

PHARMANETICS INC

Form 10-K

March 17, 2005

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

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**FORM 10-K**

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(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, 2004**

**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**

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**PharmaNetics, Inc.**

(Exact name of registrant as specified in its charter)

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**North Carolina**  
(State or other jurisdiction of

incorporation or organization)

**56-2098302**  
(I.R.S. Employer

Identification No.)

**3700 National Drive, Suite 211 Raleigh, North Carolina**  
(Address of principal executive offices)

**27612**  
(Zip Code)

**Registrant's telephone number, including area code:**

**919-781-1640**

**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)**

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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. ☐

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant based upon \$0.48 per share, the closing price of the common stock on June 30, 2004, on the OTC Bulletin Board, was approximately \$4,861,000 as of such date. Shares of common stock held by each officer and director and by each person known by the registrant who owned 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 1, 2005, the registrant had outstanding 10,604,517 shares of common stock (no par value).

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's Proxy Statement for the 2005 Annual Meeting of Shareholders are incorporated herein by reference into Part III of this report.

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**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 SEC, and including, in particular, the outcome of the Company's legal proceedings against Aventis Pharmaceuticals, Inc. and the impact of ceasing operations on the Company's ability to realize value on its assets.

**Part I**

**Item 1. Business**

PharmaNetics, Inc. (the "Company" or "PharmaNetics"), is a holding company incorporated in North Carolina in 1998 as the parent company of Cardiovascular Diagnostics, Inc. ("CVDI"). CVDI was incorporated in 1985 and, prior to ceasing substantially all of its operations in March 2004, developed, manufactured and marketed rapid diagnostics to dose, manage and screen patients on drugs affecting blood coagulation. The Company's products have included a proprietary analyzer and dry chemistry tests and controls, known as the Thrombolytic Assessment System, or TAS, that provide a physician, at the point of patient care, information that can affect therapy. The Company's tests were and can be used in the treatment of a variety of adverse conditions caused by abnormal blood clotting in different areas of the body, including angina, heart attack, stroke, deep vein thrombosis and pulmonary and arterial emboli.

TAS is a stat, or as soon as possible, point-of-care system capable of monitoring the formation and dissolution of blood clots. Such monitoring provides information which is critical to health care providers in administering drugs that either prevent the formation of blood clots or dissolve them, both of which are used in the treatment of a variety of medical disorders. Blood clotting, or hemostatic test results must be provided quickly because a majority of the drugs used to regulate clotting are cleared rapidly from the body, and certain drugs must be closely monitored to maintain drug levels within an effective treatment range. The Company believes that the TAS can provide critical information regarding the formation and dissolution of blood clots as well as drug monitoring on a timely basis, permitting quicker diagnosis and therapeutic intervention, which can improve therapy and the quality of patient care. The Company believes that this improvement may facilitate quicker transfers out of expensive critical care settings, reduce the overall length of hospital stays, reduce expenditures for laboratory equipment and its associated maintenance, and reduce the unnecessary use of drugs. In addition, point-of-care testing can reduce hospitals' costs by reducing the numerous steps, paperwork and personnel used in collecting, transporting, documenting and processing blood samples.

The Company's products have included its TAS analyzer and a menu of tests and controls. FDA approved tests that have been sold for commercial use are listed and described below under the subheading "Products". The Company formerly sold three other tests, the Lysis Onset Time ("LOT"), Ecarin Clotting Time ("ECT") and a modified ecarin clotting time test for investigational use only which are described below under the subheading "Research and Development Test Cards". In addition, the Company has obtained a special FDA approval, a Humanitarian Device Exemption, or HDE, for its ECT card, which is used in managing patients suffering from heparin induced thrombocytopenia, a condition characterized by persistent decrease in blood platelets resulting from the administration of the anti-clotting drug, heparin. HDE approval is an expedited FDA authorization process to market devices used in rare disease states where no existing solution is available. In connection with the developments described below, the Company has, since March 2004, ceased the development, production, sale and marketing of its test cards and other products.

**Litigation Against Aventis**

In November 2003, the Company filed a lawsuit in the United States District Court of the Eastern District of North

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Carolina against Aventis Pharmaceuticals, Inc. ( Aventis ). The Company, in cooperation with Aventis, has developed a rapid bedside test, known as the Enox test, that the Company believes enhances the way Lovenox®, a popular anti-blood clotting drug marketed by Aventis, currently is managed. The Company believes the test has the potential to facilitate the drug's use in patients in the cardiac community who stand to benefit from its use. Aventis collaborated with the Company in a multi-million dollar project in which it made milestone payments to the Company to develop and co-promote the test together with Lovenox for targeted patient populations. The lawsuit alleges that Aventis has engaged in false and misleading advertising of Lovenox, which damaged the Company's efforts to market and sell the Enox test card. The lawsuit also alleges that Aventis has failed to fulfill its obligation to promote the test and is systematically and falsely advising physicians that the test is not necessary through its claims that Lovenox requires no monitoring and is therapeutic from dose one. In addition to claims of false advertising, the Company's complaint includes allegations of tortious interference, fraud and breach of contract. Aventis filed counterclaims against the Company alleging slander, product disparagement, breach of contract and related claims. As part of the lawsuit, the Company requested that the court enter a preliminary injunction against Aventis to prevent Aventis from falsely advertising Lovenox.

In March 2004, the court held a hearing on the Company's motion for a preliminary injunction against Aventis. In April 2004, the court issued an order denying the Company's request for a preliminary injunction, but in denying the Company's motion, the court made a judicial determination that two of Aventis' advertising claims regarding Lovenox were literally false. First, the court found that Aventis' claim that Lovenox reaches therapeutic levels with ½ hour of administration to be literally false. Second, the court found literally false Aventis' claim that Lovenox was therapeutic from dose one. Although the court did not grant the Company's request for a preliminary injunction, one of the reasons cited by the court for not enjoining these false advertising messages was that Aventis has discontinued using these false statements in its advertising. In particular, after the Company filed its false advertising lawsuit against Aventis in November 2003, almost immediately thereafter Aventis withdrew these statements from its advertising of Lovenox. In addition, the court found that certain disparaging statements made by Aventis representatives concerning the Enox test card were also literally false. Although the court elected not to issue a preliminary injunction, the court's order ultimately left the issues in dispute for the jury to decide. The court also ruled on Aventis' Motion for Summary Judgment in which Aventis essentially sought dismissal of the Company's false advertising claims. In denying Aventis' motion, the court noted that the Company had raised genuine issues of material fact concerning its claims against Aventis and, accordingly, the court ruled that the merits of this case should ultimately be evaluated by a jury. In order to prevail in a jury trial, the Company must prove a variety of factual issues as well as substantiate its calculation of damages. The Company expects the lawsuit and any appeals, even if successful, could take a year or more to complete and consume significant time and expense.

In preparation for the trial of its lawsuit against Aventis scheduled for April 2005, in March 2005 the court ruled on each party's motions for Summary Judgment. The court dismissed all of Aventis' counterclaims against PharmaNetics, while also dismissing PharmaNetics' claim of damages against Aventis for breach of contract for failing to co-promote the jointly-developed Enox test. However, the court denied Aventis' motion to dismiss a number of PharmaNetics' other claims, including some of the claims for disparagement and false and misleading advertising, as well as claims of unfair and deceptive trade practices under state law, leaving those claims for a jury to decide. PharmaNetics believes the court's dismissal of the breach of contract claim regarding the covenant to co-promote is erroneous and is considering its options for challenging that portion of the court's decision. PharmaNetics intends to continue to pursue the lawsuit vigorously.

If the Company were to receive any proceeds in connection with the Aventis litigation, after payment of litigation and remaining contractual and operating expenses, the Company would consider distributing such proceeds to its shareholders or using them to restart operations. Such determination would depend on a variety of factors, including the size and timing of any payments, the expenses of completing the litigation, management's assessment of the viability of restarting the business, the availability of necessary personnel and the requirements of applicable law. However, there can be no assurance that the Company will prevail in the litigation against Aventis or that if it does prevail, the proceeds would be sufficient to provide significant shareholder value.

## **Cessation of Operations and Sale of Business**

In December 2003, the Company announced that, as a result primarily of the dispute and litigation with Aventis and its impact on the Company's business and prospects, it was seeking a variety of strategic alternatives, including the



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sale of its manufacturing operations. In March 2004, because a willing and able buyer for the Company's operations had not by then been identified, the Company terminated its distribution agreement with its distribution partner, Bayer Diagnostics (Bayer). In addition, the Company terminated the sales and technical service personnel formerly engaged by the Company through PDI, the contractor and provider of the Enox sales and technical support teams. Since filing the lawsuit, the Company has implemented and completed significant personnel reductions and has engaged Davenport & Company LLC (Davenport), an investment banking firm, as its financial advisor. Davenport is currently assisting the Company in pursuing a sale of its manufacturing operations and intellectual property. The Company believes these steps were necessary to conserve cash and position the Company for the proposed license or sale of its assets and intellectual property as well as to finance its lawsuit against Aventis. The Company is shifting its corporate strategy from a manufacturing/distribution model to that of a biotech model, whereby revenues, if any, would be tied to royalty streams from any future product sales. The Company is actively seeking a buyer for its operating assets and to sell or license its intellectual property with a significant portion of the potential valuation tied to royalties. In essence, if successful in implementing this new strategy, under such a potential arrangement the Company would be in a position to receive royalties on tests developed and would not be responsible for manufacturing and distribution. Although the Company has sold a substantial portion of its remaining non-critical assets, it has retained its intellectual property and the other assets it deems critical to its business and has mothballed them in an effort to sell them, subject to shareholder approval, to one or more potential buyers.

Because the Company was not able to comply with the minimum \$2.5 million stockholders' equity requirement for continued listing on the Nasdaq SmallCap Market, effective in May 2004 the Company was delisted from the Nasdaq SmallCap Market and its shares of common stock were thereafter qualified for quotation and trading on the Nasdaq OTC Bulletin Board.

The following discussion summarizes the Company's business prior to ceasing its operations in March 2004.

## **Industry Overview**

Blood testing within the practice of laboratory medicine has been evolving in response to the introduction of new cardiovascular drugs and 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 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. The Company believes that reliance on this technology makes stat laboratories inadequate and expensive, creating a need for new technology suitable for use at the point of patient care. As diagnostics move closer to the patient, the centralized lab 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.

Timely and accurate coagulation test results are important because a majority of the drugs used to regulate clotting are cleared rapidly from the body and these drugs must be closely monitored to maintain drug levels within a safe and effective treatment range. Recent advances in technology allow many blood tests to be performed at the point of patient care, where the physician can most effectively use test results. While speed is important in point-of-care testing, accuracy is critical. Because point-of-care testing is often performed by operators who lack special laboratory skills or training, error-proof testing systems are important.

## **Technology**



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The TAS was designed to perform blood analysis rapidly and accurately at the point of care to provide a solution to these current healthcare demands. 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

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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, the TAS technology has the flexibility to allow new tests to be developed by using different reagents in the test cards.

## **Products**

### **TAS Analyzer**

The TAS analyzer weighs approximately four pounds and 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.

The analyzer and test cards are designed to work effectively in a decentralized testing environment where they can be 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 in a central laboratory using traditional testing procedures. The portable analyzer has been designed with a memory capability, may be connected to a printer, and with a software upgrade may be connected to the hospital's patient information system. The internal memory of the TAS analyzer allows for the storage of up to 1,000 individual test results and has an alphanumeric keypad that allows for the input of up to a 20-character patient identification code. Additionally, the keypad provides for coded entry so only authorized personnel can gain access to the system. The analyzer can operate either on wall current or on an internal rechargeable battery.

### **Accent**

The Accent is a microprocessor-based hardware accessory to the TAS analyzer. It connects to the TAS analyzer and automatically calculates the information required by physicians to manage the anticoagulation of patients on heparin during cardiopulmonary bypass procedures. It can be used in conjunction with three of our test cards. The data collected by Accent can be transferred to a printer and/or hospital information system for storage.

### **FDA-Cleared Test Cards**

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The following describes the Company's test cards that have been cleared by the FDA.

The Enoxaparin test, or Enox test, detects the anticoagulant effect of enoxaparin, a low molecular weight heparin drug used for the treatment and prevention of blood clotting diseases. Enoxaparin is the world's top-selling low molecular weight heparin and is marketed by Aventis Pharmaceuticals in the United States under the brand name Lovenox® and outside the United States under the brand name Clexane®. This test was developed in a collaborative development program with Aventis. The test assists physicians in evaluating anticoagulation status rapidly before and during percutaneous coronary intervention (PCI), and before removing the sheath.

The PT, or Prothrombin Time, test is a general screening test that is used to assess a patient's baseline blood clotting

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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 clot formation and reduce the risk of developing additional clots. Physicians use 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. Prior to ceasing operations in March 2004, the Company manufactured and sold 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, or Activated Partial Thromboplastin Time, test is a coagulation screening test which may be used in conjunction with the PT test to provide a global assessment of a patient's ability to form a blood 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 blood clot, including patients suffering from heart attacks or strokes. Heparin also prevents blood clots from forming in patients undergoing procedures involving particular risks of clotting, such as angiography, open heart surgery, dialysis and several 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 HMT, or Heparin Management Test, is a coagulation test 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 test is a more effective test than comparable tests 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.

In addition, the Company developed two more test cards that can be combined with our HMT test to provide a system for individualized heparin management during cardiac surgery. The HTT, Heparin Titration Test, and the PRT, Protamine Response Test, cards are combined with the 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. The Company believes the HTT/PRT approach should make it easier and cost effective to incorporate individual heparin management into routine practice.

The LHMT, or Low-range Heparin Management Test, card can be used principally in cardiac catheterization and interventional cardiology procedures. It is designed to monitor the effects of concentrations of heparin above the range of the aPTT test but below that of the HMTcard.

The Company's ECT, or Ecarin Clotting Time, test card is available for use under the FDA's Humanitarian Device Exemption program. The ECT card can be used in managing patients suffering from heparin induced thrombocytopenia. The FDA's approval only allows the use of the test for managing patients who receive Refludan®, an anticoagulant drug marketed by Pharmion and Berlex for patients undergoing cardiopulmonary bypass surgery.

**Table of Contents****Research and Development Test Cards**

Prior to the cessation of operations in March 2004, the Company performed research and development in an effort to expand its menu of tests for the TAS analyzer. The Company performed research and/or development on the following tests:

<b><u>Test</u></b>	<b><u>Description</u></b>
Ecarin Clotting Time ( ECT )	Test to monitor direct thrombin inhibitors for use in patients treated for heart attack or prevention of deep vein thrombosis. Formerly sold under the HDE program.
Thrombin Inhibitor	
Management ( TIM )	Test to allow the monitoring of oral antithrombin drugs for treatment of DVT and atrial fibrillation. The test requires FDA approval.
Synthetic Xa inhibitors	Test designed to monitor the anticoagulant effect of pentasaccharides. This test has been through feasibility study and subsequent development would require field and clinical trials.
LR Enox	Test to detect the anticoagulant effects of enoxaparin sodium in special patient populations receiving enoxaparin for treatment of prophylaxis of deep vein thrombosis. This test has been developed through field trials and subsequent development would require clinical trials.
LRF	Test to monitor the effects of Ancrod, a fibrinogen-lowering drug for the treatment of stroke. This test has been developed through feasibility and subsequent development would require field and clinical trials.
SK Panel	Test to assess response to streptokinase. This test has been developed through feasibility and subsequent development would require field and clinical trials.
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. This test has been developed through feasibility and subsequent development would require field and clinical trials.

Prior to or in connection with the Company's cessation of operations in March 2004, the Company has ceased further development and regulatory approval efforts related to all of its products, including these research and development test cards. Further development of these tests will likely be depend on whether a potential acquiror of the operations emerges and the outcome of the Company's litigation with Aventis.

**Quality Control Products**

The Company also formerly developed and sold single-use crush-vial controls for each test card. These controls were formerly produced by the Company and a contract manufacturer and allow quality assurance testing at the point of care. In addition, the Company formerly developed and sold an Electronic Quality Control ( EQC ) card used to test analyzer function.

**Sales, Marketing and Distribution**

The Company has substantially ceased all sales, marketing and distribution activities relating to all of its products.

Any future sales of the Company's products, by the Company or by a potential acquiror, will depend, not only upon the outcome of the Aventis litigation and the ability of the Company to restart or sell the business to a third party, but also upon acceptance of these products 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. Coagulation testing has historically been performed and dominated by the hospital's central laboratory and the approval of the purchase of diagnostic equipment by a hospital is generally controlled by its central laboratory. PharmaNetics, along with several of its competitors, has sought to develop and sell into the newer and developing market for point-of-care coagulation testing. Central laboratories may resist yielding control of tests they have previously performed. The Company or others 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 products must be comparable to test results achieved by central laboratory systems.

#### **Collaborations**

The Company has substantially ceased all of its collaboration efforts in connection with the cessation of its operations in March 2004.

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### **Competition**

The medical diagnostic testing industry has been characterized by rapidly evolving technology and intense competition. The TAS menu competed 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 competed with other point-of-care coagulation and hematology test system manufacturers. Laboratories provide some of the same tests performed by TAS; however, these laboratory tests generally require the use of skilled technicians and complex, expensive equipment. The Company believes that TAS offers several advantages over these laboratory-based instruments, including faster results, ease-of-use, reduced opportunity for error and cost-effectiveness.

Prior to ceasing operations in March 2004, the Company formerly competed with several companies, 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 competed favorably with these systems, ITC 's installed base could give it a competitive advantage. 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 the Company in research and development, obtaining regulatory clearances, manufacturing and marketing, and may therefore represent significant competition for the Company 's products. There can be no assurance that the Company 's competitors will not succeed in developing or marketing technologies and products that will be more effective or less expensive than those of the Company or that would render the Company 's technology and products obsolete or noncompetitive.

### **Patents and Other Intellectual Property**

The Company historically pursued patent applications to provide protection from competitors. A number of U.S. and corresponding international patents have been issued to the Company covering various aspects of the TAS technology. These patents expire between now and 2013. The value of the Company 's technology will depend in part on its ability to enforce its patents, to preserve its trade secrets and for such technology to be put to use without infringing the proprietary rights of third parties. The Company 's ability to protect its proprietary position could be jeopardized by its current lack of resources and its inability to pursue additional patents or monitor and enforce its rights under existing patents. No assurance can be given that the scope of any patent protection will exclude competitors or provide competitive advantages to the Company, that any of the Company 's patents will be held valid if subsequently challenged or that others will not claim rights in or ownership to the patents and other proprietary rights held by the Company. Furthermore, others 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, or an acquiror of 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 or an acquiror.

The Company also historically relied upon unpatented trade secrets to protect its proprietary technology. In particular, the Company believes that its custom-designed automated test card production line embodies proprietary process technology. Others may independently develop or otherwise acquire equivalent technology or otherwise gain access to the Company 's proprietary technology and the Company 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.





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### **Tokuyama Soda License**

In October 2004, the Company's License Agreement with Tokuyama Soda Company, Ltd. was terminated. Under this agreement, the Company had 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. Under the agreement, Tokuyama was required to pay the Company royalties based on Tokuyama's net sales of licensed products. The Company received royalty payments under this agreement of \$57,864, \$38,366 and \$43,705 during the years ended December 31, 2004, 2003 and 2002, respectively.

### **Manufacturing**

Before ceasing production of products in March 2004, the Company operated its manufacturing facility to assemble TAS analyzers. Vendors provided all molded parts, mechanical components and printed circuit boards. The Company assembled the components and provided final mechanical, electrical and chemistry testing of each analyzer. In addition, the Company operated proprietary automated test card production equipment. This automated production equipment was custom designed by the Company and built to its specifications. The Company believes that this production machinery embodies proprietary process technology.

Most of the raw materials and components used to manufacture the Company'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. 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 any future production of these products, whether by the Company or any other party acquiring the Company's assets.

### **Government Regulation**

#### **FDA**

The medical devices previously 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:

finer,

injunction,

civil penalties,

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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.

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 FDA-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

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market introduction of new products that fall into this category. For any of the Company's products that were 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 would require a new 510(k). If the FDA requires the Company or an acquiror to submit a new 510(k) for any modification to the device, the Company or any acquiror 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 the Company or recipients of the Company's investigational use only products to comply with these requirements could result in enforcement action by the FDA.

Any products formerly manufactured or distributed by the Company pursuant to FDA clearances or approvals are, or could become, 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, when the Company was still conducting operations, imposed certain procedural and documentation requirements upon the Company with respect to design, manufacturing and quality assurance activities.

## **Regulations on Export**

Export of products that have market clearance from the FDA in the United States does 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.

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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.

Products which the Company has previously exported that do not have premarket clearance in the United States include the LOT test, the ECT test and the modified ECT test. The Company has obtained CPEs for these tests. The Company believes that these products are subject to the 510(k) requirements and, consequently, did not request 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 the Company's ability to export these tests, if the Company or an acquiror desired to do so in the future.

### **Foreign Regulations**

Sales of the Company's test products outside the United States are also subject to foreign regulatory requirements

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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 could affect the efficiency and timeliness of international market introduction of the Company's products, and there can be no assurance that the Company, if it so desired to do so in the future, would be able to obtain regulatory approvals or clearances for its products in foreign countries.

In marketing the Company's products in the member countries of the European Union prior to cessation of operations in March 2004, the Company was required to comply with the European In Vitro Diagnostics 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 formerly marketed in Europe had obtained CE Mark certification. The TAS Analyzer also must meet the requirements of the Electromagnetic Compatibility 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.

## **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. 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.

## **Other Regulations**

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

## **Reimbursement**

The Company's or an acquirer's ability to commercialize its products successfully in the future 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

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providers are instituting and the impact of any healthcare reform could have an adverse effect on the Company's or an acquiror's ability to sell its products in the future.

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 any future sale of the products.

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### **Product Liability and Insurance**

The Company faces an inherent business risk of exposure to product liability claims in the event that the use of its products is alleged to have resulted in adverse effects. The Company did not renew its product liability insurance in March 2005. Consequently, product liability claims could have a material adverse effect on the Company's business prospects and financial condition.

### **Employees**

The Company had only one employee, its chief executive officer, as of January 31, 2005. In March 2004, the Company eliminated its remaining employee workforce, except for the chief executive officer and a relatively small team of independent contractors to handle the limited administrative and financial responsibilities pending the outcome of the Aventis litigation.

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 ability to continue its litigation against Aventis. Any potential resumption of operations of the Company in the future would depend in large part upon its ability to rehire, 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 would be successful in attracting and retaining such personnel.

### **Available Information**

Our website address is [www.pharmanetics.com](http://www.pharmanetics.com). The Company will provide a copy of Form 10-K upon the written request of any shareholder. We also make available free of charge through our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission (SEC). The SEC's website is [www.sec.gov](http://www.sec.gov). The public may read and copy any materials the Company files with the SEC at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

### **Item 2. Properties**

In early 2005, the Company negotiated a termination of the lease with its landlord by making a termination payment of \$337,787. The Company's chief executive officer operates out of an office located at 3700 National Drive, Suite 211, Raleigh, North Carolina 27612.

### **Item 3. Legal Proceedings**

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In November 2003, the Company filed a lawsuit in the United States District Court of the Eastern District of North Carolina against Aventis Pharmaceuticals, Inc., the wholly-owned subsidiary of French pharmaceutical company, Aventis. The lawsuit alleges that Aventis has engaged in false and misleading advertising of its second largest drug, Lovenox<sup>®</sup>, which has damaged the Company's sales of its Enox test card, a rapid point-of-care test developed in cooperation with Aventis to enhance the way Lovenox is managed in the cardiac community. In addition to claims of false advertising, the Company's complaint includes allegations of tortious interference, fraud and breach of contract. Aventis filed counterclaims against the Company alleging slander, libel, product disparagement, breach of contract and related claims. As part of the lawsuit, the Company requested that the court enter a preliminary injunction against Aventis to prevent Aventis from falsely advertising Lovenox.

In March 2004, the court held a hearing on the Company's motion for a preliminary injunction against Aventis. In April 2004, the court issued an order denying the Company's request for a preliminary injunction, but in denying the Company's motion, the court made a judicial determination that two of Aventis' advertising claims regarding Lovenox were literally false. First, the court found that Aventis' claim that Lovenox reaches therapeutic levels within 1/2 hour of administration to be literally false. Second, the court found literally false Aventis' claim that



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Lovenox was therapeutic from dose one. Although the court did not grant the Company's request for a preliminary injunction, one of the reasons cited by the court for not enjoining these false advertising messages was that Aventis has discontinued using these false statements in its advertising. In particular, after the Company filed its false advertising lawsuit against Aventis in November 2003, almost immediately thereafter Aventis withdrew these statements from its advertising of Lovenox.

In addition, the court found that certain disparaging statements made by Aventis representatives concerning the Enox test card were also literally false. Although the court elected not to issue a preliminary injunction, its order ultimately left the issues in dispute for the jury to decide. The court also ruled on Aventis' Motion for Summary Judgment in which Aventis essentially sought dismissal of the Company's false advertising claims. In denying Aventis' motion, the court noted that the Company had raised genuine issues of material fact concerning its claims against Aventis and, accordingly, the court ruled that the merits of the case should ultimately be evaluated by a jury. In order to prevail in a jury trial, the Company must prove a variety of factual issues as well as substantiate its calculation of damages.

In preparation for the trial of its lawsuit against Aventis scheduled for April 2005, in March 2005 the court ruled on each party's motions for Summary Judgment. The court dismissed all of Aventis' counterclaims against PharmaNetics, while also dismissing PharmaNetics' claim of damages against Aventis for breach of contract for failing to co-promote the jointly-developed Enox test. However, the court denied Aventis' motion to dismiss a number of PharmaNetics' other claims, including some of the claims for disparagement and false and misleading advertising, as well as claims of unfair and deceptive trade practices under state law, leaving those claims for a jury to decide. PharmaNetics believes the court's dismissal of the breach of contract claim regarding the covenant to co-promote is erroneous and is considering its options for challenging that portion of the court's decision. PharmaNetics intends to continue to pursue the lawsuit vigorously.

## **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, 2004.

## **Executive Officers**

The following sets forth information as of March 1, 2005 with respect to the sole remaining executive officer of the Company, including his name, age, position with the Company and business experience during the last five years.

John P. Funkhouser, age 51, was elected President, Chief Executive Officer and a director of the Company in October 1993. Since April 2004, he has also served as the Company's Chief Financial Officer. Since February 1998, Mr. Funkhouser has served as Chairman of the Board of Directors of the Company. Mr. Funkhouser served as President and Chief Executive Officer of Coeur Laboratories, Inc., a wholly-owned subsidiary of CVDI, 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 has also, since early 2005, served as President and CEO of Ablatrix, Inc., a private medical device start-up company that is focused on the development of specialized surgical equipment. Mr. Funkhouser holds a B.A. from Princeton University and an M.B.A. from the University of Virginia.

## **Part II**

**Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**

**(a) Price Range of Common Stock**

Since May 13, 2004, the Company's common stock has traded on the OTC Bulletin Board under the symbol PHAR.OB. Immediately prior to May 13, 2004, the Company's common stock traded on the Nasdaq SmallCap

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Market under the symbol PHAR . The following sets forth the quarterly high and low closing prices of the common stock of the Company for the periods indicated as reported on the OTC Bulletin Board or Nasdaq SmallCap Market, as applicable. 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.

	<u>High</u>	<u>Low</u>
<u>Fiscal year ended December 31, 2004</u>		
First Quarter	\$ 2.93	\$ 1.45
Second Quarter	2.34	0.35
Third Quarter	0.55	0.37
Fourth Quarter	1.23	0.38
<u>Fiscal year ended December 31, 2003</u>		
First Quarter	10.35	6.93
Second Quarter	9.60	5.55
Third Quarter	5.93	3.80
Fourth Quarter	4.99	1.40

On December 30, 2004, the closing sale price for the common stock as reported on the OTC Bulletin Board was \$0.73 per share.

### **(b) Approximate Number Of Equity Security Holders**

As of March 1, 2005, the number of record holders of the company's common stock was approximately 99, and the Company believes that the number of beneficial owners was approximately 3,500.

### **(c) Dividends**

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

## **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 consolidated financial statements of the Company and the notes thereto included elsewhere in this Annual Report on Form 10-K along with said consolidated financial statements. See Management's Discussion and Analysis of Financial Condition and Results of Operations and Business . The historical results are not necessarily indicative of the operating results to be expected in the future.

**Table of Contents****PHARMANETICS, INC. AND SUBSIDIARIES****Selected Consolidated Financial Data (in thousands, except per share data)**

	Year Ended December 31,				
	2004	2003	2002	2001	2000
<b>RESULTS OF OPERATIONS</b>					
Net product sales to related party	\$ 1,688	\$ 5,388	\$ 3,863	\$ 2,895	\$ 3,322
Net product sales to third parties	180	126	227	1,644	947
Grant/royalty income	58	38	44	24	46
Development income	1,042	1,042	587	264	492
Total revenue	2,968	6,594	4,721	4,827	4,807
Operating expenses:					
Cost of goods sold	1,109	3,922	3,495	4,046	3,590
General and administrative	5,206	4,099	4,899	4,525	3,330
Sales and marketing	396	3,453	1,498	1,208	1,051
Research and development	374	3,997	6,008	3,950	3,685
Write-down of inventory to net realizable value(1)	378	1,973			
Impairment of long-lived assets(1)	3,189	2,516			
Total operating expenses	10,652	19,960	15,900	13,729	11,656
Operating loss	(7,684)	(13,366)	(11,179)	(8,902)	(6,849)
Other income (expense), net	139	5	63	300	515
Net and comprehensive loss	(7,545)	(13,361)	(11,116)	(8,602)	(6,334)
Beneficial conversion feature of preferred stock		(3,459)			(3,004)
Preferred stock dividends	(498)	(822)	(482)	(566)	(626)
Net and comprehensive loss attributable to common shareholders	\$ (8,043)	\$ (17,642)	\$ (11,598)	\$ (9,168)	\$ (9,964)
Basic and diluted loss per common share:					
Net and comprehensive loss attributable to common shareholders	\$ (0.79)	\$ (1.80)	\$ (1.21)	\$ (1.03)	\$ (1.31)
Weighted average shares outstanding	10,213	9,799	9,567	8,877	7,626

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	As of December 31,				
	2004	2003	2002	2001	2000
<b>FINANCIAL CONDITION</b>					
Cash and cash equivalents	\$ 2,910	\$ 8,463	\$ 9,146	\$ 14,883	\$ 5,344
Short term investments	201	282	147	85	3,904
Total assets	4,763	15,267	21,702	27,014	18,314
Long term debt and capital lease obligations, excluding current portion		617	1,095	66	36
Total liabilities	2,784	5,760	7,543	3,386	3,632
Preferred stock	12,915	12,851	7,520	7,520	8,102
Accumulated deficit	(86,898)	(78,855)	(61,214)	(49,616)	(40,448)
Contingently redeemable common stock				8,538	
Common shareholders' equity (deficit)	\$ (10,936)	\$ (3,344)	\$ 6,638	\$ 7,570	\$ 6,580

(1) In fiscal 2004, as a result of events in the first quarter 2005, the Company recorded write-downs of its long-lived assets and intangibles.

**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.****Business**

Prior to ceasing substantially all of its operations in March 2004, PharmaNetics, Inc., through its wholly-owned subsidiary Cardiovascular Diagnostics, Inc. (CVDI), had developed, manufactured and marketed rapid turnaround diagnostics to assess blood clot formation and dissolution. The Company'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 information that can affect therapy. PharmaNetics had also worked to establish itself in the emerging field of theranostics, or rapid near-patient testing, in which the diagnostic results may influence treatment decisions. The Company's tests can be used in the treatment of angina, heart attack, stroke, deep vein thrombosis and pulmonary and arterial emboli. The TAS technology can be used at the point of patient care which the Company believes 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.

**Overview**

The Company has derived income from the following sources: TAS product sales, interest income, and development income recognized in connection with collaboration agreements. Product sales have mainly consisted of the Company's routine test cards, the PT, aPTT, HMT, HTT, PRT and LHMT tests along with the related controls and analyzers. These products were distributed under a global distribution agreement with Bayer Diagnostics. In August 1998, the Company signed a five-year global distribution agreement, subject to minimum annual sales, with Chiron Diagnostics, now Bayer Diagnostics, to distribute the products. At that time and under a separate purchase agreement, the Company received an up-front investment of \$6 million from Bayer in exchange for 600,000 shares of common stock, all of which were recorded as an increase to stockholder's equity. Under that agreement, Bayer agreed to purchase minimum quantities of the Company's products covered by the agreement at pre-determined prices. The prices charged to Bayer were variable depending on purchase volumes. Subsequently, in April 2001, Bayer purchased 1,450,000 shares of common stock at a negotiated price of \$12 per share, representing a negotiated premium to market price at that time, for \$17.4 million, all of which was recorded as an increase to stockholder's equity. At that time, this investment increased Bayer's ownership percentage in the Company from approximately 7% to 19.9%. In connection with the 2001 investment, the Company entered into an amended distribution agreement with Bayer to replace the previous distribution agreement. Under the terms of the amended agreement, Bayer agreed to purchase, at the same pre-determined prices as in the original distribution agreement, the same products as covered by the original agreement. For these products distributed by Bayer, Bayer would send monthly purchase orders and the Company would transfer ownership of

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the product to and receive payment from Bayer. As requested by Bayer, and in accordance with Bayer's pre-determined delivery schedule, upon receipt of the committed purchase order, the Company would produce and transfer the product into Bayer's segregated warehouse facility at the Company. The Company did not retain any specific performance obligation with respect to product once it was completed and transferred to the segregated warehouse space. The Company sold this product to Bayer at the

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pre-determined prices set forth in the amended distribution agreement and Bayer took ownership of and assumed all risk for the inventory upon transfer and then held it for resale. Bayer does not have any right to return unsold product and has no history of requesting return. Assuming full conversion of outstanding preferred stock into common stock, Bayer now owns approximately 17% of the Company's outstanding shares and maintains the right to designate one nominee for election to the Company's board of directors. Currently, no representative from Bayer is a member of the Company's board of directors, although it retains the right to name a designee in the future.

Upon entering the amended distribution agreement with Bayer, the Company expanded its relationship with Bayer to cover collaborative distribution and supply of certain theranostic tests in the United States, principally the Enox test. The Company commercially launched this test in January 2003 to detect the anticoagulant effects of enoxaparin sodium, a leading low molecular weight heparin marketed by Aventis. Under the provisions of the amended distribution agreement, Bayer was exclusively responsible for receiving the Enox sales order from the hospital, informing the Company of the order, sending an invoice to the hospital and collecting that resulting receivable, thus assuming the credit and collection risk. For these services, Bayer received a commission of 10% of the price of each card. The Enox test inventories were maintained on the Company's books until shipment and the Company would invoice Bayer for the shipment of Enox tests and record revenue upon shipment of the product to the hospital that placed the order with Bayer, which is when all elements of the Company's revenue recognition policy have been met. The Company offered no price concession to Bayer, received payment therefore directly from Bayer within 30 to 70 days of the invoice date and Bayer's 10% commission was netted and recorded against the revenue in the financial statements.

The Company hired contract sales and technical service personnel to work with Aventis' sales force in promoting the Enox test. However, in November 2003, the Company filed a lawsuit in the eastern district of North Carolina against Aventis (See Item 3. Legal Proceedings in this report for a discussion of the lawsuit). The Company, in cooperation with Aventis, had developed a rapid bedside test, known as the Enox test, which the Company believes enhances the way Lovenox®, a popular anti-blood clotting drug marketed by Aventis, currently is managed. The Company believes the test has the potential to facilitate the drug's use in patients in the cardiac community who stand to benefit from its use. Aventis collaborated with the Company in a multi-million dollar project in which it made milestone payments to the Company to develop and co-promote the test together with Lovenox for targeted patient populations. The Company intends to aggressively pursue the lawsuit to enforce its rights, and the Company expects the lawsuit and any appeal thereof could take a year or more to complete and consume significant time and expense. The lawsuit is scheduled to go to trial in April 2005.

In December 2003, the Company announced that, primarily as a result of the Aventis litigation and its impact on the Company's business and prospects, it is pursuing a variety of strategic alternatives, including the sale of its manufacturing operations. In March 2004, because a willing and able buyer for the Company's operations had not by then been identified, the Company terminated its distribution agreement with its distribution partner, Bayer. In addition, the Company terminated the sales and technical service personnel formerly engaged by the Company through PDI, the contractor and provider of the Enox sales and technical support teams. Since filing the lawsuit, the Company has implemented and completed significant personnel reductions and has engaged Davenport & Company LLC ( "Davenport" ), an investment banking firm, as its financial advisor. Davenport is currently assisting the Company in pursuing a sale of its manufacturing operations and intellectual property. The Company believes these steps were necessary to conserve cash and position the Company for the proposed license or sale of its assets and intellectual property as well as to finance its lawsuit against Aventis. The Company is shifting its corporate strategy from a manufacturing/distribution model to that of a biotech model, whereby revenues, if any, would be tied to royalty streams from any future product sales. The Company is actively seeking a buyer for its operating assets and to sell or license its intellectual property with a significant portion of the potential valuation tied to royalties. In essence, if successful in implementing this new strategy, under such a potential arrangement, the Company would be in a position to receive royalties on tests developed and would not be responsible for manufacturing and distribution. The Company sold a substantial portion of its remaining assets, excluding its intellectual property and the other assets it deems critical to a potential buyer of the business, at auction for gross proceeds of approximately \$250,000 in January 2005.

By the end of June 2004, the Company had ceased developing, producing and selling all of its products and had terminated substantially all of its employees except its chief executive officer, who is being retained to manage the litigation against Aventis until it is completed or settled and to continue to seek a buyer of the Company's operations, manufacturing assets and intellectual property. The Company has engaged a firm, on an outsourced basis, to handle certain of its remaining administrative and accounting functions.





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### **Critical Accounting Policies and Estimates**

The consolidated financial statements have been prepared in accordance with generally accepted accounting principles, which require the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosure of contingent assets and liabilities. The Company evaluates the estimates, judgments and the policies underlying these estimates on a periodic basis as the situation changes, and regularly discusses financial events, policies, and issues with the Company's independent auditors and members of the audit committee. Actual results could differ from these estimates.

The Company believes that the following are some of the more critical judgment areas in the application of accounting policies that affect the Company's financial condition and results of operations.

#### ***Revenue Recognition***

Revenue from the sale of products is recorded when an arrangement exists, delivery has occurred or services have been rendered, the seller's price is fixed and determinable and collectibility is reasonably assured. Substantially all of the Company's product sales prior to the cessation of operations were made to the Company's distributor, Bayer. The Company's distribution agreement with Bayer was terminated in March 2004, thereby resulting in substantially no revenues in subsequent quarters. Income under license and development agreements is recognized over the anticipated period of the agreements with the collaborators, in accordance with SEC Staff Accounting Bulletin No. 104 (SAB 104). SAB 104 clarifies conditions to be met to recognize up-front non-refundable payments. Such payments are recognized over the life of the related agreement unless the payment relates to products delivered or services performed that represent the completion of the earnings process. Payments received but not recognized into income in the year of receipt are deferred and recognized over the period of the respective agreements. The Company has recognized revenue related to the development agreement with Aventis. The Company is recognizing revenue related to the Aventis development contract, which was entered into in 2000. Previous milestone payments from Aventis, which are non-refundable, remain deferred because even though the Company's development agreement with Aventis has been terminated, the Company remains under obligation not to develop another test card that would compete with Aventis through November 2006. The Company is recognizing development income from Aventis on a straight-line basis through November 2006.

#### ***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, in each period, the Company has used the intrinsic-value method to record stock based employee compensation. 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.

#### ***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 when necessary. As a result of the Company's cessation of operations and the termination of its distribution agreement with Bayer in March 2004, the Company determined that excess inventories existed at March 31, 2004 that will not

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be consumed or sold in the ordinary course of business. The Company recorded a write-down of its inventories of \$378,000 in the quarter ended March 31, 2004 to reduce them to their net realizable value of zero. There were no inventory write downs in subsequent quarters, because the net realizable value of the inventory has already been reduced to zero. In 2003, the Company recorded a write-down of its inventories of \$1,973,000 to reduce them to their net realizable value as of December 31, 2003.

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### ***Impairment of Long-Lived Assets***

The Company has adopted Statement of Financial Accounting Standards No. 144 ( FAS 144 ), Accounting for the Impairment of Disposal of Long-Lived Assets . FAS 144 requires that long-lived assets be tested for impairment whenever events or changes in circumstances indicate that their carrying amount may not be recoverable. The carrying amount is not recoverable when the undiscounted cash flows expected to be generated from the use of the long-lived assets and their eventual disposition are less than their carrying amount. The Company recorded a write-down of its long-lived assets of \$3,022,532 in 2004 to reduce the carrying amount to their net realizable value.

### ***Impairment of Intangibles***

The Company has adopted Statement of Financial Accounting Standards No. 142 ( FAS 142 ), Goodwill and Other Intangible Assets . FAS 142 requires that intangible assets be tested for impairment whenever events or changes in circumstances indicate that their carrying amount may not be recoverable. The carrying amount is not recoverable when the carrying amount exceeds its fair value. The Company recorded a write-down of its intangibles of \$166,437 in 2004 to reduce the carrying amount to their net realizable value. In 2003, impairment charges of \$193,913 were recorded related to the Company's patents and intellectual property.

## **Results of Operations**

The Company does not expect to have any operating revenue following the cessation of operations in March 2004 and operating expenses should be significantly reduced to focus almost exclusively on the Aventis litigation and maintaining the Company's financial reporting obligations.

**Year Ended December 31, 2004 vs. Year Ended December 31, 2003.** Net product sales for the year ended December 31, 2004 totaled \$1.9 million compared to \$5.5 million in 2003. The Company's revenue from Bayer totaled approximately 91% and 98% of total product revenue during 2004 and 2003, respectively. The Company suffered a decrease in revenues across all of its product categories, including specialty test cards, routine test cards, quality controls products and analyzers, all primarily due to the Company's cessation of operations in March 2004.

Development income was \$1.0 million for each of 2004 and 2003. All of the development income recognized during both periods related to collaboration payments previously received from Aventis Pharmaceuticals. During 2002, two equal milestone payments totaling \$3 million were received from Aventis in August and November. These payments are being recognized straight-line into income over the period of the agreement (through 2006) in accordance with SAB 101, as amended by SAB 104. License and royalty income increased to \$58,000 in 2004 from \$38,000 in 2003.

Cost of goods sold for the year ended December 31, 2004 was \$1.1 million compared to \$3.9 million for the same period in 2003. The \$2.8 million decrease resulted from the Company's cessation of operations in March 2004.

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General and administrative expenses were \$5.2 million for 2004 compared to \$4.1 million in 2003. This increase was previously driven by an increase in legal fees of \$1.1 million mainly related to the Company's ongoing litigation with Aventis and by the incurrence of approximately \$0.8 million in severance costs in 2004 as a result of the cessation of operations in March 2004.

Sales and marketing expenses decreased to \$396,000 for 2004 compared to \$3.5 million in 2003. This decrease was due to the Company's termination of substantially all of its sales and marketing functions by March 2004.

Research and development expenses decreased to \$374,000 million in 2004 from \$4.0 million in 2003, due to the Company's termination of all research and development projects by March 2004.

In connection with the Company's periodic and ongoing assessment of the appropriate carrying value of its assets following the cessation of its operations in March 2004, the Company recorded a write-down of its inventories of \$378,000 to reduce them to their estimated net realizable values as of December 31, 2004. As a result of ceasing production, the Company determined that excess inventories existed at the quarter ended March 31, 2004 that would not be consumed or sold in the ordinary course of business. These excess inventories of raw materials, work in process and finished goods have been written-down to their net realizable values. In 2003, the Company recorded a write-down of \$1,972,801 to reduce its inventory from standard cost to its estimate of realizable value.

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In addition, impairment charges of \$3,188,969 were recorded as of December 31, 2004 related to the Company's assets held for sale and intangibles. In accordance with the provisions of FAS 144 and 142 and as discussed in its critical accounting policy footnote related to the impairment of long-lived assets, the Company determined that the full carrying amounts of its long-lived assets were not recoverable as the cash flows expected to be generated from the use of the long-lived assets and intangibles and their eventual disposition are less than their carrying amounts. The Company determined fair value based on a sale of substantially all the assets (excluding intellectual property, manufacturing equipment and certain other assets deemed critical to a sale of the remaining business to a potential buyer) on January 13, 2005. The net book value of the assets sold was \$3.2 million for cash proceeds of approximately \$251,000. In 2003, impairment charges of \$2,229,995 were recorded related to the company's fixed assets. The inventory and long-lived asset write-downs are included in separate line items in the Company's Statement of Operations.

Other income for 2004 was income of \$139,000 compared to income of \$5,000 for 2003. This increase was principally due to the gain of \$83,000 in relation to the termination of the Bayer contract, and to a lesser degree to lower interest expense paid in 2004 as a result of repayment in March 2004 of the entire \$1.5 million loan obtained from General Electric Capital.

For 2004 and 2003, the Company paid a dividend to Series A preferred shareholders by issuing 552,108 and 110,110, respectively, shares of common stock, representing a total of \$351,790 and \$451,805 in dividends, respectively. The number of common stock dividend shares required to be issued is determined using the average of the closing prices of the common stock as reported on the Nasdaq SmallCap Market over the 30-day period ending three days prior to the end of each quarter. The number of shares to be issued is then multiplied by the closing market price of our stock on the dividend payment date to determine the amount recorded as the dividend for that period. In addition, for 2004, the Company paid dividends to Series B preferred shareholders by issuing 8,894 shares of Series B preferred stock. These shares are convertible into approximately 148,230 shares of common stock. Each quarter, the number of shares of common stock issuable from the Series B preferred stock dividend is multiplied by the closing market price of our common stock on the payment date to determine the amount recorded as the Series B dividend. For 2004, the Series B dividend totaled \$146,260. On the date of issuance of the Series B, the effective conversion price of the Series B was at a discount to the price of the common stock into which the Series B is convertible. In accordance with EITF 98-5, "Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios" and EITF 00-27 "Application of Issue No. 98-5 to Certain Convertible Instruments", this discount totaled \$3,459,000 and was recorded as a preferred stock dividend in the second quarter of 2003. The proceeds of the offering were allocated between preferred stock and warrants issued and the \$3.5 million discount was determined by subtracting the effective conversion price of the common stock of \$4.95 from the common stock market value of \$7.12 the day before the closing and multiplying that number by the number of common shares issuable upon conversion of the preferred stock.

**Year Ended December 31, 2003 vs. Year Ended December 31, 2002.** Net product sales for the year ended December 31, 2003 totaled \$5.5 million compared to \$4.1 million in 2002. The Company's revenue from Bayer totaled approximately 98% and 94% of total product revenue during 2003 and 2002, respectively. Specialty test card sales in 2003, which included the Enox and ECT tests, totaled \$365,000 compared to \$223,000 in 2002 as the Enox test was launched in January 2003. Routine test card revenues increased to \$3.4 million compared to \$2.4 million in 2002 as Bayer increased its test card purchases due to higher demand from its customers. Given higher test card sales, controls revenue, which relates to the quality control products used with the test cards, also increased to \$512,000 in 2003 compared to \$342,000 in 2002. Analyzer revenues for 2003 decreased slightly to \$1.0 million compared to \$1.1 million in the prior year.

Development income was \$1.0 million for 2003 compared to \$587,000 in 2002. All of the development income recognized during both periods related to collaboration payments previously received from Aventis Pharmaceuticals. During 2002, two equal milestone payments totaling \$3 million were received from Aventis in August and November. These payments are being recognized straight-line into income over the period of the agreement (through 2006) in accordance with SAB 104. Since the \$3 million was received in the latter half of 2002, income was recognized for only part of 2002 but was recognized during all of 2003. License and royalty income was essentially unchanged from the prior year.

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Cost of goods sold for the year ended December 31, 2003 was \$3.9 million compared to \$3.5 million for the same period in 2002. Material and labor costs increased \$362,000 associated with higher unit sales of all products. Overhead costs also increased \$65,000 compared to 2002. The gross margin improved as increased volumes allowed fixed costs to be spread over more units. In addition, sales of the Enox and HTT/PRT tests increased in 2003 compared to 2002 contributing to improved gross margins because these tests are sold at higher prices than the routine test cards.

General and administrative expenses were \$4.1 million for 2003 compared to \$4.9 million in 2002. This decrease was due to a \$1.1 million non-cash charge in 2002, that did not occur in 2003, for deferred compensation related to extending the termination date of stock options previously granted to a number of employees. In accordance with accounting guidelines, the Company recorded an expense at the modification date, December 2002, for the affected options. This decrease was partially offset by an increase in legal fees of \$282,000 mainly related to our litigation with Aventis.

Sales and marketing expenses increased to \$3.5 million for 2003 compared to \$1.5 million in 2002. This increase was due to higher compensation and travel expenses of approximately \$1.7 million in connection with the hiring of a contract sales and technical service force for the launch of the enoxaparin test card beginning in the first quarter of 2003. Depreciation expense also increased \$182,000 as new information systems were implemented related to managing sales in the first quarter of 2003.

Research and development expenses decreased to \$4.0 million in 2003 from \$6.0 million in 2002, mainly due to lower project costs of \$1.5 million compared to 2002, chiefly in the Enox, TIM and LHMT test card projects. These projects incurred development and trials expenses in 2002 that were not incurred in 2003 because research and development in these projects had been substantially completed by 2003. In addition, compensation and benefit costs decreased \$420,000 as a result of decreased compensation and benefit costs related to corporate downsizing and departmental restructuring during 2003. As of the date of this filing, the Company does not have any on-going research projects.

Other income for 2003 was income of \$5,000 compared to income of \$63,000 for 2002. This change was principally due to higher interest expense paid in 2003 under the new \$1.5 million loan obtained from General Electric Capital in December 2002.

In connection with the events leading up to the Company's decision to cease operations and production in March 2004, the Company recorded a write-down of its inventories of \$1,973,000 to reduce them to their estimated net realizable values as of December 31, 2003. As a result of ceasing production, the Company determined that excess inventories existed at December 31, 2003 that will not be consumed or sold in the ordinary course of business. These excess inventories of raw materials, work in process and finished goods have been written-down to their net realizable values.

In addition, impairment charges of \$2,516,000 were recorded related to the Company's long-lived assets. In accordance with the provisions of FAS 144 and as discussed in its critical accounting policy footnote related to the impairment of long-lived assets, the Company determined that the full carrying amount of its long-lived assets were not recoverable as the cash flows expected to be generated from the use of the long-lived assets and their eventual disposition are less than their carrying amount. The Company then estimated potential discounted future cash flows related to these assets under four scenarios in conjunction with a third-party valuation that arrived at a fair value. If the probabilities of the highest and lowest cash flow scenarios were adjusted upward or downward by 10%, the write-down would increase or decrease by \$1,060,000. The Company does not consider these assets part of a discontinued operation at December 31, 2003 as the assets were not held for sale because the Company continued to produce product in the first quarter of 2004 to meet its obligations under its distribution agreement with Bayer. The inventory and long-lived asset write-downs are included in separate line items in the Company's Statement of Operations.

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For 2003 and 2002, the Company paid a dividend to Series A preferred shareholders by issuing 110,110 and 81,087, respectively, shares of common stock, representing a total of \$451,805 and \$482,000 in dividends, respectively. The number of common stock dividend shares required to be issued is determined using the average of the closing prices

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of the common stock as reported on the Nasdaq SmallCap Market over the 30-day period ending three days prior to the end of each quarter. The number of shares to be issued is then multiplied by the closing market price of our stock on the dividend payment date to determine the amount recorded as the dividend for that period. In addition, for 2003, the Company paid dividends to Series B preferred shareholders by issuing 5,554 shares of Series B preferred stock. These shares are convertible into approximately 92,568 shares of common stock. Each quarter, the number of shares of common stock issuable from the Series B preferred stock dividend is multiplied by the closing market price of our common stock on the payment date to determine the amount recorded as the Series B dividend. For 2003, the Series B dividend totaled \$370,000. On the date of issuance of the Series B, the effective conversion price of the Series B was at a discount to the price of the common stock into which the Series B is convertible. In accordance with EITF 98-5, Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios and EITF 00-27 Application of Issue No. 98-5 to Certain Convertible Instruments, this discount totaled \$3,459,000 and was recorded as a preferred stock dividend in the second quarter of 2003. The proceeds of the offering were allocated between preferred stock and warrants issued and the \$3.5 million discount was determined by subtracting the effective conversion price of the common stock of \$4.95 from the common stock market value of \$7.12 the day before the closing and multiplying that number by the number of common shares issuable upon conversion of the preferred stock.

## **Liquidity and Capital Resources**

At December 31, 2004, the Company had cash and short-term investments of \$3.1 million and working capital of \$1.7 million, as compared to \$8.7 million and \$7.1 million, respectively, at December 31, 2003. During 2004, the Company used cash in operating activities of \$4.5 million. The operating use of cash was principally due to funding the net operating loss of the Company, including expenses relating to the Aventis lawsuit and considering the non-cash impairment charges of approximately \$3.0 million. Payables and accrued expenses at the end of 2004 were lower compared to 2003 which resulted in a cash outflow.

Net cash provided by investing activities was approximately \$97,000 in 2004. Net cash used in investing activities was \$604,000 in 2003. In 2004, the Company expended \$10,000 for new equipment and \$6,000 related to patents. The Company realized \$25,000 from the sale of fixed assets and \$88,000 from the sale of investment in 2004. The Company does not expect any significant ongoing capital expenditures.

Cash used in financing activities was \$1.1 million in 2004 as compared to net cash provided by financing activities of \$8.3 million in 2003. Cash used in financing activities was mainly attributable to capital lease payments and repayment of the remaining \$976,000 balance under the equipment loan from GE Capital in the first quarter of 2004.

The Company has sustained continuing operating losses in 2004 and had an accumulated deficit of \$86.9 million as of December 31, 2004. In December 2003, the Company announced that, due to continued legal action against Aventis and the impact of that litigation on the Company's operations and prospects, it is seeking strategic alternatives, including the sale of its manufacturing operations. As of the end of March 2004, no buyer had yet emerged and the Company, therefore, ended its distribution agreement with Bayer and ceased producing and selling all products. The Company is continuing its search for a buyer for its intellectual property and its critical business assets and intends to continue seeking a buyer during 2005. Any proceeds from the sale of these assets would likely be set aside for potential distribution to shareholders in accordance with the Company's Articles of Incorporation. The Company does not expect that the amount of these proceeds, if any, would be substantial enough for any distribution to common shareholders after giving effect to the liquidation preference of the Company's preferred shareholders.

The Company intends to pursue the lawsuit with Aventis with its existing funds which total approximately \$2,600,000 as of February 28, 2005. In addition, the Company terminated substantially all of its employees during the first quarter of 2004, resulting in severance costs of approximately \$638,000 and virtually no severance costs since that time. The Company terminated the lease for its building in the first quarter of 2005, resulting in a termination expense of approximately \$338,000. The Company believes it has sufficient resources to fund its limited ongoing operating costs and the litigation with Aventis through the anticipated trial date, which is expected to commence in April 2005.



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However, there can be no assurance that such resources will be sufficient. Pending the outcome of the trial, presently the Company does not expect to need nor does it intend to seek additional sources of financing.

**Table of Contents****Contractual Obligations**

The Company has contractual obligations under capital and operating lease agreements and other obligations for years subsequent to 2004. Future payments as of December 31, 2004 are as follows:

	2005-2006	2007-2008	After 2008	Total
Notes payable*	\$ 2,701	\$	\$	\$ 2,701
Operating leases**	337,787			337,787
Total payments	\$ 340,488	\$	\$	\$ 340,488

\* Relates to lease expense for office equipment.

\*\* This commitment is associated with operating leases. Payment due reflects cost of termination of the rental space for the building.

**Recent Accounting Pronouncements**

At its November 2004 meeting, the Emerging Issues Task Force (EITF) reached a consensus on EITF Issue No. 03-13, Applying the Conditions in Paragraph 42 of FAS 144 in Determining Whether to Report Discontinued Operations ( EITF 03-13 ). The EITF abstract provides an approach for evaluating whether the criteria in paragraph 42 of Statement of Financial Accounting Standards No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets ( FAS144 ), have been met for classifying as a discontinued operation a component of an entity that either has been disposed of or is classified as held for sale. To qualify as a discontinued operation, paragraph 42 of FAS 144 requires that the cash flows of the disposed component be eliminated from the operations of the ongoing entity and that the ongoing entity not have any significant continuing involvement in the operations of the disposed component after the disposal transaction. The Company has adopted this standard and it did not have a material impact on the Company.

In April 2004, the Emerging Issuance Task Force issued a census on EITF 03-6, Participating Securities and the Two-Class Method Under FASB Statement No. 128. The EITF significantly expanded the notion of participation rights from previous practice. Issue 03-6 does not focus on a security holder's contractual rights to ultimately receive the undistributed earnings and net assets of the company upon redemption or liquidation. Instead, it defines participation rights based solely on whether the holder would be entitled to receive any dividends if the entity declared them during the period, even if those earnings would not actually be distributed from an economic or practical perspective and even if the company has legal or contractual limitations on its ability to pay dividends (e.g., debt covenants or state law considerations on the payment of dividends). All securities that meet the definition of a participating security, regardless of whether the securities are convertible, non-convertible, or potential common stock securities, should be considered for inclusion in the computation of basic earnings per share using the two-class method. The Company currently does not anticipate this standard to have a significant impact on its financial statements.

In December 2004, FASB issued SFAS No. 123(R), Share-Based Payment, which requires that the cost resulting from all share-based payments to be recognized in the financial statements. In addition, SFAS No. 123(R) establishes fair value as the measurement objective in accounting for share-based payment arrangements and requires all entities to apply a fair-value-based measurement method in accounting for share-based payment transactions with employees. The application of SFAS 123(R) will not have a material effect on the Company's operations.

**Factors That Might Affect Future Results**

A number of uncertainties exist that might affect the Company's future operating results and stock price. There can be no assurance that the Company will be successful in its lawsuit against Aventis or that it will find a buyer for any of its assets. See "Legal Proceedings" under Item 3 of this report for a discussion of the status of the lawsuit with Aventis. The market price of the common stock could be subject to significant fluctuations in response to developments in the litigation as well as other factors which may be unrelated to the Company's performance. The

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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, such as the Company's, are particularly susceptible to volatility based on short-term trading strategies of some investors.

### **Item 7A. Quantitative and Qualitative Disclosure about Market Risk**

Not applicable.

### **Item 8. Financial Statements and Supplementary Data**

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

### **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

Not applicable

### **Item 9A. Controls and Procedures**

(a) Disclosure Controls and Procedures: Disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) are designed only to provide reasonable assurance that they will meet their objectives. As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the Company's disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures are effective to provide the reasonable assurance discussed above.

(b) Internal Control Over Financial Reporting: No change in the Company's internal control over financial reporting occurred during the Company's last fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

### **Item 9B. Other Information**

None

**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 2005 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 this Item 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 this Item 10 is incorporated by reference to the information under the headings Proposal No. 1 - Election of Directors and Section 16(a) Beneficial Ownership Reporting Compliance in the Proxy Statement.

The Board of Directors has determined that John Pirotte is an audit committee financial expert as defined in Item 401(h) of Regulation S-K.

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The Board of Directors has adopted a code of conduct that applies to all of the Company's directors and employees, including for the Company's Chief Executive Officer, Chief Financial Officer and Controller, or persons performing similar functions. The Company will provide copies of its code of conduct and code of ethics without charge upon request. To obtain a copy of our code of conduct and code of ethics, please send your written request to PharmaNetics, Inc., 3700 National Drive, Suite 211, Raleigh, North Carolina 27612, Attn: Chief Executive Officer.

### **Item 11. Executive Compensation**

The information required by this Item 11 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 this Item is incorporated by reference to the information under the heading "Other Information - Principal Shareholders" and "Other Information - Equity Compensation Plan Information" in the Proxy Statement.

### **Item 13. Certain Relationships and Related Transactions**

The Company has determined that its only related transactions are with Bayer. The information required by Item 13 of Form 10-K related to Bayer's ownership in the Company is incorporated by reference to the information under the heading "Other Information - Principal Shareholders" in the Proxy Statement. In addition, see information related to sales to Bayer under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 of this Form 10-K. The Company terminated its distribution agreement with Bayer in March 2004.

### **Item 14. Principal Accountant Fees and Services**

The information required by this Item is incorporated by reference to the information under the heading "Principal Accountant Fees and Services" in the Proxy Statement.

### **Item 15. Exhibits and Financial Statement Schedules**

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

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### (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.

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(b) Exhibits

<b>Exhibit Number</b>	<b>Description</b>
3.3(a)	Bylaws.
3.5(e)	Amended and Restated Articles of Incorporation filed with the North Carolina Secretary of State on April 30, 2003.
4.1(a)	Form of Common Stock certificate.
10.8(a)	1994 Stock Plan, as amended.
10.9(a)	1995 Stock Plan, as amended.
10.24(b)	Series A Preferred Stock and Warrant Purchase Agreement dated February 24, 2000.
10.25(b)	Form of Warrant between the Company and the Series A Investors dated February 25, 2000.
10.26(c)	Lease Agreement dated July 27, 2000 relating to 9401 Globe Center Drive, as amended by the First Lease Amendment dated September 25, 2000.
10.27(d)	Common Stock Purchase Agreement between the Registrant and Bayer Corporation dated April 23, 2001.
10.29(e)	Series B Stock Purchase and Warrant Agreement dated April 30, 2003.
10.30(e)	Form of Warrant between the Company and the Series B Investors dated May 1, 2003.
10.31(e)	Registration Rights Agreement among PharmaNetics Inc. and Series B Investors dated May 1, 2003.
10.32(e)	Shareholder s Agreement among PharmaNetics Inc. and certain Series B shareholders dated May 1, 2003.
10.33(e)	Amendment No. 1 dated April 29, 2003 to the Common Stock Purchase Agreement with the Bayer Corporation dated April 23, 2001.
10.34(f)	Collaborative Development Agreement dated August 30, 2000 with Aventis Pharmaceuticals Products, Inc.
10.38(f)	Change of Control Agreement with John Funkhouser dated October 10, 1997.
10.39(f)	Employment Agreement with James A. McGowan dated May 3, 2000.
10.40(f)	Transitional Employment Agreement with James A. McGowan dated July 4, 2003.
21.1(a)	List of Subsidiaries.
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14.
32.1	Chief Executive Officer and Chief Financial Officer Certification pursuant to Section 906 of the Sarbanes/Oxley Act of 2002.
99.1(g)	Order of the United States District Court for the Eastern District of North Carolina dated March 9, 2005 setting forth the court s ruling on the parties motions for Summary Judgment.
(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 by reference to the identically-numbered exhibit to the Registrant s Current Report on Form 8-K filed March 1, 2000.
(c)	Incorporated by reference to the identically-numbered exhibit to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2000.
(d)	Incorporated by reference to the identically-numbered exhibit to the Registrant s Current Report on Form 8-K filed April 27, 2001.
(e)	Incorporated by reference to the identically-numbered exhibit to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2003.
(f)	



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Incorporated by reference to the identically numbered exhibit to the Registrant's Amendment No. 1 to Registration Statement No. 333-106087 filed on July 30, 2003.

- (g) Incorporated by reference to the identically numbered exhibit to the Registrant's Current Report on Form 8-K filed March 15, 2005.

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**SIGNATURES**

Pursuant to the requirements 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.

Date: March 16, 2005

PHARMANETICS, INC.

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.

<b><u>Signature</u></b>	<b><u>Title</u></b>	<b><u>Date</u></b>
/s/ John P. Funkhouser _____ <b>John P. Funkhouser</b>	President, Chief Executive Officer, and Chairman (Principal Executive Officer, and Chief Accounting Officer	March 16, 2005
/s/ John K. Pirotte _____ <b>John K. Pirotte</b>	Director	March 16, 2005
/s/ James B. Farinholt, Jr. _____ <b>James B. Farinholt, Jr.</b>	Director	March 16, 2005
/s/ Richard M. Johnston _____ <b>Richard M. Johnston</b>	Director	March 14, 2005

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**PHARMANETICS, INC.**

**AND SUBSIDIARIES**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Shareholders of PharmaNetics, Inc.

In our opinion, the consolidated financial statements listed in the index appearing under Item 15(a)(1) present fairly, in all material respects, the financial position of PharmaNetics, Inc. and its subsidiaries at December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 15(a)(2) presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with auditing standards of the Public Company Accounting Oversight Board (United States), 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.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has ceased production and operations to conserve cash for the license and sale of assets and intellectual property as well as to finance its legal proceedings. These matters raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ PricewaterhouseCoopers LLP

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Raleigh, North Carolina  
March 16, 2005

**Table of Contents****PHARMANETICS, INC. AND SUBSIDIARIES**

## Consolidated Balance Sheets

December 31, 2004 and 2003

	<u>2004</u>	<u>2003</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 2,910,171	\$ 8,463,193
Account receivable from related party		498,372
Other receivables, net of allowance for doubtful accounts of \$21,000 and \$1,995, respectively	2,896	53,988
	<u>2,896</u>	<u>552,360</u>
Total receivables	2,896	552,360
Inventories		567,391
Other current assets	621,808	622,464
	<u>3,534,875</u>	<u>10,205,408</u>
Total current assets	3,534,875	10,205,408
Property and equipment, held-for-sale	1,004,112	4,656,227
Patents and intellectual property, held-for-sale	223,187	402,559
Other noncurrent assets	1,270	3,259
	<u>4,763,444</u>	<u>15,267,453</u>
Total assets	\$ 4,763,444	\$ 15,267,453
<b>LIABILITIES, CONVERTIBLE REDEEMABLE PREFERRED STOCK AND SHAREHOLDERS DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 447,140	\$ 799,894
Accrued expenses	337,004	537,742
Deferred revenue, current portion	1,042,219	1,226,487
Current portion of long-term debt	2,701	498,909
Current portion of capital lease obligations		15,381
	<u>1,829,064</u>	<u>3,078,413</u>
Total current liabilities	1,829,064	3,078,413
Deferred revenue, less current portion	955,368	2,064,551
Long-term debt, less current portion		594,056
Capital lease obligations, less current portion		23,159
	<u>955,368</u>	<u>2,681,766</u>
Total noncurrent liabilities	955,368	2,681,766
Total liabilities	2,784,432	5,760,179
Commitments and contingencies (Note 10)		
Series A convertible redeemable preferred stock, no par value; authorized 120,000 shares; 64,500 and 65,500 shares issued and outstanding at December 31, 2004 and 2003, respectively (aggregate liquidation value at December 31, 2004 of \$6,450,000)	5,359,771	5,442,873
Series B convertible redeemable preferred stock, no par value; authorized 130,000 shares; 110,248 and 101,354 shares issued and outstanding at December 31, 2004 and 2003, respectively (aggregate liquidation value at December 31, 2004 of \$11,024,800)	7,554,741	7,408,480
Shareholders' equity:		

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Common stock, no par value; authorized 40,000,000 shares; 10,604,663 and 10,021,556 shares issued and outstanding at December 31, 2004 and 2003, respectively	75,962,494	75,511,015
Accumulated deficit	(86,897,994)	(78,855,094)
	<u>                    </u>	<u>                    </u>
Total shareholders' deficit	(10,935,500)	(3,344,079)
	<u>                    </u>	<u>                    </u>
Total liabilities, convertible redeemable preferred stock and shareholders' deficit	\$ 4,763,444	\$ 15,267,453
	<u>                    </u>	<u>                    </u>

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

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**Table of Contents****PHARMANETICS, INC. AND SUBSIDIARIES**

## Consolidated Statements of Operations

For the years ended December 31, 2004, 2003 and 2002

	2004	2003	2002
Revenue:			
Net product sales to related party	\$ 1,688,000	\$ 5,387,542	\$ 3,862,694
Net product sales to third parties	179,724	125,984	227,749
Grant/royalty income	57,864	38,366	43,705
Development income	1,042,219	1,042,219	587,478
Total revenue	2,967,807	6,594,111	4,721,626
Operating expenses:			
Cost of sales	1,108,533	3,922,420	3,495,581
General and administrative	5,205,853	4,098,818	4,898,934
Sales and marketing	396,000	3,452,667	1,498,508
Research and development	374,000	3,997,333	6,007,750
Write-down of inventories	378,000	1,972,801	
Impairment of long-lived assets and intangibles	3,188,969	2,516,170	
Total operating expenses	10,651,355	19,960,209	15,900,773
Operating loss	(7,683,548)	(13,366,098)	(11,179,147)
Other income (expense):			
Interest expense	(27,952)	(130,603)	(18,413)
Interest income	54,546	85,780	122,699
Other income (expense)	112,104	49,802	(41,191)
Other income, net	138,698	4,979	63,095
Net and comprehensive loss	(7,544,850)	(13,361,119)	(11,116,052)
Amortization of beneficial conversion feature of convertible preferred stock		(3,458,781)	
Preferred stock dividends	(498,050)	(821,641)	(481,589)
Net loss attributable to common shareholders	\$ (8,042,900)	\$ (17,641,541)	\$ (11,597,641)
Basic and diluted net loss attributable to common shareholders	\$ (0.79)	\$ (1.80)	\$ (1.21)
Weighted average number of outstanding common shares	10,213,519	9,798,813	9,566,843

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





**Table of Contents****PHARMANETICS, INC. AND SUBSIDIARIES**

## Consolidated Statements of Shareholders' Equity

For the years ended December 31, 2004, 2003 and 2002

	Common Stock		Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Number of Shares	Amount		
Balances at December 31, 2001	9,485,294	\$ 57,185,936	\$ (49,615,912)	\$ 7,570,024
Stock options exercised	82,791	402,611		402,611
Issuance of stock dividends	81,087	481,589	(481,589)	
Common stock repurchases	(18,300)	(102,897)		(102,897)
Unearned compensation related to common stock options		1,346,910		1,346,910
Reclassification from contingently redeemable common stock		8,537,500		8,537,500
Net loss for the year ended December 31, 2002			(11,116,052)	(11,116,052)
Balances at December 31, 2002	9,630,872	67,851,649	(61,213,553)	6,638,096
Stock options exercised	30,574	54,916		54,916
Issuance of common stock dividends on Series A	110,110	451,805	(451,805)	
Issuance of preferred stock dividends on Series B			(369,836)	(369,836)
Issuance of warrants in connection with Series B offering		1,616,289		1,616,289
Conversions of preferred stock to common stock	250,000	2,077,575		2,077,575
Amortization of beneficial conversion feature		3,458,781	(3,458,781)	
Net loss for the year ended December 31, 2003			(13,361,119)	(13,361,119)
Balances at December 31, 2003	10,021,556	75,511,015	\$ (78,855,094)	(3,344,079)
Stock options exercised	20,999	16,589		16,589
Issuance of common stock dividends on Series A	552,108	351,790	(351,790)	
Issuance of preferred stock dividends on Series B			(146,260)	(146,260)
Conversions of preferred stock to common stock	10,000	83,100		83,100
Net loss for the year ended December 31, 2004			(7,544,850)	(7,544,850)
Balances at December 31, 2004	10,604,663	\$ 75,962,494	\$ (86,897,994)	\$ (10,935,500)

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

**Table of Contents****PHARMANETICS, INC. AND SUBSIDIARIES**

## Consolidated Statements of Cash Flows

For the years ended December 31, 2004, 2003 and 2002

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Cash flows from operating activities:			
Net loss	\$ (7,544,850)	\$ (13,361,119)	\$ (11,116,052)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of property and equipment	614,947	1,777,997	1,506,565
Amortization of intangible assets	79,255	116,033	148,073
Loss on impairment of long-lived assets	3,022,532	2,516,170	
Amortization of discount on investments, net			
(Gain) loss on trading investments	(7,060)	(35,373)	44,096
Bad debt expense	20,982		
Noncash compensation			1,346,910
Write-offs of patent costs	166,437	59,317	
Provision for inventory obsolescence		218,894	96,605
Write-down of inventory to net realizable value	378,000	1,972,801	
(Gain) loss on disposal of fixed assets		24,839	6,070
Change in operating assets and liabilities:			
Receivables	528,482	102,103	(192,068)
Inventories	189,388	(305,646)	(326,806)
Other assets	(138,807)	(92,155)	(197,787)
Accounts payable and accrued expenses	(553,490)	(400,126)	133,266
Deferred revenue	(1,293,451)	(937,237)	2,395,379
Net cash used in operating activities	<u>(4,537,635)</u>	<u>(8,343,502)</u>	<u>(6,155,749)</u>
Cash flows from investing activities:			
Purchases of property and equipment	(9,713)	(396,999)	(1,161,674)
Disposal of property and equipment	24,349	(107,029)	(100,513)
Cost to obtain patents	(5,883)	(130,045)	(106,250)
Proceeds from sales of investments	88,075	30,000	
Net cash provided by (used in) investing activities	<u>96,828</u>	<u>(604,073)</u>	<u>(1,368,437)</u>
Cash flows from financing activities:			
Principal payments on long-term debt and capital lease obligations	(1,128,804)	(445,549)	(24,151)
Proceeds from issuance of long-term debt			1,512,500
Proceeds from exercise of stock options	16,589	54,916	402,611
Proceeds from issuance of common stock			
Repurchase of common stock			(102,897)
Proceeds from issuance of Series B preferred stock, net		8,654,935	
Net cash provided by (used in) financing activities	<u>(1,112,215)</u>	<u>8,264,302</u>	<u>1,788,063</u>
Decrease in cash and cash equivalents	<u>(5,553,022)</u>	<u>(683,273)</u>	<u>(5,736,123)</u>
Cash and cash equivalents at beginning of year	<u>8,463,193</u>	<u>9,146,466</u>	<u>14,882,589</u>
Cash and cash equivalents at end of year	<u>\$ 2,910,171</u>	<u>\$ 8,463,193</u>	<u>\$ 9,146,466</u>

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Supplemental disclosures of cash flow information:			
Cash paid during the year for interest expense	\$ 27,952	\$ 122,006	\$ 18,413
Cash paid during the year for income taxes	\$	\$ (35,373)	\$

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

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**PHARMANETICS, INC. AND SUBSIDIARIES**

Notes to Consolidated Financial Statements

**1. Organization and Summary of Significant Accounting Policies**

**Business**

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, prior to ceasing operations in March 2004, was a developer, manufacturer and marketer of coagulation analyzers and rapid diagnostic tests to dose, manage and screen patients on drugs affecting coagulation. The Company formerly developed tests based on its proprietary dry chemistry diagnostic test system, known as the Thrombolytic Assessment System ("TAS"), to provide rapid and accurate evaluation of coagulation at the point of patient care.

In December 2003, the Company announced that, as a result primarily of the litigation with Aventis Pharmaceuticals (see Note 18) and its impact on the Company's business and prospects, it is seeking a variety of strategic alternatives, including the sale of its manufacturing operations. In March 2004, because a willing and able buyer for the operations had not by then been identified, the Company terminated its distribution agreement with its distribution partner, Bayer Diagnostics ("Bayer") and has ceased producing and selling all products. In addition, the Company terminated sales and technical service personnel formerly engaged by the Company through PDI, the contractor and provider of the Enox sales and technical support teams. PharmaNetics believes these steps were and are necessary in order to reduce overhead costs and to conserve cash for the license and sale of assets and the intellectual property, as well as to finance its lawsuit against Aventis. Since filing the lawsuit, the Company has implemented and completed significant personnel reductions and has engaged Davenport & Company LLC ("Davenport"), an investment banking firm, as its financial advisor. Davenport is currently assisting the Company in pursuing a sale of its manufacturing operations and intellectual property. The Company is shifting its corporate strategy from a manufacturing/distribution model to that of a biotech model, whereby revenues, if any, would be tied to royalty streams from any future product sales. The Company is actively seeking a buyer for its operating assets and to sell or license its intellectual property with a significant portion of the potential valuation tied to royalties. In essence, if successful in implementing this new strategy, the Company would be in a position to receive royalties on tests developed and would not be responsible for manufacturing and distribution.

**Principles of Consolidation**

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation. Certain reclassifications were made to the prior year financial statements to conform them to the current presentation.

**Cash Equivalents**

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

## **Inventories**

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

During 2004, the Company recorded a write-down of inventories to reduce them to their estimated net realizable values.

## **Assets Held for Sale**

The Company holds its property and equipment and patents and intellectual property as held for sale from and after April 2004. In accordance with Statement of Financial Accounting Standards No. 144 Accounting for Impairment or Disposal of Long-Lived Assets (SFAS 144), the Company records its assets at the lower of its carrying amount or fair value less cost to sell and does not depreciate or amortize the assets while it is classified as held for sale.

## **Intangibles**

The Company has adopted Statement of Financial Accounting Standards No. 142 ( FAS 142 ), Goodwill and Other Intangible Assets . FAS 142 requires that intangible assets be tested for impairment whenever events or changes in circumstances indicate that their carrying amount may not be recoverable. The carrying amount is not recoverable when the carrying amount exceeds its fair value. The Company recorded a write-down of its intangibles of \$166,437 in 2004 to reduce the carrying amount to their net realizable value. In 2003, impairment charges of \$193,913 were recorded related to the Company's patents and intellectual property.

**Table of Contents****1. Summary of Significant Accounting Policies (Continued)****Impairment of Long-Lived Assets**

The Company has adopted Statement of Financial Accounting Standards No. 144 ( FAS 144 ), Accounting for the Impairment of Disposal of Long-Lived Assets . FAS 144 requires that long-lived assets be tested for impairment whenever events or changes in circumstances indicate that their carrying amount may not be recoverable. The carrying amount is not recoverable when the undiscounted cash flows expected to be generated from the use of the long-lived assets and their eventual disposition are less than their carrying amount. The Company's fixed assets, patents and other non-current assets are considered long-lived assets.

As discussed above, events occurred in the Company's 2003 fourth quarter which indicate that the carrying amount of these assets may not be recoverable. In accordance with the provisions of FAS 144, the Company has performed impairment tests and determined that an impairment of the noted assets was present as of December 31, 2003. This analysis required the use of judgments and estimates concerning future cash flows and fair values upon disposition of assets. The Company then estimated potential discounted future cash flows related to these assets under four scenarios in conjunction with a third-party valuation that arrived at a fair value. An impairment write-down of \$2,322,257 was taken in the year ended December 31, 2003 and included in a separate line item in the Company's Statement of Operations. If the probabilities of the highest and lowest cash flow scenarios were adjusted upward and downward by 10%, the write-down would increase or decrease by \$1,060,000 respectively. See further discussion in Notes 4, 5 and 6. The Company recorded a further write-down of its long-lived assets of \$3,022,532 in 2004 to reduce the carrying amount to their net realizable value. The Company determined fair value based on a sale of substantially all the assets (excluding intellectual property, manufacturing equipment and certain other assets deemed critical to a sale of the remaining business to a potential buyer) on January 13, 2005.

**Revenue and Income Recognition Policies**

The Company records revenue from the sale of products when an arrangement exists, the product has been delivered or services have been rendered (transfer of risk occurs), the price is fixed and determinable and collectibility is reasonably assured. For all products except the Enox test, the Company records revenue from product sold to Bayer when the above elements exist and specifically upon transfer of risk (at delivery) to Bayer. Delivery occurs at the point of shipment and title legally passes at that time. Bayer assumes all risk of loss once title passes and takes ownership of the finished inventory and holds it for resale to hospitals. The Company does not retain any additional performance obligation with respect to the product once the product has been manufactured and transferred to Bayer. The product, except in the case of defects, is not returnable and there has not been a history of defective product returns. A standard pricing model is in place and the Company does not offer price protection or rights of return. The Company records product revenue from the sale of the Enox test upon shipment of the product to the hospital. The Company invoiced Bayer at the shipment date, netting a 10% commission paid to Bayer (for administration and collection services) against the product revenue, in accordance with EITF 01-09 Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products) . Bayer was not responsible for invoicing and collecting from the hospital and was required to pay the Company regardless of whether it collected from the hospital. The Company accounts for royalties on an accrual basis. Tokuyama Soda paid the Company royalties based on Tokuyama's net sales of a licensed product. The Company recognizes income under license and development agreements over the anticipated period of the agreements with its collaborators, in accordance with SEC Staff Accounting Bulletin No. 104 (SAB 101). SAB 104 clarifies conditions to be met to recognize up-front non-refundable payments. Such payments are recognized over the life of the related agreement unless the payment relates to products delivered or services performed that represent the completion of the earnings process. Payments received but not recognized into income in the year of receipt are deferred and recognized over the period of the respective agreements. For example, the Company received upfront payments for development of the Enoxaparin test card from Aventis. Pursuant to this arrangement, the Company received non-refundable milestone payments for executing the agreement, completing the development, FDA approval, and the first commercial sale of the product. There is a period of four years after the first commercial sale of the test card in which the Company cannot develop a similar test card for another entity. The Company is recognizing the milestone payments over a period of five years, based on the estimated life of the relationship.

## **Warranties**

Warranty accruals are assessed on a quarterly and annual basis for adequacy. Actual product warranty costs incurred are reviewed and increases to warranty reserves are made if levels of costs are above expectation. The Company has not experienced material warranty costs in the current or prior periods.

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**1. Summary Of Significant Accounting Policies (Continued)**

**Research and Development**

Research and development costs are charged to operations as incurred. These costs include compensation costs, supplies, clinical trial expenses, depreciation on equipment used in research and development and the cost of test cards consumed in the research and development process. The cost of cards consumed in development include material, labor and allocated manufacturing overhead.

**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 deferred tax 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 income 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, 2004, 2003 and 2002 is the same because, for loss periods, the inclusion of potential common shares would be antidilutive. Options currently outstanding that could be dilutive in the future are summarized in Note 13.

**Stock-Based Compensation**

The Company follows 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, in each period, the Company has used the intrinsic-value method to record stock based employee compensation. 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. Pro forma 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 is summarized below.

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. During



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2002, the Company recorded a non-cash expense of \$1.3 million for deferred compensation related to extending by five years the termination date of options previously granted to a number of employees. In accordance with accounting guidelines, an expense was recorded at the modification date for the affected options by multiplying the number of options by the difference in the market price of the Company's common stock on the date of the extension and the strike price of each option. This extension of the contractual life results in a one-time charge based on the options being fully vested and variable accounting will not be required in future periods.

On December 31, 2002, the FASB issued FASB Statement No. 148 ( FAS 148 ), Accounting for Stock-Based Compensation Transition and Disclosure , which amends FASB Statement No. 123 ( FAS 123 ), Accounting for Stock-Based Compensation . FAS 148 requires new disclosures including an accounting policy footnote that includes: the method of accounting for stock options; total stock compensation cost that is recognized in the income statement and would have been recognized had FAS 123 been adopted for recognition purposes as of its effective date; and pro forma net income and earnings per share (where applicable) that would have been reported had FAS 123 been adopted for recognition purposes as of its effective date.

**Table of Contents****1. Summary of Significant Accounting Policies (Continued)**

For purposes of the proforma disclosures, the fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model and the estimated fair value of equity instruments is amortized to expense over their respective vesting periods. The following assumptions were used for grants in 2004, 2003 and 2002:

	<b>2004</b>	<b>2003</b>	<b>2002</b>
Dividend yield	0%	0%	0%
Volatility	98%	87%	86%-88%
Risk free interest rate	4.3%	2.6%	3%-4.5%
Expected life of options	2 years	6 years	6 years

For 2004, 2003 and 2002, the following table summarizes the net loss and stock-based compensation expense, as reported, compared to pro forma amounts had the fair value method been applied:

	<b>2004</b>	<b>2003</b>	<b>2002</b>
Net loss attributable to common shareholders, as reported	\$ (8,042,900)	\$ (17,641,541)	\$ (11,597,641)
Net loss per basic and diluted share, as reported	\$ (0.79)	\$ (1.80)	\$ (1.21)
Employee stock based compensation, as reported	\$	\$	\$ (1,346,910)
Employee stock based compensation based on fair value method	\$ (105,865)	\$ (1,180,790)	\$ (1,443,975)
Pro forma net loss using fair value method	\$ (8,148,765)	\$ (18,822,331)	\$ (11,694,706)
Pro forma net loss per basic and diluted share	\$ (0.80)	\$ (1.92)	\$ (1.22)

**Fair Value of Financial Instruments**

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 debt is provided in Note 9.

**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 Loss**

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The Company calculates and discloses comprehensive loss 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 loss for all reporting periods in the financial statements. Comprehensive loss must be displayed with the same prominence as other financial statements. There were no items of other comprehensive loss for the years ended December 31, 2004, 2003 or 2002.

### Cash Flow Information

A supplemental schedule of non-cash financing activities during the three years ended December 31, 2004 is as follows:

	2004	2003	2002
Purchases of property, plant and equipment in accounts payable at year end	\$	\$	\$ 140,462

### Recent Accounting Pronouncements

At its November 2004 meeting, the Emerging Issues Task Force (EITF) reached a consensus on EITF Issue No. 03-13, Applying the Conditions in Paragraph 42 of FAS 144 in Determining Whether to Report Discontinued Operations ( EITF 03-13 ). The EITF abstract provides an approach for evaluating whether the criteria in paragraph 42 of Statement of Financial Accounting Standards No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets ( FAS144 ), have been met for classifying as a discontinued operation a component of an entity that either has been disposed of or is classified as held for sale. To qualify as a discontinued operation, paragraph 42 of FAS 144 requires that the cash flows of the disposed component be eliminated from the operations of the ongoing entity and that the ongoing entity not have any significant continuing involvement in the operations of the disposed component after the disposal transaction. The Company has adopted this standard in fiscal 2003.

In December 2004, FASB issued SFAS No. 123(R), Share-Based Payment, which requires that the cost resulting from all share-based payments be recognized in the financial statements. In addition, SFAS No. 123(R) establishes fair value as the measurement objective in accounting for share-based payment arrangements and requires all entities to apply a fair-value-based measurement method in accounting for share-based payment transactions with employees. The application of SFAS 123(R) will not have a material effect on the Company's operations.

In April 2004, the Emerging Issuance Task Force issued a census on EITF 03-6, Participating Securities and the Two-Class Method Under FASB Statement No. 128. The EITF significantly expanded the notion of participation rights from previous practice. Issue 03-6 does not focus on a security holder's contractual rights to ultimately receive the undistributed earnings and net assets of the company upon redemption or liquidation. Instead, it defines participation rights based solely on whether the holder would be entitled to receive any dividends if the entity declared them during the period, even if those earnings would not actually be distributed from an economic or practical perspective and even if the company has legal or contractual limitations on its ability to pay dividends (e.g., debt covenants or state law

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considerations on the payment of dividends). All securities that meet the definition of a participating security, regardless of whether the securities are convertible, non-convertible, or potential common stock securities, should be considered for inclusion in the computation of basic earnings per share using the two-class method. The Company currently does not anticipate this standard to have a significant impact on its financial statements.

In December 2004, FASB issued SFAS No. 123(R), Share-Based Payment, which requires that the cost resulting from all share-based payments be recognized in the financial statements. In addition, SFAS No. 123(R) establishes fair value as the measurement objective in accounting for share-based payment arrangements and requires all entities to apply a fair-value-based measurement method in accounting for share-based payment transactions with employees. The application of SFAS 123(R) will not have a material effect on the Company's operations.

**2. Investments**

Included in other current assets at December 31, 2004 and 2003 are trading investments of \$201,437 and \$282,452, respectively, consisting of marketable equity securities related to the Company's Supplemental Executive Retirement Plan. The related liability as of December 31, 2004 and 2003, included within accrued expenses, is \$114,894 and \$104,724, respectively.

**3. Inventories**

Inventories at December 31, 2004 and 2003 consisted of the following:

	<b>2004</b>	<b>2003</b>
Raw materials	\$ 1,465,391	\$ 2,012,903
Work in progress	30,597	134,621
Finished goods	133,236	571,174
Less: reserve		(178,506))
Less: write-down to net realizable value	(1,629,224)	(1,972,801)
	<u>\$</u>	<u>\$ 567,391</u>

The Company decided in December 2003 to cease production in March 2004. Accordingly, at December 31, 2003 the Company recorded a write-down of \$1,972,801 to reduce its inventory from standard cost to its estimated realizable value. Inventories remaining at December 31, 2003 were used in production in the first quarter of 2004. In 2004, the Company recorded a write-down of its inventories of \$378,000 to reduce the inventory to its net realizable value of zero.

**4. Property and Equipment**

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Property and equipment at December 31, 2004 and 2003 consisted of the following:

	2004	2003
Machinery and equipment	\$ 2,058,116	\$ 5,121,563
Leasehold improvements, furniture and fixtures		2,302,311
IT equipment		1,114,019
Construction in progress		510,976
Equipment under capital lease		48,548
	2,058,116	9,097,417
Less accumulated depreciation and amortization	1,054,004	4,441,190
	\$ 1,004,112	\$ 4,656,227

As of December 31, 2003, impairment charges of \$2,322,257 were recorded related to the Company's fixed assets (Note 1). In accordance with the provisions of FAS 144, the Company determined that the carrying amount of all its fixed assets may not be recoverable as the cash flows expected to be generated from the use of these assets and their eventual disposition could be less than their carrying amount. The Company then estimated potential future cash flows related to these assets under four scenarios in conjunction with a third-party valuation that arrived at a fair value.

In addition, impairment charges of \$3,188,969 were recorded as of December 31, 2004 related to the Company's assets held for sale. In accordance with the provisions of FAS 144 and as discussed in its critical accounting policy footnote related to the impairment of long-lived assets, the Company determined that the full carrying amount of its long-lived assets was not recoverable as the cash flows expected to be generated from the use of the long-lived assets and their eventual disposition are less than their carrying amount. The Company determined fair value based on a sale of substantially all the assets (excluding intellectual property, manufacturing equipment and certain other assets deemed critical to a sale of the remaining business to a potential buyer) on January 13, 2005. The net book value of the assets sold was \$3.2 million for cash proceeds of approximately \$251,100.

### 5. Patents and Intellectual Property

Patents and intellectual property at December 31, 2004 and 2003 consisted of the following:

	2004	2003
Patents	\$ 417,008	\$ 629,531
Intellectual property	197,446	145,280
	614,454	774,811
Less accumulated amortization	391,267	372,252
	\$ 223,187	\$ 402,559



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During 2004, 2003 and 2002, the Company recognized \$79,255, \$36,594 and \$71,122, respectively, of amortization related to these assets.

As of December 31, 2003, impairment charges of \$193,913 were recorded related to the Company's patents and intellectual property (Note 1). In accordance with the provisions of FAS 144, the Company determined that the carrying amount of these assets may not be recoverable as the undiscounted cash flows expected to be generated from the use of these assets and their eventual disposition could be less than their carrying amount. The Company then estimated potential discounted future cash flows related to these assets under four scenarios in conjunction with a third-party valuation that arrived at a fair value. The Company abandoned certain patents with a book value of \$166,437. The loss on patents was recorded as of December 31, 2004.

**6. Other Noncurrent Assets**

Other noncurrent assets relate to equipment produced by the Company and used by prospective customers to evaluate the Company's products. As of December 31, 2003, impairment charges of \$92,262 were recorded related to the Company's other noncurrent assets (Note 1). In accordance with the provisions of FAS 144, the Company determined that the carrying amount of these assets may not be recoverable as the undiscounted cash flows expected to be generated from the use of these assets and their eventual disposition could be less than their carrying amount. The Company then estimated potential discounted future cash flows related to these assets under four scenarios in conjunction with a third-party valuation that arrived at a fair value.

**7. Accrued Expenses**

Accrued expenses consist of the following:

	<b>2004</b>	<b>2003</b>
Accrued compensation, benefits and severances	\$ 114,894	\$ 308,336
Accrued clinical liabilities		20,417
Accrued professional fees	215,000	86,557
Accrued taxes	3,927	110,543
Other	3,183	11,889
	<b>\$ 337,004</b>	<b>\$ 537,742</b>

In accordance with Statement of Financial Accounting Standard No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, the Company recorded severances totaling \$130,000 in 2003 which are recorded in general and administrative expenses in the Company's Statement of Operations. In 2004, the Company expensed and paid \$841,000 for terminated employees.

**8. Development Income and Deferred Revenue**

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The Company recognizes development income in accordance with SEC Staff Accounting Bulletin No. 101. During 2004, 2003 and 2002, the Company recognized revenue as part of collaboration agreements with other entities of \$1,042,219, \$1,042,219 and \$587,478, respectively, of development income related to these agreements. Payments received but not recognized into income in the year of receipt are deferred and recognized over the period of the respective agreements. At December 31, 2004, total payments received but deferred to future periods aggregated approximately \$1,998,000. Previous milestone payments from Aventis remain deferred because even though the Company's development agreement with Aventis has been terminated, the Company remains under obligation not to develop another test card that would compete with Aventis through November 2006. The Company is recognizing development income from Aventis straight-line through 2006.

### 9. Long-Term Debt

Long-term debt as of December 31, 2004 and 2003 consisted of the following:

	2004	2003
Notes payable	\$ 2,701	\$ 1,092,965
Current portion of notes payable	2,701	498,909
Notes payable, excluding current portion	\$	\$ 594,056

In December 2002, the Company received a loan of \$1.5 million from GE Capital to fund capital expenditures. The loan had an interest rate of 9.5%, was collateralized by existing fixed assets with original costs totaling approximately \$9.9 million and included certain covenants related to, among other things, maintenance of the collateral, but did not contain financial covenants.

The Company repaid its outstanding debt with GE Capital in March 2004.

### 10. Commitments And Contingencies

As of December 31, 2004, the Company leases its current facility under an operating lease agreement that contains an escalation rent clause tied to a pricing index and that extends until 2011. In addition, the Company leases certain equipment under various capital and operating lease agreements. Rent expense related to operating leases totaled \$396,783, \$436,495 and \$418,553 for the years ended December 31, 2004, 2003 and 2002, respectively.



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Future minimum lease payments as of December 31, 2004 consist of \$337,787 to be paid in 2005:

### **11. CONVERTIBLE REDEEMABLE PREFERRED STOCK**

#### **Series A**

During 2000, the Company completed a private placement of 120,000 shares of Series A convertible preferred stock ( Series A ), resulting in net proceeds to the Company of \$11,220,000. The Company also issued five-year warrants to acquire 240,000 shares of common stock at \$10.00 per share. These warrants expired in February 2005. Approximately \$1,275,000 of the net proceeds was allocated to the warrants based on their relative fair value as computed by using the Black-Scholes pricing model. The Series A has a dividend of 6% payable quarterly in cash or in shares of common stock at the option of the Company. The number of common stock dividend shares to be issued at each quarterly dividend date are determined using the average of the closing prices of the common stock on the Nasdaq SmallCap Market over the 30-day period ending three days prior to the end of each quarter. The number of shares to be issued is then multiplied by the closing market value of PharmaNetics common stock on the payment date to determine the amount recorded as the dividend in the financial statements. For the year ended December 31, 2004, the Series A dividend was paid by issuing 552,108 shares of common stock and was recorded at the fair value of the common stock on the quarterly dividend payment dates.

Each share of the Series A is convertible into ten shares of common stock. The number of common shares currently reserved for conversion of preferred stock and exercise of warrants, including the related dividends, is approximately 3,900,000. The Series A is convertible at the option of the holder at any time 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 preferred 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.

Of the 120,000 shares originally issued in 2000, 55,500 of the shares have been converted into common stock since that date. Thus, at December 31, 2004, the outstanding Series A shares remaining total 64,500.

#### **Series B**

During May 2003, the Company completed a private placement of 95,800 shares of Series B convertible redeemable preferred stock ( Series B ), resulting in net proceeds to the Company of approximately \$8,700,000. The Company also issued five-year warrants, exercisable beginning November 1, 2003, to acquire 542,865 shares of common stock at \$7.20 per share. Approximately \$1,616,000 of the net proceeds was allocated to the warrants based on their relative fair value as computed using the Black-Scholes pricing model. The Series B has a dividend of 8.5% payable for the first nine quarters in additional shares of Series B preferred stock and then quarterly in cash or in shares of common stock at the

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option of the Company. The number of preferred stock dividend shares to be paid for each full quarterly period will equal 2.125% of the Series B shares outstanding on each dividend date. Any shares of common stock issued in payment of dividends after September 2005 will be valued at 90% of the volume weighted average of the closing prices of the common stock over the 30 days prior to any given quarterly dividend date, as reported on Nasdaq. For the year ended December 31, 2004, the Series B dividend was paid by issuing 8,894 shares of Series B preferred stock. These shares are convertible into approximately 148,230 shares of common stock, which number is multiplied by the closing market value of PharmaNetics stock on the quarterly dividend payment dates to determine the amount recorded as the Series B dividend.

Each share of the Series B is convertible into approximately 16.667 shares of common stock. The Series B is convertible at the option of the holder at any time. It may also be redeemed at the option of the Company after May 1, 2005 upon the occurrence of both of the following events: (a) the common stock closes at or above \$20.00 per share (adjusted for stock dividends, stock combinations, recapitalizations or the like), and (b) the common stock maintains an average daily trading volume of at least 75,000 shares per day for 30 consecutive trading days on the Company's principal trading market or automated quotation system. However, no redemption can occur if any shares of the Series A preferred would be issued and outstanding after completion of the Series B redemption.

The holders of the Series B have the right to require the Corporation to redeem all or any outstanding Series B preferred upon a change of control event, as defined. Pari passu with the Series A holders, Series B holders have a liquidation preference of the greater of (i) an amount per share that holders would have received if all shares of the Series B preferred had been converted into common stock immediately prior to a liquidation event or (ii) \$100 per preferred share plus any accrued but unpaid dividends then held, such amounts subject to customary adjustments. The liquidation preference is payable upon a liquidating event, including a change in control of the Company, thus the Series B 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 B, the effective conversion price of the Series B was at a discount to the price of the common stock into which the Series B is convertible. In accordance with EITF 98-5, Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios and EITF 00-27 Application of Issue No. 98-5 to Certain Convertible Instruments, this discount totaled \$3,459,000 and was recorded as a preferred stock dividend in the second quarter of 2003. The proceeds of the offering were allocated between preferred stock and warrants issued and the \$3.5 million discount was determined by subtracting the effective conversion price of the common stock of \$4.95 from the common stock market value of \$7.12 the day before the closing and multiplying that number by the number of common shares issuable upon conversion of the preferred stock.

### 12. Related Party Transactions

In April 2001, Bayer Diagnostics, the Company's distributor, purchased 1,450,000 shares of common stock of the Company at \$12 per share for \$17.4 million. This investment increased Bayer's ownership percentage in the Company from approximately 7% to 19.9%. At that time, the Company and Bayer entered into an amended distribution agreement to replace the previous distribution agreement between the parties entered into during 1998. Prior to March 12, 2004, Bayer marketed and distributed the Company's routine tests worldwide and the Company's enoxaparin test in countries other than the United States. See Note 1 Business for information concerning the Company's current relationship with Bayer.

### 13. 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 are reserved for issuance. In 1995, the shareholders of the Company approved the adoption of the Company's 1995 Stock Plan in which 1,613,150 shares of the Company's common stock are currently reserved for issuance.

During 2002, the Company recorded a non-cash expense of \$1.3 million for deferred compensation related to extending by five years the termination date of options previously granted to a number of employees. In accordance with accounting guidelines, an expense was recorded at the modification date for the affected options.

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A summary of the status of the Company's Plans as of December 31, 2004, 2003 and 2002, and changes during the years ending on those dates, including the weighted average exercise price (WAEP) is presented below:

	2004		2003		2002	
	Shares	WAEP	Shares	WAEP	Shares	WAEP
Outstanding at beginning of year	1,110,069	\$ 5.20	1,536,634	\$ 6.21	1,387,167	\$ 6.12
Granted	20,000	\$ 0.68	25,000	\$ 5.95	273,015	\$ 6.56
Exercised	(20,999)	\$ 0.79	(30,574)	\$ 1.80	(82,791)	\$ 4.86
Forfeited	(574,660)	\$ 6.07	(420,991)	\$ 9.19	(40,757)	\$ 8.04
Outstanding at end of year	534,410	\$ 3.59	1,110,069	\$ 5.20	1,536,634	\$ 6.21
Options exercisable at year-end	534,410	\$ 3.59	850,747	\$ 4.70	907,890	\$ 5.12

The weighted average fair value per share of options granted during the years ended December 31, 2004, 2003 and 2002 was \$0.68, \$4.38, \$4.88, respectively.

The following table summarizes information about the Plans' stock options, including the weighted average remaining contractual life (Life), at December 31, 2004:

Range of Exercise Prices	Options Outstanding and Exercisable		
	Number	Life	WAEP
\$0.68	20,000	9.4 years	\$ 0.68
\$0.79	238,762	4.4 years	\$ 0.79
\$4.50-\$5.25	106,648	2.1 years	\$ 4.78
\$5.75-\$6.00	137,000	5.6 years	\$ 6.00
\$9.70-\$15.06	32,000	5.4 years	\$ 12.08
	534,410	4.5 years	

## 14. Significant Customers and Related Party

During the years ended December 31, 2004, 2003 and 2002 there were sales to individual customers that exceeded 10% of net consolidated sales. Sales to these customers were:

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	<u>2004</u>	<u>2003</u>	<u>2002</u>
Bayer Diagnostics	\$ 1,688,000	\$ 5,387,542	\$ 3,862,694
AstraZeneca			160,000

As of December 31, 2003, there were outstanding receivables from the Company's distributor, Bayer Diagnostics, that exceeded 10% of total trade receivables. Receivables from this customer as a percentage of total trade receivables were approximately 90% in 2003.

In March 2004, the Company ended its distribution agreement with Bayer Diagnostics.

The Company generated revenue from sales to different geographic areas during 2004, 2003 and 2002 as follows:

	<u>2004</u>	<u>2003</u>	<u>2002</u>
United States	\$ 1,867,724	\$ 5,513,526	\$ 3,930,443
Sweden			160,000
<b>Total sales</b>	<u>\$ 1,867,724</u>	<u>\$ 5,513,526</u>	<u>\$ 4,090,443</u>

### 15. 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 cash in accounts with federally insured depository institutions (up to \$100,000). At December 31, 2004, 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.

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### 16. 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 \$57,864, \$38,366 and \$43,705 during the years ended December 31, 2004, 2003 and 2002, respectively. This license agreement was terminated in October 2004.

### 17. Income Taxes

The Company has not incurred income tax expense for the years ended December 31, 2004, 2003 and 2002. A reconciliation of expected income tax at the statutory U.S. federal rate of 34% with the actual income tax expense for the years ended December 31, 2004, 2003 and 2002 is as follows:

	2004	2003	2002
Expected income tax benefit at federal statutory rate	\$ (2,565,249)	\$ (4,542,780)	\$ (3,779,457)
State tax provision (benefit)	(342,695)	(545,039)	(440,877)
Other	6,703	473,540	16,240
Research and development credit	(49,540)	(216,664)	(156,107)
Change in valuation allowance	2,950,781	4,830,943	4,360,201
Net income tax provision	\$	\$	\$

The components of the net deferred tax assets and net deferred tax liabilities as of December 31, 2004 and 2003 were as follows:

	2004	2003
Deferred tax assets:		
Net operating loss carryforward	\$ 25,918,000	\$ 22,344,000
Research and development credits	926,000	876,000
Foreign tax credits	35,000	35,000
Accrued expenses		1,000
Alternative minimum tax credits	9,000	9,000
Deferred revenue	770,000	1,269,000
Inventory reserve	629,000	830,000
Fixed assets	680,000	
Other	93,000	289,000
Total gross deferred tax assets	29,060,000	25,653,000
Valuation allowance	(28,475,000)	(25,523,000)
Net deferred tax assets	585,000	130,000

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### Deferred tax liabilities:

Patents	101,000	75,000
Investment adjustment	484,000	484,000
Fixed assets		(429,000)
	<hr/>	<hr/>
Total gross deferred tax liabilities	585,000	130,000
	<hr/>	<hr/>
Net deferred taxes	\$	\$
	<hr/>	<hr/>

At December 31, 2004 and 2003, the Company had approximately \$67,618,000 and \$58,318,000, respectively, of combined federal net operating losses. These losses expire in varying amounts beginning in 2005 if not utilized. At December 31, 2004 and 2003 for state income tax purposes, the Company had net operating loss carryforwards of approximately \$64,295,000 and \$55,253,000, respectively. These carryforwards expire in varying amounts beginning in 2008 if not utilized. To the extent that a previously owned subsidiary's net operating losses incurred through 1994 (approximately \$2,000,000 at December 31, 2004) are utilized in the future, the benefit will reduce the excess cost over fair value of net assets acquired. The 2004 and 2003 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, 2004 and 2003. As a result of changes in ownership in prior years, as defined by Internal Revenue Code Section 382, the utilization of a previously owned subsidiary'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 approximately \$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 approximately \$1,954,000 per year.

### 18. Legal Proceedings

In November 2003, the Company filed a lawsuit in the United States District Court of the Eastern District of North Carolina against Aventis Pharmaceuticals, Inc., the wholly-owned subsidiary of French pharmaceutical company, Aventis. The lawsuit alleges that Aventis has engaged in false and misleading advertising of its second largest drug, Lovenox<sup>®</sup>, which has damaged the Company's sales of its Enox test card, a rapid point-of-care test developed in cooperation with Aventis to enhance the way Lovenox is managed in the cardiac community. In addition to claims of false advertising, the Company's complaint includes allegations of tortious interference, fraud and breach of contract. Aventis filed counterclaims against the Company alleging slander, libel, product disparagement, breach of contract and related claims. As part of the lawsuit, the Company requested that the court enter a preliminary injunction against Aventis to prevent Aventis from falsely advertising Lovenox.

In March 2004, the court held a hearing on the Company's motion for a preliminary injunction against Aventis. In April 2004, the court issued an order denying the Company's request for a preliminary injunction, but in denying the Company's motion, the court made a judicial determination that two of Aventis' advertising claims regarding Lovenox were literally false. First, the court found that Aventis' claim that Lovenox reaches therapeutic levels within 1/2 hour of administration to be literally false. Second, the court found literally false Aventis' claim that Lovenox was therapeutic from dose one. Although the court did not grant the Company's

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request for a preliminary injunction, one of the reasons cited by the court for not enjoining these false advertising messages was that Aventis has discontinued using these false statements in its advertising. In particular, after the Company filed its false advertising lawsuit against Aventis in November 2003, almost immediately thereafter Aventis withdrew these statements from its advertising of Lovenox.

In addition, the court found that certain disparaging statements made by Aventis representatives concerning the Enox test card were also literally false. Although the court elected not to issue a preliminary injunction, its order ultimately left the issues in dispute for the jury to decide. The court also ruled on Aventis' Motion for Summary Judgment in which Aventis essentially sought dismissal of the Company's false advertising claims. In denying Aventis' motion, the court noted that the Company had raised genuine issues of material fact concerning its claims against Aventis and, accordingly, the court ruled that the merits of the case should ultimately be evaluated by a jury. In order to prevail in a jury trial, the Company must prove a variety of factual issues as well as substantiate its calculation of damages. The lawsuit is scheduled to go to trial in April 2005. See Note 20 Subsequent Events for an update on the status of the litigation.

**19. Summary Quarterly Financial Data (Unaudited)**

The following represents a summary of operations for the quarters of 2004 and 2003:

	2004			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Total revenues	\$ 2,124	\$ 294	\$ 261	\$ 289
Operating expenses	4,645	1,035	630	4,341 <sup>(a)</sup>
Net loss before preferred stock charges	(2,435)	(720)	(363)	(4,026) <sup>(a)</sup>
Net loss attributable to common shareholders	(2,621)	(811) <sup>(b)</sup>	(473)	(4,137) <sup>(a)</sup>
Net loss attributable to common shareholders per common share	\$ (0.26)	\$ (0.08) <sup>(b)</sup>	\$ (0.05)	\$ (0.40) <sup>(a)</sup>

	2003			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Total revenues	\$ 1,423,000	\$ 1,915,000	\$ 1,641,000	\$ 1,615,000
Operating expenses	3,736,000	4,054,000	3,659,000	8,511,000 <sup>(c)</sup>
Net loss before preferred stock charges	(2,344,000)	(2,126,000)	(1,987,000)	(6,904,000) <sup>(c)</sup>
Net loss attributable to common shareholders	(2,467,000)	(5,830,000)	(2,271,000)	(7,074,000)
Net loss attributable to common shareholders per common share	\$ (0.25)	\$ (0.60)	\$ (0.23)	\$ (0.72)

<sup>(a)</sup> Includes \$3.6 million in write-downs of inventory and long-lived assets

<sup>(b)</sup> Includes \$3.5 million beneficial conversion feature charge related to issuance of Series B preferred stock

<sup>(c)</sup> Includes \$1.3 million non-cash compensation expense related to stock-based compensation

**20. Subsequent Events**



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In the first quarter of 2005, the Company negotiated a termination for the lease for its building by making a termination payment of \$337,787.

In January 2005, the Company sold substantially all of its assets (excluding intellectual property manufacturing equipment and certain other assets deemed critical to a sale of the remaining business for a potential buyer) at auction for approximately \$251,000. The assets sold had a net book value, prior to write-downs as of December 31, 2004, of approximately \$3.2 million.

In preparation for the trial of its lawsuit against Aventis scheduled for April 2005, in March 2005 the court ruled on each party's motions for Summary Judgment. The court dismissed all of Aventis' counterclaims against PharmaNetics, while also dismissing PharmaNetics' claim of damages against Aventis for breach of contract for failing to co-promote the jointly-developed Enox test. However, the court denied Aventis' motion to dismiss a number of PharmaNetics' other claims, including some of the claims for disparagement and false and misleading advertising, as well as claims of unfair and deceptive trade practices under state law, leaving those claims for a jury to decide. PharmaNetics believes the court's dismissal of the breach of contract claim regarding the covenant to co-promote is erroneous and is considering its options for challenging that portion of the court's decision. PharmaNetics intends to continue to pursue the lawsuit vigorously.

In March 2005, the PharmaNetics Board approved a resolution, subject to shareholder approval, authorizing the sale of all of the company's remaining assets, specifically including its intellectual property and its specialty manufacturing equipment. PharmaNetics has not yet found a buyer for these assets. The Board's approval of this resolution constitutes a "change of control" as defined under the PharmaNetics Supplemental Executive Retirement Plan, or SERP, entitling the company's CEO to benefit payments under the SERP equal to nine times the balance in his deferral account under the SERP. Although such payment obligation amounts to approximately \$2.2 million and is technically due and payable by the end of May 2005, the company currently has no funds to satisfy this obligation, and it intends to use its limited remaining funds to continue to pursue its litigation against Aventis. The SERP obligation is an unsecured general obligation of the company. PharmaNetics expects that the obligation would be satisfied only in the event of the receipt of proceeds, if any, from a successful completion to the Aventis litigation.

**Table of Contents****PHARMANETICS, INC.****SCHEDULE II-VALUATION AND QUALIFYING ACCOUNTS**

For the years ended December 31, 2004, 2003 and 2002

	Balance at Beginning of Period	Charge to Costs and Expenses	Deductions	Balance at End of Period
<b>YEAR ENDED DECEMBER 31, 2004</b>				
Deducted from asset accounts:				
Accounts Receivable Reserves <sup>(a)</sup>	\$ 1,995	\$ 20,982	\$ 1,977	\$ 21,000
Inventory Reserves <sup>(b)</sup>	\$ 178,506	\$	\$ 178,506	\$
Added to liability accounts:				
Warranty Reserves <sup>(c)</sup>	\$ 2,157	\$	\$ 2,157	\$
<b>YEAR ENDED DECEMBER 31, 2003</b>				
Deducted from asset accounts:				
Accounts Receivable Reserve <sup>(a)</sup>	\$ 1,995	\$	\$	\$ 1,995
Inventory Reserves <sup>(b)</sup>	\$ 75,000	\$ 218,894	\$ 115,388 <sup>(e)</sup>	\$ 178,506
Added liability accounts:				
Warranty Reserves <sup>(c)</sup>	\$ 10,000	\$	\$ 7,843 <sup>(d)</sup>	\$ 2,157
<b>YEAR ENDED DECEMBER 31, 2002</b>				
Deducted from asset accounts:				
Accounts Receivable Reserve <sup>(a)</sup>	\$ 1,995	\$	\$ <sup>(f)</sup>	\$ 1,995
Inventory Reserves <sup>(b)</sup>	\$ 75,000	\$ 96,605	\$ 96,605 <sup>(e)</sup>	\$ 75,000
Added liability accounts:				
Warranty Reserves <sup>(c)</sup>	\$ 2,638	\$ 16,008	\$ 8,646 <sup>(d)</sup>	\$ 10,000

(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.