signed a global distribution agreement with Chiron Diagnostics which has or will replace the distribution agreements which existed prior to such date. See "Item 1. Business"--. These agreements allowed the Company to reduce its sale force and are consistent with the Company's strategy of seeking to provide a comprehensive, standardized, rapid, point-of-care hemostasis testing solution, while also developing specialty tests that should have higher margins.

The growth of large IHNs has given them increased purchasing power which, along with competition from existing testing procedures for routine coagulation tests, has put pricing pressure on the Company's test cards. The Company's agreements with its distributors provide for fixed prices, which the Company could be forced to reduce as a result of pricing pressure. Fixed pricing could also have a material adverse effect on the Company's results of operations if its costs increase unexpectedly. Given the consolidating hospital market and pricing pressures, the Company's strategy has evolved towards becoming more focused on the development of specialty tests for drugs, some with narrow ranges between over- and under-dosage. The Company believes that rapid diagnostic capabilities improve patient care and turnover, and that there is a market trend to obtain diagnostic information faster in order to effect therapy sooner. The Company also believes that these trends should allow the Company to obtain higher pricing of these specialty tests. As a result, during 1997 and 1998 the Company exhibited the flexibility of the TAS platform and the potential to expand its menu of specialty tests by signing collaboration agreements with Knoll AG, Eli Lilly and Company and Astra AB to monitor the effects of certain new drugs that are in clinical trials. The Company believes that these and other collaborations for specialty tests will also further demand for analyzers and routine anticoagulant tests. The Company believes it is well positioned in its development efforts to expand its menu of tests to monitor developmental drugs where rapid therapeutic intervention is needed.

RESULTS OF OPERATIONS

YEAR ENDED DECEMBER 31, 1998 VS. YEAR ENDED DECEMBER 31, 1997. Sales for the year ended December 31, 1998 increased 16% to \$8.8 million compared to \$7.6 million in 1997. TAS analyzer revenue increased approximately \$239,000 due to a large order from Knoll received early in the year and test card revenue increased \$656,000, principally due to sales of specialty cards to Knoll and Astra during 1998. These increases were partially offset by decreases in revenue from Dade. Coeur product sales of \$4.6 million were virtually unchanged from prior year sales of \$4.7 million. The total gross profit margin improved in 1998 to 28% compared to 19% in 1997 mainly due to higher average sale prices for TAS analyzers and specialty test cards. Coeur gross margins decreased slightly from 1997 due to higher product costs.

Total operating expenses for 1998 of \$6.6 million represents a decrease of approximately \$900,000 or 12% compared to 1997. General and administrative expenses declined due to lower litigation expenses and fewer personnel. Sales and marketing expenses also declined due to fewer personnel and the elimination of a sales office in Germany in late 1997. The reduced personnel also led to decreased travel costs compared to 1997. Research and development expenses, which mainly relate to the

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Company's TAS products, increased approximately 3% in 1998 compared to 1997. The increase was primarily due to increased personnel costs, higher cost of supplies and validation processes related to on-going development projects.

Interest expense for the year ended December 31, 1998 was \$378,000 compared to \$2,000 in the prior year. The increase was due to the long-term debt financing obtained by the Company in December 1997. Interest income decreased approximately \$55,000 in 1998 compared to 1997 due to decreased investment

balances during the year as funds were used to support operations.

Grant and development income in 1998 was approximately \$643,000, a \$460,000 decrease compared to 1997. The decrease in grant income was expected as the Company's NIH grant expired during 1998. Development income also decreased as fewer milestones related to collaborative agreements were reached during 1998 compared to 1997.

YEAR ENDED DECEMBER 31, 1997 VS. YEAR ENDED DECEMBER 31, 1996. Sales for the year ended December 31, 1997 increased 19% to \$7.6 million compared to \$6.4 million in 1996. Test card sales increased \$610,000 and other TAS product sales increased \$484,000 from the prior year as a result of the initiation of the distribution agreement with Dade. Coeur product sales increased 3% to \$4,694,000 from the prior year. The gross profit margin for 1997 increased slightly to 19% from 18% in 1996. Coeur gross margins increased slightly due to higher volumes and certain decreases in product costs.

Total operating expenses in 1997 were \$7.5 million, an increase of approximately \$400,000 from 1996. General and administrative expenses in 1997 were \$3.6 million, an increase of \$661,000, or 23%, from 1996. Principal factors contributing to the increase were legal expenses, additional staffing and recruiting expenses, and increased facility expenses, including rent, depreciation and consulting related to equipment upgrades. Sales and marketing expenses in 1997 of \$1.3 million decreased approximately \$548,000 from 1996, primarily due to the reduction of the Company's sales force in September 1996 after the Dade distribution agreement was signed. Research and development expenses for 1997 were \$2.6 million, a 12% increase from 1996, primarily due to increased clinical trial expenses related to collaborations for new test card products entered into during 1997.

Interest income decreased significantly in 1997 compared to 1996 due to smaller cash balances during 1997 as funds were used for operations. Development income increased to \$825,000 in 1997 from \$0 in 1996 as milestones were achieved under collaborative agreements entered into in 1996 and 1997.

Other comprehensive (loss) income in 1997 and 1996 consists of foreign currency translation adjustments related to a foreign subsidiary. Operations of the subsidiary were ceased during 1997.

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 1998, the Company had cash and cash equivalents and short-term investments of \$7.7 million and working capital of \$11.1 million, as compared to \$5.9 million and \$8.8 million, respectively, at December 31, 1997. The Company's primary source of liquidity during 1998 was the receipt of a \$6,000,000 equity investment from Chiron

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Diagnostics in conjunction with the signing of a global distribution agreement in August 1998 for certain test cards of the Company. This increase in liquidity was partially offset by repayment of debt and the 1998 operating loss.

During 1998, the Company used cash in operating activities of \$3.3 million. The use of cash was primarily due to funding the net operating loss of the Company and growth in the Company's receivables and inventories due to increased revenues.

Net cash used in investing activities was \$4.3 million in 1998. The net cash used in 1998 resulted mainly from the purchase of short-term investments and capital expenditures. Capital expenditures for 1998 were \$0.5 million. These capital expenditures were primarily for additional automated TAS test card production equipment and leasehold improvements. The Company expects to incur capital expenditures of \$300,000 to \$400,000 during 1999.

Cash provided by financing activities was \$5.6 million in 1998. Net cash provided by financing activities for 1998 resulted from the equity investment from Chiron Diagnostics partially offset by debt repayments and payments under capital leases.

The Company expects to incur additional operating losses during 1999. The Company's working capital requirements will depend on many factors, primarily the volume of subsequent orders of TAS products from distributors, primarily Bayer Diagnostics. In addition, the Company expects to incur costs associated with clinical trials for new test cards. The Company may acquire other products, technologies or businesses that complement the Company's existing and planned products, although the Company currently has no understanding, commitment or agreement with respect to any such acquisitions. In addition, the Company may consider a joint venture or the sale of manufacturing rights to complete the commercialization of its routine anticoagulant monitoring tests. Management

believes that its existing capital resources and cash flows from operations, including that from under its distribution agreement with Bayer Diagnostics, will be adequate to satisfy its planned capital requirements through 1999. To enhance liquidity in future years, the Company plans to consider external sources of financing as needed. In addition to other debt financings such as a working capital line of credit, the Company also plans to consider equity financings such as a private placement, a secondary public offering of common stock or additional equity infusions from collaborative partners.

YEAR 2000

Computers, software and microprocessors that use only two digits to identify a year in a date field may be unable to process accurately certain date-based information at or after the year 2000. This is commonly referred to as the "Year 2000 issue". The Company is addressing the issue in several ways. First, the Company has established a team to monitor product compliance and believes that all Company products are Year 2000 compliant. Secondly, the Company is in the process of seeking Year 2000 compliance certification from its major suppliers and vendors related to their products and internal business applications. Finally, the Company has established a team to coordinate Year 2000 compliance related to internal systems.

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Many of the Company's systems use vendor-provided software and Year 2000 compliance is expected to be achieved through vendor-provided upgrades. For other internal systems, testing will be completed internally to ensure Year 2000 compliance. Currently, the Company has completed its assessment and testing of Year 2000 compliance with respect to all of its own products, 70% of its own internal systems and approximately 50% of its vendor-provided systems and applications. The Company anticipates all of its systems will have been assessed and updated through vendor provider upgrades or through completion of internal testing prior to June 30, 1999. The Company believes that the cost of its Year 2000 compliance program, which solely relates to internal personnel time, has been approximately \$25,000 through December 31, 1998 and will be approximately \$50,000 in total. The Company does not believe that its business will be materially adversely affected by the Year 2000 issue. However, the Company continues to bear risk related to the Year 2000 and could be materially adversely affected if significant customers or suppliers fail to address the issue or if vendor upgrades are not provided to the Company as required. In a worst case scenario, the Company could be forced to spend significant resources and funds to find alternative providers of systems and applications used by the Company. If completion of the Company's assessment of vendor-provided systems reveals Year 2000 non-compliance, the Company's contingency plan is to insist upon vendor compliance a reasonable time in advance of Year 2000 and to pursue arrangements with other vendors.

FACTORS THAT MAY AFFECT FUTURE RESULTS

A number of uncertainties exist that may affect the Company's future operating results and stock price, including: risks associated with development of new tests, particularly specialty tests that rely on development, regulatory approval, commercialization and market acceptance of collaborators' new drugs; market acceptance of TAS; the Company's continuing losses and the resulting potential need for additional capital in the future; managed care and continuing market consolidation, which may result in price pressure, particularly on routine tests; and FDA regulations and other regulatory guidelines affecting the Company and/or its collaborators. 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 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

In the normal course of business, the Company is exposed to variety of risks including market risk associated with interest rate movements. The Company's exposure to market risk for changes in interest rates relates primarily to the Company's investment portfolio and long-term debt. The Company's investments consist of highly liquid investments with maturities at the date of purchase between three and nine months. Due to the short-term nature of the Company's debt investments and the Company's intention to hold these investments until

maturity, the impact of interest rate changes would not have a material impact on the Company's results of operations. In addition, the Company has long-term debt obligations at a fixed interest rate. Given the fixed rate nature of this debt, the impact of interest rate changes also would not have a material impact on the Company's results of operations.

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

PART III

Certain information required by Part III is omitted from this report because the Registrant will file a definitive proxy statement for its 1999 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.

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.

| Exhibit Number | Description |
|----------------|---|
| 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. |
| 10.7(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. |
| 10.18(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(d)* | Patent Sublicense Agreement, dated December 1, 1996, with Knoll AG. |
| 10.21(d) | Development Agreement, dated August 21, 1996, with Bayer Corporation. |

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| | |
|-----------|---|
| 10.22(e)* | Distribution Agreement with Chiron Diagnostics Corporation dated August 28, 1998 |
| 10.23(e) | Common Stock Purchase Agreement with Chiron Diagnostics Corporation dated August 28, 1998 |
| 21.1(a) | List of Subsidiaries. |
| 23.1 | Consent of Independent Accountants. |
| 27.1 | Financial Data Schedule. |

* 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
- (d) 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, 1996
- (e) Incorporated herein by reference to the identically-numbered exhibit to the Registrant's Registration Statement on Form S-4 (No. 333-66017) as filed with the SEC on October 22, 1998

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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.

PHARMANETICS, INC.

Date: March 26, 1999

By: /s/ John P. Funkhouser

John P. Funkhouser
President and Chief
Executive Officer

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

| Signature | Title | Date |
|---|--|---------------|
| /s/ John P. Funkhouser ----- John P. Funkhouser | President and Director (Principal Executive Officer) | March 26,1999 |
| /s/ Paul T. Storey ----- Paul T. Storey | Treasurer and Director of Finance (Principal Financial and Accounting Officer) | March 26,1999 |
| /s/ William A. Hawkins ----- William A. Hawkins | Director | March 26,1999 |
| /s/ John K. Pirotte ----- John K. Pirotte | Director | March 26,1999 |
| /s/ Stephen R. Puckett ----- Stephen R. Puckett | Director | March 26,1999 |
| /s/ Philip R. Tracy ----- Philip R. Tracy | Director | March 26,1999 |

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PHARMANETICS, INC.
AND SUBSIDIARIES

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REPORT OF INDEPENDENT ACCOUNTANTS

February 23, 1999

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, shareholders' equity, and cash flows present fairly, in all material respects, the financial position of PharmaNetics, Inc. and subsidiaries at December 31, 1998 and 1997, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 1998, in conformity with generally accepted accounting principles. 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 of these statements in accordance with generally accepted auditing standards which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatements. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for the opinion expressed above.

/s/ PricewaterhouseCoopers LLP

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PHARMANETICS, INC. AND SUBSIDIARIES

Consolidated Balance Sheets
December 31, 1998 and 1997

| <TABLE> <CAPTION> <S> ASSETS | <C> 1998 ---- | <C> 1997 ---- |
|---|---------------------|---------------------|
| Current assets: | | |
| Cash and cash equivalents | \$ 3,997,916 | \$ 5,884,522 |
| Short term investments, held-to-maturity (estimated market value of \$3,706,075) | 3,703,119 | -- |
| Receivables: | | |
| Trade, net of allowance for doubtful accounts of \$14,226 in 1998 and \$3,792 in 1997 | 1,797,279 | 1,629,499 |
| Other | 271,256 | 258,213 |
| Total receivables | 2,068,535 | 1,887,712 |
| Inventories | 2,397,434 | 2,998,052 |
| Other current assets | 299,236 | 216,808 |
| Total current assets | 12,466,240 | 10,987,094 |
| Property and equipment, net | 4,542,924 | 4,938,125 |
| Intangible assets, net | 1,546,956 | 1,568,095 |
| Other noncurrent assets | 137,091 | 191,189 |
| | ----- | ----- |
| | \$18,693,211 | \$17,684,503 |
| | ===== | ===== |

LIABILITIES AND SHAREHOLDERS' EQUITY

| | | |
|---|------------|--------------|
| Current liabilities: | | |
| Accounts payable | \$ 429,237 | \$ 1,137,676 |
| Accrued expenses | 168,694 | 463,884 |
| Current portion of long-term debt | 723,873 | 533,218 |
| Current portion of capital lease obligations | 1,020 | 5,842 |
| Total current liabilities | 1,322,824 | 2,140,620 |
| Long-term debt, less current portion | 1,626,283 | 2,350,155 |
| Capital lease obligations, less current portion | -- | 1,020 |
| Total noncurrent liabilities | 1,626,283 | 2,351,175 |
| Total liabilities | 2,949,107 | 4,491,795 |
| | ----- | ----- |

Commitments and contingencies (Notes 9 and 15)

Shareholders' equity:

 Preferred stock, \$.001 par value; authorized 1,000,000 shares

Series A participating preferred stock, voting; no shares issued or outstanding at December 31, 1998 and 1997
Common stock, \$.001 par value; authorized 10,000,000 shares; 7,452,781 and 6,750,518 issued and outstanding at December 31, 1998 and 1997, respectively

| | | |
|----------------------------|--------------|--------------|
| Additional paid-in capital | 7,453 | 6,750 |
| Accumulated deficit | 40,009,593 | 33,826,747 |
| Unearned compensation | (24,261,942) | (20,618,789) |
| | (11,000) | (22,000) |
| | ----- | ----- |
| Total shareholders' equity | 15,744,104 | 13,192,708 |
| | ----- | ----- |
| | \$18,693,211 | \$17,684,503 |
| | ===== | ===== |

</TABLE>

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

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PHARMANETICS, INC. AND SUBSIDIARIES

Consolidated Statements of Operations
For the years ended December 31, 1998, 1997 and 1996

<TABLE>

<CAPTION>

<S>

| | <C> 1998 ---- | <C> 1997 ---- | <C> 1996 ---- |
|--|---------------------|---------------------|---------------------|
| Net sales | \$ 8,790,222 | \$7,618,473 | \$6,411,519 |
| | ----- | ----- | ----- |
| Cost of sales: | | | |
| Materials and labor | 3,781,743 | 3,961,772 | 3,121,439 |
| Overhead | 2,561,775 | 2,207,340 | 2,135,605 |
| | ----- | ----- | ----- |
| Total cost of sales | 6,343,518 | 6,169,112 | 5,257,044 |
| | ----- | ----- | ----- |
| Gross profit | 2,446,704 | 1,449,361 | 1,154,475 |
| | ----- | ----- | ----- |
| Operating expenses: | | | |
| General and administrative | 3,190,666 | 3,594,158 | 2,933,016 |
| Sales and marketing | 747,638 | 1,347,309 | 1,895,492 |
| Research and development | 2,652,491 | 2,572,649 | 2,300,462 |
| | ----- | ----- | ----- |
| Total operating expenses | 6,590,795 | 7,514,116 | 7,128,970 |
| | ----- | ----- | ----- |
| Loss from operations | (4,144,091) | (6,064,755) | (5,974,495) |
| | ----- | ----- | ----- |
| Other income (expense): | | | |
| Interest expense | (377,966) | (1,638) | (16,317) |
| Interest income | 280,762 | 335,403 | 634,989 |
| Grant income | 137,993 | 278,121 | 254,204 |
| Development income | 505,000 | 825,000 | -- |
| License fee and royalty income | 22,399 | 30,741 | 32,835 |
| | ----- | ----- | ----- |
| Other income, net | 568,188 | 1,467,627 | 905,711 |
| | ----- | ----- | ----- |
| Loss before income taxes | (3,575,903) | (4,597,128) | (5,068,784) |
| | ----- | ----- | ----- |
| Provision for income taxes | (67,250) | (82,083) | (51,860) |
| | ----- | ----- | ----- |
| Net loss | (3,643,153) | (4,679,211) | (5,120,644) |
| | ----- | ----- | ----- |
| Other comprehensive (loss) income | -- | (48,078) | 42,510 |
| | ----- | ----- | ----- |
| Comprehensive loss | \$(3,643,153) | \$(4,727,289) | \$(5,078,134) |
| | ===== | ===== | ===== |
| Basic and diluted net loss per common share | \$(0.52) | \$(0.70) | \$(0.78) |
| | ===== | ===== | ===== |
| Weighted average number of outstanding common shares | 7,007,390 | 6,722,491 | 6,566,134 |
| | ===== | ===== | ===== |

</TABLE>

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

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PHARMANETICS, INC. AND SUBSIDIARIES
 Consolidated Statements of Shareholders' Equity For the
 years ended December 31, 1998, 1997 and 1996

<TABLE>
 <CAPTION>

| | Number of Shares | Common Stock | Additional Paid-In Capital | Accumulated Other Comprehensive Income | Accumulated Deficit |
|---|---------------------|-----------------|----------------------------------|---|------------------------|
| | ----- | ----- | ----- | ----- | ----- |
| <S> | <C> | <C> | <C> | <C> | <C> |
| Balances at December 31, 1995 | 6,447,562 | \$ 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 | 100,000 | 100 | 990,595 | | |
| Exercise of stock options | 126,424 | 127 | 66,787 | | |
| Repurchase of 10,000 shares of common stock at \$4.75 per share | (10,000) | (10) | (47,490) | | |
| Amortization of unearned Compensation | | | | | |
| Net loss for the year ended December 31, 1996 | | | | | (5,120,644) |
| Other comprehensive loss | | | | (42,510) | |
| | ----- | ----- | ----- | ----- | ----- |
| Balances at December 31, 1996 | 6,663,986 | 6,664 | 33,682,330 | (48,078) | (15,939,578) |
| Exercise of stock options | 86,532 | 86 | 144,417 | | |
| Amortization of unearned compensation | | | | | |
| Net loss for the year ended December 31, 1997 | | | | | (4,679,211) |
| Other comprehensive income | | | | 48,078 | |
| | ----- | ----- | ----- | ----- | ----- |
| Balances at December 31, 1997 | 6,750,518 | 6,750 | 33,826,747 | -- | (20,618,789) |
| Issuance of 600,000 shares of common stock to Chiron Diagnostics | 600,000 | 600 | 5,999,400 | | |
| Exercise of stock options | 102,263 | 103 | 183,446 | | |
| Amortization of unearned compensation | | | | | |
| Net loss for the year ended December 31, 1998 | | | | | (3,643,153) |
| | ----- | ----- | ----- | ----- | ----- |
| Balances at December 31, 1998 | 7,452,781 | \$ 7,453 | \$ 40,009,593 | \$ -- | \$ (24,261,942) |
| | ===== | ===== | ===== | ===== | ===== |

| | Unearned Compensation | Total Shareholders' Equity |
|---|--------------------------|----------------------------------|
| | ----- | ----- |
| 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 |
| Exercise of stock options | | 66,914 |
| 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) |
| Other comprehensive loss | | (42,510) |
| | ----- | ----- |
| Balances at December 31, 1996 | (33,000) | 17,668,338 |
| Exercise of stock options | | 144,503 |
| Amortization of unearned compensation | 11,000 | 11,000 |
| Net loss for the year ended December 31, 1997 | | (4,679,211) |
| Other comprehensive income | | 48,078 |
| | ----- | ----- |
| Balances at December 31, 1997 | (22,000) | 13,192,708 |
| Issuance of 600,000 shares of common stock to Chiron Diagnostics | | 6,000,000 |
| Exercise of stock options | | 183,549 |
| Amortization of unearned compensation | 11,000 | 11,000 |
| Net loss for the year ended December 31, 1998 | | (3,643,153) |
| | ----- | ----- |
| Balances at December 31, 1998 | \$ (11,000) | \$ 15,744,104 |
| | ===== | ===== |

</TABLE>
 The accompanying notes are an integral part of the consolidated financial statements.

| <TABLE> <CAPTION> <S> | <C> 1998 ---- | <C> 1997 ---- | <C> 1996 ---- |
|---|---------------------|---------------------|---------------------|
| Cash flows from operating activities: | | | |
| Net loss | \$ (3,643,153) | \$ (4,679,211) | \$ (5,120,644) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 906,311 | 775,510 | 663,809 |
| Amortization of intangible assets | 250,043 | 196,434 | 203,479 |
| Amortization of discount on investments, net | (43,650) | (22,743) | (285,509) |
| Amortization of deferred gain on sale-leaseback | -- | -- | (4,247) |
| Amortization of unearned compensation | 11,000 | 11,000 | 11,000 |
| Provision for doubtful accounts | 11,228 | -- | -- |
| Provision for inventory obsolescence | 147,000 | 220,000 | 40,000 |
| Gain on disposal of fixed assets | -- | (2,276) | (3,192) |
| Change in assets and liabilities: | | | |
| Receivables | (192,051) | (596,148) | (488,378) |
| Inventories | 306,172 | (1,199,254) | (753,947) |
| Other assets | (28,330) | 6,661 | (80,074) |
| Accounts payable and accrued expenses | (1,003,629) | 1,004,612 | (743,426) |
| | ----- | ----- | ----- |
| Net cash used in operating activities | (3,279,059) | (4,285,415) | (6,561,129) |
| | ----- | ----- | ----- |
| Cash flows (used in) from investing activities: | | | |
| Purchases of property and equipment | (511,110) | (1,494,564) | (1,417,977) |
| Proceeds from sales of property and equipment | -- | 3,433 | 23,532 |
| Costs incurred to obtain patents and other intangibles | (81,458) | (63,969) | (93,573) |
| Purchases of short-term investments, held to maturity | (3,659,469) | (2,503,852) | (10,687,896) |
| Proceeds from maturities of investments | -- | 8,500,000 | 5,000,000 |
| | ----- | ----- | ----- |
| Net cash (used in) provided by investing activities | (4,252,037) | 4,441,048 | (7,175,914) |
| | ----- | ----- | ----- |
| Cash flows from financing activities: | | | |
| Proceeds from issuance of long-term debt | -- | 3,005,404 | -- |
| Principal payments on long-term debt and capital lease obligations | (539,059) | (185,338) | (751,446) |
| Purchase of treasury stock | -- | -- | (47,500) |
| Proceeds from issuance of common stock | -- | -- | 990,695 |
| Proceeds from exercise of stock options | 183,549 | 144,503 | 66,914 |
| Proceeds from issuance of stock to Chiron Diagnostics | 6,000,000 | -- | -- |
| | ----- | ----- | ----- |
| Net cash provided by financing activities | 5,644,490 | 2,964,569 | 258,663 |
| | ----- | ----- | ----- |
| Effect of exchange rates on cash | -- | 48,078 | (42,510) |
| | ----- | ----- | ----- |
| Net (decrease) increase in cash and cash equivalents | (1,886,606) | 3,168,280 | (13,520,890) |
| Cash and cash equivalents at beginning of year | 5,884,522 | 2,716,242 | 16,237,132 |
| | ----- | ----- | ----- |
| Cash and cash equivalents at end of year | \$ 3,997,916 | \$ 5,884,522 | \$ 2,716,242 |
| | ===== | ===== | ===== |
| Supplemental disclosures of cash flow information: | | | |
| Cash paid during the year for interest expense | \$ 368,234 | \$ 1,638 | \$ 11,589 |
| | ===== | ===== | ===== |
| Cash paid during the year for income taxes | \$ 67,250 | \$ 42,819 | \$ 76,724 |
| | ===== | ===== | ===== |

</TABLE>

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

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PHARMANETICS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

ORGANIZATION

PharmaNetics, Inc. (the "Company") is a holding company incorporated in July 1998 as the parent company of Cardiovascular Diagnostics, Inc. ("CVDI"). CVDI was incorporated in November 1985 and develops, manufactures and markets rapid turnaround diagnostics to assess blood clot formation and dissolution. CVDI develops tests based on its proprietary dry chemistry diagnostic test system,

known as the Thrombolytic Assessment System ("TAS"), to provide rapid and accurate evaluation of hemostasis at the point of patient care. CVDI's wholly-owned subsidiary, Coeur Laboratories, Inc. ("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. Cardiovascular Diagnostics Europe, BV (CDE), a wholly-owned Dutch company, distributed the Company's products in Europe until March 1997 when CDE operations were ceased.

PRINCIPLES OF CONSOLIDATION

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All 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 at the date of purchase 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 investments 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 other comprehensive income (loss), a separate component of shareholders' equity.

Premiums are amortized and discounts accreted using the effective interest rate method over the remaining terms of the related securities. Gains and losses on the sale of securities are determined using the specific-identification method.

INVENTORIES

Inventories are stated at the lower of standard cost (which approximates cost on a first-in, first-out basis) or market. The Company assesses its inventory on a periodic basis and recognizes reserves for obsolescence when necessary.

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1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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. Patent costs are capitalized and 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.

IMPAIRMENT OF LONG-LIVED ASSETS

The Company evaluates the recoverability of its property and equipment and intangible assets in accordance with Statement of Financial Accounting Standards No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived

Assets to be Disposed of ("SFAS No. 121"). SFAS No. 121 requires recognition of impairment of long-lived assets in the event the net book value of such assets exceeds the future undiscounted cash flows attributable to such assets. No such impairments were required to be recognized during the years ended December 31, 1998, 1997 and 1996.

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 and development 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. The Company periodically enters into agreements to sell its products under fixed price contracts. Management evaluates these contracts and recognizes a reserve if it becomes evident that the Company will incur losses under these agreements. No such reserves were necessary at December 31, 1998 or 1997.

INCOME TAXES

Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities. These assets, liabilities and tax carryforwards are determined 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

On December 31, 1997, the Company adopted Statement of Financial Accounting Standards, "Earnings Per Share" ("SFAS No. 128"). In accordance with SFAS 128, the Company has replaced the presentation of primary earnings per share ("EPS") with a presentation of basic EPS and has presented both basic and diluted EPS on the face of the Statement of Operations. Basic EPS excludes dilution and is computed by dividing income available to common shareholders by the weighted average number of common shares outstanding for the period. Diluted EPS

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1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

is computed using the weighted average number of shares of common and dilutive potential common shares outstanding during the period. The Company's diluted EPS for the years ended December 31, 1998, 1997 and 1996 is the same as basic EPS because, for loss periods, potential common shares (such as options) are not included in computing diluted EPS since the effect would be antidilutive. Options currently outstanding that could be dilutive in the future are summarized in Note 10.

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. Accordingly, no compensation expense has been recognized for stock options to employees that are granted with an exercise price equal to or above the trading price per share of the Company's common stock on the grant date. Note 10 summarizes the compensation cost for the Company's plans if the grants had been based on the fair value at the grant dates consistent with SFAS No. 123.

FAIR VALUE OF FINANCIAL INSTRUMENTS

Statement of Financial Accounting Standard No. 107, "Disclosures about the Fair Value of Financial Instruments" (SFAS No. 107) requires the disclosure of fair value information about financial instruments, whether or not recognized on the balance sheet, for which it is practicable to estimate the value. Where quoted market prices are not readily available, fair values are based on quoted market prices of comparable instruments. The carrying amount of cash and equivalents, accounts receivable and accounts payable approximates fair value because of the short maturity of those instruments. The estimated values of the Company's short-term investments are provided in Note 2. The fair value of the Company's long-term debt is provided in Note 8.

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.

SEGMENT INFORMATION

Beginning in 1998, the Company has adopted Statement of Financial Accounting Standards No. 131 "Disclosures about Segments of an Enterprise and Related Information" ("SFAS No. 131"). SFAS No. 131 replaces the "industry segment" approach with the "management" approach. The management approach designates the internal organization that is used by management for making operating decisions and assessing performance as the source of the Company's reportable segments. SFAS No. 131 also requires disclosures about products and services, geographic areas, and major customers. The adoption of SFAS No. 131 did not affect results of operations or financial position of the Company but did affect the disclosure of segment information. Note 11 summarizes segment information concerning the Company.

COMPREHENSIVE INCOME (LOSS)

Beginning in 1998, the Company has adopted Statement of Financial Accounting Standards No. 130 "Reporting Comprehensive Income" ("SFAS No. 130"). SFAS No. 130 requires the Company to display an amount representing comprehensive income (loss) for the period in a financial statement which is displayed with the same prominence as other financial statements. As required by SFAS No. 130, prior year information has been modified to conform with the new presentation. There were no items of other comprehensive income (loss) for the year ended December 31, 1998. The Company's only items of other comprehensive income (loss) for the years ended December 31, 1997 and 1996 relate to foreign currency translation adjustments.

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2. SHORT-TERM INVESTMENTS

Investment securities at December 31, 1998 are all classified as held-to-maturity and are summarized as follows:

<TABLE>
<CAPTION>

| | Amortized Cost | Gross Unrealized | | Estimated Market Value |
|---------------------------|-------------------|------------------|---------|---------------------------|
| | | Gains | Losses | |
| Held-to-maturity: | | | | |
| <S> | <C> | <C> | <C> | <C> |
| U.S. Treasury obligations | \$2,468,221 | \$ 8,707 | \$6,479 | \$ 2,470,449 |
| U.S. Agency obligations | 1,234,898 | 728 | -- | 1,235,626 |
| | \$3,703,119 | \$ 9,435 | \$6,479 | \$ 3,706,075 |

</TABLE>

At December 31, 1997, no short-term investments were held by the Company.

3. INVENTORIES

Inventories at December 31, 1998 and 1997 consisted of the following:

| | 1998 | 1997 |
|----------------|--------------|--------------|
| Raw materials | \$ 1,860,650 | \$ 2,122,058 |
| Finished goods | 536,784 | 875,994 |
| | \$ 2,397,434 | \$ 2,998,052 |

4. PROPERTY AND EQUIPMENT

Property and equipment at December 31, 1998 and 1997 consisted of the following:

<TABLE>
<CAPTION>
<S>

| | 1998 | 1997 |
|--------------------------------------|--------------|--------------|
| Molds and equipment | \$ 6,344,757 | \$ 6,039,207 |
| Furniture, fixtures and IT equipment | 1,030,520 | 966,927 |
| Leasehold improvements | 1,276,304 | 1,134,337 |
| Equipment under capital leases | 266,291 | 266,291 |
| | 8,917,872 | 8,406,762 |

| | | |
|--|--------------|--------------|
| Less accumulated depreciation and amortization | 4,374,948 | 3,468,637 |
| | ----- | ----- |
| | \$ 4,542,924 | \$ 4,938,125 |
| | ===== | ===== |

</TABLE>

5. INTANGIBLE ASSETS

Intangible assets at December 31, 1998 and 1997 consisted of the following:

| | 1998 | 1997 |
|-------------------------------|--------------|-------------|
| | ---- | ---- |
| Goodwill | \$ 1,802,506 | \$1,802,506 |
| Patents | 598,888 | 517,430 |
| Other | 257,446 | 110,000 |
| | ----- | ----- |
| | 2,658,840 | 2,429,936 |
| Less accumulated amortization | 1,111,884 | 861,841 |
| | ----- | ----- |
| | \$ 1,546,956 | \$1,568,095 |
| | ===== | ===== |

F-10

6. RESEARCH AND DEVELOPMENT GRANTS

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

<TABLE>

<CAPTION>

<S>

| | <C> | <C> | <C> |
|--|-----------|-----------|-----------|
| | 1998 | 1997 | 1996 |
| | ---- | ---- | ---- |
| Grant award of \$100,000 for research related to a rapid immunoassay for acute myocardial injury detection | \$ -- | \$ -- | \$ 10,466 |
| Phase II grant award of \$750,000 for research related to rapid monitoring of antithrombin agents | 137,993 | 278,121 | 243,738 |
| | ----- | ----- | ----- |
| | \$137,993 | \$278,121 | \$254,204 |
| | ===== | ===== | ===== |

</TABLE>

7. DEVELOPMENT INCOME

During 1998, the Company recognized \$505,000 of development income related to collaboration agreements with Knoll AG, Astra AB, and Dade International, and in 1997 recognized \$825,000 of development income related to collaboration agreements with Knoll AG, Eli Lilly and Company, and Dade International. All development income was the result of the Company meeting milestones under the terms of these collaboration agreements.

8. LONG-TERM DEBT

Long-term debt as of December 31, 1998 and 1997 consisted of the following:

| | 1998 | 1997 |
|--|--------------|-------------|
| | ---- | ---- |
| Convertible financial assistance agreement | \$ 50,000 | \$ 50,000 |
| Notes payable | 2,300,156 | 2,833,373 |
| | ----- | ----- |
| | 2,350,156 | 2,883,373 |
| Current portion of long-term debt | 723,873 | 533,218 |
| | ----- | ----- |
| Long-term debt, excluding current portion | \$ 1,626,283 | \$2,350,155 |
| | ===== | ===== |

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 accrued interest at 7.5% per annum, was due and paid in January 1999.

In December 1997, the Company received a loan for \$3,005,404 from Transamerica Business Credit Corporation to fund working capital and capital expenditures. The loan has an interest rate of 15%, payable monthly, and is collateralized by existing fixed assets and new equipment financed under the loan. The loan includes certain covenants relating to, among other things, the maintenance of

the collateral. Management believes the Company was in compliance with these covenants at December 31, 1998. The aggregate amounts of maturities on this loan are as follows: 1999, \$673,873; 2000, \$785,544; and 2001, \$840,739.

The fair value of long-term debt is estimated by discounting the future cash flows using current rates offered for similar debt issues. The fair values of long-term debt at December 31, 1998 and 1997 were approximately \$2,420,000 and \$2,883,000, respectively.

9. LEASES

The Company leases its office space under a noncancelable operating lease agreement which extends through 2001. In addition, the Company leases certain equipment under various capital and operating lease agreements. Rent expense related to operating leases totaled \$427,811, \$471,592 and \$416,635 for the years ended December 31, 1998, 1997 and 1996, respectively. The Company has a remaining obligation under capital leases at December 31, 1998 of \$1,030, which will be paid during 1999.

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9. LEASES (continued)

Future minimum lease payments under operating leases as of December 31, 1998 are as follows:

| Year ending December 31, | |
|------------------------------|------------|
| 1999 | \$ 400,270 |
| 2000 | 410,550 |
| 2001 | 61,721 |
| 2002 | 16,020 |
| 2003 | 12,015 |
| | ----- |
| Total minimum lease payments | \$ 900,576 |
| | ===== |

10. STOCK OPTIONS

The Company maintains two stock option plans whereby nonqualified and incentive stock options may be granted to employees, consultants and directors of the Company. Under these plans, options to purchase common stock are granted at a price determined by the Board of Directors. The options may be exercised during specified future periods and generally vest over four years and generally expire ten years from the date of grant. In 1994, the Company established the 1994 Stock Plan in which 639,249 shares of the Company's common stock were reserved for issuance. In 1995, the shareholders of the Company approved, effective upon completion of the Company's initial public offering, the adoption of the Company's 1995 Stock Plan in which 838,150 shares of the Company's common stock are reserved for issuance.

A summary of the status of the Company's Plans as of December 31, 1998, 1997 and 1996, and changes during the years ending on those dates is presented below:

<TABLE>
<CAPTION>
<S>

| | <C> 1998 | | <C> 1997 | | <C> 1996 | |
|----------------------------------|-------------|--|-------------|--|-------------|--|
| | Shares | Weighted Average Exercise Price | Shares | Weighted Average Exercise Price | Shares | Weighted Average Exercise Price |
| | ----- | ----- | ----- | ----- | ----- | ----- |
| Outstanding at beginning of year | 878,190 | \$ 2.88 | 757,796 | \$ 2.15 | 865,000 | \$ 3.58 |
| Granted | 67,634 | \$ 5.01 | 323,375 | \$ 4.88 | 109,000 | \$ 4.50 |
| Exercised | (90,266) | \$ 1.19 | (86,532) | \$ 1.67 | (126,508) | \$ 0.73 |
| Forfeited | (14,492) | \$ 4.75 | (116,449) | \$ 4.58 | (89,696) | \$ 0.58 |
| | ----- | ----- | ----- | ----- | ----- | ----- |
| Outstanding at end of year | 841,066 | \$ 3.19 | 878,190 | \$ 2.88 | 757,796 | \$ 2.15 |
| | ===== | ===== | ===== | ===== | ===== | ===== |
| Options exercisable at year-end | 527,161 | | 498,280 | | 451,558 | |
| | ===== | | ===== | | ===== | |

</TABLE>

The weighted average fair value of options granted during the years ended December 31, 1998, 1997 and 1996 was \$2.83, \$3.14 and \$2.66, respectively.

F-12

10. STOCK OPTIONS (continued)

The following table summarizes information about the Plan's stock options at December 31, 1998:

<TABLE>
<CAPTION>

| Range of Exercise Prices | Options Outstanding | | | Options Exercisable | |
|--------------------------|--------------------------------|---|---------------------------------|--------------------------------|---------------------------------|
| | Number Outstanding at 12/31/98 | Weighted Average Remaining Contractual Life | Weighted Average Exercise Price | Number Exercisable at 12/31/98 | Weighted Average Exercise Price |
| <S> | <C> | <C> | <C> | <C> | <C> |
| \$0.79 | 345,898 | 5.5 years | \$.79 | 337,036 | \$.79 |
| \$3.75 - \$6.38 | 490,168 | 8.1 years | \$ 4.81 | 185,125 | \$ 4.68 |
| \$10.00 | 5,000 | 7.4 years | \$ 10.00 | 5,000 | \$ 10.00 |
| | ----- | | | ----- | |
| | 841,066 | | | 527,161 | |
| | ===== | | | ===== | |

</TABLE>

For purposes of the proforma disclosures required by SFAS No. 123, the fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions used for grants in 1998, 1997 and 1996, respectively:

| | 1998 | 1997 | 1996 |
|--------------------------|---------|---------|---------|
| Dividend yield | ---- | ---- | ---- |
| Volatility | 51% | 65% | 63% |
| Risk free interest rate | 5.4% | 5.75% | 6.25% |
| Expected life of options | 6 years | 6 years | 6 years |

For purposes of the proforma disclosures required by SFAS No. 123, the estimated fair value of equity instruments is amortized to expense over their respective vesting periods. Had compensation cost for the Company's stock-based compensation plans, as described above, been determined consistent with SFAS No. 123, the Company's net loss and net loss per share would have been increased to the pro forma amounts indicated below. The compensation costs disclosed here may not be representative of the effects on pro forma net income in future years.

<TABLE>
<CAPTION>
<S>

| | | <C> 1998 | <C> 1997 | <C> 1996 |
|---------------------------|-------------|----------------|----------------|----------------|
| Net loss | As reported | \$ (3,643,153) | \$ (4,679,211) | \$ (5,120,644) |
| | Pro forma | (4,022,591) | (5,011,787) | (5,199,261) |
| Net loss per common share | As reported | \$ (0.52) | \$ (0.70) | \$ (0.78) |
| | Pro forma | (0.57) | (0.75) | (0.79) |

</TABLE>

11. SEGMENT INFORMATION

The Company is organized and manages its business primarily on the basis of its operating divisions, CVDI and Coeur. Each of these segments earns revenue, incurs expenses and has discrete financial information available to it. Segment expenses include allocations of certain expenses to each segment. Management evaluates the performance of its segments based on net income (loss). The accounting policies of the segments are the same as those described in the "Summary of Significant Accounting Policies".

F-13

11. SEGMENT INFORMATION (continued)

The table below presents information concerning revenues, net income (loss) and segment assets:

<TABLE>
<CAPTION>

| | 1998 | | |
|-------------------|----------------|--------------|----------------|
| | CVDI | Coeur | Consolidated |
| <S> | <C> | <C> | <C> |
| Revenues | \$ 4,140,763 | \$ 4,649,459 | \$ 8,790,222 |
| Net income (loss) | \$ (4,223,438) | \$ 580,285 | \$ (3,643,153) |

Total assets \$ 14,460,017 \$ 4,233,194 \$ 18,693,211

| 1997 | | | |
|-------------------|----------------|--------------|----------------|
| | CVDI | Coeur | Consolidated |
| | ---- | ---- | ----- |
| Revenues | \$ 2,924,008 | \$ 4,694,465 | \$ 7,618,473 |
| Net income (loss) | \$ (5,459,974) | \$ 780,763 | \$ (4,679,211) |
| Total assets | \$ 13,477,483 | \$ 4,207,020 | \$ 17,684,503 |

| 1996 | | | |
|-------------------|----------------|--------------|----------------|
| | CVDI | Coeur | Consolidated |
| | ---- | ---- | ----- |
| Revenues | \$ 1,830,056 | \$ 4,581,463 | \$ 6,411,519 |
| Net income (loss) | \$ (5,793,979) | \$ 673,335 | \$ (5,120,644) |
| Total assets | \$ 14,948,574 | \$ 3,402,781 | \$ 18,351,355 |

</TABLE>

During the years ended December 31, 1998, 1997 and 1996 there were sales to customers that exceeded 10% of net consolidated sales. Sales to these customers were: 1998 - customer A, \$2,137,715 (24%), customer B, \$1,490,867 (17%), customer C, \$1,311,631 (15%), and customer D, \$1,755,820 (20%); 1997 - customer A, \$2,291,581 (30%), customer B, \$1,375,728 (18%), and customer C, \$1,276,566 (17%); 1996 - customer A, \$2,192,778 (34%), customer B, \$671,188 (10%) and customer C, \$195,400 (3%).

The Company had operations in two geographic regions, the United States and Europe, until March 31, 1997. At that date, the Company closed its European office and European sales are now made through foreign distributors. During 1997 and 1996, revenues from those foreign operations were approximately \$99,000 and \$725,000, respectively, substantially all of which were from customers in Europe and the United Kingdom. In addition, the Company's identifiable assets of its foreign operations were less than 10% of its consolidated total assets during these periods.

The Company generated revenue from sales to different geographic areas for 1998, 1997 and 1996 as follows:

<TABLE>
<CAPTION>
<S>

| | <C> 1998 | | <C> 1997 | | <C> 1996 | |
|---------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| | Coeur | CVDI | Coeur | CVDI | Coeur | CVDI |
| | ----- | ----- | ----- | ----- | ----- | ----- |
| United States | \$3,661,512 | \$1,459,339 | \$3,441,219 | \$2,081,796 | \$2,989,640 | \$1,105,277 |
| United Kingdom | 601,045 | 246,138 | 769,942 | 188,498 | 957,980 | 188,027 |
| Germany | 85,425 | 2,028,111 | 233,817 | 116,657 | 236,603 | 405,001 |
| Sweden | -- | 247,495 | -- | 78,116 | -- | -- |
| Other foreign sales | 301,477 | 159,680 | 249,487 | 458,941 | 397,240 | 131,751 |
| Total sales | \$4,649,459 | \$4,140,763 | \$4,694,465 | \$2,924,008 | \$4,581,463 | \$1,830,056 |
| | ===== | ===== | ===== | ===== | ===== | ===== |

</TABLE>

F-14

12. CONCENTRATION OF CREDIT RISK

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents and accounts receivable. The Company places its temporary cash in accounts with federally insured depository institutions. At December 31, 1998 the Company had a majority of its cash and cash equivalents in one financial institution.

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 historical losses, in the aggregate, have not exceeded management's expectations.

13. 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 \$22,399, \$30,741 and \$32,835 during the years ended December 31 1998, 1997 and 1996, respectively.

14. INCOME TAXES

Income tax expense consisted entirely of current state taxes of \$67,250, \$82,083 and \$51,860 for the years ended December 31, 1998, 1997 and 1996, 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, 1998, 1997 and 1996 is as follows:

<TABLE>
<CAPTION>
<S>

| | <C> 1998 ---- | <C> 1997 ---- | <C> 1996 ---- |
|---|---------------------|---------------------|---------------------|
| Expected income tax benefit at federal statutory rate | \$(1,215,808) | \$(1,563,159) | \$(1,706,576) |
| State tax provision (benefit) | 7,351 | (175,748) | (114,326) |
| Goodwill amortization | 62,830 | 62,830 | 62,830 |
| Compensation paid with incentive stock options | 3,740 | 3,740 | 3,740 |
| Other | 5,361 | 7,373 | 16,192 |
| Distribution premium | 850,000 | -- | -- |
| Change in valuation allowance | 353,776 | 1,747,047 | 1,790,000 |
| | ----- | ----- | ----- |
| Net income tax provision | \$ 67,250 | \$ 82,083 | \$ 51,860 |
| | ===== | ===== | ===== |

</TABLE>

The components of the net deferred tax assets and net deferred tax liabilities as of December 31, 1998 and 1997 were as follows:

<TABLE>
<CAPTION>
<S>

| | <C> 1998 ---- | <C> 1997 ---- |
|--------------------------------------|---------------------|---------------------|
| Deferred tax assets: | | |
| Accrued expenses | \$ 5,000 | \$ 15,000 |
| Alternative minimum tax credits | 9,000 | 9,000 |
| Net operating loss carryforward | 8,922,000 | 7,825,000 |
| Research and development credits | 229,000 | 229,000 |
| Foreign tax credits | 35,000 | 35,000 |
| Other | 85,000 | 108,000 |
| | ----- | ----- |
| Total gross deferred tax assets | 9,285,000 | 8,221,000 |
| Valuation allowance | (8,417,000) | (7,923,000) |
| | ----- | ----- |
| Net deferred tax assets | 868,000 | 298,000 |
| | ----- | ----- |
| Deferred tax liabilities: | | |
| Patents | 171,000 | 159,000 |
| Investment adjustment | 490,000 | -- |
| Fixed assets | 207,000 | 139,000 |
| | ----- | ----- |
| Total gross deferred tax liabilities | 868,000 | 298,000 |
| | ----- | ----- |
| Net deferred taxes | \$ -- | \$ -- |
| | ===== | ===== |

</TABLE>

14. INCOME TAXES (continued)

At December 31, 1998 and 1997, the Company had approximately \$23,402,000 and \$20,718,000, respectively, of combined federal 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 2004 through 2018 if not utilized. At December 31, 1998 and 1997 for state income tax purposes, Cardiovascular Diagnostics, Inc. had net operating loss carryforwards of approximately \$20,169,000 and \$17,185,073, respectively. These carryforwards expire in 1999 through 2003 if not utilized. To the extent that Coeur's net operating losses incurred through 1994 (approximately \$2,000,000 at December 31, 1998) are utilized in the future, the benefit will reduce the excess of cost over fair value of net assets acquired. The 1998 valuation allowance includes an allowance against net operating losses generated by tax only deductions for stock options for approximately \$140,000, for which the benefit will go directly to shareholders equity.

Due to the Company's history of operating losses and uncertainty regarding its ability to generate taxable income in the future, management has determined that a valuation allowance equal to the amount of net deferred tax assets is required at December 31, 1998 and 1997.

As a result of changes in ownership in prior years, as defined by Internal Revenue Code Section 382, Coeur's loss carryforwards generated through December 31, 1993 and the Company's consolidated loss carryforwards generated through January 1994 will be subject to an annual limitation of \$175,000 and \$482,000, respectively.

An additional change in ownership occurred in 1995 in connection with the Company's initial public offering which subjects the loss carryforwards generated during the period from January 1994 to December 1995 to an incremental annual limitation of \$1,954,000 per year.

15. CONTINGENCIES

In March 1997, the Company filed suit in the U.S. District Court, Eastern District of North Carolina, against Boehringer Mannheim Corporation ("BMC") located in Indiana. The suit charged BMC with misappropriation of CVDI's trade secrets by improper disclosure, breach of contract, breach of fiduciary duty, unfair and deceptive trade practices, and constructive fraud. In addition, CVDI requested a declaratory judgment that neither the products nor activities of CVDI infringe U.S. Patents purportedly owned by BMC. On April 9, 1997 BMC answered the claims made by CVDI and submitted a patent infringement counterclaim against CVDI. Each party filed a motion for judgment on the pleading with respect to all claims asserted by the other party. On November 10, 1997, the Court issued a Judgment and Order granting CVDI's motion for judgment on the pleadings, holding that CVDI has a license, until June 21, 1999 or until the last of the patents expire, to the patents at issue. It dismissed all other claims of the parties. Both parties appealed and on February 1, 1999, the United States Court of Appeals for the Federal Circuit issued an opinion in which it affirmed the decision of the district court in all respects. While either party could petition for rehearing by the entire court, or could petition the United States Supreme Court to consider the case, it is management's opinion that the disposition of this matter will not have a material adverse effect on the consolidated financial position, results of operations or liquidity of the Company.

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PHARMANETICS, INC.
SCHEDULE II - VALUATION AND QUALIFYING ACCOUNTS
For the years ended December 31, 1998, 1997 and 1996

<TABLE>

<CAPTION>

| | Balance at Beginning of Period ----- | Charge to Costs and Expenses ----- | Deductions ----- | Balance at End of Period ----- |
|----------------------------------|---|---|------------------------|---|
| YEAR ENDED DECEMBER 31, 1998 | | | | |
| Deducted from asset accounts: | | | | |
| <S> | <C> | <C> | <C> | <C> |
| Accounts Receivable Reserve (a) | \$ 3,792 ===== | \$ 11,228 ===== | \$ 794 (f) ===== | \$ 14,226 ===== |
| Inventory Reserves (b) | \$231,339 ===== | \$147,000 ===== | \$293,339 (e) ===== | \$ 85,000 ===== |
| Added to liability accounts: | | | | |
| Warranty Reserves (c) | \$ 38,571 ===== | -- ===== | \$ 28,571 (d) ===== | \$ 10,000 ===== |
| YEAR ENDED DECEMBER 31, 1997 | | | | |
| Deducted from asset accounts: | | | | |
| Accounts Receivable Reserve (a) | \$ 5,000 ===== | \$ -- ===== | \$ 1,208 (f) ===== | \$ 3,792 ===== |
| Inventory Reserves (b) | \$ 48,256 ===== | \$220,000 ===== | \$ 36,917 (e) ===== | \$231,339 ===== |
| Added to liability accounts: | | | | |
| Warranty Reserves (c) | \$ 43,845 ===== | -- ===== | \$ 5,274 (g) ===== | \$ 38,571 ===== |
| YEAR ENDED DECEMBER 31, 1996 | | | | |
| Deducted from asset accounts: | | | | |
| Accounts Receivable Reserves (a) | \$ 40,395 ===== | \$ -- ===== | \$ 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 ===== | \$ -- ===== | \$ 6,155 (g) ===== | \$ 43,845 ===== |

</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 reduction in warranty reserves and costs incurred to fulfill warranty claims.
- (e) Represents inventory items written down to lower of cost or market.
- (f) Represents uncollectible accounts written off.
- (g) Represents costs incurred to fulfill warranty claims.

Report of Independent Accountants

February 23, 1999

The Board of Directors and Shareholders
PharmaNetics, Inc.

Our report on the consolidated financial statements of PharmaNetics, 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 consolidated financial statement schedule, Schedule II--Valuation and Qualifying Accounts, included 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.

PRICEWATERHOUSECOOPERS LLP

S-1

CONSENT OF INDEPENDENT ACCOUNTANTS

We consent to the incorporation by reference in the registration statements of PharmaNetics, Inc. (formerly Cardiovascular Diagnostics, Inc.) on Forms S-8 (File Nos. 333-32901, 333-32901-99 and 333-68357) of our report dated February 23, 1999 on our audits of the consolidated financial statements and the consolidated financial statement schedule of PharmaNetics, Inc. and subsidiaries as of December 31, 1998 and 1997, and for each of the three years in the period ended December 31, 1998, which report is included in this Annual Report on Form 10-K.

PRICEWATERHOUSECOOPERS LLP

Raleigh, North Carolina
March 26, 1999

<TABLE> <S> <C>

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| <INVENTORY> | 3,397,434 |
| <CURRENT-ASSETS> | 12,466,240 |
| <PP&E> | 8,917,872 |
| <DEPRECIATION> | (4,374,948) |
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| <BONDS> | 1,626,283 |
| <PREFERRED-MANDATORY> | 0 |
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| <COMMON> | 7,453 |
| <OTHER-SE> | 15,736,651 |
| <TOTAL-LIABILITY-AND-EQUITY> | 18,693,211 |
| <SALES> | 8,790,222 |
| <TOTAL-REVENUES> | 8,790,222 |
| <CGS> | 6,343,518 |
| <TOTAL-COSTS> | 6,343,518 |
| <OTHER-EXPENSES> | 6,590,795 |
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| <INCOME-PRETAX> | (3,575,903) |
| <INCOME-TAX> | 67,250 |
| <INCOME-CONTINUING> | (3,643,153) |
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| <EXTRAORDINARY> | 0 |
| <CHANGES> | 0 |
| <NET-INCOME> | (3,643,153) |
| <EPS-PRIMARY> | (0.52) |
| <EPS-DILUTED> | (0.52) |

</TABLE>