PHARMANETICS INC
Form 10-K
March 17, 2005
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

x Annual Report pursuant to Section 13 or 15(D) of the Securities Exchange Act of 1934.

For the fiscal year ended December 31, 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

PharmaNetics, Inc.

(Exact name of registrant as specified in its charter)

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)

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

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

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

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.

Table of Contents

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

Table of Contents

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

Table of Contents

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

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

Table of Contents

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

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

Table of Contents

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:

Test	Description
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 enoxparin 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.

Table of Contents

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.

Table of Contents

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:

fines,

injunction,

civil penalties,

recall or seizure of products,

total or partial suspension of production,

failure of the government to grant premarket clearance or premarket approval (PMA) for devices,

withdrawal of marketing approvals, or

criminal prosecution.

The FDA also has the authority to request repair, replacement or refund of the cost of any device manufactured or distributed by the Company.

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

Table of Contents

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.

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

Table of Contents

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 Invitro 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 Capability Directive. In Japan, the Company relies upon its collaborative partner, Tokuyama, to comply with applicable regulations regarding the product listing, manufacture and sale of products in that country.

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 acquiror 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

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.

Table of Contents

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. 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. 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

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®, 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

Table of Contents

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 Ablatrics, 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

Table of Contents

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.

	High	Low
Fiscal year ended December 31, 2004		
First Quarter	$ 2.93	$ 1.45
Second Quarter	2.34	0.35
Third Quarter	0.55	0.37
Fourth Quarter	1.23	0.38
Fiscal year ended December 31, 2003		
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
RESULTS OF OPERATIONS					
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					