PHARMANETICS INC
Form 10-K
March 25, 2003
Table of Contents

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, 2002

OR

o 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.)**
9401 GLOBE CENTER DRIVE, SUITE 140 **MORRISVILLE, NORTH CAROLINA** **(Address of principal executive offices)**	**27560** **(Zip Code)**

Registrant s telephone number, including area code:
919-582-2600

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 o

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. o

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

The aggregate market value of the voting stock held by non-affiliates of the registrant based upon $4.96 per share, the closing price of the Common Stock on June 30, 2002, on the NASDAQ National Market System, was approximately $37,014,000 as of such date. Shares of Common Stock held by each officer and director and by each person who owns 10% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status may not be conclusive for other purposes.

As of March 19, 2003, the registrant had outstanding 9,732,872 shares of Common Stock (no par value).

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company s Proxy Statement for the 2003 Annual Meeting of Shareholders are incorporated herein by reference into Part III.

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 ability of the Company to implement its business strategy, risks relating to new product development, uncertainties regarding market acceptance of the Company s products, government regulation, healthcare industry consolidation and competition.

PART I

ITEM 1. BUSINESS

PharmaNetics, Inc. (the Company or PharmaNetics), through its wholly-owned subsidiary Cardiovascular Diagnostics, Inc. (CVDI), develops, manufactures and markets rapid diagnostics to dose, manage and screen patients on drugs affecting coagulation. The Company s products are 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. PharmaNetics is establishing itself in this emerging field of theranostics, defined as rapid near-patient testing in which the diagnostic results may influence treatment decisions. The Company s current tests and tests under development are used in the treatment of angina, heart attack, stroke, deep vein thrombosis and pulmonary and arterial emboli.

TAS is a stat, or as soon as possible , point-of-care system capable of monitoring the coagulation (formation) and lysis (dissolution) of blood clots. Such monitoring provides information which is critical in administering anticoagulant and thrombolytic (clot-dissolving) drugs, which are used in the treatment of a variety of medical disorders. Hemostatic test results must be provided quickly because a majority of the drugs used to regulate clotting are cleared rapidly from the body, and certain drugs must be closely monitored to maintain drug levels within an effective treatment range. The Company believes that hospital central and stat laboratories, which currently provide the majority of such testing, generally cannot provide timely information to clinicians regarding drugs that affect coagulation and thrombolysis. Delay in providing such information can be a problem because the physician is likely to leave the patient area during this time, which may result in a further delay of diagnosis and treatment. The Company believes that the TAS can provide information regarding coagulation and thrombolysis as well as drug monitoring on a timely basis, permitting quicker diagnosis and therapeutic intervention, which will improve 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 pharmaceuticals. In addition, point-of-care testing can reduce hospitals costs by reducing the numerous steps, paperwork and personnel used in collecting, transporting, documenting and processing blood samples.

The Company currently sells domestically and internationally its TAS analyzer and a menu of tests and controls. FDA approved tests that are currently sold for commercial use are listed and described below under the subheading Products . The Company has 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 Tests Cards Under Development . In addition, the Company has obtained a Humanitarian Device Exemption, or HDE, for its ECT card, which is used in managing patients suffering from heparin induced thrombocytopenia, or HIT. HDE approval is an expedited FDA authorization process to market devices used in rare disease states where no existing solution is available. In addition, the Company is currently researching and developing other test cards for use on the TAS system.

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

Table of Contents

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.

Access to timely and accurate coagulation test results is 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. By design, most point-of-care tests require limited materials and minimum labor. Point-of-care test systems must also comply with the Clinical Laboratory Improvement Act of 1988, or CLIA, and its regulations. See Government Regulation .

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 card. Blood samples are introduced into this reagent/particle mixture, dissolving the dry reagent and freeing the magnetic particles to move within the card s chamber. When the oscillating magnetic field is generated by the TAS analyzer, the magnetic particles within the TAS card s reaction chamber move in response to the magnetic field. An optical sensor within the TAS analyzer monitors the motion of the magnetic particles without touching the blood sample. When movement diminishes to a predetermined amplitude, the TAS system determines that a clot has been formed.

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

PRODUCTS

TAS ANALYZER

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

The analyzer and test cards are designed to work effectively in a decentralized testing environment where they are used by healthcare personnel who do not need formal central laboratory training. To operate TAS, a test card is passed through the magnetic strip reader of the analyzer, which automatically initiates quality controls and begins to elicit information from the operator through a series of prompts outlining the operating procedure for the specific test to be performed. The test card is then inserted into the TAS analyzer. A single drop of unprocessed, noncitrated or citrated whole blood or plasma is then placed into the reaction chamber of the test card, which already contains the appropriate mixture of dry reagents and PIOP for the test being performed. Typically within three minutes, the screen on the TAS analyzer displays a numerical test result, which is comparable to the result which would be achieved 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. The Company s distributor, Bayer Diagnostics (Bayer), currently markets this product as the Rapidpoint Coag analyzer.

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

Table of Contents

cardiopulmonary bypass procedures. It is used in conjunction with the HTT, PRT and HMT cards and is marketed by Bayer as Rapidpoint ACCENT. The data collected by Accent can be transferred to a printer and/or hospital information system for storage.

FDA-CLEARED TEST CARDS

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

The Enoxaparin test, approved by the FDA in August 2002, detects the anticoagulant effect of the low molecular weight heparin (LMWH) enoxaparin, used for the treatment and prevention of thrombotic diseases. Enoxaparin is the world s top-selling LMWH and is marketed by Aventis Pharmaceuticals under the brand names Lovenox® and 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 test is a general screening test that is used to assess a patient s baseline hemostatic function or to monitor the use of oral anticoagulants, such as warfarin. Warfarin is widely used in the United States for long-term treatment in patients who have previously developed clots, including after heart attacks, to inhibit coagulation to reduce the risk of developing additional clots. A physician uses the PT test to monitor and maintain drug levels within a safe treatment range; too little warfarin will not prevent a new clot from developing, and too much of the drug may result in a bleeding complication. PharmaNetics manufactures and markets three different types of PT test cards, a general purpose PT test card routinely used in the United States, the PT One, which uses a more sensitive scale of measurement, and the PT-NC, which is used with finger stick samples.

The aPTT test is a coagulation screening test which may be used in conjunction with the PT to provide a global assessment of a patient s ability to form a clot. In addition, the aPTT test is used to monitor heparin, an injectable anticoagulant. Hospitals routinely use heparin as the initial treatment for patients with a clot, including patients suffering from heart attacks or strokes. Heparin also prevents clots from forming in patients undergoing procedures involving particular risks of clotting, such as angiography, open heart surgery, dialysis and 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 Company developed and markets its HMT for monitoring patients requiring high dose heparin therapy during procedures such as open heart surgery or dialysis. For example, during the course of an open heart surgery, the patient s blood may be tested as many as four to six times to assure an adequate heparin effect. The Company believes that its HMT is a more effective test than comparable tests because it is easier to use and less prone to operator error. Also, it is not sensitive to changes in blood temperature or dilution, such as typically occur during bypass surgery. The Company believes that HMT more closely correlates with a precise but time-consuming laboratory measurement of heparin concentration than comparable tests.

The HTT and PRT 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 card is used principally in cardiac catheterization and interventional cardiology procedures. It is designed to monitor the effects of concentrations of unfractionated heparin above the range of aPTT but below that of the HMT.

The Company markets it ECT card under the FDA s Humanitarian Device Exemption program. The ECT card is 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® while undergoing cardiopulmonary bypass.

TEST CARDS UNDER DEVELOPMENT

The Company is continuing research and development focused on expanding the current menu of tests for the TAS analyzer. The Company is currently researching and/or developing the following new 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
Modified Ecarin Clotting Time (TIM)	Test to allow the monitoring of oral antithrombin drugs currently in FDA phase 3

Table of Contents

	development for treatment of DVT and atrial fibrillation.
Synthetic Xa inhibitors	Test designed to monitor the anticoagulant effect of pentasaccharides
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
LRF	Test to monitor the effects of Ancrod, a fibrinogen-lowering drug for the treatment of stroke
SK Panel	Test to assess response to streptokinase
Lysis Onset Time (LOT)	Test to monitor a patient s lytic response to any thrombolytic drug used for the treatmentof heart attack, stroke or other thrombotic diseases

QUALITY CONTROL PRODUCTS

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

SALES, MARKETING AND DISTRIBUTION

The Company s current marketing strategy for its PT, aPTT, HMT, PRT, HTT and LHMT test cards relies on a distribution partner. In August 1998, the Company signed a five-year global distribution agreement, subject to minimum annual sales, with Chiron Diagnostics Corp., now a part of Bayer, to distribute these test cards. At that time, the Company received an up-front investment of $6 million in exchange for 600,000 shares of common stock. Additionally, in April 2001, Bayer 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%. In connection with the investment, the Company and Bayer entered into an amended distribution agreement to replace the previous distribution agreement. Under the terms of the amended agreement, Bayer will purchase, at pre-determined prices, the Company s routine test cards identified in the agreement.

The Company and Bayer also expanded their relationship to cover collaborative distribution and supply of certain theranostic tests in the United States. Under the provisions of the agreement related to these speciality tests, Bayer is responsible for taking the orders, shipping and collecting receivables for these tests sold by the Company s sales team. In return, Bayer will receive a 10% commission. This arrangment enables the customer to order all of the Company s products from a single source. The initial term of this agreement expires on December 31, 2003, renewable thereafter for successive five-year terms. The Company has the right to terminate the Bayer agreement if (1) Bayer fails to make payments when due to the Company, (2) Bayer fails to maintain sales to end users or (3) a distributor appointed by Bayer sells products which are competitive with the Company. Either party may terminate the Agreement upon the occurrence of any of the following: (1) the insolvency of the other party; (2) material breach of the Bayer agreement by the other party which is not cured; or (3) certain types of change-in-control transactions by the other party.

The Company also markets TAS products in Europe and other foreign countries and Bayer is the Company s exclusive distributor for all its products in these territories. In addition, Bayer has the contingent right to distribute outside the United States certain other theranostic test cards currently under development.

The Company believes that Bayer has a strong global presence and that its strategy for expanding rapid diagnostic platforms into critical care settings and its considerable presence in these specialized areas of the hospital will lead to increased placements of TAS products. The Company also believes that the TAS products are complementary with Bayer s leading market position in blood gas analysis.

The Company has a collaborative marketing program with Aventis relating to the Enox test that entails coordinating sales, marketing and educational efforts to promote the use of the test in the United States. As part of this program, the Company intends to hire a contract sales force of up to 10 sales people located around the country, and contract technical service representatives, to work with Aventis Lovenox® sales force, which numbers approximately 700. The program provides for joint calls on qualified hospitals and joint marketing efforts. The Company anticipates that the ENOX test may facilitate the use of Lovenox in some cardiology patients and in certain special populations. PharmaNetics believes the ENOX test may provide physicians with a tool to more confidently prescribe enoxaparin for all of their patients, because they can assess the anticoagulant state of patients who could be sent to the catheterization laboratory. As noted above, Bayer will market the Enox test in other parts of the world and also is responsible for the distribution of these tests.

The commercial success of the Company s products will depend upon their acceptance by the medical community as being useful and cost-effective. Market acceptance will depend upon several factors, including the establishment of the utility and cost-effectiveness of the Company s tests and the receipt of regulatory clearances in the United States and elsewhere. The availability

Table of Contents

of point-of-care hemostasis test systems has been limited to date, so by selling point-of-care hemostasis test products, the Company is targeting an essentially new market. Diagnostic tests similar to those developed by the Company are generally performed by a central laboratory at a hospital or clinic. The approval of the purchase of diagnostic equipment by a hospital is generally controlled by its central laboratory. The Company expects central laboratories will resist yielding control of tests they have previously performed. The Company will also have to demonstrate to physicians that its diagnostic products perform as intended, meaning that the level of accuracy and precision attained by the Company s products must be comparable to test results achieved by central laboratory systems. Failure of the Company s products to achieve market acceptance would have a material adverse effect on the Company.

The Company is substantially dependent upon Bayer as its principal distributor for marketing and distribution of its PT, aPTT, HMT, HTT, PRT and LHMT test cards and the related controls and analyzer. Bayer will also market the Enox test in foreign countries and will distribute the Enox test worldwide. There can be no assurance that Bayer will be successful in its marketing or selling these products in sufficient volume to produce profitability for the Company. Also, there can be no assurance that the Company could build a cost-effective and adequate sales and marketing staff to replace Bayer in selling these routine products. The loss of the Company s distributor or the inability to enter into agreements with new distributors to sell TAS products in additional countries could have a material adverse effect on the Company.

COLLABORATIONS

The Company s strategy is to increasingly focus on becoming a leader in the theranostic testing market, specifically managing new therapeutics which affect coagulation. Many drugs currently under development may require faster, more accurate assessment, given short half-lives and narrow therapeutic windows, and thus the Company believes physicians will increasingly demand therapeutic drug monitoring. To further the goal of establishing itself in the emerging field of theranostics, the Company has entered into development agreements with major pharmaceutical companies such as The Medicines Company and Knoll AG (now a part of Abbott Laboratories) pursuant to which the Company is developing test cards for potential use in patient identification and monitoring of therapies affecting coagulation being investigated by these companies.

In relation to the development of the ecarin clotting time cards to monitor direct thrombin inhibitors, the Company has a worldwide exclusive sublicense from Abbott to use the reagent associated with the test. During 2001, the Company terminated an Interim Agreement with AstraZeneca related to Astra s development of an oral thrombin inhibitor and received a payment of $1.5 million as part of the cessation of this agreement. The Company believes the medical community will embrace the need for a test for managing therapeutic levels in patients receiving oral and injectable direct thrombin inhibitors. To this end, the Company is presently in the process of collecting its own data and conducting clinical trials necessary to submit an FDA application for this test. The test would be used with three FDA-approved thrombin inhibitors on the market.

The Company s intent is to enter into additional collaborations to expand its theranostic test card menu. Within the cardiovascular market, drugs affecting coagulation, such as thrombin inhibitors, platelet inhibitors and low molecular weight heparins, are under development by pharmaceutical companies. The Company s strategy is to increase its number of collaborations, expand current collaborations, increase involvement of leading research centers and physician thought leaders and further the involvement of Bayer in working with other pharmaceutical companies to engage in outcome studies related to new theranostic tests.

The Company s strategy is focusing its theranostic test development efforts on drugs in Phase 2 or Phase 3 development. The Company believes this will help reduce development risk as these drugs have a greater chance of approval than those just beginning clinical trials. Additionally, in the past under this collaboration model, the pharmaceutical company with whom the Company is collaborating has paid for the clinical trials and provided the Company access to the regulatory data associated with the test to be used in submitting a 510(k) notification. This approach has allowed the Company to cost-effectively develop its tests.

COMPETITION

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

The Company has several competitors, including Roche Diagnostics, International Technidyne Corporation (ITC) and Medtronic, that manufacture and market point-of-care coagulation and hematology test systems. ITC, in particular, has a large

Table of Contents

installed base of systems, which it has been selling for over 20 years. Despite the fact that the Company believes that TAS competes favorably with these systems, ITC s installed base could give it a competitive advantage. The Company believes that potential customers will base their purchasing decisions upon a combination of factors, including accuracy and precision, speed, cost-effectiveness, data management, ease-of-use, compliance with CLIA guidelines, and availability of a comprehensive test menu. If the Company introduces additional blood tests beyond its initial coagulation and hematology tests, it will compete with other companies that market similar products to hospitals for use in laboratories and at the point of patient care. Other manufacturers and academic institutions may be conducting research and development with respect to blood testing technologies and other companies may in the future engage in research and development activities regarding products that compete with those of the Company. Many of the companies in the medical technology industry, including those listed above, have substantially greater capital resources, research and development staffs, sales and manufacturing capabilities and manufacturing facilities than the Company. Such entities may be developing or could in the future attempt to develop additional products competitive with TAS. Many of these companies also have substantially greater experience than the Company in research and development, obtaining regulatory clearances, manufacturing and marketing, and may therefore represent significant competition for the Company. There can be no assurance that the Company s competitors will not succeed in developing or marketing technologies and products that will be more effective or less expensive than those being marketed by the Company or that would render the Company s technology and products obsolete or noncompetitive.

PATENTS AND OTHER INTELLECTUAL PROPERTY

The Company pursues patent applications to provide protection from competitors. 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 2004 and 2013. The Company has filed, and is pursuing, a number of additional U.S. and international patent applications.

The Company s success will depend in part on its ability to enforce its patents, to preserve its trade secrets and to operate without infringing the proprietary rights of third parties. The Company s ability to protect its proprietary position is also in part dependent on the issuance of additional patents on current and future applications. No assurance can be given that any patent applications will be issued, that the scope of any patent protection will exclude competitors or provide competitive advantages to the Company, that any of the Company s patents will be held valid if subsequently challenged or that others will not claim rights in or ownership to the patents and other proprietary rights held by the Company. Furthermore, others might have developed or will develop similar products, duplicate the Company s products or design around the Company s patents. If any relevant claims of third-party patents are upheld as valid and enforceable, the Company could be prevented from practicing the subject matter claimed in such patents or could be required to obtain licenses from the patent owners of each of such patents or to redesign its products or processes to avoid infringement. Such licenses might not be available or, if available, could be on terms unacceptable to the Company.

The Company also relies upon unpatented trade secrets to protect its proprietary technology. In particular, 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.

TOKUYAMA SODA LICENSE

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

Until the earlier of October 2004 or the expiration of the last Japanese patent covering the licensed technology, Tokuyama must pay the Company royalties based on Tokuyama s net sales of licensed products. The Company can terminate the Tokuyama License if Tokuyama fails to make a required payment or report (or makes a false report), or if Tokuyama voluntarily ceases the manufacture and sale of licensed products for 12 months, and if, in any such case, Tokuyama fails to remedy such default within 60 days after notice thereof from the Company.

In December 1995, the Company and Tokuyama amended the Tokuyama license to, among other things, provide the Company with the right to market PT and aPTT tests and analyzers in an Asian country (other than Japan, Taiwan and South Korea) if Tokuyama has not attained annual net sales of $250,000 in the country by June 30, 1996 or within 12 months of the time when export to such country becomes authorized. In the event the Company exercises this right, it and Tokuyama may both

Table of Contents

market in the country and must each pay royalties to the other. To date, the Company has not exercised this right. The amendment also provides that the Company owns all rights outside Asia to improvements made by Tokuyama to the Company s technology, and must pay royalties to Tokuyama based on the Company net sales of products incorporating such improvements.

The Company received royalty payments under this agreement of $43,705, $24,000 and $58,909 during the years ended December 31, 2002, 2001, and 2000, respectively.

MANUFACTURING

The Company operates its manufacturing facility to assemble TAS analyzers. Vendors currently provide all molded parts, mechanical components and printed circuit boards. The Company assembles the components and provides final mechanical, electrical and chemistry testing of each analyzer. In addition, the Company operates 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. The equipment has been designed to allow for increased production as dictated by customer demand. Current annual manufacturing capacity is approximately 15 million cards.

The FDC Act requires the Company to manufacture its products in registered establishments and in accordance with Good Manufacturing Practice, or GMP, now known as Quality System Regulations, or QSR. The Company is registered as a medical device manufacturer and is subject to periodic inspections by the FDA. In addition, The Company has maintained ISO 9001 certification since 1997. To be successful, the Company must manufacture its products in compliance with regulatory requirements, in sufficient quantities and on a timely basis, while maintaining product quality and acceptable manufacturing costs.

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. However, the Company maintains enough supply to produce test cards for an extended period of time. The Company believes that, in the event of an interruption in the availability of supplies, the Company has enough supply at its facility to fulfill its needs until an alternative source can be procured. The Company seeks to maintain long-term agreements with its suppliers when possible. The reliance on sole or limited suppliers and the inability to maintain long-term agreements with suppliers involves several risks, including the inability to obtain an adequate supply of required raw materials and components and reduced control over pricing, quality and timely delivery. Any interruption in supply could have a material adverse effect on the Company.

GOVERNMENT REGULATION

FDA

The medical devices marketed and manufactured by the Company are subject to extensive regulation by the FDA. Pursuant to the FDC Act, the FDA regulates the clinical testing, manufacture, design control, labeling, distribution and promotion of medical devices. Noncompliance with applicable requirements can result in, among other things:

Fines

Injunction

civil penalties

recall or seizure of products

total or partial suspension of production

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

withdrawal of marketing approvals or

criminal prosecution.

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

Before a new device can be introduced into the market, the manufacturer must generally obtain marketing clearance through either a 510(k) notification, the HDE process or the more time-consuming PMA process. All of the Company s currently cleared products have qualified for either the 510(k) process or the accelerated HDE process. Commercial distribution of a device for which a 510(k) is required can begin only after the FDA issues an order finding the device to be substantially equivalent to a predicate legally marketed medical device. The FDA has recently been requiring a more rigorous demonstration of substantial equivalence than in the past. It generally takes from four to twelve months from submission of a 510(k) application to obtain a 510(k) clearance, but it might take longer. The FDA might determine that a proposed device is not substantially

Table of Contents

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

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

the device will be used for investigational purposes only;

results will not be used for diagnostic purposes without confirmation of the diagnosis under another medically established diagnostic device or procedure;

all investigations will be conducted with approval from an institutional review board, or IRB, using an IRB-approved study protocol, and patient informed consent; and

the device will be labeled, and labeling will be maintained, in accordance with the applicable labeling regulations

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

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

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

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 exports 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. Failure of the Company to obtain a CPE for the export of its products in the future could have a material adverse effect on the Company The Company believes that these products are subject to the 510(k) requirements and, consequently, has not requested FDA approval for export. However, there can be no assurance that the FDA would agree with the Company that a 510(k) is needed rather than a PMA. If the FDA disagreed, it could significantly delay and impair the Company s ability to continue

exporting these tests and could have a material adverse effect on the Company.

Table of Contents

FOREIGN REGULATIONS

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

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

CLIA

The Company s products are also subject to the requirements of the Clinical Laboratory Improvement Act of 1988, or CLIA. The CLIA requires all laboratories, including those performing blood chemistry tests, to meet specified standards in the areas of personnel qualification, administration, participation in proficiency testing, patient test management, quality control, quality assurance and inspections. The regulations have established three levels of regulatory control based on test complexity waived , moderate complexity and high complexity . The PT, aPTT, HMT, HTT, PRT, LHMT and Enox tests performed by TAS have been categorized by the FDA and the Centers for Disease Control and Prevention as moderate complexity tests. There can be no assurance that these tests will not be recategorized, or that other tests performed by the TAS will not be categorized as high complexity tests or that such a categorization will not have a material adverse effect on the Company. Furthermore, there can be no assurance that regulations under and future administrative interpretations of CLIA will not have an adverse impact on the potential market for the Company s products.

Laboratories that perform either moderate or high complexity tests must meet certain standards, with the major difference in requirements being quality control and personnel standards. Quality control standards for moderate complexity tests (not modified by laboratories) are being implemented by the FDA in stages, while laboratories performing high complexity and modified moderate complexity tests currently must meet all of the quality control requirements. Personnel standards for high complexity tests require that personnel have more education and experience than personnel conducting moderate complexity tests. All laboratories performing moderately complex or highly complex tests are required to obtain either a registration certificate or certification of accreditation from the Health Care Financing Administration. With certain specified exceptions, each site for laboratory testing must file a separate application and separately meet all CLIA requirements. Multiple laboratory sites within a hospital located at contiguous buildings on the same campus and under common direction may file a single application. As a result of the CLIA requirements, hospitals may be discouraged from expanding point-of-care testing. Because CLIA certification must be obtained by laboratories, the Company does not possess sufficient data to make a determination as to the cost of certification to a laboratory or the potential inhibiting effect of CLIA certification on the purchase of the Company s products by laboratories.

OTHER REGULATIONS

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

Manufacturers are also subject to numerous federal, state and local laws relating to such matters as safe working

Table of Contents

conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. There can be no assurance that the Company will not be required to incur significant costs to comply with such laws and regulations now or in the future or that such laws or regulations will not have a material adverse effect upon the Company.

Changes in existing requirements or adoption of new requirements or policies could adversely affect the ability of the Company to comply with regulatory requirements.

REIMBURSEMENT

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

There can be no assurance that reimbursement in the United States or foreign countries will be available for any of the Company s products, or that if available it will not be decreased in the future, or that any reduction in reimbursement amounts will not reduce the demand for or the price of the Company s products. The unavailability of third-party reimbursement or the inadequacy of the reimbursement for medical procedures using the Company s tests would have a material adverse effect on the Company. Moreover, the Company is unable to forecast what additional legislation or regulations, if any, relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulations would have on the Company.

PRODUCT LIABILITY AND INSURANCE

The Company faces an inherent business risk of exposure to product liability claims in the event that the use of its products is alleged to have resulted in adverse effects. The Company maintains product liability insurance with coverage of up to $15 million per claim, with an annual aggregate policy limit of $16 million. There can be no assurance that liability claims will not exceed the coverage limits of such policies or that such insurance will continue to be available on commercially acceptable terms, or at all. Consequently, product liability claims could have a material adverse effect on the company s business, financial condition and results of operations.

EMPLOYEES

The Company had 89 employees as of December 31, 2002. Fourteen employees were engaged in research and development (6 of which have Ph D s), 38 in manufacturing and quality control, 15 in software, engineering and facilities, 8 in sales/marketing and 14 in finance/administration. Many of the Company s executive and technical personnel have had experience with biomedical diagnostics companies. None of the Company s employees are covered by a collective bargaining agreement and the Company believes that employee relations are good.

The Company s success depends to a significant extent upon management and technical personnel, none of whom have employment agreements with the Company. Although the Company maintains a $500,000 key man life insurance policy on its chief executive officer, the loss of the service of this officer could have a material adverse effect on the Company s business, financial condition and results of operations. The Company also believes that its future success will depend in large part upon its ability to attract and retain highly skilled technical, management and sales and marketing personnel. Competition for such personnel is intense, and there can be no assurance that the Company will be successful in attracting and retaining such personnel. The Company s failure to attract, hire and retain these personnel would have a material adverse effect on the Company.

Available Information

Our website address is www.pharmanetics.com. We 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

Table of Contents

as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission.

ITEM 2. PROPERTIES

During 2001, the Company relocated its executive offices to a new facility located at 9401 Globe Center Drive, Suite 140, Morrisville, North Carolina 27560. The Company currently leases and occupies approximately 55,000 square feet of development, production and administration space at this location. The Company believes that its facilities are adequate for its operations and that suitable additional space will be available if and when needed.

ITEM 3. LEGAL PROCEEDINGS

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

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

No matters were submitted to a vote of the shareholders during the fourth quarter ended December 31, 2002.

EXECUTIVE OFFICERS OF THE COMPANY

The following sets forth information as of March 19, 2003 with respect to all the executive officers of the Company, including their names, ages, positions with the Company and business experience during the last five years.

John P. Funkhouser, age 49, was elected President, Chief Executive Officer and a director of the Company in October 1993. In February 1998, Mr. Funkhouser was appointed Chairman of the Board of Directors of the Company. Mr. Funkhouser served as President and Chief Executive Officer of Coeur 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 holds a B.A. from Princeton University and an M.B.A. from the University of Virginia.

James A. McGowan, age 59, was elected Chief Financial Officer of the Company in May 2000. Since 1982, Mr. McGowan has been a principal of McGowan Associates, a boutique venture capital and consulting firm. Venture capital activities have included a partnership with First Chicago Corp (McGowan Leckinger) and a co-investment with The Thomas Lee Company (Sterling Merchandise). Mr. McGowan s consulting activities have ranged from interim executive positions at Filenes Basement, The TAC Group and the TJX Companies to strategic consulting projects for Arthur Andersen and a variety of small to mid-size growth companies. Prior to founding McGowan Associates, Mr. McGowan was the chief financial officer and a principal-selling stockholder of three retail chains that were acquired by large public companies. Mr. McGowan was a Certified Public Accountant and holds a B.S. from Boston University and an M.B.A from Suffolk University.

Michael D. Riddle, age 50, has been Executive Vice President of Sales, Marketing, and Business Development since January 1999. Mr. Riddle also served as Vice President, Sales and Marketing, from January 1995 to January 1999. Prior to joining the Company, Mr. Riddle was employed by American Home Products for seven years in various positions, most recently as Vice President of Sales and Marketing for Sherwood Medical Devices. Mr. Riddle attended Bromley College of Technology (Kent, United Kingdom).

Mark X. Triscott, age 49, joined the company in May 2001 as Vice President of Research and Development. Prior to joining the company Dr. Triscott was employed at Sigma Diagnostics for more than five years in various positions including, Principal Scientist , Manager, Coagulation Research and Development, and Manager responsible for all Diagnostics Research and Development. Dr. Triscott has a Science degree with First Class Honours from the University of Queensland (Australia), where he also completed a Doctorate in Microbiology. He did a post-doctoral fellowship at Bowman Gray School of Medicine, Winston-Salem North Carolina, where he held an adjunct faculty position in Biochemistry. Dr Triscott is an inventor on several issued and pending US and foreign patents, and has published more than 30 peer reviewed articles, chapters and abstracts.

Paul T. Storey, age 36, was elected Treasurer and Secretary in February 1998. Since December 1997, Mr. Storey has also served as Director of Finance of the Company. Prior to joining the Company, Mr. Storey was employed for more than eight years at KPMG Peat Marwick LLP, most recently as a senior manager. Mr. Storey is a Certified Public Accountant and holds a B.A. in Accounting from Furman University.

Table of Contents

PART II

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

(A) PRICE RANGE OF COMMON STOCK

The Company s common stock trades on the Nasdaq National Market under the symbol PHAR . The following sets forth the quarterly high and low closing sales prices of the common stock of the Company for the periods indicated as reported by Nasdaq. These prices are based on quotations between dealers, which do not reflect retail mark-up, mark-down or commissions, and do not necessarily represent actual transactions.

	High	Low
Fiscal year ended December 31, 2002		
First Quarter	$ 9.88	$ 6.50
Second Quarter	8.15	4.96
Third Quarter	6.99	3.50
Fourth Quarter	7.04	4.89
Fiscal year ended December 31, 2001		
First Quarter	$ 12.81	$ 6.81
Second Quarter	11.15	7.75
Third Quarter	10.45	6.75
Fourth Quarter	8.00	6.16

(B) APPROXIMATE NUMBER OF EQUITY SECURITY HOLDERS

As of March 19, 2003, the number of record holders of the company s common stock was approximately 100, and the Company believes that the number of beneficial owners was approximately 3,000.

(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,				
	2002	**2001**	**2000**	**1999**	**1998**
RESULTS OF OPERATIONS					
Net sales	$ 4,090	$ 4,539	$ 4,269	$ 3,909	$ 4,141
Cost of goods sold	3,495	4,046	3,590	3,179	2,847
Gross profit	595	493	679	730	1,294
Operating expenses:					
General and administrative	4,899	4,525	3,330	2,715	2,815
Sales and marketing	1,498	1,208	1,051	799	707
Research and development	6,008	3,950	3,685	2,777	2,509
Total operating expenses	12,405	9,683	8,066	6,291	6,031
Other income, net	694	588	1,053	147	514
Loss from continuing operations	(11,116)	(8,602)	(6,334)	(5,414)	(4,223)
Discontinued operations:					
Income from operations				18	580
Loss on disposal				(826)	
Net loss	(11,116)	(8,602)	(6,334)	(6,222)	(3,643)
Beneficial conversion feature of Series A Preferred Stock			(3,004)		
Preferred stock dividends	(482)	(566)	(626)		
Net and comprehensive loss attributable to common shareholders	$ (11,598)	$ (9,168)	$ (9,964)	$ (6,222)	$ (3,643)
Basic and diluted loss per common share:					
Net loss attributable to common shareholders	$ (1.21)	$ (1.03)	$ (1.31)	$ (0.83)	$ (0.52)
Weighted average shares outstanding	9,567	8,877	7,626	7,469	7,007
Pro forma amounts assuming SAB 101was retroactively applied/(1):					
Net and comprehensive loss attributable to common shareholders	$ (11,598)	$ (9,168)	$ (9,964)	$ (5,926)	$ (3,475)
Basic and diluted loss attributable to common shareholders per share	$ (1.21)	$ (1.03)	$ (1.31)	$ (0.79)	$ (0.50)

	As of December 31,				
	2002	**2001**	**2000**	**1999**	**1998**
FINANCIAL CONDITION					
Cash and cash equivalents	$ 9,146	$ 14,883	$ 5,344	$ 3,661	$ 3,998

Short term investments			3,904	1,500	3,703
Total assets	21,702	27,014	18,314	11,647	18,693
Long term debt and capital lease obligations, excluding current portion	1,095	66	36	862	1,626
Total liabilities	7,543	3,386	3,632	2,039	2,949
Accumulated deficit	(61,214)	(49,616)	(40,448)	(30,484)	(24,262)
Series A Preferred stock	7,520	7,520	8,102		
Contingently redeemable common stock		8,538			
Common shareholders equity	$ 6,638	$ 7,570	$ 6,580	$ 9,608	$ 15,744

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

Table of Contents

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

OVERVIEW

PharmaNetics, Inc., through its wholly-owned subsidiary Cardiovascular Diagnostics, Inc. (CVDI), develops, manufactures and markets rapid turnaround diagnostics to assess blood clot formation and dissolution. 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 evaluation of hemostasis. PharmaNetics is also establishing itself in the emerging field of theranostics, or rapid near-patient testing, in which the diagnostic results may influence treatment decisions. Current tests and tests under development are used in the treatment of angina, heart attack, stroke, deep vein thrombosis and pulmonary and arterial emboli. The TAS technology is used at the point of patient care which provides many potential benefits, including faster results for better treatment of patients, reduced usage of blood products for bleeding complications, quicker patient transfers from costly critical care settings and reduced hospital costs due to less paperwork and personnel time in processing blood samples.

The Company currently derives income from the following sources: TAS product sales, interest income, and development income recognized in connection with collaboration agreements. Currently, product sales mainly consist 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 are distributed under a global distribution agreement with Bayer Diagnostics. Bayer s strength is in critical care areas of the hospital which the Company believes should facilitate the placement of the TAS technology. The Company s revenue from Bayer totaled approximately 94% of all revenue during 2002.

In addition, the Company s business strategy has evolved towards becoming more focused on theranostics, the development of specialty tests for drugs, some with narrow ranges between over- and under-dosage. Rapid diagnostic capabilities might improve patient care and turnover, and there is a market trend to obtain diagnostic information faster in order to effect therapy sooner. The Company believes that physicians are beginning to see the need for drug management tools and, consequently, the Company is seeking greater involvement of physician thought leaders during development of new test cards. The Company also believes that these trends should allow the Company to obtain higher pricing of these specialty tests. In furtherance of that objective, the Company commercially launched its first theranostic test, the Enox test, in January 2003 to detect the anticoagulant effects of enoxaparin sodium, a leading low molecular weight heparin marketed by Aventis. The Company s test is being sold through a coordinated advertising, marketing and educational program with Aventis. The Company has hired contract sales and technical service personnel to work with Aventis sales force in promoting the test.

The Company also has exhibited the flexibility of the TAS platform and the potential to expand its menu of specialty tests by signing development agreements with major pharmaceutical companies to monitor the effects of certain new drugs that are in clinical trials or currently being marketed. Increased placement of specialty tests might also further demand for analyzers and routine anticoagulant tests. The Company believes it is well positioned in its development efforts to expand its menu of tests to monitor developmental drugs where rapid therapeutic intervention is needed.

CRITICAL ACCOUNTING POLICIES

Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles, which require us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosure of contingent assets and liabilities. We evaluate our estimates, judgments and the policies underlying these estimates on a periodic basis as the situation changes, and regularly discuss financial events, policies, and issues with our independent accountants and members of our audit committee. Actual results could differ from these estimates. We believe that the following are some of the more critical judgment areas in the application of our accounting policies that affect our 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 in 2002 were made to the Company s distributor, Bayer. 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. 101 (SAB 101). SAB 101 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, over the agreement period.

Table of Contents

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. 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.

RESULTS OF OPERATIONS

Year Ended December 31, 2002 vs. Year Ended December 31, 2001. Sales for the year ended December 31, 2002 decreased to $4.1 million compared to $4.5 million in 2001. Specialty test card sales in 2002 totaled $223,000 compared to $1.6 million in 2001. In 2001, the Company recorded specialty card revenue of $1.5 million related to a payment from AstraZeneca for specialty test cards previously purchased in 2000 that was required as part of the cessation of a collaboration agreement in 2001. Routine test card sales were essentially flat in 2002, totaling $2.4 million compared to $2.3 million in 2001. However, analyzer revenues increased strongly in 2002, totaling $1.1 million compared to $284,000 in 2001 as Bayer purchased additional units to meet customer demands. Controls revenue, which relates to the quality control products used with the test cards, also increased in 2002 to $342,000 compared to $257,000 in 2001. The gross profit margin in 2002 was 15% compared to 11% in 2001. Gross margin increased because higher material and labor costs from higher unit sales of analyzers were offset by decreased operational and technical support overhead devoted to producing test cards for sale. As a result of a new accounting software system, production overhead costs in 2002 of approximately $1.1 million have been classified as research and development expense in the statement of operations based on test cards produced and consumed in development activities.

Total operating expenses for 2002 totaled $12.4 million compared to $9.7 million 2001. General and administrative expenses increased $375,000 compared to 2001. Expenses related to relocating the Company s facility decreased compared to 2001 as these costs incurred in 2001 were not incurred in 2002. In addition, the Company incurred expenses related to implementing an ERP system during 2001 that were not incurred during 2002. These decreases totaled $700,000. The decreases were offset by a $1.1 million non-cash charge 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 for the affected options.

Sales and marketing expenses increased to $1.5 million from $1.2 million due to budgeted higher compensation costs of current personnel, fees related to recruiting a contract sales and technical service force and a $137,000 non-cash charge for deferred compensation related to extending the termination date of option grants for sales personnel. The contract sales and technical service personnel began work in January 2003. Consequently, the Company expects to incur significantly higher sales and marketing expense in 2003 than it did in 2002.

Research and development expenses increased in 2002 to $6.0 million from $4.0 million in 2001 related to budgeted personnel cost increases and higher costs associated with on-going development projects for supplies, experimental test cards and clinical trials expense. Development expense related to the Enox test alone increased approximately $1 million compared to the prior year. The Company also recorded a $71,000 non-cash charge for deferred compensation related to extending the termination date of option grants for research personnel.

Interest expense for the year ended December 31, 2002 decreased compared to 2001. In June 2001, the Company paid off debt to Transamerica Business Credit Corp. that had been entered into in 1997 to fund working capital and capital expenditures. The Company entered into a new loan with GE Capital in December 2002. See Liquidity and Capital Resources . Interest income decreased in 2002 compared to 2001 due to significantly decreased interest rates and also lower average cash balances which lowered returns during the year.

Development income totaled $587,000 in 2002 compared to $264,000 in 2001. Development income in both years was derived from a collaboration agreement signed with Aventis Pharmaceuticals during 2000 related to the Company s enoxaparin test. The milestone payments received in 2002 of $3 million were deferred and are being recognized into income, along with milestone payments previously received , over the remaining life of this agreement of four years.

In February 2000, the Company completed a private placement of 120,000 shares of Series A convertible preferred stock. The Series A has a dividend of 6% payable quarterly in cash or in shares of common stock at the option of the Company. During

Table of Contents

the year ended December 31, 2002, the Series A dividend was paid by issuing 81,087 shares of common stock totaling $481,589.

Year Ended December 31, 2001 vs. Year Ended December 31, 2000. Sales for the year ended December 31, 2001 increased to $4.5 million compared to $4.3 million in 2000. Specialty test card sales in 2001 were $1.6 million, of which $1.5 million related to a payment from AstraZeneca for specialty test cards previously purchased in 2000 that was required as part of the cessation of a collaboration agreement in 2001. This sales level compares to specialty test card revenue of approximately $600,000 recorded in 2000 when specialty test cards were purchased by a collaborative partner for use in their clinical trials. Routine test card sales increased 9% to $2.3 million in 2001 compared to $2.1 million in 2000 as Bayer increased placements of the TAS system. These increases were offset by decreases in analyzer sales and controls, as total analyzer revenue in 2001 was $290,000 compared to $1.1 million in 2000, and control revenue was $257,000 in 2001 compared to $385,000 in 2000. Analyzer sales decreased in 2001 as Bayer reduced its inventory of analyzers that it had purchased from the Company during 2000. The gross profit margin in 2001 was 11% compared to 16% in 2000. Gross margin decreased mainly due to increased costs in overhead related to increased production equipment and its related depreciation, production costs associated with the Company s plant relocation during 2001 and additional manufacturing and quality control personnel. The 2001 gross margin was aided by increased revenue from specialty test cards, principally the $1.5 million received from AstraZeneca.

Total operating expenses for 2001 totaled $9.7 million compared to $8.1 million 2000. General and administrative expenses increased $1.2 million compared to 2000 due to several factors. Higher personnel costs from salary and benefit increases were incurred as well as from additional personnel hired into administration. Increased facility and equipment costs were incurred related to the Company s relocation to new facilities. In addition, the Company incurred implementation costs in improving its management information systems during 2001.

Sales and marketing expenses increased due to higher compensation costs and expenditures related to marketing materials and training, mostly related to the enoxaparin test. Research and development expenses increased approximately 7% in 2001 compared to 2000. The change was mainly due to increased personnel and increased clinical trial costs related to the Company s enoxaparin test project and the project to further optimize our PT test.

Interest expense for the year ended December 31, 2001 decreased compared to 2000. In June 2001, the Company paid off debt to Transamerica Business Credit Corp. that had been entered into in 1997 to fund working capital and capital expenditures. Interest income decreased in 2001 compared to 2000 due to significantly decreased interest rates which lowered returns during the year.

Development income totaled $264,000 in 2001 compared to $492,000 in 2000. Development income in 2001 was derived from a collaboration agreement signed with Aventis Pharmaceuticals during 2000 related to the Company s enoxaparin test. The milestone payments received, which totaled $2 million through the end of 2001, are being recognized into income over the life of this agreement. Development income in 2000 was related to agreements signed previously with Bayer Diagnostics and Aventis. The Bayer development agreement ended in 2000.

In February 2000, the Company completed a private placement of 120,000 shares of Series A convertible preferred stock. The Series A has a dividend of 6% payable quarterly in cash or in shares of common stock at the option of the Company. During the year ended December 31, 2001, the Series A dividend was paid by issuing 69,604 shares of common stock totaling $566,210.

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2002, the Company had cash and cash equivalents of $9.1 million and working capital of $9.5 million, as compared to $14.9 million and $15.8 million, respectively, at December 31, 2001. During 2002, the Company used cash in operating activities of $6.2 million. The use of cash was principally due to funding the net operating loss of the Company and increased inventories to support expected product sale increases. The operating uses of cash were partially offset by funding provided through the collaboration with Aventis that was recorded as deferred revenue.

Net cash used in investing activities was $1.4 million in 2002. Net cash provided by investing activities was $400,000 in 2001. The net cash used mainly resulted from expenditures for new machinery and management information systems equipment. The Company expects capital expenditures in 2003 to be lower than in 2002 and to range from $500,000 to $1,000,000.

Cash provided by financing activities was $1.8 million in 2002 as compared to $16.7 million in 2001. In 2002, the Company obtained a 3-year $1.5 million equipment loan from GE Capital. As of December 31, 2002, the outstanding balance under the GE Capital loan was approximately the full $1.5 million. During 2001, the Company issued common stock to Bayer for $17.4 million. The 2001 cash provided by financing activities was reduced by the pay off of the Company s debt owed to Transamerica Business Credit Corp.

Table of Contents

The Company has sustained continuing operating losses in 2002 and had an accumulated deficit of $61.2 million as of December 31, 2002. The Company expects to incur operating losses until product revenues reach a sufficient level to support ongoing operations. In addition, in the years ended December 31, 2002 and 2001, the Company had negative cash flows from operations of approximately $6.2 million and $7.6 million, respectively. In addition to the capital expenditures noted above, the Company expects to incur additional operating losses during 2003, including additional sales and marketing expenses to support the new contract salesforce. The Company s working capital requirements will depend on many factors, primarily the volume of subsequent orders of TAS products from distributors, primarily Bayer, and from sales of specialty test cards such as the Enoxaparin test. In addition, the Company expects to incur costs associated with research and development of new test cards. The Company might acquire other products, technologies or businesses that complement the Company s existing and planned products, although the Company currently has no understanding, commitment or agreement with respect to any such acquisitions. In addition, the Company might consider a joint venture or the sale of manufacturing rights to complete the commercialization of its routine anticoagulant monitoring tests. Management believes that its existing capital resources and cash flows from operations, including that from its distribution agreement with Bayer, will be adequate to satisfy its planned liquidity and cash requirements through 2003.

If additional liquidity becomes necessary in the future, the Company will consider external sources of financing as needed. These financings may take the form of equity financings such as a private placement of common or preferred stock, a follow-on public offering of common stock or additional equity infusions from collaborative partners.

The 2001 common stock purchase agreement with Bayer contains a provision that, upon the occurrence of a change in control, as defined in the agreement, the Company would be required to compensate Bayer, in cash or shares of common stock, for any difference between per share prices originally paid by Bayer and the amount received by the Company s shareholders in the change of control transaction. In accordance with applicable accounting guidelines, the Company previously transferred to temporary equity an amount equal to the change in control payment called for by the purchase agreement. Because this change of control provision expired on December 31, 2002, the Company has transferred that amount from temporary equity back to permanent equity.

CONTRACTUAL OBLIGATIONS

The Company has contractual obligations under notes payable, capital and operating lease agreements for years subsequent to 2002. Future payments as of December 31, 2002 are as follows:

Year ending December 31,

	Notes Payable	Capital Leases	Operating Leases	Total
2003	$ 585,971	$ 26,729	$ 370,469	$ 983,169
2004	583,762	19,521	373,618	976,901
2005	579,376	19,521	370,917	969,814
2006		6,506	347,865	354,371
2007			358,300	358,300
Thereafter			1,140,695	1,140,695
Total payments	$ 1,749,109	$ 72,277	$ 2,961,864	$ 4,783,250

RECENT ACCOUNTING PRONOUNCEMENTS

In 2001, the FASB issued SFAS No. 143, Accounting for Asset Retirement Obligations, which addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. This statement requires that the fair value of a liability for an asset retirement obligation be recognized in the period in which it is incurred if a reasonable estimate of fair value can be made. This statement is effective for financial statements issued for fiscal years beginning after June 15, 2002. The Company does not presently have any asset retirement obligations, and thus this statement is not expected to materially impact the results of operations, financial

condition, or cash flows.

In June 2002, the FASB issued Statement No. 146 (FAS 146), Accounting for Exit or Disposal Activities . FAS 146 addresses significant issues regarding the recognition, measurement, and reporting of costs that are associated with exit and disposal activities, including restructuring activities that are currently accounted for pursuant to the guidance set forth in Emerging Issues Task Force Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring) . The scope of FAS 146 includes (1) costs related to terminating a contract that is not a capital lease (2) termination benefits received by employees who are involuntarily terminated under the terms of a one-time benefit arrangement that is not an ongoing benefit arrangement or an individual deferred-

Table of Contents

compensation contract and (3) costs to consolidate facilities or relocate employees. FAS 146 will be effective for exit or disposal activities that are initiated after December 31, 2002. The Company does not expect this pronouncement to have a material impact on its financial statements.

In December 2002 the FASB issued SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure, which amends SFAS No. 123, Accounting for Stock-Based Compensation, to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. These provisions of SFAS No. 148 are effective for financial statements for fiscal years ending after December 15, 2002. The Company has not and does not anticipate implementing the voluntary change to the fair value based method of accounting for stock-based compensation. The Company has implemented the disclosure provisions of SFAS No. 148 beginning with the December 31, 2002 consolidated financial statements.

On November 21, 2002, the Emerging Issues Task Force concluded on EITF 00-21, Accounting for Revenue Arrangements with Multiple Deliverables which is proposed to be effective for revenue arrangements entered into in fiscal periods beginning after December 15, 2002. EITF 00-21 requires an analysis of whether (1) a delivered item has stand-alone value to the customer; (2) there is objective and reliable evidence of the fair value of the undelivered items; and (3) the delivery of the undelivered item is probable and substantially within the control of the vendor if the arrangement includes a general right of return relative to the delivered item. As a consequence, the application of EITF 00-21 may result in the acceleration of revenues for some arrangements and the deferral of revenue for others, even though EITF 00-21 does not address the timing or pattern of revenue recognition for a unit of accounting. The Staff also noted that although the SAB 101 guidance that relates to multiple-element arrangements will be superseded by EITF 00-21, the revenue-recognition guidance in SAB 101 will still apply to units of accounting that other authoritative literature does not specifically address with respect to revenue recognition. This statement did not have a material effect on the results of operations, financial condition, or cash flows.

On November 25, 2002, the Financial Standards Board issued FASB Interpretation No. 45 (FIN 45), Guarantor s Accounting and Disclosure Requirements for Guarantees, including Indirect Guarantees of Indebtedness of Others (an interpretation of FASB Statements No. 5, 57 and 107 and rescission of FASB Interpretation No. 34). FIN 45 clarifies the requirements of FASB Statement No. 5, Accounting for Contingencies, relating to a guarantor s accounting for, and disclosure of, the issuance of certain types of guarantees. The Company does not anticipate this statement to materially impact the results of operations, financial condition, or cash flows.

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 new tests, particularly specialty tests, can be developed, receive regulatory approval, and be commercialized and accepted in the market. Other risks include: market acceptance of TAS; the Company s continuing losses and the resulting potential need for additional capital in the future; managed care and continuing market consolidation, which may result in price pressure, particularly on routine tests; competition within the diagnostic testing industry and FDA regulations and other regulatory guidelines affecting the Company and/or its collaborators. The market price of the common stock could be subject to significant fluctuations in response to variations in the Company s quarterly operating results as well as other factors which may be unrelated to the Company s performance. The stock market in recent years has experienced extreme price and volume fluctuations that often have been unrelated or disproportionate to the operating performance of and announcements concerning public companies. Such broad fluctuations may adversely affect the market price of the Company s common stock. Securities of issuers having relatively limited capitalization are particularly susceptible to volatility based on short-term trading strategies of certain investors.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

In the normal course of business, the Company is exposed to variety of risks including market risk associated with interest rate movements. The Company s exposure to market risk for changes in interest rates relates primarily to any investments the Company may hold at various times and also related to its long-term debt. When investing, the Company s purchases consist of highly liquid investments with maturities at the date of purchase between three and twelve months, thus, due to the short-term nature of such investments and the Company s usual intention to hold these investments until maturity, the impact of interest rate changes would not have a material impact on the Company s results of operations. In addition, all of the Company s long-term debt obligations are at fixed interest rates. Given the fixed rate nature of the debt, the impact of interest rate changes also would not have a material impact on the Company s results of operations.

Table of Contents

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

Not applicable

PART III

Certain information required by Part III is omitted from this report because the Registrant intends to file a definitive proxy statement for its 2003 Annual Meeting of Shareholders (the Proxy Statement) within 120 days after the end of its fiscal year pursuant to Regulation 14A promulgated under the Securities Exchange Act of 1934, as amended, and the information included therein is incorporated herein by reference to the extent provided below.

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

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

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

ITEM 11. EXECUTIVE COMPENSATION

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

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

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

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The Company has no such relationships or transactions to report this year.

ITEM 14. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures. Within 90 days prior to the date of 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, Chief Financial Officer and Director of Finance, of the effectiveness of the design and operation of the Company s disclosure controls and procedures pursuant to Exchange Act Rule 13a-14. Based upon that evaluation, the Company s Chief Executive Officer, Chief Financial Officer and Director of Finance have concluded that the Company s disclosure controls and procedures are effective.

(b) Changes in internal controls. There have been no significant changes in the Company s internal controls or, to the knowledge of these officers, in other factors that could significantly affect these controls subsequent to the date of their evaluation.

Table of Contents

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

The Company

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

(1) Financial Statements.

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

(2) Financial Statement Schedules.

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

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

(3) The exhibits filed as part of this Report are listed in Item 15(c) below.

(b) The Company filed the following Current Reports on Form 8-K during the quarter ended December 31, 2002:

On November 18, 2002, the Company issued a press release announcing the results of its 600-patient ELECT trial.

On December 19, 2002, the Company issued a press release announcing the receipt of a final milestone payment from Aventis Pharmaceuticals Inc. and the closing of a 3-year $1.5 million loan from GE Capital.

(c) Exhibits

Exhibit Number	Description
3.3(a)	Bylaws.
3.4(f)	Amended and Restated Articles of Incorporation filed with the North Carolina Secretary of State on February 24, 2000
4.1(a)	Form of Common Stock certificate.
10.2(a)*	License Agreement with Tokuyama Soda Company, Ltd., dated October 6, 1988.
10.3(a)	Form of International Distributor Agreement.
10.4(a)*	Purchasing Agreement with VHA Inc., dated April 1,1995
10.8(a)	1994 Stock Plan, as amended.
10.9(a)	1995 Stock Plan, as amended.
10.10(a)*	License Agreement with Duke University, dated January 22, 1993.