

Edgar Filing: PHARMANETICS INC - Form 10-K

PHARMANETICS INC  
Form 10-K  
March 30, 2001

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, 2000 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 incorporation or organization)	(I.R.S. Employer Identification No.)

5301 DEPARTURE DRIVE, RALEIGH, NORTH CAROLINA	27616
(Address of principal executive offices)	(Zip Code)

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

SECURITIES REGISTERED PURSUANT TO SECTION 12(B) OF THE ACT: NONE

SECURITIES REGISTERED PURSUANT TO SECTION 12(G) OF THE ACT: COMMON STOCK (NO 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 \$8.00 per share, the closing price of the Common Stock on  
March 16, 2001, on the NASDAQ National Market System, was approximately  
\$62,242,000 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 16, 2001, the registrant had outstanding 7,851,948 shares of Common

## Edgar Filing: PHARMANETICS INC - Form 10-K

Stock (no par value).

### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company's Proxy Statement for the 2001 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 Might Affect Future Results" and elsewhere, as well as in the Company's other filings with the Securities and Exchange Commission, and including, in particular, the ability of the Company to implement its business strategy, risks relating to new product development, uncertainties regarding market acceptance of the Company's products, government regulation, healthcare industry consolidation and competition.

### PART I

#### ITEM 1. BUSINESS

PharmaNetics, Inc. (the "Company"), through its wholly-owned subsidiary Cardiovascular Diagnostics, Inc. ("CVDI"), develops, manufactures and markets rapid turnaround diagnostics to assess blood clot formation and dissolution. CVDI's products are a proprietary analyzer and dry chemistry tests, known as the Thrombolytic Assessment System or TAS, that provide, at the point of patient care, rapid and 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. CVDI's 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 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 disorders. 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 hospital central and stat laboratories, which currently provide the majority of such testing, generally cannot provide timely information to clinicians regarding drugs that affect coagulation and thrombolysis. Delay in providing such information can be a problem because 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 and thrombolysis as well as drug monitoring on a timely basis, 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.

## Edgar Filing: PHARMANETICS INC - Form 10-K

The Company currently sells domestically and internationally its TAS analyzer and a menu of tests and controls. Of these tests, the following have received Food and Drug Administration, or FDA, clearance under Section 510(k) of the Food, Drug and Cosmetic Act and are currently sold for commercial use: Prothrombin Time ("PT"); PT non-citrated ("PTNC"); PT One; activated Partial Thromboplastin Time ("aPTT"); Heparin Management test ("HMT"); and Heparin Management Panel and Accent system which combines the TAS technology and the currently marketed HMT with two new test cards, the Heparin Titration test ("HTT") and Protamine Response test ("PRT") with the Accent, a hardware accessory to the TAS analyzer. The Low Range Heparin Management Test ("LHMT") has been cleared by the FDA and will begin to be sold during 2001. 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". In addition, the Company has obtained a Humanitarian Device Exemption, or HDE, for its ECT card, which is used in managing patients suffering from heparin induced thrombocytopenia, or HIT. HDE approval is an accelerated FDA authorization process to market devices used in rare disease states where no existing solution is available.

### INDUSTRY OVERVIEW

Blood testing within the practice of laboratory medicine has been evolving in response to the physician's demand for information. This demand for information is particularly acute in blood testing, where access to timely and accurate results is critical to effective patient care. Initially, hospital blood analysis was performed in multiple small laboratories that typically used time-consuming manual techniques. The accuracy of tests performed under these conditions varied considerably depending upon, among other factors, the skill of the laboratory personnel. The advent of automated blood testing 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. As diagnostics move closer to the patient, the centralized lab

-2-

has had a reduced role in the purchasing decisions for point-of-care systems. The physician is more likely to have influence over the use of point-of-care technology given its ability to be a valuable tool for managing therapy.

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 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 often performed by operators who lack 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, or CLIA, and its 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

## Edgar Filing: PHARMANETICS INC - Form 10-K

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, or 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.

TAS can test unprocessed whole blood or plasma. Whole blood is obtained 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 significant time to the process. Plasma, which is typically used in laboratory testing, is whole blood which has had various cellular components removed through spinning the blood in a centrifuge for 10 to 15 minutes.

The analyzer and test cards are designed to work effectively in a decentralized testing environment where they are used by healthcare personnel who do not need formal central laboratory training. To operate TAS, a test card is passed 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, noncitrated or citrated 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

## Edgar Filing: PHARMANETICS INC - Form 10-K

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

-3-

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. It is currently marketed by the Company's distributor, Bayer Diagnostics, as the Rapidpoint Coag analyzer.

### ACCENT

The Accent is a hardware accessory to the TAS analyzer cleared for marketing by the FDA during 2000. The Accent is a microprocessor-based device that connects to the TAS analyzer and automatically calculates the information required by physicians to manage the anticoagulation of patients during cardiopulmonary bypass procedures. It is used in conjunction with the HTT, PRT and HMT cards and is marketed by Bayer as Rapidpoint ACCENT. The data collected by Accent can be transferred to a printer and/or hospital information system for storage.

### FDA-CLEARED TEST CARDS

The following describes CVDI's test cards that have been cleared 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, 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, and 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 aPTT test is a coagulation screening test which may be used in conjunction with the PT to provide a global assessment of a patient's ability to form a clot. In addition, the aPTT test is used to monitor heparin, an injectable anticoagulant. Hospitals routinely use heparin as the initial treatment for patients with a clot, including patients suffering from heart attacks or strokes. Heparin also prevents clots from forming in patients undergoing procedures involving particular risks of clotting, such as angiography, open heart surgery, dialysis 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. The Company developed and markets its HMT for monitoring patients requiring high dose heparin therapy during procedures such as open heart surgery 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 comparable tests

## Edgar Filing: PHARMANETICS INC - Form 10-K

because it is easier to use and less prone to operator error. Also, it 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 comparable tests.

During 2000, the HTT and PRT were cleared for marketing by the FDA. The HTT and PRT cards are combined with the currently marketed HMT to provide a system for total individualized heparin management during cardiac surgery. Heparin management is complicated due to patients' widely variable response to this drug as well as its clearance rate from the blood during surgery. Heparin dosing based on weight-based protocols is often unreliable, particularly in complicated cases with patients receiving simultaneous therapy. CVDI believes the HTT/PRT approach should make it easier and cost effective to incorporate individual heparin management into routine practice.

The LHMT card was also cleared for marketing by the FDA during 2000. This test is used principally in cardiac catheterization and interventional cardiology procedures. It is designed to monitor the effects of low to moderate levels of heparin.

The Company also received approval from the FDA during 2000 for a HDE for its ECT card, which is used in managing patients suffering from heparin induced thrombocytopenia. The approval covers the use of the test for managing patients who receive Refludan while undergoing cardiopulmonary bypass.

-4-

### TEST CARDS UNDER DEVELOPMENT

The Company is continuing research and development focused on expanding the current menu of tests for the TAS analyzer. CVDI is currently developing the following new tests:

Test	Description
Enoxaparin Test	Test to monitor the anticoagulant effect of enoxaparin (Aventis) used for the treatment and prevention of thrombotic diseases
Protein C Test	Test for monitoring and screening potential treatments 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 AstraZeneca
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

### QUALITY CONTROL PRODUCTS

The Company also develops single-use "crush-vial" controls for each test card.

## Edgar Filing: PHARMANETICS INC - Form 10-K

These controls are produced by CVDI and a contract manufacturer and allow quality assurance testing at the point of care. In addition, the Company sells an Electronic Quality Control ("EQC") card used to test analyzer function.

### SALES AND MARKETING

CVDI's marketing strategy for its PT, aPTT and HMT test cards relies on a distribution partner. In December 1998, previous distribution agreements with Dade Behring and Avecor Cardiovascular were terminated, at which time Chiron Diagnostics Corporation became CVDI's new distribution partner pursuant to the agreement discussed below. In connection with the CVDI's termination of the Dade agreement, CVDI agreed to continue to supply for three years the cards currently sold to Dade's contracted customers. In November 1998, Bayer acquired Chiron Diagnostics and it became a part of Bayer Diagnostics.

In August 1998, CVDI signed a five-year global distribution agreement, subject to minimum annual sales, with Chiron Diagnostics 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 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. 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 with Bayer Diagnostics, Bayer Diagnostics agreed to purchase minimum quantities of CVDI's products covered by the Bayer agreement during the term of the Bayer agreement at pre-determined prices. The Bayer agreement is renewable for successive five-year terms. CVDI has the right to terminate the Bayer 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, or (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 Bayer

-5-

agreement by the 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 and Bayer Diagnostics is CVDI's exclusive distributor in these territories.

The Company's strategy is to increasingly focus on becoming a leader in the theranostic testing market, specifically managing new therapeutics which affect coagulation. Many drugs currently under development may require faster, more accurate assessment, given short half-lives and narrow therapeutic windows, and thus the Company believes physicians will increasingly demand therapeutic drug monitoring. To further the goal of establishing itself in the emerging field of theranostics, the Company has entered into collaborative agreements with Aventis Pharmaceuticals, Knoll AG and AstraZeneca in which the Company is developing test cards for potential use in patient identification and monitoring of therapies affecting coagulation being investigated by these companies. Under certain of these agreements, CVDI has agreed to develop and supply test cards. Under each of these agreements, CVDI has granted the other party rights to

## Edgar Filing: PHARMANETICS INC - Form 10-K

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 use the reagent within the test.

CVDI's intent is to enter into additional collaborations to expand its theranostic test card menu. Within the cardiovascular market, drugs affecting coagulation, such as thrombin inhibitors, platelet inhibitors and low molecular weight heparins, are under development by pharmaceutical companies. The Company's strategy is to increase its number of collaborations, expand current collaborations, increase involvement of leading research centers and physician "thought leaders" and further the involvement of Bayer in working with other pharmaceutical companies to engage in outcome studies related to new theranostic tests. During 2000, the Company continued to expand its clinical trial programs with the Enoxaparin card. Additionally, a multi-center study was initiated with the TIMI Study Group at Harvard Medical School to investigate the predictive value of the LOT test in patients receiving thrombolytic therapy. The Company believes that the use of the test in combination with the electrocardiogram will provide physicians with a valuable tool to help physicians with an early predictor of failed therapy.

The Company's strategy is focusing its theranostic test development efforts on drugs in Phase II or Phase III development. The Company believes this will help reduce development risk as these drugs have a greater chance of approval than those just beginning clinical trials. Additionally, under this model the pharmaceutical company pays for the clinical trials and provides the Company access to the regulatory data associated with the test to be used in submitting a 510(k). This approach is designed to allow the Company to cost-effectively develop its tests. If the Company is unsuccessful in implementing its business strategy, its results of operations will be adversely impacted.

The commercial success of the Company's products will depend upon their acceptance by the medical community 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 and the receipt of regulatory clearances in the United States and elsewhere. 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 central laboratories will resist yielding 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 routine test cards, the PT, aPTT, and HMT and the related controls and analyzer. Bayer also distributes the specialty cards HTT and PRT. 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



## Edgar Filing: PHARMANETICS INC - Form 10-K

The medical diagnostic testing industry is characterized by rapidly evolving technology and intense competition. The current TAS menu competes in the coagulation and hematology testing market with manufacturers that provide testing equipment to central and stat laboratories of hospitals. These laboratories currently perform a substantial portion of such testing. The TAS menu also competes 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

-6-

results, ease-of-use, reduced opportunity for error and cost-effectiveness.

CVDI has several competitors, including Roche Diagnostics, 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, data management, ease-of-use, compliance with CLIA guidelines, and availability of a comprehensive test menu. If CVDI introduces additional blood tests beyond its initial coagulation and hematology tests, it will compete with other 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 that compete 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 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

## Edgar Filing: PHARMANETICS INC - Form 10-K

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 might have developed 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 might 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 might 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.

### LICENSES

#### TOKUYAMA SODA LICENSE

CVDI is a party to a License Agreement with Tokuyama Soda Company, Ltd. 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 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. 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.

-7-

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 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 improvements made by Tokuyama to 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 \$58,909, \$89,507 and \$22,399 during the years ended December 31, 2000, 1999, and 1998, respectively.

### MANUFACTURING

CVDI operates its manufacturing facility to assemble TAS analyzers. Vendors currently provide all molded parts, mechanical components and printed circuit

## Edgar Filing: PHARMANETICS INC - Form 10-K

boards. CVDI assembles the components and provides final mechanical, electrical and chemistry testing of each analyzer. In addition, CVDI operates proprietary automated test card production equipment. 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. Upon moving into a new facility during 2001, manufacturing capacity will increase to approximately 15 million cards.

The FDC Act requires the Company to manufacture its products in registered establishments and in accordance with Good Manufacturing Practice, or GMP, now known as Quality System Regulations, or QSR. CVDI is registered as a medical device manufacturer and is subject to periodic inspections by the FDA. In addition, CVDI has maintained ISO 9001 certification since 1997.

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 might 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, some 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.

### 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, design control, labeling, distribution and promotion of medical devices. Noncompliance with applicable requirements can result in, among other things:

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

## Edgar Filing: PHARMANETICS INC - Form 10-K

Before a new device can be introduced into the market, the manufacturer must generally obtain marketing clearance through either a 510(k) notification, the HDE process or the more time-consuming PMA process. All of the Company's currently cleared products have qualified for either the 510(k) process or the accelerated HDE 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) application to obtain a 510(k) clearance, but it might take longer. The FDA might 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 might require that additional 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 might be prohibited from marketing the modified device until the 510(k) is cleared by the FDA.

Pursuant to FDA policy, manufacturers of devices labeled "for investigational use only" must establish a controlled program under which investigational devices are distributed to or utilized only by individuals, laboratories or healthcare facilities that have provided the manufacturer with a written certification of compliance indicating that:

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

## Edgar Filing: PHARMANETICS INC - Form 10-K

certain instances by the Federal Trade Commission. The FDA actively enforces regulations prohibiting marketing of products for unapproved uses.

### 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, or 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 LOT test, the ECT test and the modified ECT test.

-9-

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 these tests 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 order to market the Company's products in the member countries of the European Union, the Company is required to comply with the European Medical Devices Directive and to obtain CE Mark certification 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 display the CE Mark. All of the applicable Company products marketed in Europe have obtained CE Mark

## Edgar Filing: PHARMANETICS INC - Form 10-K

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 the Clinical Laboratory Improvement Act of 1988, or CLIA. The CLIA 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, HMT, HTT and PRT tests performed by TAS have been categorized by the FDA and the Centers for Disease Control and Prevention 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 by the FDA 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.

### 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 might 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

## Edgar Filing: PHARMANETICS INC - Form 10-K

Healthcare Organizations. Various states and municipalities might 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 may depend 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, or 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. In addition, under current HCFA regulations, equipment costs generally are not reimbursed separately, but rather are included in a single, fixed-rate, per-patient reimbursement. 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, might 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.

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.

### DISCONTINUED OPERATIONS

In June 1999, the Company sold substantially all of the operating assets and liabilities of its Coeur Laboratories, Inc. subsidiary. Prior to this sale, the Company operated Coeur as a manufacturer and seller of disposable power injection syringes. Upon the sale of Coeur, the Company retained Coeur's cash, receivables and certain other assets.

### PRODUCT LIABILITY AND INSURANCE

## Edgar Filing: PHARMANETICS INC - Form 10-K

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 \$14 million per claim, with an annual aggregate policy limit of \$15 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 91 employees as of December 31, 2000. Thirteen employees were engaged in research and development (7 of which have Ph D's), 37 in manufacturing and quality control, 19 in software, engineering and facilities, 8 in sales/marketing and 14 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,

-11-

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 currently occupies approximately 45,000 square feet of development, production and administration space at this location. The Company is in the process of moving all its development, production and administrative operations to a new facility located at 9401 Globe Center Drive, Suite 140, Morrisville, North Carolina 27560. This move is expected to be completed by the third quarter of 2001.

### ITEM 3. LEGAL PROCEEDINGS

The Company is not a party to any material legal proceedings as of the date of this Form 10-K.

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

No matters were submitted to a vote of the shareholders during the fourth quarter ended December 31, 2000.

### EXECUTIVE OFFICERS OF THE COMPANY

The following sets forth information as of March 31, 2001 with respect to all



## Edgar Filing: PHARMANETICS INC - Form 10-K

the executive officers of the Company, including their names, ages, positions with the Company and business experience during the last five years.

John P. Funkhouser, age 47, 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. Mr. Funkhouser served as President and Chief Executive Officer of Coeur from 1992 until completion of the sale of Coeur in June 1999. 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.

James A. McGowan, age 57, was elected Chief Financial Officer of the Company in May 2000. Since 1982, Mr. McGowan has been a principal of McGowan Associates, a boutique venture capital and consulting firm. Venture capital activities have included a partnership with First Chicago Corp (McGowan Leckinger) and a co-investment with The Thomas Lee Company (Sterling Merchandise). Mr. McGowan's consulting activities have ranged from interim executive positions at Filenes Basement, The TAC Group and the TJX Companies to strategic consulting projects for Arthur Andersen and a variety of small to mid-size growth companies. Prior to founding McGowan Associates, Mr. McGowan was the chief financial officer and a principal-selling stockholder of three retail chains that were acquired by large public companies. Mr. McGowan is a Certified Public Accountant and holds a B.S. from Boston University and an M.B.A. from Suffolk University.

Dick D. Timmons II, age 55, 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.

Michael D. Riddle, age 48, has been Executive Vice President of Sales, Marketing, and Business Development since January 1999. Mr. Riddle also served as Vice President, Sales and Marketing, from January 1995 to January 1999. Prior to joining the Company, Mr. Riddle was employed by American Home Products for seven years in various positions, most recently as Vice President of Sales and Marketing for Sherwood Medical Devices. Mr. Riddle attended Bromley College of Technology (Kent, United Kingdom).

Peter J. Scott, age 52, 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 seven 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.

-12-

Cynthia Pritchard, Ph.D., age 49, has served as Executive Director of Research and Development since 1997. Dr. Pritchard has been director and principal scientist since joining the Company in 1992. Prior to joining the Company, Dr. Pritchard had over 20 years in diagnostic test development experience with Syva, Serono, Becton Dickenson and Gene-Trak Systems. Dr. Pritchard holds a B.A. in Bacteriology from the University of South Florida and a Ph.D. in Biochemistry

## Edgar Filing: PHARMANETICS INC - Form 10-K

from Virginia Tech.

Paul T. Storey, age 34, 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 Company's common stock trades 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 the Company for the fiscal years ended December 31, 2000 and 1999 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, 2000		
First Quarter	\$ 18	\$ 9
Second Quarter	19 7/8	11 7/8
Third Quarter	22 3/4	17 1/16
Fourth Quarter	19	9 5/8
Fiscal year ended December 31, 1999		
First Quarter	\$ 6	\$ 2 5/8
Second Quarter	7	3 3/4
Third Quarter	7 13/16	4 1/2
Fourth Quarter	9 1/4	4 13/16

##### (b) Approximate Number of Equity Security Holders

As of March 15, 2001, the number of record holders of the company's common stock was approximately 100, and the Company believes that the number of beneficial owners was approximately 2,600.

##### (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 on its common stock.

-13-

#### ITEM 6. SELECTED CONSOLIDATED 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)

Edgar Filing: PHARMANETICS INC - Form 10-K

			Year Ended December 31, -----
RESULTS OF OPERATIONS	2000 ----	1999 ----	1998 ----
Net sales	\$ 4,269	\$ 3,909	\$ 4,141
Cost of goods sold	3,581	3,179	2,847
Gross profit	688	730	1,294
Operating expenses:			
General and administrative	3,330	2,715	2,815
Sales and marketing	1,050	799	707
Research and development	3,697	2,777	2,509
Total operating expenses	8,075	6,291	6,031
Other income, net	1,053	147	514
Loss from continuing operations	(6,334)	(5,414)	(4,223)
Discontinued operations:			
Income from operations	-	18	580
Loss on disposal	-	(826)	-
	-----	-----	-----
Net loss	(6,334)	(6,222)	(3,643)
Beneficial conversion feature of Series A Preferred Stock	(3,004)	-	-
Preferred stock dividends	(626)	-	-
	-----	-----	-----
Net and comprehensive loss attributable to common shareholders	\$ (9,964)	\$ (6,222)	\$ (3,643)
	=====	=====	=====
Basic and diluted loss per common share:			
Net loss	\$ (0.83)	\$ (0.83)	\$ (0.52)
Net loss attributable to common shareholders	\$ (1.31)	\$ (0.83)	\$ (0.52)
Weighted average shares outstanding	7,626	7,469	7,007
Pro forma amounts assuming SAB 101 was retroactively applied(1):			
Net and comprehensive loss attributable to common shareholders	\$ (9,964)	\$ (5,926)	\$ (3,475)
Basic and diluted loss attributable to common shareholders per share	\$ (1.31)	\$ (0.79)	\$ (0.50)
			As of December 3 -----
FINANCIAL CONDITION	2000 ----	1999 ----	1998 ----
Cash and cash equivalents	\$ 5,344	\$ 3,661	\$ 3,998
Short term investments	3,904	1,500	3,703
Total assets	18,314	11,647	18,693

## Edgar Filing: PHARMANETICS INC - Form 10-K

Long term debt and capital lease obligations, excluding current portion	36	862	1,626
Total liabilities	3,632	2,039	2,949
Accumulated deficit	(40,448)	(30,484)	(24,262)
Series A Preferred stock	8,102	-	-
Common shareholders' equity	\$ 6,580	\$ 9,608	\$ 15,744

(1) In fiscal 2000, the Company adopted SEC Staff Accounting Bulletin No. 101 ("SAB 101"). Under this method of accounting, development payments are deferred and recognized into income over the period of the related agreement. The amounts disclosed assume that SAB 101 was retroactively applied to prior years.

-14-

### 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 market acceptance risk, development and clinical trials risk, 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, dependence on third party distributors and collaborative partners 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.

PharmaNetics, Inc., through its wholly-owned subsidiary Cardiovascular Diagnostics, Inc. ("CVDI"), develops, manufactures and markets rapid turnaround diagnostics to assess blood clot formation and dissolution. CVDI's products are a proprietary analyzer and dry chemistry tests, known as the Thrombolytic Assessment System or TAS that provide, at the point of patient care, rapid and 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.

The Company currently derives income from the following sources: TAS product sales; interest income; and development income recognized in connection with collaboration agreements. The TAS technology is used at the point of patient care which provides many potential benefits, including faster results for better treatment of patients, reduced usage of blood products for bleeding complications, quicker patient transfers from costly critical care settings and reduced hospital costs due to less paperwork and personnel time in processing blood samples. Currently, product sales mainly consist of the Company's routine test cards, the PT, aPTT and HMT tests along with the related controls and analyzers. Upon introduction of these products in 1993 and 1995, the Company distributed these routine products through a direct sales force. However, given a consolidating hospital industry, CVDI determined that distribution arrangements, rather than a direct sales force, were needed to penetrate the market. In August 1998 CVDI signed a global distribution agreement with Chiron Diagnostics, now known as Bayer Diagnostics, which has replaced the distribution agreements which existed prior to such date. Bayer's strength is in critical care areas of the hospital which the Company believes should facilitate the

## Edgar Filing: PHARMANETICS INC - Form 10-K

placement of the TAS technology.

In addition, the Company's business strategy has evolved towards becoming more focused on theranostics, the development of specialty tests for drugs, some with narrow ranges between over- and under-dosage. Rapid diagnostic capabilities might improve patient care and turnover, and there is a market trend to obtain diagnostic information faster in order to effect therapy sooner. The Company believes that physicians are beginning to see the need for drug management tools and consequently, the Company is seeking greater involvement of physician thought leaders during development. The Company also believes that these trends should allow the Company to obtain higher pricing of these specialty tests. As a result, 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, AstraZeneca and Aventis to monitor the effects of certain new drugs that are in clinical trials or currently being marketed. Increased placement of specialty tests may 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, 2000 VS. YEAR ENDED DECEMBER 31, 1999. Sales for the year ended December 31, 2000 increased 10% to \$4.3 million compared to \$3.9 million in 1999. This increase was largely attributable to increased analyzer sales as total analyzer revenue in 2000 was \$1,065,000 compared to \$795,000 in 1999. 2000 revenue from test cards and controls sales totaled \$2.8 million, essentially unchanged compared to 1999. The gross profit margin in 2000 was 16% compared to 19% in 1999, the reduction mainly due to increased costs in overhead related to additional personnel.

Total operating expenses for 2000 totaled \$8.1 million compared to \$6.3 million 1999. General and administrative expenses increased compared to 1999 due to more personnel and increased facility costs, some of which related to the Company's planned move to new facilities, expected to be completed in the third quarter of 2001. Sales and marketing expenses increased due to new expenditures for marketing research. Research and development expenses increased approximately 33% in 2000 compared to 1999. The change was mainly due to increased personnel and increased clinical trial costs related to the Company's development projects.

Interest expense for the year ended December 31, 2000 decreased to \$200,000 compared to \$313,000 in the prior year as the Company continued to pay down its debt. Interest income increased in 2000 compared to 1999 due to increased average investment balances during the year due to the preferred stock issuance in February 2000.

-15-

Development income totaled \$491,000 in 2000 compared to \$100,000 in 1999. This increase was due to revenues derived from collaboration agreements signed with Bayer Diagnostics and Aventis during 2000.

In February 2000, the Company completed a private placement of 120,000 shares of Series A convertible preferred stock for aggregate proceeds of \$11,220,000. The Series A has a dividend of 6% payable quarterly in cash or in shares of common stock at the option of the Company. During the year ended December 31, 2000, the Series A dividend was paid by issuing 40,065 shares of common stock totaling \$626,638. In addition, on the date of the Company's issuance of the Series A, the effective conversion price of the preferred stock was at a discount to the price of the common stock into which the Series A is convertible. In accordance

## Edgar Filing: PHARMANETICS INC - Form 10-K

with accounting guidelines at the time of the preferred stock issuance, this discount totaled \$975,600. It was recorded as a preferred stock dividend and amortized over the three-month period until conversion was possible. In November 2000, further accounting guidance was issued which required the Company to record an additional discount of \$2,027,990 during the Company's fourth quarter.

YEAR ENDED DECEMBER 31, 1999 VS. YEAR ENDED DECEMBER 31, 1998. Sales for the year ended December 31, 1999 decreased 6% to \$3.9 million compared to \$4.1 million in 1998. This decline was largely attributable to decreased analyzer revenue from Knoll in 1999 compared to 1998. Of total analyzer revenue in 1998 of \$1.5 million, \$1.4 million was the result of sales to Knoll for their clinical trials. Total analyzer revenue in 1999 was \$795,000. 1999 revenue from test card sales totaled \$2.8 million, a 16% increase compared to 1998. The gross profit margin in 1999 was 19% compared to 31% in 1998 mainly due to lower average sale prices for TAS analyzers and routine cards.

Total operating expenses for 1999 of \$6.3 million represents an increase of 4% compared to 1998. General and administrative expenses declined slightly compared to 1998, which included one-time expenses related to the formation of the holding company. Sales and marketing expenses increased slightly due to higher personnel costs compared to 1998. Research and development expenses increased approximately 11% in 1999 compared to 1998. The change was primarily due to increased personnel costs.

Interest expense for the year ended December 31, 1999 decreased to \$313,000 compared to \$378,000 in the prior year as the Company continued to pay down its debt. Interest income decreased slightly in 1999 compared to 1998 due to decreased average investment balances during the year as funds were used to support operations.

Grant and development income decreased in 1999 approximately \$543,000 compared to 1998. 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 1999 compared to 1998.

### LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2000, the Company had cash and cash equivalents and short-term investments of \$9.2 million and working capital of \$8.4 million, as compared to \$5.2 million and \$6.5 million, respectively, at December 31, 1999. The Company's cash position increased during the year due to the issuance of preferred stock offset by capital expenditures, repayment of debt and the funding of operating losses.

During 2000, the Company used cash in operating activities of \$2.7 million. The use of cash was due to funding the net operating loss of the Company, partially offset by funding provided by decreased receivables and increased payables and receipt of funds from collaborations that was recorded as deferred revenue.

Net cash used in investing activities was \$6.2 million in 2000. The net cash used resulted mainly from the net purchases of short-term investments and expenditures for new equipment and leasehold improvements related to the Company's planned move to new facilities, expected to be complete in the third quarter of 2001. The Company expects to incur capital expenditures of \$1,500,000 to \$2,500,000 during 2001.

Cash provided by financing activities was \$10.6 million in 2000. This increase principally resulted from the issuance of preferred stock in February 2000.

The Company expects to incur additional operating losses during 2001. The Company's working capital requirements will depend on many factors, primarily

## Edgar Filing: PHARMANETICS INC - Form 10-K

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 might 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 might 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 its distribution agreement with Bayer Diagnostics, will be adequate to satisfy its planned capital requirements through 2001. If

-16-

additional liquidity becomes necessary in the future, the Company will consider external sources of financing as needed. These financings may take the form of equity financings such as a private placement of common or preferred stock, a secondary public offering of common stock or additional equity infusions from collaborative partners, as well as debt financings such as a working capital line of credit.

### RECENT ACCOUNTING PRONOUNCEMENTS

In December 1999, the Securities and Exchange Commission (the "SEC") issued Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" ("SAB 101"). SAB 101, as amended by SAB 101A and SAB 101B, provided broad conceptual discussions and industry-specific guidance concerning revenue recognition. The Company adopted SAB 101 in January 2000 and, accordingly, is amortizing collaborative revenue received over the anticipated development period.

The Emerging Issues Task Force (the "EITF") issued No. 98-5 "Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios" ("EITF 98-5"). EITF 98-5 provides guidance concerning the accounting for issuances of convertible preferred stock and warrants. On the date of the Company's issuance of the Series A Preferred Stock, the effective conversion price of the preferred stock was at a discount to the price of the common stock into which the Series A is convertible. In accordance with EITF 98-5 guidance at the time of the preferred stock issuance, this discount totaled \$975,600. It was recorded as a preferred stock dividend and amortized over the three-month period until conversion was possible. In November 2000, the EITF issued further interpretations which required the Company to record an additional discount of \$2,027,990 during the Company's 2000 fourth quarter.

In March 2000, the Financial Accounting Standards Board issued Interpretation No. 44, ("FIN 44") "Accounting for Certain Transactions Involving Stock Compensation - An Interpretation of APB 25". This interpretation clarifies: the definition of employee for purposes of applying APB 25, the criteria for determining whether a plan qualifies as a noncompensatory plan, the accounting consequence of various modifications to the terms of previously fixed stock options or awards, and the accounting for an exchange of stock compensation awards in business combinations. FIN 44 was effective on July 1, 2000 and the Company adopted its provisions. The adoption did not have a material impact on the Company's consolidated results of operations.

### FACTORS THAT MIGHT AFFECT FUTURE RESULTS

A number of uncertainties exist that might affect the Company's future operating results and stock price, including: risks associated with development of new

## Edgar Filing: PHARMANETICS INC - Form 10-K

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; competition within the diagnostic testing industry 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 twelve 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.

-17-

### 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 intends to file a definitive proxy statement for its 2001 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



## Edgar Filing: PHARMANETICS INC - Form 10-K

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
-----	-----
3.3(a)	Bylaws.
3.4(f)	Amended and Restated Articles of Incorporation filed with the North Carolina Secretary of State on

-18-

4.1(a)	February 24, 2000 Form of Common Stock certificate.
10.2(a)*	License Agreement with Tokuyama Soda Company, Ltd., dated October 6, 1988.
10.3(a)	Form of International Distributor Agreement.

## Edgar Filing: PHARMANETICS INC - Form 10-K

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.
10.8(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.
10.18(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.
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
10.24(f)	Series A Preferred Stock and Warrant Purchase Agreement dated February 24, 2000
10.25(f)	Form of Warrant between the Company and the Series A Investors dated February 25, 2000
10.26	Lease Agreement dated July 27, 2000 relating to 9401 Globe Center Drive, as amended by the First Lease Amendment dated September 25, 2000.
21.1(a)	List of Subsidiaries.
23.1	Consent of Independent Accountants.

\* Confidential treatment granted.

(a) Incorporated herein by reference to the identically-numbered exhibit 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.

(f) Incorporated by reference to the identically-numbered exhibit to the Registrant's Current Report on Form 8-K filed March 1, 2000.

-19-

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.

## Edgar Filing: PHARMANETICS INC - Form 10-K

Date:

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, Chief Executive Officer and Chairman (Principal Executive Officer)	March 28, 2001
/s/ James A. McGowan ----- James A. McGowan	Chief Financial Officer (Principal Financial Officer)	March 28, 2001
/s/ Paul T. Storey ----- Paul T. Storey	Treasurer and Director of Finance (Principal Accounting Officer)	March 28, 2001
/s/ William A. Hawkins ----- William A. Hawkins	Director	March 28, 2001
/s/ John K. Pirotte ----- John K. Pirotte	Director	March 28, 2001
/s/ Stephen R. Puckett ----- Stephen R. Puckett	Director	March 28, 2001
/s/ Philip R. Tracy ----- Philip R. Tracy	Director	March 28, 2001
/s/ Frances L. Tuttle ----- Frances L. Tuttle	Director	March 28, 2001
/s/ James B. Farinholt, Jr. ----- James B. Farinholt, Jr.	Director	March 28, 2001

-20-

PHARMANETICS, INC.  
AND SUBSIDIARIES

INDEX

Edgar Filing: PHARMANETICS INC - Form 10-K

Page(s)

Consolidated Financial Statements:

Report of Independent Accountants	F-2
Consolidated Balance Sheets as of December 31, 2000 and 1999	F-3
Consolidated Statements of Operations for the Years Ended December 31, 2000, 1999 and 1998	F-4
Consolidated Statements of Shareholders' Equity for the Years Ended December 31, 2000, 1999 and 1998	F-5
Consolidated Statements of Cash Flows for the Years Ended December 31, 2000, 1999 and 1998	F-6
Notes to Consolidated Financial Statements	F-7 - F-16

F-1

REPORT OF INDEPENDENT ACCOUNTANTS

The Board of Directors and Shareholders of PharmaNetics, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of shareholders' equity and of cash flows present fairly, in all material respects, the financial position of PharmaNetics, Inc. and subsidiaries (the "Company") at December 31, 2000 and 1999, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2000, in conformity with accounting principles generally accepted in the United States of America. 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 auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, 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 our opinion.

/s/ PricewaterhouseCoopers LLP

Raleigh, North Carolina  
February 14, 2001

F-2

PHARMANETICS, INC. AND SUBSIDIARIES  
Consolidated Balance Sheets  
December 31, 2000 and 1999

Edgar Filing: PHARMANETICS INC - Form 10-K

ASSETS

Current assets:

Cash and cash equivalents  
Short term investments, held-to-maturity (estimated  
market value of \$3,902,489 and \$1,498,590, respectively)

Receivables:

Trade, net of allowance for doubtful accounts of \$4,339  
and \$29,556, respectively  
Other

Total receivables

Inventories

Other current assets

Total current assets

Property and equipment, net  
Patents and intellectual property, net  
Other noncurrent assets

Total assets

LIABILITIES, REDEEMABLE PREFERRED STOCK AND SHAREHOLDERS' EQUITY

Current liabilities:

Accounts payable  
Accrued expenses  
Deferred revenue, current portion  
Current portion of long-term debt  
Current portion of capital lease obligations

Total current liabilities

Noncurrent liabilities:

Deferred revenue, less current portion  
Long-term debt, less current portion  
Capital lease obligations, less current portion

Total noncurrent liabilities

Total liabilities

Commitments and contingencies (Note 10)

Series A convertible preferred stock, no par value; authorized 120,000 shares;  
97,500 and 0 shares issued and outstanding at December 31, 2000 and 1999,  
respectively (aggregate liquidation value at December 31, 2000 of \$9,750,000)

Shareholders' equity:

Common stock, no par value; authorized 40,000,000 shares; 7,851,225 and

## Edgar Filing: PHARMANETICS INC - Form 10-K

7,480,919 issued and outstanding at December 31, 2000 and 1999, respectively  
Accumulated deficit

Total shareholders' equity

Total liabilities, redeemable preferred stock and shareholders' equity

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

F-3

PHARMANETICS, INC. AND SUBSIDIARIES  
Consolidated Statements of Operations  
For the years ended December 31, 2000, 1999 and 1998

	2000 ----	1999 ----
Net sales	\$ 4,269,234	\$ 3,909,234
Cost of sales:		
Materials and labor	1,422,152	1,226,152
Overhead	2,158,613	1,953,613
Total cost of sales	3,580,765	3,179,765
Gross profit	688,469	730,469
Operating expenses:		
General and administrative	3,330,411	2,715,411
Sales and marketing	1,050,733	798,733
Research and development	3,693,604	2,777,604
Total operating expenses	8,074,748	6,291,748
Loss from operations	(7,386,279)	(5,561,279)
Other income (expense):		
Interest expense	(200,391)	(312,391)
Interest income	702,572	270,572
Grant income	--	--
Development income	491,666	100,666
License fee and royalty income	58,909	89,909
Other income, net	1,052,756	146,756

Edgar Filing: PHARMANETICS INC - Form 10-K

Loss from continuing operations	(6,333,523)	(5,414)
Discontinued operations:		
Income from operations of Coeur Laboratories, Inc. (net of income taxes of \$0, \$13,685 and \$67,250, respectively)	-	17
Loss on disposal of Coeur Laboratories, Inc. (including income taxes of \$14,000)	-	(826)
Net and comprehensive loss	(6,333,523)	(6,222)
Amortization of beneficial conversion feature of Series A convertible preferred stock	(3,003,590)	
Preferred stock dividends	(626,638)	
Net and comprehensive loss attributable to common shareholders	\$ (9,963,751)	\$ (6,222)
Basic and diluted net loss per common share:		
From continuing operations	\$ (0.83)	\$ (0.83)
From discontinued operations	\$ -	\$ -
Net and comprehensive loss	\$ (0.83)	\$ (0.83)
Net loss attributable to common shareholders	\$ (1.31)	\$ (1.31)
Weighted average number of outstanding common shares	7,626,473	7,469

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

F-4

PHARMANETICS, INC. AND SUBSIDIARIES  
Consolidated Statements of Shareholders' Equity  
For the years ended December 31, 2000, 1999 and 1998

	Common Stock		Accumulated	Une
	Number of	Amount	Deficit	Compe
	Shares	Amount	Deficit	Compe
	-----	-----	-----	-----
Balances at December 31, 1997	6,750,518	\$33,833,497	\$ (20,618,789)	\$
Issuance of 600,000 shares of common stock to Chiron Diagnostics	600,000	6,000,000	--	--
Stock options exercised	90,263	107,049	--	--
Stock-based compensation	12,000	76,500	--	--
Amortization of unearned compensation	--	--	--	--
Net loss for the year ended December 31, 1998	--	--	(3,643,153)	--
	-----	-----	-----	-----

Edgar Filing: PHARMANETICS INC - Form 10-K

Balances at December 31, 1998	7,452,781	40,017,046	(24,261,942)
Stock options exercised	16,138	24,647	--
Stock-based compensation	12,000	51,000	--
Amortization of unearned compensation	--	--	--
Net loss for the year ended December 31, 1999	--	--	(6,222,470)
	-----	-----	-----
Balances at December 31, 1999	7,480,919	40,092,693	(30,484,412)
Issuance of warrants	--	1,106,403	--
Conversions of preferred stock to common stock	225,000	2,011,050	--
Stock options exercised	104,241	177,585	--
Warrants exercised	1,000	10,000	--
Issuance of stock dividends	40,065	626,638	(626,638)
Amortization of beneficial conversion feature	--	3,003,590	(3,003,590)
Net loss for the year ended December 31, 2000	--	--	(6,333,523)
	-----	-----	-----
Balances at December 31, 2000	7,851,225	\$47,027,959	\$(40,448,163)
	=====	=====	=====

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

F-5

PHARMANETICS, INC. AND SUBSIDIARIES  
Consolidated Statements of Cash Flows For  
the years ended December 31, 2000, 1999 and 1998

	2000	1999	1998
	-----	-----	-----
Cash flows from operating activities:			
Net loss	\$ (6,333,523)	\$(6,222,470)	\$(3,643,523)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock based compensation	--	51,000	76,000
Depreciation and amortization	971,781	890,424	906,000
Amortization of intangible assets	159,421	222,850	250,000
Loss on disposal of Coeur Laboratories, Inc.	--	826,093	--
Amortization of discount on investments	(371,043)	(46,881)	(43,000)
Amortization of unearned compensation	--	11,000	11,000
Provision for doubtful accounts	3,574	--	11,000
Provision for inventory obsolescence	109,460	95,462	147,000
Gain on disposal of fixed assets	(9,782)	--	--
Change in operating assets and liabilities:			
Receivables	661,634	1,066,777	(192,000)
Inventories	(65,950)	261,365	306,000
Other assets	(190,731)	(91,621)	(28,000)
Accounts payable and accrued expenses	1,225,297	(145,880)	(1,003,000)
Deferred revenue	1,128,869	--	--
	-----	-----	-----
Net cash used in operating activities	(2,710,993)	(3,081,881)	(3,202,000)
	-----	-----	-----
Cash flows from investing activities:			
Purchases of property and equipment	(4,146,849)	(404,452)	(511,000)



## Edgar Filing: PHARMANETICS INC - Form 10-K

Costs incurred to obtain patents and other intangibles	(37,223)	(52,849)	(81,072)
Purchases of short-term investments, held to maturity	(10,533,080)	(3,250,000)	(3,659,080)
Proceeds from maturities of investments	8,500,000	5,500,000	1,661,150
Proceeds from sale of segment	--	1,661,150	--
	-----	-----	-----
Net cash (used in) provided by investing activities	(6,217,152)	3,453,849	(4,252,303)
	-----	-----	-----
 Cash flows from financing activities:			
Principal payments on long-term debt and capital lease obligations	(796,218)	(733,625)	(539,593)
Proceeds from exercise of stock options and warrants	187,585	24,647	107,538
Proceeds from issuance of stock to Chiron Diagnostics	--	--	6,000
Proceeds from issuance of Series A preferred stock	11,219,621	--	--
	-----	-----	-----
Net cash provided by (used in) financing activities	10,610,988	(708,978)	5,567,473
	-----	-----	-----
Net increase (decrease) in cash and cash equivalents	1,682,843	(337,010)	(1,886,406)
Cash and cash equivalents at beginning of year	3,660,906	3,997,916	5,884,322
	-----	-----	-----
Cash and cash equivalents at end of year	\$ 5,343,749	\$ 3,660,906	\$ 3,997,916
	=====	=====	=====
 Supplemental disclosures of cash flow information:			
Cash paid during the year for interest expense	\$ 200,391	\$ 334,467	\$ 368,858
	=====	=====	=====
Cash paid during the year for income taxes	\$ 0	\$ 13,685	\$ 67,000
	=====	=====	=====

See Note 1 for supplemental disclosures of non-cash financing and investing activities.

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

F-6

### PHARMANETICS, INC. AND SUBSIDIARIES Notes to Consolidated Financial Statements

#### 1. ORGANIZATION AND 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. Coeur Laboratories, Inc. ("Coeur"), which sold and manufactured disposable power injection syringes, is a wholly-owned subsidiary of Cardiovascular Diagnostics, Inc. In June 1999, substantially all of the operating assets and liabilities of Coeur were sold. Cardiovascular Diagnostics Europe, BV ("CDE") is a wholly-owned Dutch company that distributed the Company's products in Europe until March 1997 when it ceased operations.

##### PRINCIPLES OF CONSOLIDATION

The consolidated financial statements include the accounts of the Company and

## Edgar Filing: PHARMANETICS INC - Form 10-K

its wholly-owned subsidiaries, including Coeur through June 15, 1999. All intercompany balances and transactions have been eliminated in consolidation.

### CASH EQUIVALENTS

The Company considers all highly liquid investments with a maturity of three months or less at the date of purchase to be cash equivalents.

### INVESTMENTS

Investments consist primarily of United States government agency obligations, notes and corporate bonds. The Company invests in high-credit quality investments in accordance with its investment policy which minimizes the possibility of loss. Investments with maturities at date of purchase beyond three months and which mature at or less than twelve months from the balance sheet date are classified as current. Investments are considered to be held-to-maturity and are accounted for in accordance with Statement of Financial Accounting Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities." Realized gains and losses are determined using the specific identification method and transactions are recorded on a settlement date basis.

### 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.

### 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.

### PATENTS AND INTELLECTUAL PROPERTY

Patents and intellectual property costs are capitalized and are amortized using the straight-line method over their estimated useful lives of 17 years. Periods of amortization are evaluated periodically to determine whether later events and circumstances warrant revised estimates of useful lives.

F-7

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

### IMPAIRMENT OF LONG-LIVED ASSETS

The Company evaluates the recoverability of its property and equipment, patents and intellectual property 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

## Edgar Filing: PHARMANETICS INC - Form 10-K

ended December 31, 2000, 1999 and 1998.

### REVENUE AND INCOME RECOGNITION POLICIES

Revenue from the sale of products is recorded when all risks of ownership have passed to the buyer. Income under license and development agreements, including up-front development payments, is recognized over the anticipated period of research or license with the collaborators. 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, 2000 or 1999.

### 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 more likely than not expected to be realized.

### NET LOSS PER COMMON SHARE

Basic net loss per common share attributable to common shareholders excludes dilution and is computed by dividing net loss attributable to common shareholders by the weighted average number of common shares outstanding for the period. Diluted net loss attributable to common shareholders is computed using the weighted average number of shares of common and dilutive potential common shares outstanding during the period. The Company's basic and diluted net loss attributable to common shareholders for the years ended December 31, 2000, 1999 and 1998 is the same because, for loss periods, potential common shares would be antidilutive. Options currently outstanding that could be dilutive in the future are summarized in Note 12.

### STOCK-BASED COMPENSATION

The Company has 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 granted to employees with an exercise price equal to or above the trading price per share of the Company's common stock on the grant date. Note 12 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.

In March 2000, the Financial Accounting Standards Board issued Interpretation No. 44, ("FIN 44") "Accounting for Certain Transactions Involving Stock Compensation - An Interpretation of APB 25". This interpretation clarifies: the definition of employee for purposes of applying APB 25, the criteria for determining whether a plan qualifies as a noncompensatory plan, the accounting consequence of various modifications to the terms of previously fixed stock options or awards, and the accounting for an exchange of stock compensation awards in business combinations. FIN 44 was effective on July 1, 2000 and the Company adopted its provisions. The adoption did not have a material impact on the Company's consolidated results of operations.

### FAIR VALUE OF FINANCIAL INSTRUMENTS

## Edgar Filing: PHARMANETICS INC - Form 10-K

The carrying amount of cash and cash equivalents, accounts receivable, accounts payable and accrued expenses 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 debt is provided in Note 9.

F-8

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

#### 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.

#### COMPREHENSIVE INCOME (LOSS)

The Company calculates and discloses comprehensive income in accordance with 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. There were no items of other comprehensive income (loss) for 2000, 1999 or 1998.

#### CASH FLOW INFORMATION

A supplemental schedule of non-cash financing activities follows:

	Year Ended D	
	2000	199
	-----	-----
Acquisition of assets through capital leases	\$ 20,863	\$39
Amortization of beneficial conversion feature of Series A Preferred Stock	3,003,590	
Dividends on convertible preferred stock	626,638	
Conversion of Series A Preferred Stock into common stock	2,011,050	
Issuance of warrants in conjunction with preferred stock financing	62,400	
Purchases of property, plant and equipment in accounts payable at year end	\$ 734,162	\$

#### RECENT ACCOUNTING PRONOUNCEMENTS

In December 1999, the Securities and Exchange Commission (the "SEC") issued Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" ("SAB 101"). SAB 101, as amended by SAB 101A and SAB 101B, provided broad conceptual discussions and industry-specific guidance concerning revenue recognition. The four major criteria that must be met in recognizing revenue under SAB 101 are: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller's price to the buyer is fixed or determinable; and (4) collectibility is reasonably assured. The Company adopted SAB 101 in January 2000 and, accordingly, is amortizing collaborative revenue received over the anticipated development period. No cumulative effect adjustment was required as a result of the adoption as work under these arrangements was completed prior to 2000. Had the

## Edgar Filing: PHARMANETICS INC - Form 10-K

Company applied SAB 101 retroactively to 1999, the Company's net and comprehensive loss and the loss per share attributable to common shareholders would have been \$5,926,220 and \$0.79 respectively, compared to the actual loss and loss per share of \$6,222,470 and \$0.83 respectively. Had the Company applied SAB 101 retroactively to 1998, the Company's net and comprehensive loss and the loss per share attributable to common shareholders would have been \$3,474,820 and \$0.50, respectively, compared to the actual loss and loss per share of \$3,643,153 and \$0.52 respectively.

The Emerging Issues Task Force (the "EITF") has issued No. 98-5, "Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios" ("EITF 98-5"). EITF 98-5 provides guidance concerning the accounting for issuances of convertible preferred stock and warrants. On the date of the Company's issuance of the Series A Preferred Stock, the effective conversion price of the preferred stock was at a discount to the price of the common stock into which the Series A is convertible. In accordance with EITF 98-5 guidance at the time of the preferred stock issuance, this discount totaled \$975,600. It was recorded as a preferred stock dividend and amortized over the three-month period until conversion was possible. In November 2000, the EITF issued further interpretations of EITF 98-5 which required the Company to record an additional discount of \$2,027,990 during the Company's fourth quarter.

F-9

### 2. SHORT-TERM INVESTMENTS

Investment securities at December 31, 2000 and 1999 are all classified as held-to-maturity and are summarized as follows:

	Amortized Cost	Gross Unrealized -----		Estimated Market Value
	-----	Gains -----	Losses -----	-----
2000				
Held-to-maturity:				
Corporate bonds	\$ 934,364	\$147	\$ 253	\$ 934,259
U.S. Agency obligations	2,969,759	--	1,529	2,968,230
	-----	-----	-----	-----
	\$3,904,123	\$147	\$1,782	\$3,902,489
	=====	=====	=====	=====
1999				
Held-to-maturity:				
U.S. Agency obligations	\$1,500,000	\$ --	\$1,410	\$1,498,590
	=====	=====	=====	=====

### 3. INVENTORIES

Inventories at December 31, 2000 and 1999 consisted of the following:

2000	1999
-----	-----

## Edgar Filing: PHARMANETICS INC - Form 10-K

Raw materials	\$1,132,168	\$1,100,794
Finished goods	153,815	228,699
	-----	-----
	\$1,285,983	\$1,329,493
	=====	=====

#### 4. PROPERTY AND EQUIPMENT

Property and equipment at December 31, 2000 and 1999 consisted of the following:

	2000	1999
	-----	-----
Molds and equipment	\$ 8,243,771	\$4,288,174
Furniture, fixtures and IT equipment	1,267,857	1,088,875
Leasehold improvements	1,315,891	1,302,856
Equipment under capital leases	305,587	284,724
	-----	-----
	11,133,106	6,964,629
Less accumulated depreciation and amortization	4,709,276	3,761,512
	-----	-----
	\$ 6,423,830	\$3,203,117
	=====	=====

The Company leases certain equipment under capital lease arrangements. The cost of equipment under capital leases at December 31, 2000 and 1999 was \$305,587 and 284,724, respectively, and the accumulated amortization was \$265,539 and \$255,078, respectively.

#### 5. PATENTS AND INTELLECTUAL PROPERTY

Patents, intellectual property and intangible assets at December 31, 2000 and 1999 consisted of the following:

	2000	1999
	-----	-----
Patents	\$619,952	\$582,729
Intangible assets	197,446	197,446
	-----	-----
	817,398	780,175
Less accumulated amortization	281,179	211,457
	-----	-----
	\$536,219	\$568,718
	=====	=====

F-10

#### 6. RESEARCH AND DEVELOPMENT GRANTS

The Company has recognized \$137,993 as other income during 1998 related to a grant award from the National Institutes of Health Small Business Innovation Research.

## Edgar Filing: PHARMANETICS INC - Form 10-K

### 7. ACCRUED EXPENSES

Accrued expenses consist of the following:

	2000 -----	1999 -----
Accrued clinical liabilities	\$502,750	\$ 11,107
Accrued compensation and benefits	31,804	51,041
Accrued professional fees	38,195	17,665
Other	76,017	92,036
	-----	-----
	\$648,766	\$171,849
	=====	=====

### 8. DEVELOPMENT INCOME AND DEFERRED REVENUE

In 2000, the Company began recognizing development income in accordance with SEC Staff Accounting Bulletin No. 101. During 2000, 1999 and 1998, the Company received payments as part of collaboration agreements with other entities and recognized \$491,666, \$100,000 and \$505,000, respectively, of development income related to these agreements. Under SAB 101, payments received under collaboration agreements are deferred and recognized as income over the period of the respective agreements. Total payments received in 2000 but deferred to future periods totaled \$1,128,869. No cumulative effect adjustment was required as a result of the adoption of SAB 101.

### 9. DEBT

Debt obligations as of December 31, 2000 and 1999 consisted of the following:

	2000 ----	1999 ----
Notes payable	\$854,221	\$1,626,283
Current portion of notes payable	844,072	785,544
	-----	-----
Long-term notes payable, excluding current portion	\$ 10,149	\$ 840,739
	=====	=====

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, 2000. This loan, with a remaining balance of \$840,739 at December 31, 2000, matures in 2001. Other notes payable mature as follows: 2001 - \$3,333; 2002 - \$3,705; 2003 - \$4,119; and 2004 - \$2,325.

The fair value of the debt is estimated by discounting the future cash flows using current rates that would be offered to the Company for similar debt issues. The fair values of long-term debt at December 31, 2000 and 1999 were approximately \$868,000 and \$1,652,000, respectively.

## Edgar Filing: PHARMANETICS INC - Form 10-K

### 10. LEASES

As of December 31, 2000, the Company leases its current facility under a month-to-month operating lease agreement. The Company has entered into a lease agreement for a new facility that begins in April 2001 and extends until 2011. In addition, the Company leases certain equipment under various capital and operating lease agreements. Rent expense related to operating leases totaled \$435,386, \$413,010 and \$427,811 for the years ended December 31, 2000, 1999 and 1998, respectively. Future minimum lease payments as of December 31, 2000 are as follows:

Year ending December 31,	Capital Leases -----	Operating Leases -----
2001	\$19,438	\$ 450,086

F-11

### 10. LEASES (continued)

	Capital Leases -----	Operating Leases -----
2002	19,438	331,464
2003	8,168	333,640
2004	-	327,896
2005	-	337,733
Thereafter	-	1,846,860
	-----	-----
Total minimum lease payments	47,044	\$3,627,679
		=====
Imputed interest (8% to 8.5%)	(4,542)	
	-----	
Present value of minimum lease payments	42,502	
Less current maturities	16,617	
	-----	
Long-term capital lease obligations	\$25,885	
	=====	

The historical carrying value of the Company's capital lease obligations approximates their fair value because the interest rates on these obligations approximate rates currently available to the Company.

### 11. PREFERRED STOCK

During 2000, the Company completed a private placement of 120,000 shares of Series A convertible preferred stock ("Series A"), resulting in net proceeds of \$11,219,621. The Company also issued five-year warrants to acquire 240,000



## Edgar Filing: PHARMANETICS INC - Form 10-K

shares of common stock at \$10.00 per share. Approximately \$1,275,000 of the net proceeds was allocated to the warrants based on their relative fair value. The Series A has a dividend of 6% payable quarterly in cash or in shares of common stock at the option of the Company. For the year ended December 31, 2000, the Series A dividend was paid by issuing 40,065 shares of common stock.

Each share of the Series A is convertible into ten shares of common stock at \$10.00 per share. The Series A is convertible after May 28, 2000 at the option of the holder or may be redeemed at the option of the Company upon the occurrence of any of the following events: (a) the common stock closes at or above \$20.00 per share for 20 consecutive trading days, (b) a completion by the Company of a follow-on public offering of at least \$10 million at a per share price of at least \$15.00, (c) the acquisition of the Company by another entity by means of a transaction that results in the transfer of 50% or more of the outstanding voting power of the Company, (d) a sale of all or substantially all of the Company's assets, or (e) at any time after February 28, 2004.

The holders of the Series A have a liquidation preference of \$100 per share plus any accrued but unpaid dividends then held, such amounts subject to certain adjustments. The liquidation preference is payable upon a change in control of the Company, thus the Series A is carried in the mezzanine section of the balance sheet. The holders also have the right to vote together with the common stock on an as-if-converted basis.

On the date of issuance of the Series A, the effective conversion price of the Series A was at a discount to the price of the common stock into which the Series A is convertible. In accordance with EITF 98-5, "Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios", this discount totaled \$3,003,590 and was recorded as a preferred stock dividend.

### 12. 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 were reserved for issuance.

F-12

### 12. STOCK OPTIONS (continued)

A summary of the status of the Company's Plans as of December 31, 2000, 1999 and 1998, and changes during the years ending on those dates is presented below:

	2000 ----		1999 ----
Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
-----	-----	-----	-----

Edgar Filing: PHARMANETICS INC - Form 10-K

Outstanding at beginning of year	1,211,887	\$ 4.09	841,066	\$3.19	8
Granted	228,000	\$12.73	453,500	\$5.80	
Exercised	(113,987)	\$ 3.14	(16,138)	\$1.53	(
Forfeited	(14,002)	\$ 6.07	(66,541)	\$5.03	(
	-----	-----	-----	-----	
Outstanding at end of year	1,311,898	\$ 5.63	1,211,887	\$4.09	8
	=====	=====	=====	=====	
Options exercisable at year-end	787,273		623,261		5
	=====		=====		

The weighted average fair value of options granted during the years ended December 31, 2000, 1999 and 1998 was \$8.97, \$3.90 and \$2.83, respectively.

The following table summarizes information about the Plan's stock options at December 31, 2000:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding at 12/31/00	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable at 12/31/00	Weighted Average Exercise Prices
\$0.79	289,791	3.5 years	\$ 0.79	289,791	\$ 0.79
\$3.75-\$ 4.50	139,482	5.1 years	\$ 4.39	129,482	\$ 4.44
\$5.00-\$ 6.38	655,625	8.1 years	\$ 5.59	339,000	\$ 5.54
\$9.63-\$15.06	227,000	9.5 years	\$12.68	29,000	\$14.02
	-----			-----	
	1,311,898			787,273	
	=====			=====	

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 2000, 1999 and 1998:

	2000	
	----	
Dividend yield	0%	
Volatility	75%	
Risk free interest rate	5%-6.5%	
Expected life of options	6 years	6

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

## Edgar Filing: PHARMANETICS INC - Form 10-K

not be representative of the effects on pro forma net income (loss) in future years.

		2000 ----
Net loss attributable to common shareholders	As reported Pro forma	\$ (9,963,751) \$ (11,136,256)
Net loss attributable to common shareholders per common share	As reported Pro forma	\$ (1.31) \$ (1.46)

F-13

### 13. SEGMENT INFORMATION AND SIGNIFICANT CUSTOMERS

Prior to the sale of substantially all the operating assets and liabilities of Coeur in 1999, the Company organized and managed its business primarily on the basis of its operating divisions, CVDI and Coeur. Each of these segments earned revenue, incurred expenses and has discrete financial information available to it. Segment expenses include allocations of certain expenses to each segment. Management evaluated 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".

The table below presents information concerning revenues, net income (loss) and segment assets for 1999 and 1998:

		1999 ----		
	CVDI ----	Coeur -----	Consolidated -----	
Revenues	\$ 3,909,379	\$1,800,883	\$ 5,710,262	
Net income (loss)	\$(5,414,299)	\$ 17,922	\$(5,396,377)	
Total assets	\$11,646,932	\$ --	\$11,646,932	
		1998 ----		
	CVDI ----	Coeur -----	Consolidated -----	
Revenues	\$ 4,140,763	\$4,649,459	\$ 8,790,222	
Net income (loss)	\$(4,223,442)	\$ 580,289	\$(3,643,153)	
Total assets	\$14,460,017	\$4,233,194	\$18,693,211	

During the years ended December 31, 2000, 1999 and 1998 there were sales to CVDI customers that exceeded 10% of net consolidated sales. Sales to these customers were:

2000	1999	1998
------	------	------

## Edgar Filing: PHARMANETICS INC - Form 10-K

	-----	-----	-----
Customer A	\$ 257,561	\$ 991,345	\$1,311,611
Customer B	3,335,775	1,857,353	3,690
Customer C	-	431,380	1,755,820
Customer D	600,000	320,000	-

As of December 31, 2000 and 1999, there were outstanding receivables from customers that exceeded 10% of total trade receivables. Receivables from these customers as a percentage of total trade receivables were as follows: 2000 - customer B, 92%; 1999 - customer A, 19%; customer B, 37%; customer D, 40%.

CVDI generated revenue from sales to different geographic areas for 2000, 1999 and 1998 as follows:

	2000 -----	1999 -----	1998 -----
United States	\$3,669,234	\$3,007,657	\$1,459,339
United Kingdom	-	83,157	246,138
Germany	-	440,042	2,028,111
Sweden	600,000	327,750	247,495
Other foreign sales	-	50,773	159,680
	-----	-----	-----
Total sales	\$4,269,234 =====	\$3,909,379 =====	\$4,140,763 =====

#### 14. 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, 2000, 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.

#### 15. 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 \$58,909, \$89,507 and \$22,399 during the years ended December 31 2000, 1999 and 1998, respectively.

F-14

#### 16. INCOME TAXES

Income tax expense consisted entirely of current state taxes of \$0, \$27,753 and \$67,250 for the years ended December 31, 2000, 1999 and 1998, respectively. A reconciliation of expected income tax at the statutory Federal rate of 34% with

## Edgar Filing: PHARMANETICS INC - Form 10-K

the actual income tax expense for the years ended December 31, 2000, 1999 and 1998 is as follows:

	2000 ----	1999 ----	
Expected income tax benefit at federal statutory rate	\$(2,148,144)	\$(2,115,640)	\$ (
State tax provision (benefit)	(194,935)	(210,074)	
Goodwill amortization	--	303,681	
Compensation paid with incentive stock options	--	3,740	
Other	91,694	35,775	
Distribution premium	--	--	
Research and development credit	(60,849)	(166,625)	
Change in valuation allowance	2,312,234	2,176,896	
	-----	-----	
Net income tax provision	\$ --	\$ 27,753	\$
	=====	=====	=

The components of the net deferred tax assets and net deferred tax liabilities as of December 31, 2000 and 1999 are as follows:

	2000 ----	1999 ----	
<b>Deferred tax assets:</b>			
Accrued expenses	\$ 5,000	\$ 2,000	
Alternative minimum tax credits	9,000	9,000	
Net operating loss carryforward	12,989,000	11,014,000	
Research and development credits	456,000	395,000	
Foreign tax credits	35,000	35,000	
Other	180,000	84,000	
	-----	-----	
Total gross deferred tax assets	13,674,000	11,539,000	
Valuation allowance	(12,927,000)	(10,615,000)	
	-----	-----	
Net deferred tax assets	747,000	924,000	
	-----	-----	
<b>Deferred tax liabilities:</b>			
Patents	163,000	176,000	
Investment adjustment	488,000	490,000	
Fixed assets	96,000	258,000	
	-----	-----	
Total gross deferred tax liabilities	747,000	924,000	
	-----	-----	
Net deferred taxes	\$ --	\$ --	
	=====	=====	

At December 31, 2000 and 1999, the Company has approximately \$34,000,000 and \$28,773,000, respectively, of combined federal net operating losses. These losses expire in varying amounts beginning in 2004 if not utilized. At December 31, 2000 and 1999 for state income tax purposes, Cardiovascular Diagnostics, Inc. had net operating loss carryforwards of approximately \$30,935,000 and \$25,725,000, respectively. These carryforwards expire in varying amounts beginning in 2008 if not utilized. To the extent that Coeur's net operating losses incurred through 1994 (approximately \$2,000,000 at December 31, 2000) are

## Edgar Filing: PHARMANETICS INC - Form 10-K

utilized in the future, the benefit will reduce the excess cost over fair value of net assets acquired. The 2000 and 1999 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, 2000 and 1999.

As a result of changes in ownership in prior years, as defined by Internal Revenue Code Section 382, the utilization of 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.

F-15

### 17. SUMMARY OF QUARTERLY FINANCIAL DATA (UNAUDITED)

The following represents a summary of operations for the quarters of 2000 and 1999:

	2000					
	First Quarter -----	Second Quarter -----	Third Quarter -----	Fourth Quarter -----	First Quarter -----	Seco Quar -----
Net sales	\$ 1,489,000	1,377,000	743,000	660,000	1,011,000	1,126
Gross profit	581,000	404,000	(45,000)	(252,000)	317,000	226
Net loss before preferred stock charges	(1,031,000)	(1,270,000)	(1,749,000)	(2,284,000)	(1,032,000) (d)	(2,338
Net loss attributable to common shareholders	(1,479,000) (a)	(2,047,000) (b)	(1,917,000)	(4,521,000) (c)	(1,032,000) (d)	(2,338
Net loss before preferred stock charges per common share	(0.14)	(0.17)	(0.23)	(0.29)	(0.14)	(
Net loss attributable to common shareholders per common share	\$ (0.20)	\$ (0.27)	\$ (0.25)	\$ (0.58)	\$ (0.14)	\$ (

(a) Includes \$377,000 of amortization of beneficial conversion feature of the Series A Preferred Stock

(b) Includes \$598,000 of amortization of beneficial conversion feature of the Series A Preferred Stock

Edgar Filing: PHARMANETICS INC - Form 10-K

(c) Includes \$2,028,000 of amortization of beneficial conversion feature of the Series A Preferred Stock. This amount resulted from a change in accounting principle retroactively applied to the Series A Preferred Stock transaction.

(d) Includes \$175,000 of income from operations of a discontinued segment

(e) Includes \$983,000 of loss from operations and disposal of a discontinued segment

F-16

PHARMANETICS, INC.  
 SCHEDULE II - VALUATION AND QUALIFYING ACCOUNTS  
 For the years ended December 31, 2000, 1999 and 1998

	Balance at Beginning of Period -----	Charge to Costs and Expenses -----	Deductions -----	Balance End of Peri -----
YEAR ENDED DECEMBER 31, 2000				
Deducted from asset accounts:				
Accounts Receivable Reserve (a)	\$ 29,556 =====	\$ 3,574 =====	\$ 28,791 (f) =====	\$ 4, =====
Inventory Reserves (b)	\$100,000 =====	\$109,460 =====	\$ 84,460 (e) =====	\$125, =====
Added liability accounts:				
Warranty Reserves (c)	\$ 5,942 =====	-- =====	\$ 1,899 (g) =====	\$ 4, =====
YEAR ENDED DECEMBER 31, 1999				
Deducted from asset accounts:				
Accounts Receivable Reserve (a)	\$ 14,226 =====	\$ 40,000 =====	\$ 24,670 (f) =====	\$ 29, =====
Inventory Reserves (b)	\$ 85,000 =====	\$ 95,462 =====	\$ 80,462 (e) =====	\$100, =====
Added liability accounts:				
Warranty Reserves (c)	\$ 10,000 =====	-- =====	\$ 4,058 (g) =====	\$ 5, =====
YEAR ENDED DECEMBER 31, 1998				
Deducted from asset accounts:				
Accounts Receivable Reserves (a)	\$ 3,792 =====	\$ 11,228 =====	\$ 794 (f) =====	\$ 14, =====
Inventory Reserves (b)	\$231,339 =====	\$147,000 =====	\$293,339 (e) =====	\$ 85, =====
Added to liability accounts:				
Warranty Reserves (c)	\$ 38,571 =====	\$ -- =====	\$ 28,571 (d) =====	\$ 10, =====

Edgar Filing: PHARMANETICS INC - Form 10-K

- (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.

S-1

REPORT OF INDEPENDENT ACCOUNTANTS ON  
FINANCIAL STATEMENT SCHEDULES

To the Board of Directors of PharmaNetics, Inc.

Our audits of the consolidated financial statements referred to in our report dated February 14, 2001 appearing in this Form 10-K of PharmaNetics, Inc., also included an audit of the financial statement schedules listed in Item 14(a)(2) of this Form 10-K. In our opinion, these financial statement schedules present fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements.

/s/ PricewaterhouseCoopers LLP

Raleigh, North Carolina  
February 14, 2001