

PHARMANETICS INC  
Form 424B3  
July 07, 2004  
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**PROSPECTUS**

FILED PURSUANT TO RULE 424(b)(3)

REGISTRATION NO. 333-106087

**2,472,364 SHARES**

**PHARMANETICS, INC.**  
**COMMON STOCK**

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The shareholders of PharmaNetics, Inc. listed herein are offering and selling from time to time up to 2,472,364 shares of our common stock under this resale prospectus. We will not receive any proceeds from the sale of the shares.

Our common stock is traded on the OTC Bulletin Board under the symbol PHAR.OB. On June 25, 2004, the last sale price of our common stock on the OTC Bulletin Board was \$0.48 per share.

The selling shareholders may offer the shares through public or private transactions, on or off the OTC Bulletin Board, at prevailing market prices or at privately negotiated prices. See Plan of Distribution.

**Investing in our common stock involves risks. See Risk Factors beginning on page 7.**

**Neither the SEC nor any state securities commission has approved or disapproved our securities or determined that this prospectus is truthful or complete. It is illegal for anyone to tell you otherwise.**

**The date of this prospectus is June 30, 2004.**

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### **Prospectus Summary**

#### **About PharmaNetics**

Prior to ceasing substantially all of our operations in March 2004, we developed, manufactured and marketed rapid diagnostics to dose, manage and screen patients on drugs affecting coagulation. Our 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. Our tests were and can be used in the treatment of a variety of adverse conditions caused by abnormal blood clotting in different areas of the body, including angina, heart attack, stroke, deep vein thrombosis and pulmonary and arterial emboli.

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

Our products include the TAS analyzer and a menu of tests and controls. We currently have seven tests approved by the Food and Drug Administration, or FDA, that have been sold for commercial use. We have sold three other tests for investigational use only. In addition, we have obtained a special FDA approval for humanitarian devices for one of our test cards used in managing patients suffering from heparin induced thrombocytopenia, a condition characterized by persistent decrease in blood platelets resulting from the administration of the anti-clogging drug, heparin. This special approval is an expedited FDA authorization process to market devices used in rare disease states where no existing solution is available.

#### **Recent Developments**

In November 2003, we filed a lawsuit in the eastern district of North Carolina against Aventis Pharmaceuticals, Inc. In cooperation with Aventis, we had developed a rapid bedside test, known as the Enox test, that we believe enhances the way Lovenox<sup>®</sup>, a popular anti-blood clotting drug marketed by Aventis, currently is managed. We believe the test has the potential to facilitate the drug's use in patients in the cardiac community who stand to benefit from its use. Aventis collaborated with us in a multi-million dollar project in which it made milestone payments to us to develop and co-promote the test together with Lovenox for targeted patient populations. The lawsuit alleges that Aventis has engaged in false and misleading advertising of

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Lovenox, which damaged our efforts to market and sell the Enox test card. The lawsuit also alleges that Aventis has failed to fulfill its obligation to promote the test and is systematically and falsely advising physicians that the test is not necessary through its claims that Lovenox requires no monitoring and is therapeutic from dose one. We are seeking injunctive relief against Aventis to stop these actions and demanding that Aventis promote the need for monitoring as required in Lovenox's labeling and as required by the development agreement we entered into with Aventis in August 2000.

In March 2004, the court hearing our case against Aventis held a hearing on our motion for a preliminary injunction against Aventis. In April 2004, the court issued an order denying our request for a preliminary injunction, but in denying our motion, the court made a judicial determination that two of Aventis' advertising claims regarding Lovenox were literally false. First, the court found that Aventis' claim that Lovenox reaches therapeutic levels with 1/2 hour of administration to be literally false. Second, the court found literally false Aventis' claim that Lovenox was therapeutic from dose one. Although the court did not grant our request for a preliminary injunction, one of the reasons cited by the court for not enjoining these false advertising messages was that Aventis has discontinued using these false statements in its advertising. In particular, after we filed our false advertising lawsuit against Aventis in November 2003, almost immediately thereafter Aventis withdrew these statements from its advertising of Lovenox.

In addition, the court found that certain disparaging statements made by Aventis representatives concerning our Enox test card were also literally false. However, rather than issue a preliminary injunction, the court ultimately left this issue for the jury to decide. The court also ruled on Aventis' motion for summary judgment in which Aventis essentially sought dismissal of our false advertising claims. In denying Aventis' motion, the court noted that we had raised genuine issues of material fact concerning our claims against Aventis and, accordingly, the court ruled that the merits of this case should ultimately be evaluated by a jury. In order to prevail in a jury trial, we must prove a variety of factual issues as well as substantiate our calculation of damages. We intend to aggressively pursue the lawsuit to enforce our rights, and we expect the lawsuit could take a year or more to complete and consume significant time and expense.

In December 2003, we announced that, as a result primarily of the Aventis litigation and its impact on our business and prospects, we are seeking a variety of strategic alternatives, including the sale of our manufacturing operations. In March 2004, because a willing and able buyer for our operations had not by then been identified, we terminated our distribution agreement with our distribution partner, Bayer Diagnostics. In addition, we terminated the sales and technical service personnel formerly engaged by us through PDI, the contractor and provider of the Enox sales and technical support teams. Since filing the lawsuit, we have implemented personnel reductions and have engaged Davenport & Company LLC, an investment banking firm, as our financial advisor. Davenport & Company is currently assisting us in pursuing a sale of our manufacturing operations and intellectual property. We believe these steps were and are necessary in order to reduce overhead costs and to conserve cash for the proposed license or sale of assets and the intellectual property as well as to finance our lawsuit against Aventis. We are shifting our corporate strategy from a manufacturing/distribution model to that of a biotech model, whereby revenues, if any, would be tied to royalty streams from any future product sales. We are actively seeking a buyer for our operating assets and to sell or license our intellectual

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property with a significant portion of the potential valuation tied to royalties. In essence, under this new model we would be in a position to receive royalties on tests developed and would not be responsible for manufacturing and distribution.

By the end of March 2004, we have ceased developing, producing and selling all of our products and plan to terminate substantially all remaining employees except our chief executive officer. We plan to retain the chief executive officer to manage the Aventis litigation until it is completed or settled and to continue to seek a buyer of our operations, manufacturing assets and intellectual property. We expect to engage other personnel to conduct business for us on a contract basis as necessary during the course of these efforts. If we were to receive any proceeds in connection with the Aventis litigation, after payment of litigation and remaining operating expenses, we would consider distributing such remaining proceeds, if any, to our shareholders or using them to restart operations. Such determination would depend on a variety of factors, including the size and timing of any payments, the expenses of completing the litigation, management's assessment of the viability of restarting the business and availability of necessary personnel. However, there can be no assurance that we will prevail in the litigation against Aventis or that if we do prevail, the proceeds would be sufficient to provide significant shareholder value. At this time, we believe as a result of these cost-cutting actions, that we have the financial ability to fund the lawsuit to its conclusion.

Due to our failure to comply with the requirements for continued listing of our shares of common stock on the Nasdaq SmallCap Market, we were delisted from the Nasdaq SmallCap Market on May 13, 2004. Our common stock is quoted and trades on the OTC Bulletin Board.

## **Products**

The following summarizes our products and test cards, all of which we have ceased manufacturing, developing and marketing as a result of the Recent Developments described above.

The TAS analyzer weighs approximately four pounds and is about the size of a typical office telephone. 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. Typically within three minutes of inserting a test card with a single drop of blood or plasma into the analyzer, 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.

Our Accent product is a microprocessor-based hardware accessory to the TAS analyzer. It connects to the TAS analyzer and automatically calculates the information required by physicians to manage the anticoagulation of patients on heparin during cardiopulmonary bypass procedures. It can be used in conjunction with three of our test cards.

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

Our enoxaparin test, or Enox test, detects the anticoagulant effect of enoxaparin, a low molecular weight heparin drug used for the treatment and prevention of blood-clotting diseases. Enoxaparin is the world's top-selling low molecular weight heparin and is marketed by Aventis Pharmaceuticals in the United States under the brand name Lovenox<sup>®</sup> and outside of the United States under the brand name Clexane<sup>®</sup>.



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Our PT, or Prothrombin Time, test is a general screening test that is used to assess a patient's baseline blood-clotting function or to monitor the use of oral anticoagulants, such as warfarin. Warfarin is widely used in the United States for long-term treatment in patients who have previously developed clots, including after heart attacks, to inhibit clot formation and reduce the risk of developing additional clots. Physicians use our PT test to monitor and maintain drug levels within a safe treatment range.

Our aPTT, or Activated Partial Thromboplastin Time, test is a coagulation-screening test which may be used in conjunction with our PT test to provide a global assessment of a patient's ability to form a blood clot. In addition, our aPTT test is used to monitor heparin, an injectable anticoagulant. Hospitals routinely use heparin as the initial treatment for patients with a blood clot, including patients suffering from heart attacks or strokes. Heparin also prevents blood clots from forming in patients undergoing procedures involving particular risks of clotting, such as angiography, open heart surgery, dialysis and several other surgeries. Heparin must be closely monitored to assure adequate anticoagulation without increasing the risk of developing a bleeding complication.

Because aPTT tests are generally incapable of monitoring high levels of heparin, we formerly developed and marketed our HMT, or Heparin Management Test, card for monitoring patients requiring high dose heparin therapy during procedures such as open heart surgery or dialysis. In addition, we have two more test cards that can be combined with our HMT test to provide a system for individualized heparin management during cardiac surgery.

Our LHMT, or Low-range Heparin Management Test, card is used principally in cardiac catheterization and interventional cardiology procedures. It is designed to monitor the effects of concentrations of heparin above the range measured by our aPTT card but below that of our HMT card.

Our ECT, or Ecarin Clotting Time, card is used to manage patients suffering from heparin-induced thrombocytopenia. The FDA's approval for this test only allows the use of the test for managing patients who receive Refludan<sup>®</sup>, an anticoagulant drug marketed by Pharmion and Berlex for patients undergoing cardiopulmonary bypass surgery.

## **Company Information**

PharmaNetics, Inc. is a holding company incorporated in North Carolina in 1998 as the parent company of Cardiovascular Diagnostics, Inc. Cardiovascular Diagnostics, Inc. was incorporated in 1985 and was our sole operating subsidiary until we ceased substantially all of our operations in March 2004. Our principal executive offices are located at 9401 Globe Center Drive, Suite 140, Morrisville, North Carolina 27560. Our telephone number at that location is (919) 582-2600. Information contained on our website, [www.pharmanetics.com](http://www.pharmanetics.com), is not a part of this prospectus.

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**The Offering**

Shares of common stock offered by us	None
Shares of common stock which may be sold by the selling shareholders	2,472,364(1)
Use of proceeds	We will not receive any proceeds from the resale of shares offered hereby, all of which proceeds will be paid to the selling shareholders
Risk factors	The purchase of our common stock involves a high degree of risk. You should carefully review and consider Risk Factors beginning on page 7.
OTC Bulletin Board Symbol	PHAR.OB

- (1) Consists of: (a) 1,725,168 shares of common stock issuable upon conversion of currently outstanding shares of Series B preferred stock; (b) 542,865 shares of common stock issuable upon exercise of warrants; and (c) 204,331 shares of common stock issuable upon the exercise of Series B Preferred Stock that we are required to issue in payment of the remaining in-kind dividends on our Series B preferred stock from the date of this prospectus through September 2005.

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**Risk Factors**

You should be aware that there are various risks to an investment in our common stock, including those described below. You should carefully consider these risk factors, together with all of the other information included in this prospectus, before you decide to invest in shares of our common stock.

**We expect continued losses, which could have an adverse impact on your investment.**

We anticipate that we will continue to incur losses and negative cash flows for the foreseeable future. Since our inception as a public company, we have reported operating losses and operating cash flow deficits as we organized and launched our business operations. During this period, we incurred significant operating expenses and made significant investments in our business without an established source of revenue. Although we ceased substantially all operations in March 2004, we will continue to be required to spend substantial funds to continue our litigation efforts against Aventis and satisfy our continuing SEC reporting obligations. There can be no assurance that we will receive any proceeds from the Aventis litigation, or that if we ever re-start operations, that we will generate sufficient revenue to make us profitable. As of March 31, 2004, we had incurred cumulative losses since inception of approximately \$81.5 million.

**Our products have not achieved and might not achieve market acceptance in an essentially new market, which could limit the marketability of our assets.**

The commercial success of our products, whether marketed by us or an acquiror, 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 our tests and the receipt of regulatory clearances in the United States and elsewhere. The availability of point-of-care hemostasis test systems has been limited to date, so our point-of-care hemostasis test products are targeting an essentially new market. Diagnostic tests similar to those developed by us 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. We expect there will be resistance by central laboratories to yield control of tests they have previously performed. We, or an acquiror, will also have to demonstrate to physicians that our diagnostic products perform as intended, meaning that the level of accuracy and precision attained by our products must be comparable to test results achieved by central laboratory systems. Failure of our products to achieve broader market acceptance could have a material adverse effect on us and our ability to sell our assets to a purchaser.

Prior to ceasing substantially all operations in March 2004, we were substantially dependent upon Bayer Diagnostics as our principal distributor for marketing and distribution of our products. If we were to restart operations or sell our assets to a third party, there can be no assurance that Bayer Diagnostics, or any other distributors will be successful in marketing or selling our products or that we, or an acquiror, could build a cost-effective and adequate sales and marketing staff. The substantial dependence on distribution partners could have a material adverse effect on us and our ability to sell our assets to a purchaser.



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**Intense competition and the risk of technological obsolescence might render our products noncompetitive.**

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

Prior to ceasing substantially all operations in March 2004, we had several competitors, including Roche Diagnostics, International Technidyne Corporation and Medtronic, that manufacture and market point-of-care coagulation and hematology test systems. International Technidyne Corporation, in particular, has a large installed base of systems, which it has been selling for over 20 years. Despite the fact that we believe that TAS is capable of competing favorably with these systems, International Technidyne Corporation's installed base could give it a competitive advantage. We believe 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. 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 our products. 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 us. Even if we attain sufficient financial resources to restart operations, there can be no assurance that we can rebuild our sales and marketing team and operational workforce in order to be competitive. 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 we do in research and development, obtaining regulatory clearances, manufacturing and marketing, and may therefore represent significant competition for us. There can be no assurance that our competitors will not succeed in developing or marketing technologies and products that will be more effective or less expensive than those formerly marketed by us or that would render our technology and products obsolete or noncompetitive. Even if we attain sufficient financial resources to restart operations, there can be no assurance that we can rebuild our sales and marketing team and operational workforce in order to be competitive.

**Our heavy dependence on patents and proprietary technology could be costly to us.**

Our success, or the success of an acquiror of our assets, will depend in part on the ability to enforce our patents, to preserve our trade secrets and to operate without infringing the proprietary rights of third parties. The scope of any patent protection might not exclude competitors or provide competitive advantages to us or an acquiror. Any of our patents could be held invalid if subsequently challenged and others might claim rights in or ownership to the

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patents and other proprietary rights held by us. Furthermore, others might have developed or will develop similar products, duplicate our products or design around our patents. If any relevant claims of third-party patents are upheld as valid and enforceable, we or an acquiror 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 our products or processes to avoid infringement. Such licenses might not be available or, if available, could be on unacceptable terms.

We also rely upon unpatented trade secrets to protect our proprietary technology. In particular, we believe that our 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 our proprietary technology and we 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. These factors could hinder our efforts to sell our intellectual property and other assets.

**The sale of the shares registered in this offering could cause our stock price to decline.**

All shares registered in this offering will be freely tradable upon effectiveness of this registration statement. The sale of a significant amount of shares registered in this offering, or the prospect of such a sale, at any given time could cause the trading price of our common stock to decline and to be highly volatile.

**A significant number of our shares are eligible for future sale and the sale of our shares into the market might negatively affect our stock price.**

As of May 31, 2004, we had outstanding:

warrants to purchase an aggregate of approximately 793,865 shares of our common stock; and

preferred stock that is convertible into an aggregate of approximately 2,367,668 shares of common stock.

We have also reserved for issuance 1,639,187 shares of our common stock pursuant to stock plans, under which options to purchase 563,972 shares of common stock were outstanding as of May 31, 2004.

The existence of these securities may adversely affect us or our shareholders for many reasons, including:

the market price of our common stock might be adversely affected;

if any of these securities are exercised, the value of the common stock held by shareholders will be diluted if the value of the common stock immediately prior to the exercise of these securities exceeds the exercise price;

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some of these securities give the holders of them the opportunity, at nominal cost, to profit from a rise in the market price of our common stock; and

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the terms upon which we could issue additional shares of common stock or obtain other sources of financing may be adversely affected.

Holders of warrants and options are also likely to exercise them when, in all likelihood, we could obtain additional financing from other sources on terms more favorable than those provided by the warrants and options.

### **If third-party payors do not provide coverage or reimburse patients for our products and related treatment, our ability to sell our assets and technology could suffer.**

Our ability to sell our assets and technology successfully or execute on our new business model may depend in part on the extent to which reimbursement for the cost of our 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, collectively known as 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 diminish the marketability and value of our TAS products. The cost containment measures that healthcare providers are instituting and the impact of any healthcare reform could have an adverse effect on our ability to sell our assets and may have a material adverse effect on us.

There can be no assurance that reimbursement in the United States or foreign countries will be available for any of our 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 our products. The unavailability of third-party reimbursement or the inadequacy of the reimbursement for medical procedures using our tests would have a material adverse effect on us.

### **We have issued preferred stock and could issue additional preferred stock and take other actions that might discourage third parties from acquiring us in a transaction that you might consider to be in your best interest.**

Our board of directors has the authority, without further action by the shareholders, to issue up to 1,000,000 shares of preferred stock, 65,000 of which are outstanding as Series A preferred stock and 103,508 are outstanding as Series B preferred stock, and to fix the rights, preferences, privileges and restrictions, including voting rights, of such shares. Holders of our Series A and Series B preferred stock have rights to have their shares redeemed by us in connection with a change of control. The rights of the holders of the common stock are subject to the rights of the holders of our outstanding preferred stock, and will be subject to, and may be

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adversely affected by, the rights of the holders of any preferred stock that we may issue in the future. Issuing preferred stock could have the effect of making it more difficult for a third party to acquire a majority of our outstanding voting stock, thereby delaying, deferring or preventing a change in control of our company. Furthermore, the preferred stock may have other rights, including economic rights, senior to our common stock, and as a result, issuing preferred stock could have a material adverse effect on the market value of our common stock and the price that investors might be willing to pay for your shares.

Certain provisions of our articles of incorporation and our bylaws could make it more difficult for a third party to acquire, and could discourage a third party from attempting to acquire, control of our company. Some of them eliminate the right of shareholders to act by written consent and impose various procedural and other requirements which could make it more difficult for shareholders to undertake certain corporate actions. These provisions could limit the price that certain investors might be willing to pay in the future for shares of our common stock and may have the effect of delaying or preventing a change in control of us. We may in the future adopt other measures that may have the effect of delaying, deferring or preventing a change in control of the company. Certain of these measures may be adopted without any further vote or action by the shareholders, although we have no present plans to adopt any such measures.

### **We could be exposed to product liability claims that could prevent or interfere with our efforts to sell our assets or businesses.**

We face an inherent business risk of exposure to product liability claims in the event that the use of our previously-sold products is alleged to have resulted in adverse effects. We maintain product liability insurance with coverage of up to \$15 million per claim, with an annual aggregate policy limit of \$16 million. Liability claims could exceed the coverage limits of such policies and such insurance might not continue to be available on commercially acceptable terms, or at all. We might elect or be forced to drop our insurance coverage in connection with our efforts to focus our limited remaining resources to pursue litigation against Aventis. Consequently, product liability claims could have a material adverse effect on our business, financial condition and results of operations.

### **We might not be able to use net operating loss carryforwards.**

As of December 31, 2003, we had net operating loss carryforwards for federal income tax purposes of approximately \$58.3 million, which will expire at various dates beginning in 2004 if not utilized. Our ability to use these net operating loss and credit carryforwards to offset future tax obligations, if any, may be limited by changes in ownership. In addition, our decision to cease substantially all of our operations in March 2004 makes it less likely that we would be in a position to use net operating loss carryforwards before they expire. Any limitation on the use of net operating loss carryforwards, to the extent it increases the amount of federal income tax that we must actually pay, may have an adverse impact on our financial condition.

### **We do not presently anticipate paying cash dividends on our common stock.**

We are not currently generating any significant revenues. Even if we are successful in our litigation against Aventis, we can provide no assurance that the proceeds derived therefrom,

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if any, will be sufficient to pay cash dividends on our common stock or to make any distribution at all. In addition, our outstanding preferred stock contains restrictions on our ability to declare and pay dividends on our common stock. Consequently, we do not anticipate paying any cash dividends on our common stock for the foreseeable future.

**Because we are no longer listed on the Nasdaq National Market or the Nasdaq SmallCap Market, the value and liquidity of your shares could be impaired.**

Our common stock is currently traded on the Over-the-Counter Bulletin Board. As such, our stock could be subject to what are known as the penny stock rules. The penny stock rules place additional requirements on broker-dealers who sell or make a market in such securities. Consequently, if we become subject to those rules, the ability or willingness of broker-dealers to sell or make a market in our common stock could decline. In addition, the Over-the-Counter Bulletin Board is generally a significantly less active market than the Nasdaq National Market or the Nasdaq SmallCap Market. As a result, your ability to resell your shares of our common stock, and the market price of those shares, could be adversely affected.

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**Special Note Regarding Forward-Looking Statements**

Some of the statements contained in this prospectus discuss our plans and strategies for our business and are forward-looking statements as that term is defined in the Private Securities Litigation Reform Act. The words anticipates, believes, estimates, expects, plans, intends and similar expressions are meant to identify these statements as forward-looking statements, but they are not the exclusive means of identifying them. The forward-looking statements in this prospectus reflect the current views of our management; however, various risks, uncertainties and contingencies could cause our actual results, performance or achievements to differ materially from those expressed or implied by these statements, including:

The success or failure of our efforts to prevail in our litigation against Aventis or to sell portions of our assets and technology;

Our history of losses and negative operating cash flows;

Our future capital needs and the uncertainty of additional funding; and

The other factors discussed in the Risk Factors section and elsewhere in this prospectus.

We assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise. For a discussion of important risks of an investment in our common stock, including factors that could cause actual results to differ materially from results referred to in the forward-looking statements, see the Risk Factors section of this prospectus. In light of the risks and uncertainties discussed in Risk Factors and elsewhere in this prospectus, events referred to in forward-looking statements in this prospectus might not occur.

**Use of Proceeds**

We will not receive any of the proceeds from the sale of shares of the common stock offered by the selling shareholders. We are registering the shares for sale to provide the holders thereof with freely tradable securities, but the registration of such shares does not necessarily mean that any of such shares will be offered or sold by the holders thereof.

**Selling Shareholders**

The shares offered under this prospectus may be sold from time to time for the account of the selling shareholders named in the following table. The table also contains information regarding each selling shareholder's beneficial ownership of shares of our common stock as of June 1, 2004, and as adjusted to give effect to the sale of the shares. As of June 1, 2004, we had 10,094,290 shares of common stock outstanding.

**Beneficial Ownership  
Prior To Offering**

**Beneficial Ownership  
After Offering (1)**

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(as of June 1, 2004)

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Name	Number of Shares(2)	Number of Shares To Be Sold(3)	Number of Shares	Percent of Class
Camden Partners Strategic Fund II-A, L.P.(4)	1,142,166	1,226,434		
Camden Partners Strategic Fund II-B, L.P.(4)	67,756	72,755		
AIG DKR SoundShore Private Investors Holding Fund Ltd.(5)	130,482	140,107		
BayStar Capital II, LP(6)	237,240	254,741		
Capital Ventures International(7)	142,344	152,846		
Crestview Capital Fund I, LP(8)	130,429	140,160		
Crestview Capital Fund II, LP(8)	35,586	38,211		
Crestview Capital Offshore Fund, Inc.(8)	11,815	12,686		
Mainfield Enterprises Inc.(9)	113,875	122,277	5,000	*
Omicron Master Trust(10)	118,620	127,368		
Smithfield Fiduciary LLC(11)	142,344	152,846		
SG Cowen Securities Corporation(12)	31,933	31,933		
Totals:	2,304,690	2,472,364	5,000	*%

\* Less than one percent

(1) Assumes the sale of all the shares offered hereby. This registration statement also shall cover any additional shares of common stock which become issuable in connection with the shares registered for resale hereby by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without the receipt of consideration which results in an increase in the outstanding shares of our common stock.



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- (2) Represents shares of common stock issuable upon conversion of currently outstanding shares of Series B preferred stock and upon the exercise of currently exercisable warrants.
- (3) Includes 332,840 total shares representing our obligation to issue 2.125% cumulative quarterly dividends on the Series B preferred stock through September 2005. Through June 30, 2004, 165,122 of these dividend shares have been issued to the selling shareholders, but the remaining 167,718 dividend shares have not yet been earned or issued. The number of dividend shares we have registered hereunder will be sufficient to cover all of the dividends we would be required to pay to the selling shareholders through September 2005, assuming no prior conversions or redemptions of the preferred shares. Any dividends we might elect to pay in shares of common stock, in lieu of cash, after September 2005 are not registered for resale hereunder and are not required to be so registered.
- (4) Richard M. Johnston has been appointed to our Board of Directors as the designee of the Series B preferred shareholders. Mr. Johnston, David L. Warnock, Donald W. Hughes and Richard M. Berkeley are the managing members of Camden Partners Strategic II, LLC which serves as the general partner to Camden Partners Strategic Fund II-A, L.P. and Camden Partners Strategic Fund II-B, L.P. As such, each of these individuals may be deemed indirect beneficial owners of these shares to the extent of his pecuniary interest therein. Each of these individuals disclaims beneficial ownership of these shares, except to the extent of his indirect pecuniary interest therein.
- (5) Howard Fischer, as the President of the portfolio manager of AIG DKR SoundShore Private Investors Holding Fund Ltd., has the power to vote and dispose of these shares. As such, he may be deemed the beneficial owner of these shares, which ownership he disclaims except to the extent of his pecuniary interest therein.
- (6) Steve Darby, Steven M. Lamar and Lawrence Goldfarb are the managing members of the general partner of BayStar Capital II, LP, each having the power to vote and/or dispose of these shares. As such, each of these individuals may be deemed beneficial owners of these shares, which ownership each of them disclaims except to the extent of his pecuniary interest therein.
- (7) Heights Capital Management, Inc., a Delaware corporation, has the power to vote and dispose of these shares.
- (8) Stewart Flink and Richard Levy may be deemed the beneficial owners of these shares by virtue of their power to vote and dispose of the shares. Each of them disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein.
- (9) Avi Vigder, as the President of the sub-manager of Mainfield Enterprises, Inc., has the power to vote and dispose of these shares. As such, he may be deemed the beneficial owner of these shares, which ownership he disclaims except to the extent of his pecuniary interest therein.
- (10) Omicron Capital, L.P., a Delaware limited partnership ( "Omicron Capital" ), serves as investment manager to Omicron Master Trust, a trust formed under the laws of Bermuda ( "Omicron" ), Omicron Capital, Inc., a Delaware corporation ( "OCI" ), serves as general partner of Omicron Capital, and Winchester Global Trust Company Limited ( "Winchester" ) serves as the trustee of Omicron. By reason of such relationships, Omicron Capital and OCI may be deemed to share dispositive power over the shares of our common stock owned by Omicron, and Winchester may be deemed to share voting and dispositive power over the shares of our common stock owned by Omicron. Omicron Capital, OCI and Winchester disclaim beneficial ownership of such shares of our common stock. Omicron Capital has delegated authority from the board of directors of Winchester regarding the portfolio management decisions with respect to the shares of common stock owned by Omicron and, as of April 21, 2003, Mr. Olivier H. Morali and Mr. Bruce T. Bernstein, officers of OCI, have delegated authority from the board of directors of OCI regarding the portfolio management decisions of Omicron Capital with respect to the shares of common stock owned by Omicron. By reason of such delegated authority, Messrs. Morali and Bernstein may be deemed to share dispositive power over the shares of our common stock owned by Omicron. Messrs. Morali and Bernstein disclaim beneficial ownership of such shares of our common stock and neither of such persons has any legal right to maintain such delegated authority. No other person has sole or shared voting or dispositive power with respect to the shares of our common stock being offered by Omicron, as those terms are used for purposes under Regulation 13D-G of the Securities Exchange Act of 1934, as amended. Omicron and Winchester are not affiliates of one another, as that term is used for purposes of the Securities Exchange Act of 1934, as amended, or of any other person named in this prospectus as a selling stockholder. No person or group (as that term is used in Section 13(d) of the Securities Exchange Act of 1934, as amended, or the SEC's Regulation 13D-G) controls Omicron and Winchester.
- (11) Glen Dubin and Henry Swieca may be deemed the beneficial owners of these shares by virtue of their control of the trading manager of Smithfield Fiduciary, LLC, which has voting control and investment discretion with respect to these shares. Each of the trading manager and Messrs. Dubin and Swieca disclaim beneficial ownership of these shares, except to the extent of their pecuniary interest therein.
- (12) Consists of a warrant to purchase shares of our common stock at \$7.20 per share issued in consideration for placement agent services provided to us in connection with the Series B preferred private placement. We also paid SG Cowen Securities Corporation cash commissions of \$622,700 for their services, representing 6.5% of the gross proceeds raised.

We issued an aggregate of 95,800 shares of Series B preferred stock, convertible 16.6667-for-1 into a total of 1,596,665 of our common stock, to the selling shareholders in connection with our \$9,579,990 private placement in May 2003. We also issued warrants to the

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investors to purchase a total of 510,932 shares of common stock at \$7.20 per share, along with a warrant to the placement agent to purchase 31,933 shares of common stock at \$7.20 per share, in connection with this private placement. We agreed to register for resale all of these shares, along with common stock issuable upon conversion of Series B preferred stock which we are required to issue as dividends on the Series B preferred stock through September 2005, and to pay substantially all of the expenses of offering them under this prospectus.

**Dividend Policy**

We have never paid a cash dividend on our common stock. We anticipate that for the foreseeable future any earnings will be retained for use in our business or to fund the litigation against Aventis and, accordingly, do not anticipate the payment of cash dividends on our common stock.

**Market For Securities**

Due to our failure to comply with the requirements for continued listing of our shares of common stock on the Nasdaq SmallCap Market, we were delisted from the Nasdaq SmallCap Market on May 13, 2004. Our common stock is currently listed on the OTC Bulletin Board under the symbol PHAR.OB. For each full fiscal quarter since the beginning of 2002, the high and low closing sales prices for our common stock, as reported by Nasdaq and the OTC Bulletin Board, were as set forth below. These prices are based on quotations between dealers, which do not reflect retail mark-up, mark-down or commissions, and may not necessarily represent actual transactions.

	<u>High</u>	<u>Low</u>
<b>2002</b>		
First quarter	\$ 9.88	\$ 6.50
Second quarter	\$ 8.15	\$ 4.96
Third quarter	\$ 6.99	\$ 3.50
Fourth quarter	\$ 7.04	\$ 4.89
<b>2003</b>		
First quarter	\$ 10.35	\$ 6.93
Second quarter	\$ 9.60	\$ 5.55
Third quarter	\$ 5.93	\$ 3.80
Fourth quarter	\$ 4.99	\$ 1.40
<b>2004</b>		
First quarter	\$ 2.90	\$ 1.45
Second quarter (through June 25)	\$ 2.34	\$ 0.35

On June 25, 2004, the high and low sales prices of our common stock, as reported by the OTC Bulletin Board, were \$0.48 and \$0.47, respectively. As of March 25, 2004, the number of record holders of our common stock was approximately 99 and we believe that the number of beneficial owners was approximately 3,500.

**Table of Contents****Selected Consolidated Financial Data**

You should read the selected consolidated financial data set forth below in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations, Business and our financial statements and the related notes included elsewhere in this prospectus. The historical results are not necessarily indicative of the operating results to be expected in the future.

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

	Three Months Ended March 31		Year Ended December 31,				
	2004	2003	2003	2002	2001	2000	1999
<b>RESULTS OF OPERATIONS</b>							
Net product sales to related party	1,688	1,147	\$ 5,388	\$ 3,863	\$ 2,895	\$ 3,322	\$ 1,957
Net product sales to third parties	175	15	126	227	1,644	947	1,952
Grant/royalty income			38	44	24	46	90
Development income	261	261	1,042	587	264	492	100
Total Revenue	2,124	1,423	6,594	4,721	4,827	4,807	4,099
Operating expenses:							
Cost of goods sold	1,107	683	3,922	3,495	4,046	3,590	3,179
General and administrative	2,390	1,062	4,099	4,899	4,525	3,330	2,715
Sales and marketing	396	728	3,453	1,498	1,208	1,051	799
Research and development	374	1,263	3,997	6,008	3,950	3,685	2,777
Write-down of inventory to net realizable value(2)	378		1,973				
Impairment of long-lived assets(2)			2,516				
Total operating expenses	4,645	3,736	19,960	15,900	13,729	11,656	9,470
Operating loss	(2,521)	(2,313)	(13,366)	(11,179)	(8,902)	(6,849)	(5,371)
Other income (expense), net	86	(31)	5	63	300	515	(43)
Loss from continuing operations	(2,435)	(2,344)	(13,361)	(11,116)	(8,602)	(6,334)	(5,414)
Discontinued operations:							
Income from operations							18
Loss on disposal							(826)
Net and comprehensive loss	(2,435)	(2,344)	(13,361)	(11,116)	(8,602)	(6,334)	(6,222)
Beneficial conversion feature of preferred stock			(3,459)			(3,004)	
Preferred stock dividends	(186)	(123)	(822)	(482)	(566)	(626)	
Net loss attributable to common shareholders	(2,621)	(2,467)	\$ (17,642)	\$ (11,598)	\$ (9,168)	\$ (9,964)	\$ (6,222)

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Basic and diluted loss per common share:							
Net loss attributable to common shareholders	\$ (0.26)	\$ (0.25)	\$ (1.80)	\$ (1.21)	\$ (1.03)	\$ (1.31)	\$ (0.83)
Weighted average shares outstanding	10,022	9,701	9,799	9,567	8,877	7,626	7,469
Pro forma amounts assuming SAB 101 was retroactively applied(1):							
Net and comprehensive loss attributable to common shareholders	\$ (2,621)	\$ (2,467)	\$ (17,642)	\$ (11,598)	\$ (9,168)	\$ (9,964)	\$ (5,926)
Basic and diluted loss attributable to common shareholders per share	\$ (0.26)	\$ (0.25)	\$ (1.80)	\$ (1.21)	\$ (1.03)	\$ (1.31)	\$ (0.79)

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	As of March 31	As of December 31,				
	2004	2003	2002	2001	2000	1999
<b>FINANCIAL CONDITION</b>						
Cash and cash equivalents	\$ 5,716	\$ 8,463	\$ 9,146	\$ 14,883	\$ 5,344	\$ 3,661
Short term investments	286	282	147	85	3,904	1,500
Total assets	11,260	15,267	21,702	27,014	18,314	11,647
Long term debt and capital lease obligations, excluding current portion	21	617	1,095	66	36	862
Total liabilities	4,188	5,760	7,543	3,386	3,632	2,039
Accumulated deficit	(81,477)	(78,855)	(61,214)	(49,616)	(40,448)	(30,484)
Preferred stock	12,896	12,851	7,520	7,520	8,102	
Contingently redeemable common stock				8,538		
Common shareholders' equity (deficit)	\$ (5,824)	\$ (3,344)	\$ 6,638	\$ 7,570	\$ 6,580	\$ 9,608

- (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.
- (2) In fiscal 2003, as a result of events in the fourth quarter, the Company recorded write-downs of its inventories and long-lived assets.

**Table of Contents****Supplementary Quarterly Financial Data**

Certain quarterly financial data is set forth below:

	<b>2004</b>			
	<b>First</b>			
	<b>Quarter</b>			
Total revenues	\$ 2,124,000			
Gross profit	581,000			
Net loss before preferred stock charges	(2,435,000)			
Net loss before preferred stock charges per common share	\$ (0.24)			
Net loss attributable to common shareholders	(2,621,000)			
Net loss attributable to common shareholders per common share	\$ (0.26)			
	<b>2003</b>			
	<b>First</b>	<b>Second</b>	<b>Third</b>	<b>Fourth</b>
	<b>Quarter</b>	<b>Quarter</b>	<b>Quarter</b>	<b>Quarter</b>
Total revenues	\$ 1,423,000	\$ 1,915,000	\$ 1,641,000	\$ 1,615,000
Gross profit	479,000	665,000	424,000	23,000
Net loss before preferred stock charges	(2,344,000)	(2,126,000)	(1,987,000)	(6,904,000)(a)
Net loss before preferred stock charges per common share	\$ (0.24)	\$ (0.22)	\$ (0.20)	\$ (0.70)(a)
Net loss attributable to common shareholders	(2,467,000)	(5,830,000)(b)	(2,271,000)	(7,074,000)(a)
Net loss attributable to common shareholders per common share	\$ (0.25)	\$ (0.60)(b)	\$ (0.23)	\$ (0.72)(a)
	<b>2002</b>			
	<b>First</b>	<b>Second</b>	<b>Third</b>	<b>Fourth</b>
	<b>Quarter</b>	<b>Quarter</b>	<b>Quarter</b>	<b>Quarter</b>
Total revenues	\$ 1,057,000	\$ 937,000	\$ 1,307,000	\$ 1,421,000
Gross profit	37,000	77,000	254,000	227,000
Net loss before preferred stock charges	(2,255,000)	(2,323,000)	(2,185,000)	(4,353,000)(c)
Net loss attributable to common shareholders per common share	\$ (0.24)	\$ (0.24)	\$ (0.23)	\$ (0.45)(c)
Net loss attributable to common shareholders	(2,381,000)	(2,426,000)	(2,293,000)	(4,498,000)(c)
Net loss attributable to common shareholders per common share	\$ (0.25)	\$ (0.25)	\$ (0.24)	\$ (0.47)(c)

(a) Includes \$4.5 million in write-downs of inventory and long-lived assets

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

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

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**Management's Discussion and Analysis of Financial Condition  
and Results of Operations**

**Business**

Prior to ceasing substantially all of our operations in March 2004, through our wholly-owned subsidiary Cardiovascular Diagnostics, Inc., we had developed, manufactured and marketed rapid turnaround diagnostics to assess blood clot formation and dissolution. Our products are a proprietary analyzer and dry chemistry tests, known as the Thrombolytic Assessment System, or TAS, that provide, at the point of patient care, rapid and accurate information that can affect therapy. We had also worked to establish our company in the emerging field of theranostics, or rapid near-patient testing, in which the diagnostic results may influence treatment decisions. Our tests can be used in the treatment of angina, heart attack, stroke, deep vein thrombosis and pulmonary and arterial emboli. The TAS technology can be used at the point of patient care which we believe provides many potential benefits, including faster results for better treatment of patients, reduced usage of blood products for bleeding complications, quicker patient transfers from costly critical care settings and reduced hospital costs due to less paperwork and personnel time in processing blood samples.

**Overview**

We have derived income from the following sources: TAS product sales, interest income, and development income recognized in connection with collaboration agreements. Product sales have mainly consisted of our routine test cards, the PT, aPTT, HMT, HTT, PRT and LHMT tests along with the related controls and analyzers. These products were distributed under a global distribution agreement with Bayer Diagnostics. In August 1998, we signed a five-year global distribution agreement, subject to minimum annual sales, with Chiron Diagnostics, now Bayer Diagnostics, to distribute the products. At that time and under a separate purchase agreement, we received an up-front investment of \$6 million from Bayer in exchange for 600,000 shares of our common stock, all of which were recorded as an increase to stockholder's equity. Under that agreement, Bayer agreed to purchase minimum quantities of our products covered by the agreement at pre-determined prices. The prices charged to Bayer were variable depending on purchase volumes. Subsequently, in April 2001, Bayer purchased 1,450,000 shares of our common stock at a negotiated price of \$12 per share, representing a negotiated premium to market price at that time, for \$17.4 million, all of which was recorded as an increase to stockholder's equity. At that time, this investment increased Bayer's ownership percentage in our company from approximately 7% to 19.9%. In connection with the 2001 investment, we entered into an amended distribution agreement with Bayer to replace the previous distribution agreement. Under the terms of the amended agreement, Bayer agreed to purchase, at the same pre-determined prices as in the original distribution agreement, the same products as covered by the original agreement. For these products distributed by Bayer, Bayer would send monthly purchase orders and we would transfer ownership of the product to and receive payment from Bayer. As requested by Bayer, and in accordance with Bayer's pre-determined delivery schedule, upon receipt of the committed purchase order, we would produce and transfer the product into Bayer's segregated space at our warehouse facility. We do not retain any specific performance obligation with respect to product once it has been completed and transferred to the segregated warehouse space. We sold this product to Bayer at the pre-determined prices set forth in the amended distribution agreement and Bayer took ownership of and assumed all risk for the



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inventory upon transfer and then held it for resale. Bayer does not have any right to return unsold product and has no history of requesting return. Assuming full conversion of outstanding preferred stock into common stock, Bayer now owns approximately 17% of our outstanding shares and maintains the right to designate one nominee for election to our board of directors. Currently, no representative from Bayer is a member of our board of directors, although it retains the right to name a designee in the future.

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

In December 2003, we announced that, primarily as a result of the Aventis litigation and its impact on our business and prospects, we are pursuing a variety of strategic alternatives, including the sale of our manufacturing operations. At that time, we also announced that, if a willing and able buyer for our operations is not identified, we would terminate our distribution agreement with our distribution partner, Bayer Diagnostics. As required under our distribution agreement with Bayer, we provided Bayer 90-day notice that we would terminate this agreement effective March 12, 2004. In addition, we provided 90-day notice to PDI, the contractor and provider of the Enox sales and technical support teams, that the sales and technical service personnel would be terminated by March 12, 2004. We believe these steps were and are necessary in order to reduce overhead costs and to conserve cash for the license or sale of assets and the intellectual property as well as to finance our lawsuit against Aventis. In conjunction with these actions, we recorded an impairment charge of \$2.5 million related to our long-lived assets. Since filing the lawsuit, we have implemented significant personnel reductions and have engaged Davenport & Company LLC, an investment banking firm, as our financial advisor. Davenport & Company is currently assisting us in pursuing a sale of our manufacturing operations and intellectual property. By the end of March 2004, because no buyer had yet emerged, we ended our distribution agreement with Bayer and ceased producing and selling all products. We are shifting our corporate strategy from a manufacturing/distribution model to that of a biotech model, whereby revenues, if any, would be tied to royalty streams from any future product sales. We are actively seeking a buyer for our operating assets and to sell or license our intellectual property with a significant portion of the potential valuation tied to royalties. In essence, if successful in implementing this new strategy, we would receive royalties on tests developed and would not be responsible for manufacturing and distribution.

## **Critical Accounting Policies**

The consolidated financial statements have been prepared in accordance with generally accepted accounting principles, which require us to make estimates and judgments that affect the

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reported amounts of assets, liabilities, revenues, expenses and related disclosure of contingent assets and liabilities. We evaluate the 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 auditors and members of the audit committee. Actual results could differ from these estimates. In addition, in March 2004, we ended our distribution agreement with Bayer and ceased producing and selling all products.

We believe that the following are some of the more critical judgment areas in the application of 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 our product sales in 2002, 2003 and in the first quarter of 2004 were made to our 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. We have recognized revenue related to the development agreement with Aventis. We are recognizing revenue related to the Aventis development contract, which was entered into in 2000. Previous milestone payments from Aventis, which are non-refundable, remain deferred because even though our development agreement with Aventis has been terminated, we remain under obligation not to develop another test card that would compete with Aventis through November 2006. We are recognizing development income from Aventis on a straight-line basis through November 2006.

### **Stock-Based Compensation**

We have adopted Statement of Financial Accounting Standards No. 123, Accounting for Stock Based Compensation (SFAS No. 123). As permitted by SFAS No. 123, we have chosen to continue to apply APB Opinion No. 25 Accounting for Stock Issued to Employees (APB No. 25) and related interpretations in accounting for our stock plans. Accordingly, in each period, we have 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 our common stock on the grant date. During 2002, we 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.

### **Inventories**

Inventories are stated at the lower of standard cost (which approximates cost on a first-in, first-out basis) or market. We assess our inventory on a periodic basis and recognize reserves

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when necessary. We recorded a write-down of our inventories of \$1,973,000 to reduce them to their net realizable value as of December 31, 2003. In December 2003, we notified Bayer of our intention to terminate our distribution agreement in March 2004. Due to the resulting ceasing of sales and production, we determined that excess inventories existed at December 31, 2003 and March 31, 2004 that will not be consumed or sold in the ordinary course of business. These excess inventories of raw materials, work in process and finished goods have been written-down to their net realizable values.

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

We have adopted Statement of Financial Accounting Standards No. 144 ( FAS 144 ), Accounting for the Impairment of Disposal of Long-Lived Assets . FAS 144 requires that long-lived assets be tested for impairment whenever events or changes in circumstances indicate that their carrying amount may not be recoverable. The carrying amount is not recoverable when the undiscounted cash flows expected to be generated from the use of the long-lived assets and their eventual disposition are less than their carrying amount. Our fixed assets, patents and other non-current assets are considered long-lived assets. Events occurred in our 2003 fourth quarter which indicate that the carrying amount of these assets may not be recoverable. In accordance with the provisions of the statement, we have performed impairment tests and determined that an impairment of the noted assets is present as of December 31, 2003. This analysis requires the use of judgments and estimates concerning future cash flows and fair values upon disposition of assets. We then estimated potential discounted future cash flows related to these assets under four scenarios in conjunction with a third-party valuation that arrived at a fair value. An impairment write-down of \$2,516,000 has been taken in the year ended December 31, 2003 and is included in a separate line item in our Statement of Operations. If the probabilities of the highest and lowest cash flow scenarios were adjusted upward and downward by 10%, the write-down would increase or decrease by \$1,060,000 respectively. See Notes 1, 4, 5 and 6 to the consolidated financial statements included in this prospectus.

## **Results of Operations**

We do not expect to have any operating revenue following the cessation of operations in March 2004 and operating expenses should be significantly reduced to focus almost exclusively on the Aventis litigation, potential sale of assets and maintaining our financial reporting obligations.

## **Three Months Ended March 31, 2004 vs March 31, 2003**

Net product sales for the quarter ended March 31, 2004 were \$1,863,000 compared to \$1,162,000 in the same period in 2003. Sales to Bayer represented 91% and 99% of our product sales in the quarters ended March 31, 2004 and 2003, respectively. Revenues from routine test cards and controls increased \$735,000 in the 2004 period compared to the 2003 period because Bayer increased its orders prior to termination of the distribution agreement on March 12, 2004.

Development income was \$261,000 in the quarters in March 31, 2004 and 2003. All of the development income recognized in these quarters relates to collaboration payments previously received from Aventis Pharmaceuticals in 2000, 2001 and 2002. We are recognizing these payments into income over the period of the agreement in accordance with SAB 104.

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Cost of goods sold for the quarter ended March 31, 2004 was \$1,107,000 compared to \$683,000 in the comparable period in 2003. High volumes of routine test cards and controls in the first quarter of 2004 resulted in increased costs of goods sold.

General and administrative expenses were \$2,390,000 in the first quarter of 2004 compared to \$1,062,000 for the comparable period in 2003. These expenses were higher primarily due to a \$638,000 in expenses related to severing employees during the quarter and due to increased legal expenses of \$615,000, principally related to our litigation with Aventis. Depreciation expense also increased by \$106,000 as fixed assets are being depreciated over a shorter life than in 2003. Sales and marketing expenses were \$396,000 in the first quarter of 2004 compared to \$728,000 in the same period in 2003 due to lower compensation and travel expenses of approximately \$278,000 in connection with terminating our contract sales and technical service force related to enoxaparin test as well as severing our own sales, marketing and distribution personnel. Promotion and other marketing expenses decreased \$48,000 due to ceasing marketing efforts in the first quarter in 2004. Research and development expenses decreased to \$374,000 in the first quarter of 2004 compared to \$1,263,000 in the same period in 2003 due to ceasing research and development during the first quarter of 2004 on all projects which resulted in reduced personnel and project costs.

Net interest and other income (expense) for the quarter ended March 31, 2004, which is composed of interest income, interest expense and other income, was a net income of \$86,000 compared to a net expense of \$31,000 in the first quarter of 2003. The increase was mainly due to recognition of deferred revenue at the date of termination of the Bayer agreement related to amounts previously paid to us.

During the quarters ended March 31, 2004 and 2003, we paid a dividend to Series A preferred shareholders by issuing 41,690 and 12,913 shares of common stock respectively, representing a total dividend payment for accounting purposes valued at \$100,000 and \$123,000, respectively. The number of common stock dividend shares required to be issued is determined using the average of the closing prices of the common stock as reported on the principal trading exchange over the 30-day period ending three days prior to the end of each quarter. The number of shares to be issued is then multiplied by the closing market price of our common stock on the dividend payment date to determine the amount recorded as the dividend for the period. In addition, for the quarter ended March 31, 2004, we paid dividends to Series B preferred shareholders by issuing 2,154 shares of Series B preferred stock. These shares are convertible into approximately 35,901 shares of common stock, which number is multiplied by the closing market price of our stock on the dividend payment date to determine the amount recorded as the Series B dividend of \$86,000.

**Year Ended December 31, 2003 vs. Year Ended December 31, 2002.**

Net product sales for the year ended December 31, 2003 totaled \$5.5 million compared to \$4.1 million in 2002. Our revenue from Bayer totaled approximately 98% and 94% of total product revenue during 2003 and 2002, respectively. Specialty test card sales in 2003, which included the Enox and ECT tests, totaled \$365,000 compared to \$223,000 in 2002 as the Enox test was launched in January 2003. Routine test card revenues increased to \$3.4 million compared to \$2.4 million in 2002 as Bayer increased its test card purchases due to higher

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demand from its customers. Given higher test card sales, controls revenue, which relates to the quality control products used with the test cards, also increased to \$512,000 in 2003 compared to \$342,000 in 2002. Analyzer revenues for 2003 decreased slightly to \$1.0 million compared to \$1.1 million in the prior year.

Development income was \$1.0 million for 2003 compared to \$587,000 in 2002. All of the development income recognized during both periods related to collaboration payments previously received from Aventis Pharmaceuticals. During 2002, two equal milestone payments totaling \$3 million were received from Aventis in August and November. These payments are being recognized straight-line into income over the period of the agreement (through 2006) in accordance with SAB 101. Since the \$3 million was received in the latter half of 2002, income was recognized for only part of 2002 but was recognized during all of 2003. License and royalty income was essentially unchanged from the prior year.

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

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

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

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

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

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

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

For 2003 and 2002, we paid a dividend to Series A preferred shareholders by issuing 110,110 and 81,087, respectively, shares of common stock, representing a total of \$451,805 and \$482,000 in dividends, respectively. The number of common stock dividend shares required to be issued is determined using the average of the closing prices of the common stock as reported on the Nasdaq SmallCap Market over the 30-day period ending three days prior to the end of each quarter. The number of shares to be issued is then multiplied by the closing market price of our stock on the dividend payment date to determine the amount recorded as the dividend for that period. In addition, for 2003, we paid dividends to Series B preferred shareholders by issuing 5,554 shares of Series B preferred stock. These shares are convertible into approximately 92,568 shares of common stock. Each quarter, the number of shares of common stock issuable from the Series B preferred stock dividend is multiplied by the closing market price of our common stock on the payment date to determine the amount recorded as the Series B dividend. For 2003, the Series B dividend totaled \$370,000. On the date of issuance of the Series B, the effective conversion price of the Series B was at a discount to the price of the common stock into which the Series B is convertible. In accordance with EITF 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios* and EITF 00-27 *Application of Issue No. 98-5 to Certain Convertible Instruments*, this discount totaled \$3,459,000 and was recorded as a preferred stock dividend in the second quarter of 2003. The proceeds of the offering were allocated between preferred stock and warrants issued and the \$3.5 million discount was determined by subtracting the effective conversion price of the common stock of \$4.95 from the common stock market value of \$7.12 the day before the closing and multiplying that number by the number of common shares issuable upon conversion of the preferred stock.

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**Year Ended December 31, 2002 vs. Year Ended December 31, 2001.**

Net product sales for the year ended December 31, 2002 decreased to \$4.1 million compared to \$4.5 million in 2001. Our revenue from Bayer totaled approximately 94% and 64 % of total product revenue during 2002 and 2001, respectively. Specialty test card sales in 2002 totaled \$223,000 compared to \$1.6 million in 2001. In 2001, we recorded specialty card revenue of \$1.5 million related to a payment received from AstraZeneca following their communication that they desired to terminate an interim agreement entered into in 2000. AstraZeneca had previously purchased specialty test cards in 2000 to be used in their clinical trials, but exercised their right to terminate the agreement in 2001 by paying an increased price for the test cards previously purchased. We had an obligation to supply test cards to Astra through the end of 2001, thus the \$1.5 million was recognized into sales over the final three quarters of 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 in 2002, totaling \$1.1 million compared to \$284,000 in 2001 as Bayer purchased additional units to meet customer demands. Controls revenue also increased in 2002 to \$342,000 compared to \$257,000 in 2001.

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 ours 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 accordance with SAB 101.

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. Prior to 2002, data was not available from the accounting system to capture or make an estimate of production overhead costs related to research and development activities. Thus, in 2001 all production overhead costs are reported in cost of goods sold.

General and administrative expenses in 2002 increased \$375,000 compared to 2001. Expenses related to relocating our facility decreased compared to 2001 as these costs incurred in 2001 were not incurred in 2002. In addition, we 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, we 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.

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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. We 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, we paid off debt to Transamerica Business Credit Corp. that had been entered into in 1997 to fund working capital and capital expenditures. We 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.

In February 2000, we 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 our option. During the year ended December 31, 2002, the Series A dividend was paid by issuing 81,087 shares of common stock totaling \$481,589.

## **Liquidity and Capital Resources**

At March 31, 2004, we had cash, cash equivalents and short-term investments of \$6.0 million and working capital of \$4.4 million, as compared to \$8.7 million and \$7.1 million, respectively, at December 31, 2003. During 2003 and the first quarter of 2004, we used cash in operating activities of \$8.3 million and \$1.6 million, respectively. The operating use of cash was principally due to funding our net operating loss, offset by non-cash charges for depreciation expense and the write-down inventory. Payables and accrued expenses at the end of 2003 were lower compared to 2002, which resulted in a cash outflow. Larger costs for fixed assets, inventory and clinical trials were incurred and included in payables and accrued expenses at the end of 2002 compared to 2003. Deferred revenue decreased during 2003 due to amortization of the Aventis up-front milestone payments into income, which is reflected as a use of cash. No cash inflows from development agreements occurred during 2003.

Net cash used in investing activities was \$604,000 in 2003. Net cash provided by investing activities was \$1.4 million in 2002. In 2003, we expended \$397,000 for new production machinery and for computer equipment and \$107,000 related to patents. Short-term investments increased \$130,000 in 2003 compared to 2002.

Cash provided by financing activities was \$8.3 million in 2003 as compared to \$1.8 million in 2002. Cash provided by financing activities was mainly attributable to the completion of a private placement of 95,800 shares of Series B convertible redeemable preferred stock in May 2003. See a discussion of the terms of the Series B preferred stock in **Note 11 Convertible Redeemable Preferred Stock** of the Notes to the Consolidated Financial Statements. In 2003, we paid down our long-term debt to General Electric and our capital leases by \$446,000, leaving a total of \$1,132,000 in total debt and capital leases due thereunder on December 31, 2003. Cash used in financing activities in the quarter ended March 31, 2004 was due to payments on our debt and capital leases. We paid the remaining balance of our outstanding equipment loan from General Electric (GE). The debt and capital lease paydown including repaying the remainder of the GE debt during the quarter, totaled \$1.1 million.



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We have sustained continuing operating losses in 2003 and 2004 and had an accumulated deficit of \$81.5 million as of March 31, 2004. In December 2003, we announced that, due to continued legal action against Aventis and the impact of that litigation on our operations and prospects, we are seeking strategic alternatives, including the sale of our manufacturing operations. We also announced that, if a willing and able buyer for our operations is not identified, we would terminate our distribution agreement with Bayer. We notified Bayer that we would terminate this agreement. By the end of 2004, because no buyer had yet emerged, we ended our distribution agreement with Bayer and ceased producing and selling all products. We are continuing our search for a buyer and intend to continue seeking a buyer during 2004.

We intend to pursue the lawsuit with Aventis with our existing funds, which totals approximately \$6.0 million as of March 31, 2004. During March 2004, we repaid the entire amount of our outstanding note payable with General Electric using \$976,000 of cash. We plan to eliminate capital and operating leases for office equipment by expending approximately \$200,000. In addition, we have terminated substantially all of our employees during the first quarter of 2004, resulting in severance costs of approximately \$638,000. We will continue to lease our building in 2004, resulting in anticipated expense in the last nine months of 2004 of approximately \$297,000. We believe we have sufficient resources to fund our limited on-going operating costs and the litigation with Aventis through the anticipated trial date, which is expected to occur between the first and third quarters of 2005. However, we can provide no assurance that our resources will ultimately be sufficient. Pending the outcome of the litigation, presently we do not expect to need nor do we intend to seek additional sources of financing.

Barring the receipt of proceeds from a successful completion of the Aventis litigation or revenues and profit from future operations, the holders of our common stock would not be in a position to receive proceeds from any liquidation or sale of the company unless and until the aggregate liquidation preference of approximately \$16 million held by our preferred stockholders had first been satisfied.

**Contractual Obligations**

We have contractual obligations under notes payable, capital and operating lease agreements and other obligations for years subsequent to 2003. Future payments as of December 31, 2003 are as follows:

	<b>2004</b>	<b>2005- 2006</b>	<b>2007- 2008</b>	<b>After 2008</b>	<b>Total</b>
Notes payable*	\$ 581,363	\$ 627,425			\$ 1,208,788
Capital leases**	19,521	26,028			45,549
Operating leases***	384,751	748,803	753,843	879,378	2,766,775
Other contractual obligations****	75,375				75,375
<b>Total payments \$</b>	<b>\$ 1,061,010</b>	<b>\$ 1,402,256</b>	<b>\$ 753,843</b>	<b>\$ 879,378</b>	<b>\$ 4,096,487</b>

\* The contractual obligation for principal and interest related to the loan with General Electric, totaling \$1.2 million as of December 31, 2003. This loan was repaid in full in March 2004.

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- \*\* Relates to lease expense for office equipment. We intend to eliminate the capital lease during 2004 at an estimated cost of \$50,000.
- \*\*\* These commitments are associated with operating leases. Payments due reflect future rent expense for the building and equipment. We intend to seek a sub-lease for the building and to eliminate the equipment operating leases at an estimated cost of \$150,000.
- \*\*\*\* Relates to inventory purchase commitments remaining as of the end of March 2004.

**Recent Accounting Pronouncements**

In May 2003, the FASB issued SFAS No. 150 ( SFAS No. 150 ), Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity . This Statement establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. Some of the provisions of this Statement are consistent with the current definition of liabilities in FASB Concepts Statement No. 6, *Elements of Financial Statements*. The remaining provisions of this Statement are consistent with the Board's proposal to revise that definition to encompass certain obligations that a reporting entity can or must settle by issuing its own equity shares, depending on the nature of the relationship established between the holder and the issuer. While the Board still plans to revise that definition through an amendment to Concepts Statement 6, the Board decided to defer issuing that amendment until it has concluded its deliberations on the next phase of this project. That next phase will deal with certain compound financial instruments including puttable shares, convertible bonds, and dual-indexed financial instruments. These provisions of SFAS No. 150 are effective for financial statements for fiscal years ending after June 15, 2003. The next phase of this FASB project may require us to reclassify our preferred stock from the mezzanine section to either the liabilities or equity section of the balance sheet. The application of SFAS No. 150 will not have a material effect on our operations.

In November 2002, the FASB approved FASB Interpretation No. (FIN) 45, Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of

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Indebtedness to Others . FIN 45 elaborates on the existing disclosure requirements for most guarantees. It also clarifies that at the time a company issues a guarantee, the company must recognize an initial liability for the fair value, or market value, of the obligations it assumes under that guarantee and must disclose that information in its interim and annual financial statements. The disclosure requirements of FIN 45 were effective for financial statements of interim or annual periods ending after December 31, 2002. We have adopted the disclosure provisions of this interpretation and it did not have a material impact on the consolidated financial statements.

In January 2003, the FASB approved FASB Interpretation No. (FIN) 46, Consolidation of Variable Interest Entities . The primary objectives of FIN 46 are to provide guidance on the identification of entities for which control is achieved through means other than through voting rights ( variable interest entities or VIEs ) and how to determine when and which business enterprise should consolidate the VIE (the primary beneficiary ). This new model for consolidation applies to an entity which either (1) the equity investors (if any) do not have a controlling financial interest or (2) the equity investment at risk is insufficient to finance that entity's activities without receiving additional subordinated financial support from other parties. In addition, FIN 46 requires that both the primary beneficiary and all other enterprises with a significant variable interest in a VIE make additional disclosures. This statement is effective no later than the first interim or annual reporting period beginning after June 15, 2003. The adoption of FIN 46 did not have a material impact on the consolidated financial statements.

## **Factors That Might Affect Future Results**

A number of uncertainties exist that might affect our future operating results and stock price. There can be no assurance that we will be successful in our lawsuit against Aventis or that we will find a buyer for any of our assets. See the section entitled Business-Recent Developments in this prospectus for a discussion of the status of our litigation against Aventis. Other risks include: market acceptance of TAS; our continuing losses and the resulting potential need for additional capital in the future; managed care and continuing market consolidation; competition within the diagnostic testing industry and FDA regulations and other regulatory guidelines affecting us and/or our collaborators or potential acquirors. The market price of our common stock could be subject to significant fluctuations in response to variations in our quarterly operating results as well as other factors which may be unrelated to our 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 our common stock. Securities of issuers having relatively limited capitalization are particularly susceptible to volatility based on short-term trading strategies of certain investors.

## **Quantitative and Qualitative Disclosure About Market Risk**

In the normal course of business, we are exposed to a variety of risks including market risk associated with interest rate movements. Our exposure to market risk for changes in interest rates relates primarily to any investments we may hold at various times. When investing, our 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 our usual intention to hold these investments until maturity, the impact of interest rate changes would not have a material impact on our results of operations. During 2004, we repaid our outstanding note payable with General Electric.

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**Business**

We are a holding company incorporated in North Carolina in 1998 as the parent company of Cardiovascular Diagnostics, Inc. Cardiovascular Diagnostics, Inc. was incorporated in 1985 and was our sole operating subsidiary until we ceased substantially all of our operations in March 2004.

Prior to ceasing substantially all of our operations in March 2004, we developed, manufactured and marketed rapid diagnostics to dose, manage and screen patients on drugs affecting coagulation. Our 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. Our tests were and can be used in the treatment of a variety of adverse conditions caused by abnormal blood clotting in different areas of the body, including angina, heart attack, stroke, deep vein thrombosis and pulmonary and arterial emboli.

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

Our products include our TAS analyzer and a menu of tests and controls. FDA approved tests that have been sold for commercial use are listed and described below under the subheading Products. We have sold three other tests, the Lysis Onset Time, Ecarin Clotting Time and a modified ecarin clotting time test for investigational use only which are described below under the subheading Research and Development Test Cards. In addition, we have obtained a special FDA approval, a Humanitarian Device Exemption, or HDE, for our Ecarin Clotting Time card, which can be used in managing patients suffering from heparin induced thrombocytopenia, a condition characterized by persistent decrease in blood platelets resulting from the administration of the anti-clotting drug, heparin. HDE approval is an expedited FDA authorization process to market devices used in rare disease states where no existing solution is available. In connection with the Recent Developments described below, we have ceased the development, production, sale and marketing of our test cards and other products.

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### **Recent Developments**

In November 2003, we filed a lawsuit in the eastern district of North Carolina against Aventis Pharmaceuticals, Inc. In cooperation with Aventis, we developed a rapid bedside test, known as the Enox test, that we believe enhances the way Lovenox<sup>®</sup>, a popular anti-blood clotting drug marketed by Aventis, currently is managed. We believe the test has the potential to facilitate the drug's use in patients in the cardiac community who stand to benefit from its use. Aventis collaborated with us in a multi-million dollar project in which it made milestone payments to us to develop and co-promote the test together with Lovenox for targeted patient populations. The lawsuit alleges that Aventis has engaged in false and misleading advertising of Lovenox, which damaged our efforts to market and sell the Enox test card. The lawsuit also alleges that Aventis has failed to fulfill its obligation to promote the test and is systematically and falsely advising physicians that the test is not necessary through its claims that Lovenox requires no monitoring and is therapeutic from dose one. We are seeking injunctive relief against Aventis to stop these actions and are demanding that Aventis promote the need for monitoring as required in Lovenox's labeling and as required by the development agreement we entered into with Aventis in August 2000.

In March 2004, the court hearing our case against Aventis held a hearing on our motion for a preliminary injunction against Aventis. In April 2004, Judge Louise W. Flanagan issued an order denying our request for a preliminary injunction, but in denying our motion, Judge Flanagan made a judicial determination that two of Aventis' advertising claims regarding Lovenox were literally false. First, the court found that Aventis' claim that Lovenox reaches therapeutic levels with 1/2 hour of administration to be literally false. Second, the Court found literally false Aventis' claim that Lovenox was therapeutic from dose one. Although Judge Flanagan did not grant our request for a preliminary injunction, one of the reasons cited by the court for not enjoining these false advertising messages was that Aventis has discontinued using these false statements in its advertising. In particular, after we filed our false advertising lawsuit against Aventis in November 2003, almost immediately thereafter Aventis withdrew these statements from its advertising of Lovenox.

In addition, the court found that certain disparaging statements made by Aventis representatives concerning our Enox test card were also literally false. However, rather than issue a preliminary injunction, the court ultimately left this issue for the jury to decide. The court also ruled on Aventis' motion for summary judgment in which Aventis essentially sought dismissal of our false advertising claims. In denying Aventis' motion, Judge Flanagan noted that we had raised genuine issues of material fact concerning our claims against Aventis and, accordingly, Judge Flanagan ruled that the merits of this case should ultimately be evaluated by a jury. In order to prevail in a jury trial, we must prove a variety of factual issues as well as substantiate our calculation of damages. We intend to aggressively pursue the lawsuit to enforce our rights, and we expect the lawsuit could take a year or more to complete and consume significant time and expense.

In December 2003, we announced that, as a result primarily of the Aventis litigation and its impact on our business and prospects, we are seeking a variety of strategic alternatives, including the sale of our manufacturing operations. In March 2004, because a willing and able buyer for our operations had not by then been identified, we terminated our distribution agreement with our distribution partner, Bayer Diagnostics. In addition, we terminated PDI, the

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contractor and provider of the Enox sales and technical support teams. Since filing the lawsuit, we have implemented personnel reductions and have engaged Davenport & Company LLC, an investment banking firm, as our financial advisor. Davenport & Company is currently assisting us in pursuing a sale of our manufacturing operations and intellectual property. We believe these steps were and are necessary in order to reduce overhead costs and to conserve cash for the proposed license or sale of our assets and intellectual property as well as to finance our lawsuit against Aventis. We are shifting our corporate strategy from a manufacturing/distribution model to that of a biotech model, whereby revenues, if any, would be tied to royalty streams from any future product sales. We are actively seeking a buyer for our operating assets and to sell or license our intellectual property with a significant portion of the potential valuation tied to royalties. In essence, under this new model we would be in a position to receive royalties on tests developed and would not be responsible for manufacturing and distribution. This does not preclude us from initiating future operations related to new products.

We have ceased developing, producing and selling all of our products and plan to terminate substantially all remaining employees except our chief executive officer. We plan to retain our chief executive officer to manage the Aventis litigation until it is completed or settled and to continue to seek a buyer of our operations, manufacturing assets and intellectual property. We expect to engage other personnel to conduct business for us on a contract basis as necessary during the course of these efforts. If we were to receive any proceeds in connection with the Aventis litigation, after payment of litigation and remaining operating expenses, we would consider distributing such remaining proceeds, if any, to our shareholders or using them to restart operations. Such determination would depend on a variety of factors, including the size and timing of any payments, the expenses of completing the litigation, management's assessment of the viability of restarting the business and availability of necessary personnel. However, there can be no assurance that we will prevail in the litigation against Aventis or that if we do prevail, the proceeds would be sufficient to provide significant shareholder value. At this time, we believe as a result of these cost-cutting actions, that we have the financial ability to fund the lawsuit to its conclusion.

Due to our failure to comply with the requirements for continued listing of our shares of common stock on the Nasdaq SmallCap Market, we were delisted from the Nasdaq SmallCap Market on May 13, 2004. Our common stock now trades on the Nasdaq OTC Bulletin Board.

The following discussion summarizes our business prior to ceasing our operations in March 2004.

## **Industry Overview**

Blood testing within the practice of laboratory medicine has been evolving in response to the introduction of new cardiovascular drugs and the physician's demand for information. This demand for information is particularly acute in blood testing, where access to timely and accurate results is critical to effective patient care. Initially, hospital blood analysis was performed in multiple small laboratories that typically used time-consuming manual techniques. The advent of automated blood testing allowed for centralization and standardization of laboratory tests. With improved access to blood analysis, physicians began to use laboratory tests as a primary diagnostic tool and consequently demanded more tests and faster results. In an effort to meet this demand, some hospitals established decentralized stat laboratories nearer the

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patient. These laboratories typically rely on technology designed for efficiency in a high-volume centralized department. We believe that reliance on this technology makes stat laboratories inadequate and expensive, creating a need for new technology suitable for use at the point of patient care. As diagnostics move closer to the patient, the centralized lab has had a reduced role in the purchasing decisions for point-of-care systems. The physician is more likely to have influence over the use of point-of-care technology given its ability to be a valuable tool for managing therapy.

Timely and accurate coagulation test results are important because a majority of the drugs used to regulate clotting are cleared rapidly from the body and these drugs must be closely monitored to maintain drug levels within a safe and effective treatment range. Recent advances in technology allow many blood tests to be performed at the point of patient care, where the physician can most effectively use test results. While speed is important in point-of-care testing, accuracy is critical. Because point-of-care testing is often performed by operators who lack special laboratory skills or training, error-proof testing systems are important. 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. Our 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. Our 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. We believe that TAS is the only point-of-care system capable of monitoring both coagulation and dissolution of clots. Furthermore, the TAS technology has the flexibility to allow new tests to be developed by using different reagents in the test cards.

## **Products**

### *TAS Analyzer*

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

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The analyzer and test cards are designed to work effectively in a decentralized testing environment where they can be used by healthcare personnel who do not need formal central laboratory training. To operate TAS, a test card is passed through the magnetic strip reader of the analyzer, which automatically initiates quality controls and begins to elicit information from the operator through a series of prompts outlining the operating procedure for the specific test to be performed. The test card is then inserted into the TAS analyzer. A single drop of unprocessed, noncitrated or citrated whole blood or plasma is then placed into the reaction chamber of the test card, which already contains the appropriate mixture of dry reagents and PIOP for the test being performed. Typically within three minutes, the screen on the TAS analyzer displays a numerical test result, which is comparable to the result which would be achieved in a central laboratory using traditional testing procedures. The portable analyzer has been designed with a memory capability, may be connected to a printer, and with a software upgrade may be connected to the hospital's patient information system. The internal memory of the TAS analyzer allows for the storage of up to 1,000 individual test results and has an alphanumeric keypad that allows for the input of up to a 20-character patient identification code. Additionally, the keypad provides for coded entry so only authorized personnel can gain access to the system. The analyzer can operate either on wall current or on an internal rechargeable battery.

### *Accent*

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

### *FDA-Cleared Test Cards*

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

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

The PT, or Prothrombin Time, test is a general screening test that is used to assess a patient's baseline blood clotting function or to monitor the use of oral anticoagulants, such as warfarin. Warfarin is widely used in the United States for long-term treatment in patients who have previously developed clots, including after heart attacks, to inhibit clot formation and reduce the risk of developing additional clots. Physicians use the PT test



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to monitor and maintain drug levels within a safe treatment range; too little warfarin will not prevent a new clot from developing, and too much of the drug may result in a bleeding complication. Prior to ceasing operations in March 2004, we manufactured and sold three different types of PT test cards, a general purpose PT test card routinely used in the United States, the PT One, which uses a more sensitive scale of measurement, and the PT-NC, which is used with finger stick samples.

The aPTT, or Activated Partial Thromboplastin Time, test is a coagulation screening test which may be used in conjunction with the PT test to provide a global assessment of a patient's ability to form a blood clot. In addition, the aPTT test is used to monitor heparin, an injectable anticoagulant. Hospitals routinely use heparin as the initial treatment for patients with a blood clot, including patients suffering from heart attacks or strokes. Heparin also prevents blood clots from forming in patients undergoing procedures involving particular risks of clotting, such as angiography, open heart surgery, dialysis and several other surgeries. Heparin must be closely monitored to assure adequate anticoagulation without increasing the risk of developing a bleeding complication. Time is particularly important when monitoring heparin, since the intravenously administered drug affects a patient's coagulation system within minutes.

Generally, aPTT tests are incapable of monitoring high levels of heparin. The HMT, or Heparin Management Test, is a coagulation test for monitoring patients requiring high dose heparin therapy during procedures such as open heart surgery or dialysis. For example, during the course of an open heart surgery, the patient's blood may be tested as many as four to six times to assure an adequate heparin effect. We believe that our HMT test is a more effective test than comparable tests because it is easier to use and less prone to operator error. Also, it is not sensitive to changes in blood temperature or dilution, such as typically occur during bypass surgery.

In addition, we developed two more test cards that can be combined with our HMT test to provide a system for individualized heparin management during cardiac surgery. The HTT, Heparin Titration Test, and the PRT, Protamine Response Test, cards are combined with the HMT to provide a system for total individualized heparin management during cardiac surgery. Heparin management is complicated due to patients' widely variable response to this drug as well as its clearance rate from the blood during surgery. Heparin dosing based on weight-based protocols is often unreliable, particularly in complicated cases with patients receiving simultaneous therapy. We believe the HTT/PRT approach should make it easier and cost effective to incorporate individual heparin management into routine practice.

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

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

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*Research and Development Test Cards*

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

<b><u>Test</u></b>	<b><u>Description</u></b>
Ecarin Clotting Time	Test to monitor direct thrombin inhibitors for use in patients treated for heart attack or prevention of deep vein thrombosis. Sold under the HDE program.
Thrombin Inhibitor Management	Test to allow the monitoring of oral antithrombin drugs for treatment of DVT and atrial fibrillation. The test was submitted to the FDA for review in April 2003 and we are awaiting completion of the FDA review.
Synthetic Xa inhibitors	Test designed to monitor the anticoagulant effect of pentasaccharides. This test has been through feasibility study and subsequent development would require field and clinical trials.
LR Enox	Test to detect the anticoagulant effects of enoxaparin sodium in special patient populations receiving enoxparin for treatment of prophylaxis of deep vein thrombosis. This test has been developed through field trials and subsequent development would require clinical trials.
LRF	Test to monitor the effects of Ancrod, a fibrinogen-lowering drug for the treatment of stroke. This test has been developed through feasibility and subsequent development would require field and clinical trials.
SK Panel	Test to assess response to streptokinase. This test has been developed through feasibility and subsequent development would require field and clinical trials.
Lysis Onset Time	Test to monitor a patient's lytic response to any thrombolytic drug used for the treatment of heart attack, stroke or other thrombotic diseases. This test has been developed through feasibility and subsequent development would require field and clinical trials.

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

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### *Quality Control Products*

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

### **Sales, Marketing and Distribution**

We have substantially ceased all sales, marketing and distribution activities relating to all of our products. Our marketing strategy for most of our test cards formerly relied on a distribution partner. In August 1998, we 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, we received an up-front investment of \$6 million in exchange for 600,000 shares of our common stock. Additionally, in April 2001, Bayer purchased 1,450,000 shares of our common stock at \$12 per share for \$17.4 million. This investment increased Bayer's ownership percentage in our company from approximately 7% to 19.9% at that time. In connection with the investment, we entered into an amended distribution agreement with Bayer to replace the previous distribution agreement. Under the terms of the amended agreement, Bayer was required to purchase, at pre-determined prices, our routine test cards identified in the agreement. Bayer provided a six-month rolling purchasing forecast, three months of which represented firm orders. We generally sought to maintain a two to three month level of inventory on hand to meet the firm purchasing forecasts.

We also expanded our relationship with Bayer to cover collaborative distribution and supply of certain theranostic tests in the United States, principally the enox test card. Under the provisions of the agreement related to these specialty tests, which agreement expired in March 2004, Bayer was responsible for taking the orders, shipping and collecting receivables for these tests sold by our contract sales team. In return, Bayer received a 10% commission. This arrangement enabled the customer to order all of our products from a single source.

We also marketed TAS products in the European Union, Australia and Canada with Bayer formerly acting as our exclusive distributor for all our products in these territories.

In December 2003, we announced that, as a result primarily of the Aventis litigation and its impact on our business and prospects, we are seeking a variety of strategic alternatives, including the sale of our manufacturing operations. In connection with these developments, we terminated our distribution agreement with our distribution partner, Bayer Diagnostics. In addition, we terminated our relationship with PDI, the contractor and provider of the Enox sales and technical support teams.

As part of our former marketing strategy for the enox test, during 2003, we hired a contract sales force of 9 sales people located throughout the United States, and six contract technical service representatives, to work with Aventis' Lovenox® sales force, which numbers approximately 700. We believe 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.

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Any future sales of our products, by us or by a potential acquiror, will depend, not only upon the outcome of the Aventis litigation and our ability to restart or sell the business to a third party, but also upon acceptance of these products by the medical community as being useful and cost-effective. Market acceptance will depend upon several factors, including the establishment of the utility and cost-effectiveness of our tests and the receipt of regulatory clearances in the United States and elsewhere. Coagulation testing has historically been performed and dominated by the hospital's central laboratory and the approval of the purchase of diagnostic equipment by a hospital is generally controlled by its central laboratory. Along with several of our competitors, we have sought to develop and sell into the newer and developing market for point-of-care coagulation testing. Central laboratories may resist yielding control of tests they have previously performed. We, or others, will also have to demonstrate to physicians that our diagnostic products perform as intended, meaning that the level of accuracy and precision attained by the products must be comparable to test results achieved by central laboratory systems.

## **Collaborations**

We have substantially ceased all of our collaboration efforts in connection with the cessation of our operations in March 2004. Over the past several years, our strategy was 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 we believe physicians will increasingly demand therapeutic drug monitoring. To further the goal of establishing our company in the emerging field of theranostics, we 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 we developed 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 test cards to monitor direct thrombin inhibitors, we have a worldwide exclusive sublicense from Abbott to use the reagent associated with the test. We believe 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, during 2003, we filed a 510(k) submission with the FDA for our Thrombin Inhibitor Management Test for the rapid management of The Medicines Company's anticoagulant, Angioma® and are awaiting completion of the FDA review. We do not currently intend to pursue further regulatory approval for any other test.

## **Competition**

The medical diagnostic testing industry has been characterized by rapidly evolving technology and intense competition. The TAS menu competed in the coagulation and hematology testing market with manufacturers that provide testing equipment to central and stat laboratories of hospitals. These laboratories currently perform a substantial portion of such testing. The TAS menu also competed with other point-of-care coagulation and hematology test system manufacturers. Laboratories provide some of the same tests performed by TAS;

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however, these laboratory tests generally require the use of skilled technicians and complex, expensive equipment. We believe that TAS offers several advantages over these laboratory-based instruments, including faster results, ease-of-use, reduced opportunity for error and cost-effectiveness.

Prior to ceasing operations in March 2004, we formerly competed with several companies, including Roche Diagnostics, International Technidyne Corporation and Medtronic, that manufacture and market point-of-care coagulation and hematology test systems. International Technidyne Corporation, in particular, has a large installed base of systems, which it has been selling for over 20 years. Despite the fact that we believe that TAS competed favorably with these systems, International Technidyne Corporation's installed base could give it a competitive advantage. Other manufacturers and academic institutions may be conducting research and development with respect to blood testing technologies and other companies may in the future engage in research and development activities regarding products that compete with those of the Company. Many of the companies in the medical technology industry, including those listed above, have substantially greater capital resources, research and development staffs, sales and manufacturing capabilities and manufacturing facilities than us. 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 we do in research and development, obtaining regulatory clearances, manufacturing and marketing, and may therefore represent significant competition for our products. There can be no assurance that our competitors will not succeed in developing or marketing technologies and products that will be more effective or less expensive than ours or that would render our technology and products obsolete or noncompetitive.

## **Patents and Other Intellectual Property**

We historically pursued patent applications to provide protection from competitors. A number of U.S. and corresponding international patents have been issued to us covering various aspects of the TAS technology. These patents expire between 2004 and 2013. The value of our technology will depend in part on our ability to enforce our patents, to preserve our trade secrets and for such technology to be put to use without infringing the proprietary rights of third parties. Our ability to protect our proprietary position could be jeopardized by our current lack of resources and our inability to pursue additional patents or monitor and enforce our rights under existing patents. 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 us, that any of our 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 we hold. Furthermore, others might have developed or will develop similar products, duplicate our products or design around our patents. If any relevant claims of third-party patents are upheld as valid and enforceable, we, or an acquiror of our business, 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 our products or processes to avoid infringement. Such licenses might not be available or, if available, could be on terms unacceptable to us or an acquiror of our business.

We also historically relied upon unpatented trade secrets to protect our proprietary technology. In particular, we believe that our custom-designed automated test card production line embodies proprietary process technology. Others may independently develop or otherwise

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acquire equivalent technology or otherwise gain access to our proprietary technology and we 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**

We are a party to a License Agreement with Tokuyama Soda Company, Ltd. pursuant to which we 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 we negotiate in good faith with Tokuyama for 90 days prior to marketing or licensing in these Asian nations any new products that we develop 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 us royalties based on Tokuyama's net sales of licensed products. We 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 we provided notice thereof.

In December 1995, we amended the Tokuyama license to, among other things, provide us 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 we exercise this right, we and Tokuyama may both market in the country and must each pay royalties to the other. To date, we have not exercised this right. The amendment also provides that we own all rights outside Asia to improvements made by Tokuyama to our technology, and must pay royalties to Tokuyama based on our net sales of products incorporating such improvements.

We received royalty payments under this agreement of \$38,366, \$43,705 and \$24,000 during the years ended December 31, 2003, 2002, and 2001, respectively.

### **Manufacturing**

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

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



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Most of the raw materials and components used to manufacture our TAS products are readily available. However, some of these materials are obtained from a sole supplier or a limited group of suppliers. PIOP and some reagents used in the TAS test cards are obtained from single sources. The reliance on sole or limited suppliers and the inability to maintain long-term agreements with suppliers involves several risks, including the inability to obtain an adequate supply of required raw materials and components and reduced control over pricing, quality and timely delivery. Any interruption in supply could have a material adverse effect on any future production of these products, whether by us or any other party acquiring our assets.

## **Government Regulation**

### *FDA*

The medical devices previously marketed and manufactured by us 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 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 us.

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 premarket approval process. All of our currently FDA-cleared products have qualified for either the 510(k) process or the accelerated HDE process. Commercial distribution of a device for which a 510(k) is required can begin only after the FDA issues an order finding the device to be substantially equivalent to a predicate legally marketed medical device. The FDA has recently been requiring a more rigorous demonstration of substantial equivalence than in the past. It generally takes from four to twelve



months from submission of a 510(k)

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application to obtain a 510(k) clearance, but it might take longer. The FDA might determine that a proposed device is not substantially equivalent to a legally marketed device, or that additional information is needed before a substantial equivalence determination can be made. A request for additional data might require that additional clinical studies of the device's safety and efficacy be performed. A not substantially equivalent determination or a request for additional information could delay the market introduction of new products that fall into this category. For any of our products that were cleared through the 510(k) process, modifications or enhancements that could significantly affect the safety or efficacy of the device or that constitute a major change to the intended use of the device would require a new 510(k). If the FDA requires us, or an acquiror, to submit a new 510(k) for any modification to the device, we, or any acquiror, might be prohibited from marketing the modified device until the 510(k) is cleared by the FDA.

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

the device will be used for investigational purposes only;

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

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

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

The failure of us or recipients of our investigational use only products to comply with these requirements could result in enforcement action by the FDA.

Any products formerly manufactured or distributed by us 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, when we were still conducting operations, imposed certain procedural and documentation requirements upon us 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.

### *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

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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 premarket approval 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 we have previously exported that do not have premarket clearance in the United States include the Lysis Onset Time test, the Ecarin Clotting Time test and the modified Ecarin Clotting Time test. We have obtained CPEs for these tests. We believe that these products are subject to the 510(k) requirements and, consequently, did not request FDA approval for export. However, there can be no assurance that the FDA would agree with us that a 510(k) is needed rather than a premarket approval. If the FDA disagreed, it could significantly delay and impair our ability to export these tests, if we or an acquiror desired to do so in the future.

### *Foreign Regulations*

Sales of our 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 could affect the efficiency and timeliness of international market introduction of our products, and there can be no assurance that we, if we so desired to do so in the future, would be able to obtain regulatory approvals or clearances for our 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 sales of the affected products.

In marketing our products in the member countries of the European Union prior to cessation of operations in March 2004, we were 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 our applicable products formerly marketed in Europe had obtained CE Mark certification. The TAS Analyzer also must and does meet the requirements of the Electromagnetic Capability Directive. In Japan, we rely upon our collaborative partner, Tokuyama, to comply with applicable regulations regarding the product listing, manufacture and sale of products in that country. We believe that our products are in compliance with applicable regulations in Japan.

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*CLIA*

Our 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. If such a categorization occurred, future sales of products, if any, could be adversely impacted. 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 our products.

*Other Regulations*

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

**Reimbursement**

Our, or an acquiror s, ability to commercialize our products successfully in the future may depend in part on the extent to which reimbursement for the cost of such products and related treatment will be available from government health administration authorities (such as the Health Care Financing Administration, or HCFA), which determines Medicare reimbursement levels, private health insurers and other organizations, collectively known as 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 our TAS products. The cost containment measures that healthcare providers are instituting and the impact of any healthcare reform could have an adverse effect on our, or an acquiror s, ability to sell our products in the future.

There can be no assurance that reimbursement in the United States or foreign countries will be available for any of our 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

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our products. The unavailability of third-party reimbursement or the inadequacy of the reimbursement for medical procedures using our tests would have a material adverse effect on any future sale of the products.

## **Product Liability and Insurance**

We face an inherent business risk of exposure to product liability claims in the event that the use of our products is alleged to have resulted in adverse effects. We maintain 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 our business prospects and financial condition.

## **Employees**

In connection with the cessation of our operations, we eliminated all of our employees, except for our chief executive officer and a relatively small team of independent contractors to handle the limited administrative and financial responsibilities pending the outcome of the Aventis litigation.

We maintain a \$500,000 key man life insurance policy on our chief executive officer. The loss of the service of this officer could have a material adverse effect on our ability to continue our litigation against Aventis. Any potential resumption of our operations in the future would depend in large part upon our ability to rehire, attract and retain highly skilled technical, management and sales and marketing personnel. Competition for such personnel is intense, and there can be no assurance that we would be successful in attracting and retaining such personnel.

## **Properties**

Our offices are located at 9401 Globe Center Drive, Suite 140, Morrisville, North Carolina 27560. We currently lease and occupy approximately 55,000 square feet of development, production and administration space at this location.

## **Legal Proceedings**

In November 2003, we filed a lawsuit in the eastern district of North Carolina against Aventis Pharmaceuticals, Inc. In cooperation with Aventis, we had developed a rapid bedside test, known as the Enox test, that we believe enhances the way Lovenox®, a popular anti-blood clotting drug marketed by Aventis, currently is managed. We believe the test has the potential to facilitate the drug's use in patients in the cardiac community who stand to benefit from its use. Aventis collaborated with us in a multi-million dollar project in which it made milestone payments to us to develop and co-promote the test together with Lovenox for targeted patient populations. The lawsuit alleges that Aventis has engaged in false and misleading advertising of Lovenox, which damaged our efforts to market and sell the Enox test card. The lawsuit also alleges that Aventis has failed to fulfill its obligation to promote the test and is systematically and falsely advising physicians that the test is not necessary through its claims that Lovenox requires no monitoring and is therapeutic from dose one. We are seeking injunctive relief



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against Aventis to stop these actions and demanding that Aventis promote the need for monitoring as required in Lovenox's labeling and as required by the development agreement we entered into with Aventis in August 2000.

In March 2004, the court hearing our case against Aventis held a hearing on our motion for a preliminary injunction against Aventis. In April 2004, the court issued an order denying our request for a preliminary injunction, but in denying our motion, the court made a judicial determination that two of Aventis' advertising claims regarding Lovenox were literally false. First, the court found that Aventis' claim that Lovenox reaches therapeutic levels with 1/2 hour of administration to be literally false. Second, the court found literally false Aventis' claim that Lovenox was therapeutic from dose one. Although the court did not grant our request for a preliminary injunction, one of the reasons cited by the court for not enjoining these false advertising messages was that Aventis has discontinued using these false statements in its advertising. In particular, after we filed our false advertising lawsuit against Aventis in November 2003, almost immediately thereafter Aventis withdrew these statements from its advertising of Lovenox.

In addition, the court found that certain disparaging statements made by Aventis representatives concerning our Enox test card were also literally false. However, rather than issue a preliminary injunction, the court ultimately left this issue for the jury to decide. The court also ruled on Aventis' motion for summary judgment in which Aventis essentially sought dismissal of our false advertising claims. In denying Aventis' motion, the court noted that we had raised genuine issues of material fact concerning our claims against Aventis and, accordingly, the court ruled that the merits of this case should ultimately be evaluated by a jury. In order to prevail in a jury trial, we must prove a variety of factual issues as well as substantiate our calculation of damages. We intend to aggressively pursue the lawsuit to enforce our rights, and we expect the lawsuit could take a year or more to complete and consume significant time and expense.

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Our executive officers and directors and their ages as of June 1, 2004 are as follows:

<u>Name</u>	<u>Age</u>	<u>Positions</u>
John P. Funkhouser	50	President, Chairman and Chief Executive Officer
John K. Pirotte	54	Director
Stephen R. Puckett	51	Director
Richard M. Johnston	69	Director
James B. Farinholt, Jr.	69	Director

*John P. Funkhouser* was elected our President, Chief Executive Officer and a director in October 1993. Before his employment with us, 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.

*John K. Pirotte* has been President of Axxiom Manufacturing, Inc., a privately held manufacturer of air blast equipment since 2003. He has also been Chairman and Chief Executive Officer of CORPEX Technologies Inc., a privately held company that develops and markets surface active chemical technology, since 1990 and President of Matrix Surface Technologies Inc., a privately held company that develops and markets mechanical surface treatment technologies, since 1997. Mr. Pirotte also was President and Chief Operating Officer of Teleion Wireless, Inc., a privately held wireless data communications company, from August 2000 to March 2002. He is a member of the Board of Directors of Digital Recorders, Inc. a NASDAQ listed company (symbol TBUS) that manufactures and sells advanced technology products to the transportation industry. He is a founding director of North Carolina Enterprise Corp., a venture capital fund. Mr. Pirotte holds a B.A. degree from Princeton University and an M.S. from New York University Graduate School of Business Administration.

*Stephen R. Puckett* is Chairman of the Board of Directors of MedCath Incorporated, a provider of cardiology and cardiovascular services that he founded in 1988. He also formerly served as President and Chief Executive Officer of MedCath. He is also Chairman of the Board of Hospital Partners of America, Inc. He has also served as Executive Vice President and Chief Operating Officer of the Charlotte Mecklenburg Hospital Authority. Mr. Puckett holds a B.S. and an M.S. in Health Management from the University of Alabama.

*Richard M. Johnston* serves on the Board of Managers, is the Chairman and Executive Vice President of Camden Partners, Inc., and Chairman and Chief Executive Officer of Camden Partners Holdings L.L.C. Mr. Johnston joined Camden Partners in 2000. Previously, Mr. Johnston was Vice President Investments and a Director of The Hillman Company where he was employed since 1961. The Hillman Company is an investment holding company with diversified operations. Mr. Johnston is a director of several private companies, including Medivance, Inc., Webmedx, Inc., Atricare, Inc., Masterplan, and Lombard Medical plc. He was



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Chairman of the Board of The Western Pennsylvania Hospital from 1979 to 1999, The Western Pennsylvania Healthcare System from 1984 to 2000, and the West Penn Allegheny Health System from inception in 2000 to 2002. Mr. Johnston holds a B.S. degree from Washington and Lee University and a M.B.A. from The Wharton Graduate School, University of Pennsylvania.

*James B. Farinholt, Jr.* is a Managing Director of Tall Oaks Capital Partners, LLC, which manages an investment fund focused on businesses primarily in information technology and the life sciences. Mr. Farinholt retired in 2002 as Special Assistant to the President for Economic Development of Virginia Commonwealth University, advising on campus expansion and commercialization of scientific discoveries. He is a member of the Board of Directors of the Virginia Commonwealth University Intellectual Properties Foundation. He is also a member of the Board of Directors of Owens & Minor, a public company that is the nations largest distributor of brand name hospital supplies. Mr. Farinholt holds a B.S. from Hampden-Sydney College.

**Executive Compensation***Summary Compensation*

The following table reflects all cash and noncash compensation paid by us for services rendered to us in all capacities for the fiscal years ended December 31, 2003, 2002 and 2001 to our chief executive officer and the other two executive officers whose cash compensation for the year ended December 31, 2003 exceeded \$100,000:

Name and Principal Position	Annual Compensation			Long-Term Compensation	All Other Compensation
	Year	Salary	Bonus	Awards Options/SARs	
John P. Funkhouser, President, Chief Executive Officer	2003	\$ 280,000	\$	\$	\$ 26,475(4)
	2002	250,000	30,000	238,762(3)	24,175(5)
	2001	250,000	25,000		9,375(6)
Michael D. Riddle, Vice President, Sales, Marketing & Business Development(1)	2003	189,231			20,138(8)
	2002	175,000	25,000	62,973(7)	20,738(9)
	2001	170,654	8,500		13,575(10)
James A. McGowan, Vice President, Chief Financial Officer(2)	2003	153,846			19,499(11)
	2002	200,000	35,000		33,713(12)
	2001	200,000	15,000		25,665(13)

(1) Mr. Riddle resigned in November 2003.

(2) Mr. McGowan resigned in June 2003.

(3) Does not represent a new grant, but rather an extension of the term of prior grants otherwise scheduled to expire in 2004. The exercise price of the extended options was not changed.

(4) Consists of car allowance of \$4,600 and \$21,875 vesting in contributions to the Supplemental Executive Retirement Plan

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- (5) Consists of car allowance of \$2,300 and \$21,875 vesting in contributions to the Supplemental Executive Retirement Plan
- (6) Consists of vesting in contributions to the Supplemental Executive Retirement Plan
- (7) Includes options for the purchase of 22,973 shares that do not represent a new grant, but rather the extension of the term of prior grants otherwise scheduled to expire in 2004 and 2005.
- (8) Consists of car allowance of \$7,200 and \$12,938 vesting in contributions to the Supplemental Executive Retirement Plan
- (9) Consists of car allowance of \$7,800 and \$12,938 vesting in contributions to the Supplemental Executive Retirement Plan
- (10) Consists of car allowance of \$7,200 and \$6,375 vesting in contributions to the Supplemental Executive Retirement Plan
- (11) Consists of apartment lease of \$8,520, car allowance of \$1,675, \$1,804 in 401k matching contributions and \$7,500 vesting in contributions to the Supplemental Executive Retirement Plan
- (12) Consists of apartment lease of \$17,040, \$1,673 in 401k matching contributions and \$15,000 vesting in contributions to the Supplemental Executive Retirement Plan
- (13) Consists of apartment lease of \$17,040, \$1,125 in 401k matching contributions and \$7,500 vesting in contributions to the Supplemental Executive Retirement Plan

**Table of Contents***Option Grants, Exercises and Holdings and Fiscal Year-End Option Values*

There were no option grants in 2003 to our chief executive officer or the other two executive officers whose cash compensation for the year ended December 31, 2003 exceeded \$100,000.

The following table sets forth information concerning option exercises during 2003 and option holdings as of December 31, 2003 by our chief executive officer and the other two executive officers whose cash compensation for the year ended December 31, 2003 exceeded \$100,000.

**Fiscal Year-End Option Values**

Name	Shares Acquired on Exercise	Value Realized	Number of Unexercised Options at December 31, 2003		Value of Unexercised In-the- Money Options at December 31, 2003(1)	
			Exercisable(2)	Unexercisable(2)	Exercisable(2)	Unexercisable(2)
John P. Funkhouser			395,410	50,000	\$ 260,251	\$
Michael D. Riddle	22,973	\$ 15,162	0	0		
James A. McGowan			0	0		

- (1) Calculated by subtracting the exercise price from \$1.88, the closing price of our common stock as reported by the Nasdaq SmallCap Market on December 31, 2003, the last business day of the fiscal year ended December 31, 2003, and multiplying the difference by the number of shares underlying each option.
- (2) The first number represents the number or value (as called for by the appropriate column) of exercisable options; the second number represents the number or value (as appropriate) of unexercisable options

**Equity Compensation Plan Information**

The following table provides information as of December 31, 2003 on all our equity compensation plans currently in effect.

Plan Category	(a)	(b)	(c)
		Number of securities to be issued  upon exercise of outstanding options or warrants	Weighted- average exercise price of outstanding options or warrants

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			<u>reflected in column (a)</u>
Equity compensation plans approved by shareholders:			
1994 and 1995 Stock Option Plans	1,110,069	\$ 5.20	589,326
Equity compensation plans not approved by shareholders:			
Warrants issued to Series A and B preferred stock placement agents	43,933	\$ 8.18	0
<b>Total</b>	<b>1,154,002</b>	<b>\$ 5.31</b>	<b>589,326</b>

The warrants to purchase 41,933 shares of our common stock issued to our Series A and Series B preferred stock placement agents were not required to be, and were not, approved by our shareholders. These warrants were issued as compensation to the placement agents for our

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Series A and Series B preferred stock offerings completed in February 2000 and May 2003, respectively. The warrants have standard price-based antidilution protection for issuances at less than fair market value.

## **Employment Agreements and Termination of Employment and Change of Control Agreements**

In the interest of promoting organizational stability in the context of a potential acquisition or change of control, we entered into a change of control agreement with Mr. Funkhouser in October 1997. Under this agreement, if Mr. Funkhouser resigns or his employment is terminated for any reason within two years following a change of control of our company, he is entitled to receive a severance payment from us, payable in full and in cash within 30 days, equal to two times the total compensation paid by us to Mr. Funkhouser, including all wages, salary, bonuses and incentive compensation, during the twelve months preceding the year in which the severance obligation becomes payable.

In July 2003, we entered into a transitional employment agreement with Mr. McGowan, pursuant to which we engaged him to render, at our request, services as we deemed necessary in order to maintain continuity with customers and contacts. The term of the transitional agreement was for three months. Pursuant to this agreement, Mr. McGowan waived certain severance benefits under his original employment letter agreement and we agreed to pay him \$16,667 per month during the 3-month transition period.

In October 2003, we entered into a consulting agreement with Mr. Riddle, pursuant to which we engaged him to render, at our request, consulting and advisory services in order to maintain continuity of relationships with customer and contacts and to be available to assist with our litigation against Aventis. The term of the consulting agreement is one year, commencing on December 1, 2003. Pursuant to this agreement, we agreed to pay Mr. Riddle \$50,000 for his continued employment through November 30, 2003 and \$50,000 for his consulting services during the remainder of the consulting term.

In April 2004, we entered into a new employment agreement with Mr. Funkhouser to continue his employment as our chief executive officer for a term of one year, subject to automatic one-year renewals so long as we continue to have shares of our common stock registered under Section 12 of the Securities Act of 1933. Mr. Funkhouser will receive as compensation thereunder a base salary of \$170,000 per year and such other benefits as he has received during his employment with us and as are provided from time to time to our other executive employees, if any. During the term of this agreement, or any renewal thereof, unless Mr. Funkhouser is terminated for cause or due to death or disability or his voluntary termination, we cannot terminate his employment and are required to continue to pay him his then-current base salary for the remainder of the term.

## **Supplemental Executive Retirement Plan**

Effective February 21, 2001, we implemented a non-qualified Supplemental Executive Retirement Plan, or SERP. All of our executive officers are eligible for the plan. SERP agreements have been entered into with each of Messrs. Funkhouser, Riddle and McGowan. The SERP is a non-qualified, unfunded, deferred compensation plan in which each participant's account is represented by an unsecured promise by us to pay future benefits. Provided the

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participant continues to be a full-time employee, we have agreed to provide credits to each participant's account, the timing and amount to be determined by our board of directors in its sole discretion. Each allocation of these credits vests ratably on a quarterly basis over a four-year period. The account balance equals the aggregate of all allocations adjusted for investment gain or loss (as determined by the return on the investments selected by the participant and approved by us), less any distributions made to a participant or his beneficiaries. Each participant may make investment suggestions for his account, but the investment decision for each account is in our sole discretion. Each participant, or his beneficiaries, is entitled to receive an amount equal to his vested account balance if the participant terminates employment. Each participant, or his beneficiaries, is entitled to receive an amount equal to his total account balance (vested and unvested) if: (1) the participant suffers a disability while a full-time employee, (2) the participant dies while a full-time employee, or (3) the participant is a full-time employee at his normal retirement date, defined as the first day of the calendar month following the month in which the participant retires from service on or after he reaches age 65. In addition, upon a change in control, the participant would also receive a payment of nine times the sum of (1) all contributions made to the participant's deferral account balance (vested and unvested and disregarding investment gains and losses) as of the date of the change of control and (2) \$50,000 for Mr. Funkhouser and \$30,000 for each of Mr. Riddle and Mr. McGowan. For the year ending December 31, 2003, the Board of Directors allocated to Mr. Funkhouser's account \$95,175 and to Mr. Riddle's account \$34,870. Future participation in the SERP terminated for Messrs. Riddle and McGowan effective immediately upon their terminations of employment in 2003; provided, however, their vested account balances will become payable to each of them on the one year anniversary of their employment termination dates and they remain eligible to receive their change in control payment (as described above) during this one-year tail period.

## **Compensation of Directors**

Directors who are also employees receive no compensation for serving on our board of directors. Each of our non-employee directors receives a retainer of \$5,000 per year, \$2,000 per meeting of the board of directors, \$1,000 per committee meeting of the board of directors and \$500 per telephonic meeting of the board of directors that he or she attends. In 2003, each non-employee director who was also not then an affiliate of the company received a non-qualified option grant of 5,000 shares of our common stock upon re-election to our board of directors. We reimburse all directors for expenses incurred to attend board of director meetings.

## **Compensation Committee Interlocks and Insider Participation**

The members of the compensation committee of our board of directors are currently Messrs. Pirotte, Puckett and Farinholt. Messrs. Pirotte, Puckett and Farinholt were not at any time during the fiscal year ended December 31, 2003, or at any other time, one of our officers or employees. None of our executive officers serve as a member of the board of directors or compensation committee of any entity which has one or more executive officers serving as a member of our board of directors or compensation committee.

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**Certain Relationships and Related Transactions**

Our largest beneficial stockholder, Bayer Diagnostics, was also our largest customer and our sole distribution partner prior to our ceasing substantially all operations in March 2004. In 2003 and 2002, approximately 98% and 94%, respectively, of our total product revenues were derived from sales to Bayer as our sole distribution partner. In March 2004, we allowed our distribution agreement with Bayer to expire by its terms. Bayer has a contractual right to designate a nominee for election to our board of directors, but they are not currently exercising that right. Their former designee to our board of directors, Fran Tuttle, resigned from our board of directors in October 2003.

In May 2003, we completed a \$9.5 million private placement to a group of accredited investors led by Camden Partners Strategic Fund II-A, L.P. and Camden Partners Strategic Fund II-B, L.P. As a result of this private placement, Camden Partners Strategic Fund II-A, L.P. and Camden Partners Strategic Fund II-B, L.P. now beneficially own, in the aggregate, approximately 10% of our common stock. The investors in this private placement have a contractual right to elect a member to our board of directors. Currently, that member is Richard M. Johnston, who is a managing member of the general partner of the lead investors in the private placement. We agreed to and did file a registration statement with the Securities and Exchange Commission in order to register the resale of the shares of common stock issuable to the investors in this financing. This prospectus is part of that registration statement.

**Table of Contents****Principal Shareholders**

The following table sets forth certain information regarding the ownership of shares of our common stock, Series A preferred stock and Series B preferred stock as of June 1, 2004 by (1) each person known by us to own beneficially more than 5% of the outstanding shares of our common stock, Series A preferred stock or Series B preferred stock, (2) each of our current directors, (3) each of our chief executive officer and the other two most highly compensated executive officers other than the chief executive officer whose cash compensation for the year ended December 31, 2003 exceeded \$100,000, and (4) all of our current directors and executive officers as a group. As of June 1, 2004, we had 10,094,290 shares of common stock, 64,500 shares of Series A preferred stock and 103,508 shares of Series B preferred stock outstanding. Each share of Series A preferred stock is currently convertible into 10 shares of common stock and each share of Series B Preferred Stock is currently convertible into 16.667 shares of common stock. Except as indicated in footnotes to this table, the persons named in this table have sole voting and investment power with respect to all shares of common stock and preferred stock indicated. Share ownership in the case of common stock includes shares issuable upon conversion of Series A preferred stock and upon exercise of outstanding options and warrants that may be exercised within 60 days after June 1, 2004 for purposes of computing the percentage of common stock owned by such person but not for purposes of computing the percentage owned by any other person. Percentage voting power is calculated assuming the common stock, Series A preferred stock and Series B preferred stock vote together as one class with each share of common stock entitled to one vote, each share of Series A preferred stock entitled to 10 votes and each share of Series B preferred stock entitled to approximately 14.04 votes (even though each share of Series B preferred stock is convertible into 16.667 shares of common stock).

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		% of Total Voting Power
	Number of Shares	Percent of Class	Number of Shares	Percent of Class	Number of Shares	Percent of Class	
Bayer Corporation 63 North Street Medfield, MA 02052	2,050,000	20.3%					16.8%
Camden Partners(6) One South Street, Suite 2150 Baltimore, MD 21202	1,190,407(7)	10.5%			55,103	53.2 %	7.5%
Joseph H. Sherrill, Jr. 1510 Stickney Point Road Sarasota, FL 34231	498,715(1)	5.6%	6,000	9.3%			4.6%
Elliot Bossen 3100 Tower Boulevard, #1104 Durham, NC 27707	155,008(2)	1.5%	10,000	15.5%			1.1%
Leonardo, L.P. 245 Park Avenue	310,016(3)	3.0%	20,000	31.0%			2.2%



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New York, NY 10167							
AIG Sound Shore Funds(4)	206,386(5)	2.0%	6,500	10.1%	5,943	5.7%	1.3%
1281 East Main Street, 3rd Floor							
Stamford, CT 06902							
Baystar Capital II LP	233,421(8)	2.3%			10,805	10.4%	1.5%
80 E Sir Francis Drake Blvd., Suite 2B							
Larkspur, CA 94939							
Capital Ventures International(4)	140,053(9)	1.4%			6,483	6.3%	*
425 California Street, Suite 1100							
San Francisco, CA 94104							
Crestview Capital(4)	175,070(10)	1.7%			8,104	7.8%	1.1%
95 Revere Drive, Suite F							
Northbrook, IL 60062							
Mainfield Enterprises	112,036(11)	1.1%			5,186	5.0%	*
660 Madison Ave., 18th Floor							
New York, NY 10019							
Omicron Master Trust	116,702(12)	1.1%			5,402	5.2%	*
810 Seventh Ave.							
New York, NY 10019							
Smithfield Fiduciary LLC	140,053(13)	1.4%			6,483	6.3%	*
9 West 57th Street, 27th Floor							
New York, NY 10019							
John P. Funkhouser	420,110(14)	4.0%					*
Stephen R. Puckett	29,000(15)	*					*
John K. Pirotte	28,000(15)	*					*
James B. Farinholt, Jr.	21,500(16)	*					*
Richard M. Johnston	1,195,407(17)	10.5%			55,103	53.2%	7.5%
All current executive officers and directors as a group (6 persons)	1,717,767(18)	14.5%			55,103	53.2%	11.9%

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\* Less than one percent

(1) As reported in the Schedule 13G dated January 20, 2004 filed with the SEC by Joseph H. Sherrill Jr. Includes 60,000 shares of common stock issuable to Mr. Sherrill upon conversion of shares of Series A preferred stock and a warrant to purchase 12,000 shares of common stock.

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- (2) Consists of: (a) 35,008 shares of common stock and (b) 100,000 shares of common stock issuable upon conversion of Series A preferred stock and 20,000 shares of common stock issuable upon exercise of a warrant.
- (3) Consists of: (a) 70,016 shares of common stock and (b) 200,000 shares of common stock issuable upon conversion of Series A preferred stock and 40,000 shares of common stock issuable upon exercise of a warrant.
- (4) Consists of separate but affiliated limited partnerships or companies.
- (5) Consists of 65,000 shares of common stock issuable upon conversion of Series A preferred stock, 99,052 shares of common stock issuable upon conversion of Series B preferred stock and 42,334 shares of common stock issuable upon exercise of warrants.
- (6) Consists of Camden Partners Strategic Fund II-A, L.P. and Camden Partners Strategic Fund II-B, L.P., two affiliated investment funds for which Mr. Johnston, one of our directors, is a managing member of the general partner.
- (7) Consists of 866,974 shares of common stock issuable upon conversion of Series B preferred stock and 256,773 shares of common stock issuable upon exercise of warrants held by Camden Partners Strategic Fund II-A, L.P. and 51,428 shares of common stock issuable upon conversion of Series B preferred stock and 15,232 shares of common stock issuable upon exercise of warrants held by Camden Partners Strategic Fund II-B, L.P.
- (8) Consists of 180,087 shares of common stock issuable upon conversion of Series B preferred stock and 53,334 shares of common stock issuable upon exercise of warrants.
- (9) Consists of 108,052 shares of common stock issuable upon conversion of Series B preferred stock and 32,001 shares of Common stock issuable upon exercise of warrants.
- (10) Consists of 135,069 shares of common stock issuable upon conversion of Series B preferred stock and 40,001 shares of common stock issuable upon exercise of warrants.
- (11) Consists of 86,435 shares of common stock issuable upon conversion of Series B preferred stock and 25,601 shares of common stock issuable upon exercise of warrants.
- (12) Consists of 90,035 shares of common stock issuable upon conversion of Series B preferred stock and 26,667 shares of common stock issuable upon exercise of warrants.
- (13) Consists of 108,052 shares of common stock issuable upon conversion of Series B preferred stock and 32,001 shares of common stock issuable upon exercise of warrants.
- (14) Includes 395,410 shares underlying options.
- (15) Includes 22,000 shares underlying options.
- (16) Includes 20,000 shares underlying options.
- (17) Includes: (i) 5,000 shares underlying options; and (ii) the 1,190,407 shares of common stock beneficially owned by Camden Partners Strategic Fund II-A, L.P. and Camden Partners Strategic Fund II-B, L.P. Mr. Johnston is a managing member of the general partner to these two funds and, as such, may be deemed the indirect beneficial owner of these shares to the extent of his pecuniary interest therein. Mr. Johnston disclaims beneficial ownership of these shares, except to the extent of his indirect pecuniary interest therein.
- (18) Includes shares referenced in footnotes (14) through (17).

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**Description of Capital Stock**

**Authorized Stock**

As of the date of this prospectus, our authorized capital stock consists of 40,000,000 shares of common stock, no par value per share, and 1,000,000 shares of preferred stock, no par value per share. 120,000 shares of our preferred stock have been designated Series A preferred stock, 130,000 shares have been designated Series B preferred stock and 750,000 shares remain undesignated. The description below is a summary of all material provisions of our common stock and preferred stock.

**Common Stock**

The holders of our common stock are entitled to one vote per share on all matters voted on by the shareholders, including elections of directors. Subject to the preferential rights, if any, of holders of any then outstanding preferred stock, the holders of common stock are entitled to receive dividends when, as and if declared by our Board of Directors out of funds legally available therefor. The terms of the common stock do not grant to the holders thereof any preemptive, subscription, redemption, conversion or sinking fund rights. Subject to the preferential rights of holders of any then outstanding preferred stock, the holders of common stock are entitled to share ratably in our assets legally available for distribution to shareholders in the event of a liquidation, dissolution, winding up or certain change of control transactions. As of June 1, 2004, 10,094,290 shares of common stock were issued and outstanding, 793,865 shares of common stock were reserved for issuance upon the exercise of certain outstanding warrants and approximately 1,639,187 shares of common stock were reserved for issuance pursuant to our stock plans.

Our Articles of Incorporation and Bylaws, as amended, contain certain provisions that may have the effect of delaying, deferring, or preventing our change of control. In addition, the Board generally has the authority, without further action by shareholders, to fix the relative powers, preferences, and rights of the unissued shares of our preferred stock. Provisions that could discourage an unsolicited tender offer or takeover proposal, such as extraordinary voting, dividend, redemption, or conversion rights, could be included in this preferred stock.

**Preferred Stock**

Pursuant to our Certificate of Incorporation, we have the authority to issue up to 1,000,000 shares of preferred stock, no par value per share, in one or more series as determined by our Board of Directors. The Board of Directors may, without further action by our shareholders, issue one or more series of preferred stock and fix the rights and preferences of such shares, including the dividend rights, dividend rates, conversion rights, exchange rights, voting rights, terms of redemption, redemption price or prices, liquidation preferences and the number of shares constituting any series or the designation of such series. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of holders of preferred stock issued by us in the future. In particular, the issuance of additional shares of preferred stock may adversely affect the voting power of the common holders. In addition, the issuance of preferred stock could have the effect of making it more difficult for a third party to acquire us, or of discouraging a third party from attempting to acquire control of us.

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As of June 1, 2004, we had designated 120,000 shares of Series A Preferred Stock, of which 65,000 shares were issued and outstanding, and 130,000 shares of Series B Preferred Stock, of which 103,508 shares were issued and outstanding. 750,000 shares of our preferred stock remain undesignated.

The following is a summary of the terms, rights and privileges of our Series A and Series B preferred stock.

Relative Seniority. Subject to the rights of any additional series of preferred stock that may be designated by the Board of Directors, our Series A and Series B preferred stock rank on an equal basis with each other and senior to all other equity securities, including the common stock, with respect to dividends, conversions, redemption rights, liquidations and distributions of assets.

Dividends. Holders of Series B preferred stock are entitled to receive cumulative dividends at a quarterly rate of \$2.125 per share. Until September 2005, dividends on the Series B preferred stock will be paid in additional shares of Series B preferred stock, with such additional shares valued at the original issuance price of \$100.00 per share. Thereafter, dividends on the Series B preferred stock will be paid, at our option, in cash or in shares of common stock, with such shares of common stock to be valued at 90% of the volume weighted average of the closing prices of our common stock for the 30 days prior to the dividend date. However, we are obligated to pay any quarterly dividend due to holders of our Series B preferred stock in cash if we declare and pay cash dividends on our Series A preferred stock for the same period, or if the issuance of common stock would violate the rules, regulations and interpretations of Nasdaq or NASD absent shareholder approval. In addition, holders of our Series B preferred stock are entitled to receive dividends in the same form and per share amount as any dividends declared or paid with respect to the Series A preferred stock or common stock, except for the regular quarterly dividends payable to holders of our Series A preferred stock. Accrued but unpaid dividends on our Series B preferred stock shall be declared and paid, at the holder's election, immediately prior to our sale or liquidation, redemption of the Series B preferred stock or conversion of the Series B preferred stock.

Holders of Series A preferred stock are entitled to receive cumulative dividends at a quarterly rate of \$1.50 per share. Dividends on the Series A preferred stock will be paid, at our option, in cash or in shares of common stock, with such shares of common stock to be valued at the average of the closing bid or sale prices of our common stock as reported for the 30 days prior to the dividend date. However, if there is no active public market for our common stock, the value shall be the fair market value of our common stock as mutually determined by us and the holders of a majority of the then outstanding shares of Series B and Series A preferred stock.

Liquidation. Upon a change of control, liquidation, dissolution or winding up of our affairs, each holder of shares our Series A and Series B preferred stock will be entitled, on an equal basis with all other holders of our preferred stock, to a liquidation preference prior in right to any holders of common stock. The liquidation preference for each share of Series B preferred stock will be equal to the greater of the \$100.00 per share original purchase price of the Series B

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preferred stock plus all accrued but unpaid dividends, or the amount the holder of such share would have received if all shares of Series B preferred stock had been converted into common stock immediately prior to the liquidation event. The liquidation preference for each share of Series A preferred stock will be equal to the \$100.00 per share original purchase price of the Series A preferred stock plus all accrued but unpaid dividends. If insufficient assets are available to pay the full liquidation preferences of the Series A and Series B preferred stock, then the entire assets to be distributed shall be distributed ratably to holders of our preferred stock, based on the number of shares of common stock into which such shares are then convertible.

Conversion. At any time, holders of our Series A and Series B preferred stock may convert all or a portion of those shares into a number of shares of common stock computed by multiplying the number of shares to be converted by the original \$100.00 purchase price for those shares plus all accrued but unpaid dividends, and dividing the result by the conversion price then in effect. The conversion prices for the Series B and Series A preferred stock are initially set at \$6.00 and \$10.00, respectively, and are subject to adjustment from time to time to account for, among other things, stock splits, recapitalizations and other similar events. In addition, the Series B preferred stock conversion price is subject to a weighted average anti-dilution adjustment in the event we issue securities at a price below the original Series B preferred stock conversion price. Similarly, the Series A preferred stock conversion price is subject to a weighted average anti-dilution adjustment in the event we issue securities at a price determined to be below the fair market value of such securities.

Redemption. Beginning in May 2005, so long as a registration statement providing for the resale of the common stock issuable upon conversion of the Series B preferred stock is effective and no shares of Series A preferred stock are outstanding, we may, at our sole option, elect to redeem all outstanding shares of Series B preferred stock not previously converted into common stock if our common stock closes at or above \$20.00 per share and we have maintained an average daily trading volume of at least 75,000 shares per day for 30 consecutive days. The redemption price will be equal to the original purchase price of the Series B preferred stock plus all accrued but unpaid dividends.

In addition, upon the election of holders of a majority of the outstanding Series B preferred stock, we will be required to redeem all of the Series B preferred stock upon a change of control, whether via a merger, sale of assets, change in board control or liquidation. Depending on the type of change in control, the redemption price will be equal to the greater of the original purchase price of the Series B preferred stock plus accrued and unpaid dividends and either the fair market value of the Series B preferred stock or the fair market value of the Series B preferred stock on an as converted to common stock basis.

So long as a registration statement providing for the resale of the common stock issuable upon conversion of the Series A preferred stock is effective, we may, at our sole option, elect to redeem all outstanding shares of Series A preferred stock not previously converted into common stock if our common stock closes at or above \$20.00 per share for 20 consecutive trading days, we complete a follow-on public offering of at least \$10,000,000 at a price per share of common stock of at least \$15.00, we are acquired by another entity in a transaction that results in the transfer of 50% or more of our outstanding voting power, we sell all or substantially all of our assets, or at any time beginning in May 2007. The redemption price will be equal to the original purchase price of the Series A preferred stock plus all accrued but unpaid dividends.

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**Voting.** Holders of shares of Series A and Series B preferred stock are entitled to vote on all matters submitted to shareholders for a vote, voting together with the holders of our common stock as a single class, and entitled to a number of votes equal to the number of shares of common stock into which the preferred stock is then convertible (or, in the case of the Series B preferred stock, the number of shares of common stock into which the Series B could have been converted into when issued, assuming it was issued with a conversion price equal to fair market value on the date of grant in accordance with Nasdaq Marketplace Rules. The Series B Preferred Stock currently votes 14.04 votes for each share and the Series A Stock votes 10 votes for each share). We may not, without the prior approval of holders of a majority of the outstanding Series B preferred stock, alter or change the rights, preferences or privileges of the Series B preferred stock, create any new series of preferred stock or the issuance of additional shares of capital stock ranking senior to the Series B preferred stock, increase or decrease the authorized number of shares of Series B preferred stock, or redeem or repurchase any of our outstanding securities except pursuant to equity incentive plans or as required under our Articles of Incorporation. Similarly, we may not, without the prior approval of holders of at least two-thirds of the outstanding Series A preferred stock, alter or change the rights, preferences or privileges of the Series A preferred stock, create any new series of preferred stock or the issuance of additional shares of capital stock ranking senior to the Series A preferred stock, or increase or decrease the authorized number of shares of Series A preferred stock if any of such actions would adversely affect the Series A preferred stock in manner different from the other outstanding shares of our preferred stock.

**Board Representation.** So long as at least 20% of the Series B preferred stock issued in our May 2003 financing remain outstanding, holders of our Series B preferred stock shall be entitled to elect one member of our Board of Directors.

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**Plan of Distribution**

The selling shareholders may offer the shares at various times in one or more of the following transactions (which may involve cross or block transactions):

on any national securities exchange or quotation service on which the shares may be listed or quoted at the time of sale;

in the over-the-counter market;

in transactions otherwise than on such exchanges or services or in the over-the-counter market;

through the writing of options; or

in a combination of any of the above.

The selling shareholders may sell shares at market prices then prevailing, at prices related to prevailing market prices, at negotiated prices or at fixed prices. In connection with sales of the shares or otherwise, the selling shareholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the shares in the course of hedging the positions they assume. The selling shareholders may also sell shares short and deliver shares to close out such short positions, or loan or pledge shares to broker-dealers that in turn may sell such securities.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers.

The selling shareholders may use broker-dealers to sell shares. If this happens, broker-dealers will either receive discounts or commissions from the selling shareholders, or they will receive commissions from purchasers of shares for whom they have acted as agents.

**The selling shareholders and any broker-dealers who act in connection with the sale of the shares hereunder may be deemed to be underwriters within the meaning of the Securities Act, and any commissions they receive and proceeds of any sale of the shares may be deemed to be underwriting discounts and commissions under the Securities Act.**

To our knowledge, based on inquiry, we believe that five of the selling shareholders, consisting of Smithfield Fiduciary, LLC, Crestview Capital Fund I, LP, Crestview Capital Fund II, LP, Crestview Capital Offshore Fund, Inc. and Capital Ventures International, are affiliates of a broker-dealer and that SG Cowen Securities Corporation is a broker-dealer. Each of them has advised us that it purchased or acquired the securities in the ordinary course of business and that at the time of the purchase of the securities to be resold hereunder, it had no agreements or understanding, directly or indirectly, with any person to distribute the securities.



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Neither we nor the selling shareholders can presently estimate the amount of such compensation. We know of no existing arrangements between any selling shareholders, any other shareholder, broker, dealer, underwriter or agent relating to the sale or distribution of the shares.

We will pay all of the expenses incident to the registration, offering and sale of the shares to the public other than commissions or discounts of underwriters, broker-dealers or agents. We also agreed to indemnify the selling shareholders and certain related persons against certain liabilities, including liabilities under the Securities Act.

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Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore, unenforceable.

We have advised the selling shareholders that during such time as they may be engaged in a distribution of the shares included in this prospectus they are required to comply with Regulation M promulgated under the Securities Exchange Act of 1934, as amended. With certain exceptions, Regulation M precludes the selling shareholders, any affiliated purchasers, and any broker-dealer or other person who participates in such distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the shares offered hereby.

This offering will terminate on the earlier of (a) the date on which all the shares may be sold within a 90 day period without restrictions pursuant to Rule 144 under the Securities Act, (b) the date on which all shares offered by this prospectus have been sold by the selling shareholders, or (c) May 1, 2005.

**Legal Matters**

The validity of the issuance of the shares of common stock offered hereby will be passed upon for us by Wyrick Robbins Yates & Ponton LLP, Raleigh, North Carolina.

**Experts**

The consolidated financial statements of PharmaNetics, Inc. as of December 31, 2003 and 2002 and for each of the three years in the period ended December 31, 2003 included in this prospectus have been so included in reliance upon the report of PricewaterhouseCoopers LLP, and independent registered public accounting firm, given on the authority of said firm as experts in accounting and auditing.

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**Where You Can Find More Information**

We have filed with the Securities and Exchange Commission a registration statement on Form S-1, including exhibits, schedules and amendments, under the Securities Act with respect to the shares of common stock to be sold in this offering. This prospectus does not contain all the information included in the registration statement. For further information about us and the shares of our common stock to be sold in this offering, please refer to this registration statement.

We file annual, quarterly and special reports, proxy statements and other information with SEC. You may read and copy any document we file at the SEC's public reference room at 450 Fifth Street, N. W., Washington, D.C. 20549. You should call the SEC at 1-800-SEC-0330 for further information on the public reference rooms. Our SEC filings are also available to the public at the SEC's web site at <http://www.sec.gov>. Our Commission filing number is 0-25133.

You may request, and we will provide, a copy of our filings, at no cost to you, by writing or telephoning us at the following address:

PharmaNetics, Inc.

Investor Relations

9401 Globe Center Drive, Suite 140

Morrisville, North Carolina 27560

(919) 582-2600

This prospectus is part of a registration statement we filed with the SEC. You should rely only on the information or representations provided in this prospectus. We have authorized no one to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front of the document.

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**PHARMANETICS, INC. AND SUBSIDIARIES**

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**Report of Independent Registered Public Accounting Firm**

**The Board of Directors and Shareholders of PharmaNetics, Inc**

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of PharmaNetics, Inc. and its subsidiaries at December 31, 2003 and 2002, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2003 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

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

/s/ PricewaterhouseCoopers LLP

Raleigh, North Carolina

April 13, 2004

**Table of Contents****PHARMANETICS, INC. AND SUBSIDIARIES****Consolidated Balance Sheets****December 31, 2003 and 2002**

	<u>2003</u>	<u>2002</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 8,463,193	\$ 9,146,466
Account receivable from related party	498,372	542,705
Other receivables, net of allowance for doubtful accounts of \$1,995	53,988	111,758
	<u>          </u>	<u>          </u>
Total receivables	552,360	654,463
Inventories, net	567,391	2,453,442
Other current assets	622,464	503,348
	<u>          </u>	<u>          </u>
Total current assets	10,205,408	12,757,719
Property and equipment, net	4,656,227	8,292,059
Patents and intellectual property, net	402,559	580,054
Other noncurrent assets	3,259	71,801
	<u>          </u>	<u>          </u>
Total assets	\$ 15,267,453	\$ 21,701,633
<b>LIABILITIES, CONVERTIBLE REDEEMABLE PREFERRED STOCK AND SHAREHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 799,894	\$ 1,276,762
Accrued expenses	537,742	461,000
Deferred revenue, current portion	1,226,487	1,089,362
Current portion of long-term debt	498,909	461,565
Current portion of capital lease obligations	15,381	20,462
	<u>          </u>	<u>          </u>
Total current liabilities	3,078,413	3,309,151
	<u>          </u>	<u>          </u>
Deferred revenue, less current portion	2,064,551	3,138,913
Long-term debt, less current portion	594,056	1,055,837
Capital lease obligations, less current portion	23,159	39,190
	<u>          </u>	<u>          </u>
Total noncurrent liabilities	2,681,766	4,233,940
	<u>          </u>	<u>          </u>
Total liabilities	5,760,179	7,543,091
	<u>          </u>	<u>          </u>
Commitments and contingencies (Note 10)		
Series A convertible redeemable preferred stock, no par value; authorized 120,000 shares; 65,500 and 90,500 shares issued and outstanding at December 31, 2003 and 2002 (aggregate liquidation value at December 31, 2003 of \$6,550,000)	5,442,873	7,520,446
Series B convertible redeemable preferred stock, no par value; authorized 130,000 shares; 101,354 shares issued and outstanding at December 31, 2003 (aggregate liquidation value at December 31,	7,408,480	

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2003 of \$10,135,400)		
Shareholders' equity:		
Common stock, no par value; authorized 40,000,000 shares; 10,021,556 and 9,630,872 issued and outstanding at December 31, 2003 and 2002, respectively	75,511,015	67,851,649
Accumulated deficit	(78,855,094)	(61,213,553)
Total shareholders' equity	<u>(3,344,079)</u>	<u>6,638,096</u>
Total liabilities, convertible redeemable preferred stock and shareholders' equity	<u>\$ 15,267,453</u>	<u>\$ 21,701,633</u>

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

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**Table of Contents****PHARMANETICS, INC. AND SUBSIDIARIES****Consolidated Statements of Operations****For the years ended December 31, 2003, 2002 and 2001**

	<u>2003</u>	<u>2002</u>	<u>2001</u>
<b>Revenue:</b>			
Net product sales to related party	\$ 5,387,542	\$ 3,862,694	\$ 2,895,902
Net product sales to third parties	125,984	227,749	1,642,940
Grant/royalty income	38,366	43,705	24,000
Development income	1,042,219	587,478	263,833
	<u>6,594,111</u>	<u>4,721,626</u>	<u>4,826,675</u>
<b>Operating expenses:</b>			
Cost of sales	3,922,420	3,495,581	4,046,329
General and administrative	4,098,818	4,898,934	4,524,361
Sales and marketing	3,452,667	1,498,508	1,207,939
Research and development	3,997,333	6,007,750	3,950,289
Write-down of inventories	1,972,801		
Impairment of long-lived assets	2,516,170		
	<u>19,960,209</u>	<u>15,900,773</u>	<u>13,728,918</u>
Operating loss	<u>(13,366,098)</u>	<u>(11,179,147)</u>	<u>(8,902,243)</u>
<b>Other income (expense):</b>			
Interest expense	(130,603)	(18,413)	(72,194)
Interest income	85,780	122,699	421,486
Other income (expense)	49,802	(41,191)	(48,588)
	<u>4,979</u>	<u>63,095</u>	<u>300,704</u>
Net and comprehensive loss	<u>(13,361,119)</u>	<u>(11,116,052)</u>	<u>(8,601,539)</u>
Amortization of beneficial conversion feature of convertible preferred stock	(3,458,781)		
Preferred stock dividends	(821,641)	(481,589)	(566,210)
	<u>\$ (17,641,541)</u>	<u>\$ (11,597,641)</u>	<u>\$ (9,167,749)</u>
Basic and diluted net loss attributable to common shareholders	<u>\$ (1.80)</u>	<u>\$ (1.21)</u>	<u>\$ (1.03)</u>
Weighted average number of outstanding common shares	<u>9,798,813</u>	<u>9,566,843</u>	<u>8,877,270</u>

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





**Table of Contents****PHARMANETICS, INC. AND SUBSIDIARIES****Consolidated Statements of Shareholders Equity****For the years ended December 31, 2003, 2002 and 2001**

	Common Stock		Accumulated Deficit	Total Shareholders Equity
	Number of Shares	Amount		
Balances at December 31, 2000	7,851,225	\$ 47,027,959	\$ (40,448,163)	\$ 6,579,796
Conversions of preferred stock to common stock	70,000	581,722		581,722
Stock options exercised	79,965	314,441		314,441
Common stock issued	1,450,000	17,359,464		17,359,464
Issuance of stock dividends	69,604	566,210	(566,210)	
Common stock repurchases	(35,500)	(126,360)		(126,360)
Reclassification to contingently redeemable common stock		(8,537,500)		(8,537,500)
Net loss for the year ended December 31, 2001			(8,601,539)	(8,601,539)
Balances at December 31, 2001	9,485,294	57,185,936	(49,615,912)	7,570,024
Stock options exercised	82,791	402,611		402,611
Issuance of stock dividends	81,087	481,589	(481,589)	
Common stock repurchases	(18,300)	(102,897)		(102,897)
Unearned compensation related to common stock options		1,346,910		1,346,910
Reclassification from contingently redeemable common stock		8,537,500		8,537,500
Net loss for the year ended December 31, 2002			(11,116,052)	(11,116,052)
Balances at December 31, 2002	9,630,872	67,851,649	(61,213,553)	6,638,096
Stock options exercised	30,574	54,916		54,916
Issuance of common stock dividends on Series A	110,110	451,805	(451,805)	
Issuance of preferred stock dividends on Series B			(369,836)	(369,836)
Issuance of warrants in connection with Series B offering		1,616,289		1,616,289
Conversions of preferred stock to common stock	250,000	2,077,575		2,077,575
Amortization of beneficial conversion feature		3,458,781	(3,458,781)	
Net loss for the year ended December 31, 2003			(13,361,119)	(13,361,119)
Balances at December 31, 2003	10,021,556	\$ 75,511,015	\$ (78,855,094)	\$ (3,344,079)

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

**Table of Contents****PHARMANETICS, INC. AND SUBSIDIARIES****Consolidated Statements of Cash Flows****For the years ended December 31, 2003, 2002 and 2001**

	<u>2003</u>	<u>2002</u>	<u>2001</u>
<b>Cash flows from operating activities:</b>			
Net loss	\$ (13,361,119)	\$ (11,116,052)	\$ (8,601,539)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of property and equipment	1,777,997	1,506,565	1,301,912
Amortization of intangible assets	116,033	148,073	203,951
Loss on impairment of long-lived assets	2,516,170		
Amortization of discount on investments, net			(30,877)
(Gain) loss on trading investments	(35,373)	44,096	8,120
Noncash compensation		1,346,910	
Write-offs of patent costs	59,317		
Provision for inventory obsolescence	218,894	96,605	84,574
Write-down of inventory to net realizable value	1,972,801		
(Gain) loss on disposal of fixed assets	24,839	6,070	61,121
Change in operating assets and liabilities:			
Receivables	102,103	(192,068)	(161,322)
Inventories	(305,646)	(326,806)	(1,021,832)
Other assets	(92,155)	(197,787)	81,173
Accounts payable and accrued expenses	(400,126)	133,266	(198,586)
Deferred revenue	(937,237)	2,395,379	704,027
Net cash used in operating activities	<u>(8,343,502)</u>	<u>(6,155,749)</u>	<u>(7,569,278)</u>
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment	(396,999)	(1,161,674)	(3,314,221)
Costs incurred to obtain patents and other intangibles	(107,029)	(100,513)	(87,398)
Purchases of trading investments	(130,045)	(106,250)	(93,000)
Proceeds from sales/maturities of investments	30,000		3,935,000
Net cash provided by (used in) investing activities	<u>(604,073)</u>	<u>(1,368,437)</u>	<u>440,381</u>
<b>Cash flows from financing activities:</b>			
Principal payments on long-term debt and capital lease obligations	(445,549)	(24,151)	(879,808)
Proceeds from issuance of long-term debt		1,512,500	
Proceeds from exercise of stock options	54,916	402,611	314,441
Proceeds from issuance of common stock			17,359,464
Repurchase of common stock		(102,897)	(126,360)
Proceeds from issuance of Series B preferred stock, net	8,654,935		
Net cash provided by financing activities	<u>8,264,302</u>	<u>1,788,063</u>	<u>16,667,737</u>
Net increase (decrease) in cash and cash equivalents	(683,273)	(5,736,123)	9,538,840
Cash and cash equivalents at beginning of year	9,146,466	14,882,589	5,343,749
Cash and cash equivalents at end of year	<u>\$ 8,463,193</u>	<u>\$ 9,146,466</u>	<u>\$ 14,882,589</u>

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	<u>                    </u>	<u>                    </u>	<u>                    </u>
Supplemental disclosures of cash flow information:			
Cash paid during the year for interest expense	\$ 122,006	\$ 18,413	\$ 72,194
	<u>                    </u>	<u>                    </u>	<u>                    </u>
Cash paid during the year for income taxes	\$ 0	\$ 0	\$ 0
	<u>                    </u>	<u>                    </u>	<u>                    </u>

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

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**PHARMANETICS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements**

**1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**BUSINESS**

PharmaNetics, Inc. (the Company) is a holding company incorporated in July 1998 as the parent company of Cardiovascular Diagnostics, Inc. (CVDI). CVDI was incorporated in November 1985 and is a developer, manufacturer and marketer of coagulation analyzers and rapid diagnostic tests to dose, manage and screen patients on drugs affecting coagulation. The Company develops tests based on its proprietary dry chemistry diagnostic test system, known as the Thrombolytic Assessment System (TAS), to provide rapid and accurate evaluation of coagulation at the point of patient care. Cardiovascular Diagnostics Europe, BV (CDE) is a wholly-owned Dutch company that distributed the Company's products in Europe until March 1997 when it ceased operations.

In December 2003, the Company announced that, as a result primarily of the litigation with Aventis Pharmaceuticals (see Note 18) and its impact on the Company's business and prospects, it is seeking a variety of strategic alternatives, including the sale of its manufacturing operations. At that time, the Company also announced that, if a willing and able buyer for the operations is not identified, it would terminate its distribution agreement with its distribution partner, Bayer Diagnostics (Bayer). As required under the distribution agreement with Bayer, PharmaNetics provided Bayer 90-day notice that it would terminate this agreement effective March 12, 2004. In addition, the Company provided 90-day notice to PDI, the contractor and provider of the Enox sales and technical support teams, that the sales and technical service personnel would be terminated by March 12, 2004. PharmaNetics believes these steps were and are necessary in order to reduce overhead costs and to conserve cash for the license and sale of assets and the intellectual property as well as to finance its lawsuit against Aventis. Since filing the lawsuit, the Company has implemented personnel reductions and has engaged Davenport & Company LLC (Davenport), an investment banking firm, as its financial advisor. Davenport is currently assisting the Company in pursuing a sale of its manufacturing operations and intellectual property. As of the end of March 2004, no buyer has emerged and the Company has ended its distribution agreement with Bayer and has ceased producing and selling all products. The Company is shifting its corporate strategy from a manufacturing/distribution model to that of a biotech model, whereby revenues are tied to royalty streams from future product sales. The Company is actively seeking a buyer for its operating assets and to sell or license its intellectual property with a significant portion of the potential valuation tied to royalties. In essence, the Company would be receiving royalties on tests developed and would not be responsible for manufacturing and distribution. This does not preclude the Company from initiating future operations related to new products.

**PRINCIPLES OF CONSOLIDATION**

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

**CASH EQUIVALENTS**

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

## **INVENTORIES**

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

During 2003, the Company recorded a write-down of inventories to reduce them to their estimated net realizable values. See Note 3.

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**PHARMANETICS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements Continued**

**PROPERTY AND EQUIPMENT**

Property and equipment are stated at cost and are depreciated using the straight-line method over the estimated useful lives of the respective assets, which are as follows: machinery and equipment 7 years; furniture and fixtures 7 years; leasehold improvements and capital leases - the shorter of the estimated useful lives of the asset, or the term of the lease; IT equipment 3 to 5 years.

Expenditures for repairs and maintenance are charged to expense as incurred. The costs of major renewals and betterments are capitalized and depreciated over their estimated useful lives. Upon disposition, the cost and related accumulated depreciation of property and equipment are removed from the accounts and any resulting gain or loss is reflected in operations.

**PATENTS AND INTELLECTUAL PROPERTY**

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

**IMPAIRMENT OF LONG-LIVED ASSETS**

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

As discussed above, events occurred in the Company s 2003 fourth quarter which indicate that the carrying amount of these assets may not be recoverable. In accordance with the provisions of FAS 144, the Company has performed impairment tests and determined that an impairment of the noted assets is present as of December 31, 2003. This analysis requires the use of judgments and estimates concerning future cash flows and fair values upon disposition of assets. The Company then estimated potential discounted future cash flows related to these assets under four scenarios in conjunction with a third-party valuation that arrived at a fair value. An impairment write-down of \$2,516,000 has been taken in the year ended December 31, 2003 and is included in a separate line item in the Company s Statement of Operations. If the probabilities of the highest and lowest cash flow scenarios were adjusted upward and downward by 10%, the write-down would increase or decrease by \$1,060,000 respectively. See further discussion in Notes 4, 5 and 6.

**REVENUE AND INCOME RECOGNITION POLICIES**

The Company records revenue from the sale of products when an arrangement exists, the product has been delivered or services have been rendered (transfer of risk occurs), the price is fixed and determinable and collectibility is reasonably assured. For all products except the Enox test, the Company records revenue from product sold to Bayer when the above elements exist and specifically upon transfer of risk (at delivery) to Bayer. Delivery occurs at the point of shipment and title legally passes at that time. Bayer assumes all risk of loss once title passes and takes ownership of the finished inventory and holds it for resale to hospitals. The Company does not retain any additional performance obligation with respect to the product once the product has been manufactured and transferred to Bayer. The product, except in the case of defects, is not returnable and there has not been a history of defective product returns. A standard pricing model is in place and the Company does not offer price protection or rights of return. The Company records product revenue from the sale of the Enox test upon shipment of the product to the hospital. The Company invoices Bayer at the shipment date, netting a 10% commission paid to Bayer (for administration and collection services) against the product revenue, in accordance with EITF 01-09 Accounting for Consideration Given by a Vendor to a



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**PHARMANETICS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements    Continued**

Customer (Including a Reseller of the Vendor's Products) . Bayer is responsible for invoicing and collecting from the hospital and must pay the Company regardless of whether it collects from the hospital. The Company accounts for royalties on an accrual basis. Tokuyama Soda pays the Company royalties based on Tokuyama's net sales of a licensed product. The Company recognizes income under license and development agreements over the anticipated period of the agreements with its collaborators, in accordance with SEC Staff Accounting Bulletin No. 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. For example, the Company received upfront payments for development of the Enoxaparin test card from Aventis. Pursuant to this arrangement, the Company received non-refundable milestone payments for executing the agreement, completing the development, FDA approval, and the first commercial sale of the product. There is a period of four years after the first commercial sale of the test card in which the Company cannot develop a similar test card for another entity. The Company is recognizing the milestone payments over a period of five years, based on the estimated life of the relationship.

**WARRANTIES**

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

**RESEARCH AND DEVELOPMENT**

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

**INCOME TAXES**

Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities. These deferred tax assets, liabilities and tax carryforwards are determined using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts more likely than not expected to be realized.

**NET LOSS PER COMMON SHARE**

Basic net loss per common share attributable to common shareholders excludes dilution and is computed by dividing net loss attributable to common shareholders by the weighted average number of common shares outstanding for the period. Diluted net income attributable to common shareholders is computed using the weighted average number of shares of common and dilutive potential common shares outstanding during the period. The Company's basic and diluted net loss attributable to common shareholders for the years ended December 31, 2003, 2002 and 2001 is the same because, for loss periods, the inclusion of potential common shares would be antidilutive. Options currently outstanding that could be dilutive in the future are summarized in Note 13.

#### **STOCK-BASED COMPENSATION**

The Company follows Statement of Financial Accounting Standards No. 123, Accounting for Stock Based Compensation (SFAS No. 123). As permitted by SFAS No. 123, the Company has chosen to continue to apply APB Opinion No. 25 Accounting for Stock Issued to Employees (APB No. 25) and related interpretations in accounting for its stock plans. Accordingly, in each period, the Company has used the intrinsic-value method to record stock based

**Table of Contents****PHARMANETICS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued**

employee compensation. No compensation expense has been recognized for stock options granted to employees with an exercise price equal to or above the trading price per share of the Company's common stock on the grant date. Pro forma compensation cost for the Company's plans if the grants had been based on the fair value at the grant dates consistent with SFAS No. 123 is summarized below.

In March 2000, the Financial Accounting Standards Board issued Interpretation No. 44, ( FIN 44 ) Accounting for Certain Transactions Involving Stock Compensation An Interpretation of APB 25 . This interpretation clarifies: the definition of employee for purposes of applying APB 25, the criteria for determining whether a plan qualifies as a noncompensatory plan, the accounting consequence of various modifications to the terms of previously fixed stock options or awards, and the accounting for an exchange of stock compensation awards in business combinations. During 2002, the Company recorded a non-cash expense of \$1.3 million for deferred compensation related to extending by five years the termination date of options previously granted to a number of employees. In accordance with accounting guidelines, an expense was recorded at the modification date for the affected options by multiplying the number of options by the difference in the market price of the Company's common stock on the date of the extension and the strike price of each option. This extension of the contractual life results in a one-time charge based on the options being fully vested and variable accounting will not be required in future periods.

On December 31, 2002, the FASB issued FASB Statement No. 148 (FAS 148), Accounting for Stock-Based Compensation Transition and Disclosure , which amends FASB Statement No. 123 (FAS 123), Accounting for Stock-Based Compensation . FAS 148 requires new disclosures including an accounting policy footnote that includes: the method of accounting for stock options; total stock compensation cost that is recognized in the income statement and would have been recognized had FAS 123 been adopted for recognition purposes as of its effective date; and pro forma net income and earnings per share (where applicable) that would have been reported had FAS 123 been adopted for recognition purposes as of its effective date. These disclosures are required to be made in annual financial statements and in quarterly information provided to shareholders without regard to whether the entity has adopted FAS 123 for recognition purposes. The Company has not implemented the voluntary change to the fair value based method of accounting for stock-based compensation. The Company implemented the disclosure provisions of SFAS No. 148 beginning with the December 31, 2002 consolidated financial statements.

For purposes of the proforma disclosures, the fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model and the estimated fair value of equity instruments is amortized to expense over their respective vesting periods. The following assumptions were used for grants in 2003, 2002 and 2001:

	<u>2003</u>	<u>2002</u>	<u>2001</u>
Dividend yield	0%	0%	0%
Volatility	87%	86%-88%	133%
Risk free interest rate	2.6%	3%-4.5%	4.5%-5%
Expected life of options	6 years	6 years	6 years

For 2003, 2002 and 2001, the following table summarizes the net loss and stock-based compensation expense, as reported, compared to pro forma amounts had the fair value method been applied:

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	<u>2003</u>	<u>2002</u>	<u>2001</u>
Net loss attributable to common shareholders, as reported	\$ (17,641,541)	\$ (11,597,641)	\$ (9,167,749)
Net loss per basic and diluted share, as reported	\$ (1.80)	\$ (1.21)	\$ (1.03)
Stock based compensation, as reported	\$	(1,346,910)	
Stock based compensation based on fair value method	\$ (1,180,790)	\$ (1,443,975)	\$ (1,193,849)
Pro forma net loss using fair value method	\$ (18,822,331)	\$ (11,694,706)	\$ (10,361,598)
Pro forma net loss per basic and diluted share	\$ (1.92)	\$ (1.22)	\$ (1.17)

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**Table of Contents****PHARMANETICS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements    Continued****FAIR VALUE OF FINANCIAL INSTRUMENTS**

The carrying amount of cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximates fair value because of the short maturity of those instruments. The estimated values of the Company's debt is provided in Note 9.

**USE OF ESTIMATES IN THE PREPARATION OF THE FINANCIAL STATEMENTS**

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates.

**COMPREHENSIVE INCOME (LOSS)**

The Company calculates and discloses comprehensive income in accordance with Statement of Financial Accounting Standards No. 130

Reporting Comprehensive Income (SFAS No. 130). SFAS No. 130 requires the Company to display an amount representing comprehensive income (loss) for all reporting periods in the financial statements. Comprehensive income (loss) must be displayed with the same prominence as other financial statements. There were no items of other comprehensive income (loss) for the years ended December 31, 2003, 2002 or 2001.

**CASH FLOW INFORMATION**

A supplemental schedule of non-cash financing activities during the three years ended December 31, 2003 is as follows:

	<u>2003</u>	<u>2002</u>	<u>2001</u>
Acquisition of assets through capital leases	\$	\$	\$ 71,790
Dividends on convertible preferred stock	821,641	481,589	566,210
Conversion of Series A Preferred Stock into common stock	2,077,575		581,722
Purchases of property, plant and equipment in accounts payable at year end		140,462	55,750
Amortization of beneficial conversion feature of Series B Preferred Stock	3,458,781		

**RECENT ACCOUNTING PRONOUNCEMENTS**

In May 2003, the FASB issued SFAS No. 150 ( SFAS No. 150 ), Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity . This Statement establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. Some of the provisions of this Statement are consistent with the current definition of liabilities in FASB Concepts Statement No. 6, *Elements of Financial Statements*. The remaining provisions of this Statement are consistent with the Board s proposal to revise that definition to encompass certain obligations that a reporting entity can or must settle by issuing its own equity shares, depending on the nature of the relationship established between the holder and the issuer. While the Board still plans to revise that definition through an amendment to Concepts Statement 6, the Board decided to defer issuing that amendment until it has concluded its deliberations on the next phase of this project. That next phase will deal with certain compound financial instruments including puttable shares, convertible bonds, and dual-indexed financial instruments. These provisions of SFAS No. 150 are effective for financial statements for fiscal years ending after June 15, 2003. The next phase of this FASB project may require the Company to reclassify its preferred stock from the mezzanine section to either the liabilities or equity section of the balance sheet. The application of SFAS No. 150 will not have a material effect on the Company s operations.

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In November 2002, the FASB approved FASB Interpretation No. (FIN) 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness to Others*. FIN 45 elaborates on the existing disclosure requirements for most guarantees. It also clarifies that at the time a company issues a guarantee, the company must recognize an initial liability for the fair value, or market value, of the obligations it assumes under that guarantee and must disclose that information in its interim and annual financial statements. The disclosure requirements of FIN 45 are effective for financial statements of interim or annual periods ending after December 31, 2002. The Company has adopted the disclosure provisions of this interpretation and it did not have a material impact on the consolidated financial statements.

In January 2003, the FASB approved FASB Interpretation No. (FIN) 46, *Consolidation of Variable Interest Entities*. The primary objectives of FIN 46 are to provide guidance on the identification of entities for which control is achieved through means other than through voting rights (variable interest entities or VIEs) and how to determine when and which business enterprise should consolidate the VIE (the primary beneficiary). This new model for consolidation applies to an entity which either (1) the equity investors (if any) do not have a controlling financial interest or (2) the equity investment at risk is insufficient to finance that entity's activities without receiving additional subordinated financial support from other parties. In addition, FIN 46 requires that both the primary beneficiary and all other enterprises with a significant variable interest in a VIE make additional disclosures. This statement is effective no later than the first interim or annual reporting period beginning after June 15, 2003. The approval and implementation of FIN 46 did not have a material impact on the consolidated financial statements.

**2. INVESTMENTS**

Included in other current assets at December 31, 2003 and 2002 are trading investments of \$282,452 and \$147,034, respectively consisting of marketable equity securities related to the Company's Supplemental Executive Retirement Plan. The related liability as of December 31, 2003 and 2002, included within accrued expenses, is \$104,724 and \$53,053, respectively.

**3. INVENTORIES**

Inventories at December 31, 2003 and 2002 consisted of the following:

	<u>2003</u>	<u>2002</u>
Raw materials	\$ 2,012,903	\$ 1,869,012
Work in progress	134,621	280,480
Finished goods	571,174	378,950
Less: reserve	(178,506)	(75,000)
Less: write-down to net realizable value	(1,972,801)	

	<u>\$ 567,391</u>	<u>\$ 2,453,442</u>
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The Company decided in December 2003 to cease production in March 2004. Accordingly, at December 31, 2003 the Company recorded a write-down of \$1,972,801 to reduce its inventory from standard cost to its estimated realizable value. Inventories remaining at December 31, 2003 were used in production in the first quarter of 2004.

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**Table of Contents****PHARMANETICS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements    Continued****4. PROPERTY AND EQUIPMENT**

Property and equipment at December 31, 2003 and 2002 consisted of the following:

	<u>2003</u>	<u>2002</u>
Machinery and equipment	\$ 5,121,563	\$ 7,696,387
Leasehold improvements, furniture and fixtures	2,302,311	3,377,585
IT equipment	1,114,019	1,328,173
Construction in progress	510,976	1,316,494
Equipment under capital lease	48,548	92,653
	<u>9,097,417</u>	<u>13,811,292</u>
Less accumulated depreciation and amortization	4,441,190	5,519,233
	<u>\$ 4,656,227</u>	<u>\$ 8,292,059</u>

Accumulated amortization of equipment under capital lease at December 31, 2003 and 2002 was \$38,288 and \$38,418, respectively.

As of December 31, 2003, impairment charges of \$2,229,995 were recorded related to the Company's fixed assets (Note 1). In accordance with the provisions of FAS 144, the Company determined that the carrying amount of all its fixed assets may not be recoverable as the cash flows expected to be generated from the use of these assets and their eventual disposition could be less than their carrying amount. The Company then estimated potential future cash flows related to these assets under four scenarios in conjunction with a third-party valuation that arrived at a fair value.

The Company has assessed the remaining estimated life of its leasehold improvements, furniture and fixtures. Due to events in the Company's fourth quarter (Note 1), the estimated useful lives of the leasehold improvements have been reduced from ten years to two years. The estimated lives of the furniture and fixtures has been reduced from seven years to two years. These changes in lives will be recognized prospectively.

**5. PATENTS AND INTELLECTUAL PROPERTY**

Patents and intellectual property at December 31, 2003 and 2002 consisted of the following:

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	<u>2003</u>	<u>2002</u>
Patents	\$ 629,531	\$ 807,864
Intellectual property	145,280	197,446
	<u>774,811</u>	<u>1,005,310</u>
Less accumulated amortization	372,252	425,256
	<u>\$ 402,559</u>	<u>\$ 580,054</u>

During 2003, 2002 and 2001, the Company recognized \$36,594, \$71,122, and \$73,802, respectively, of amortization related to these assets.

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

**Table of Contents****PHARMANETICS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements    Continued****6. OTHER NONCURRENT ASSETS**

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

**7. ACCRUED EXPENSES**

Accrued expenses consist of the following:

	<u>2003</u>	<u>2002</u>
Accrued compensation, benefits and severances	\$ 308,336	\$ 250,871
Accrued clinical liabilities	20,417	105,867
Accrued professional fees	86,557	38,813
Accrued taxes	110,543	52,128
Other	11,889	13,321
	<u>\$ 537,742</u>	<u>\$ 461,000</u>

In accordance with Statement of Financial Accounting Standard No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, the Company recorded severances totaling \$130,000 which are recorded in general and administrative expenses in the Company's Statement of Operations. The total amount of severance expense expected to be incurred during 2004 is approximately \$525,000.

**8. DEVELOPMENT INCOME AND DEFERRED REVENUE**

The Company recognizes development income in accordance with SEC Staff Accounting Bulletin No. 101. During 2003, 2002 and 2001, the Company received payments as part of collaboration agreements with other entities and recognized \$1,042,219, \$587,478, and \$263,833, respectively, of development income related to these agreements. Payments received but not recognized into income in the year of receipt are deferred and recognized over the period of the respective agreements. At December 31, 2003, total payments received but deferred to future

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periods aggregated \$3,291,038. Previous milestone payments from Aventis remain deferred because even though the Company's development agreement with Aventis has been terminated, the Company remains under obligation not to develop another test card that would compete with Aventis through November 2006. The Company is recognizing development income from Aventis straight-line through 2006.

### 9. LONG-TERM DEBT

Long-term debt as of December 31, 2003 and 2002 consisted of the following:

	<u>2003</u>	<u>2002</u>
Notes payable	\$ 1,092,965	\$ 1,517,402
Current portion of notes payable	498,909	461,565
Notes payable, excluding current portion	<u>\$ 594,056</u>	<u>\$ 1,055,837</u>

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

**Table of Contents****PHARMANETICS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued**

The Company repaid its outstanding debt with GE Capital in March 2004. After this repayment, remaining notes payable aggregate \$7,553.

The fair value of the debt at December 31, 2003 is estimated by discounting the future cash flows using current rates that would be offered to the Company for similar debt issues. The fair values of long-term debt at December 31, 2003 and 2002 were approximately \$1,093,000 and \$1,517,000, respectively.

**10. COMMITMENTS AND CONTINGENCIES**

As of December 31, 2003, the Company leases its current facility under an operating lease agreement that contains an escalation rent clause tied to a pricing index and that extends until 2011. In addition, the Company leases certain equipment under various capital and operating lease agreements. Rent expense related to operating leases totaled \$436,495, \$418,553, and \$511,541 for the years ended December 31, 2003, 2002 and 2001, respectively.

Future minimum lease payments as of December 31, 2003 are as follows:

	<b>Capital Leases</b>	<b>Operating Leases</b>
	<u>          </u>	<u>          </u>
2004	\$ 19,521	\$ 384,751
2005	19,521	383,971
2006	6,507	364,832
2007		375,191
2008		378,652
Thereafter		879,378
	<u>          </u>	<u>          </u>
Total minimum lease payments	45,549	\$ 2,766,775
		<u>          </u>
Imputed interest	(7,009)	
	<u>          </u>	
Present value of minimum lease payments	38,540	
Less current maturities	(15,381)	
	<u>          </u>	
Long-term capital lease obligations	\$ 23,159	
	<u>          </u>	

In addition, the Company has contractual commitments to purchase \$75,000 of raw material inventory as of March 2004.

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

### **SERIES A**

During 2000, the Company completed a private placement of 120,000 shares of Series A convertible preferred stock ( Series A ), resulting in net proceeds to the Company of \$11,220,000. The Company also issued five-year warrants to acquire 240,000 shares of common stock at \$10.00 per share. Approximately \$1,275,000 of the net proceeds was allocated to the warrants based on their relative fair value as computed by using the Black-Scholes pricing model. The Series A has a dividend of 6% payable quarterly in cash or in shares of common stock at the option of the Company. The number of common stock dividend shares to be issued at each quarterly dividend date are determined using the average of the closing prices of the common stock on the Nasdaq SmallCap Market over the 30-day period ending three days prior to the end of each quarter. The number of shares to be issued is then multiplied by the closing market value of PharmaNetics common stock on the payment date to determine the amount recorded as the dividend in the financial statements. For the year ended December 31, 2003, the Series A dividend was paid by issuing 110,110 shares of common stock and was recorded at the fair value of the common stock on the quarterly dividend payment dates.

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**PHARMANETICS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements    Continued**

Each share of the Series A is convertible into ten shares of common stock. The number of common shares currently reserved for conversion of preferred stock and exercise of warrants, including the related dividends, is approximately 1,281,000. The Series A is convertible at the option of the holder at any time or may be redeemed at the option of the Company upon the occurrence of any of the following events: (a) the common stock closes at or above \$20.00 per share for 20 consecutive trading days, (b) a completion by the Company of a follow-on public offering of at least \$10 million at a per share price of at least \$15.00, (c) the acquisition of the Company by another entity by means of a transaction that results in the transfer of 50% or more of the outstanding voting power of the Company, (d) a sale of all or substantially all of the Company's assets, or (e) at any time after February 28, 2004.

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

Of the 120,000 shares originally issued in 2000, 54,500 of the shares have been converted into common stock since that date. Thus, at December 31, 2003, the outstanding Series A shares remaining total 65,500.

**SERIES B**

During May 2003, the Company completed a private placement of 95,800 shares of Series B convertible redeemable preferred stock ( Series B ), resulting in net proceeds to the Company of approximately \$8,700,000. The Company also issued five-year warrants, exercisable beginning November 1, 2003, to acquire 542,865 shares of common stock at \$7.20 per share. Approximately \$1,616,000 of the net proceeds was allocated to the warrants based on their relative fair value as computed using the Black-Scholes pricing model. The Series B has a dividend of 8.5% payable for the first nine quarters in additional shares of Series B preferred stock and then quarterly in cash or in shares of common stock at the option of the Company. The number of preferred stock dividend shares to be paid for each full quarterly period will equal 2.125% of the Series B shares outstanding on each dividend date. Any shares of common stock issued in payment of dividends after September 2005 will be valued at 90% of the volume weighted average of the closing prices of the common stock over the 30 days prior to any given quarterly dividend date, as reported on Nasdaq. For the year ended December 31, 2003, the Series B dividend was paid by issuing 5,554 shares of Series B preferred stock. These shares are convertible into approximately 92,569 shares of common stock, which number is multiplied by the closing market value of PharmaNetics stock on the quarterly dividend payment dates to determine the amount recorded as the Series B dividend.

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

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The holders of the Series B have the right to require the Corporation to redeem all or any outstanding Series B preferred upon a change of control event, as defined. Pari passu with the Series A holders, Series B holders have a liquidation preference of the greater of (i) an amount per share that holders would have received if all shares of the Series B preferred had been converted into common stock immediately prior to a liquidation event or (ii) \$100 per preferred share plus any accrued but unpaid dividends then held, such amounts subject to customary adjustments. The liquidation preference is payable upon a liquidating event, including a change in control of the Company, thus the Series B is carried in the mezzanine section of the balance sheet. The holders also have the right to vote together with the common stock on an as-if-converted basis.

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**Table of Contents****PHARMANETICS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements    Continued**

On the date of issuance of the Series B, the effective conversion price of the Series B was at a discount to the price of the common stock into which the Series B is convertible. In accordance with EITF 98-5, Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios and EITF 00-27 Application of Issue No. 98-5 to Certain Convertible Instruments, this discount totaled \$3,459,000 and was recorded as a preferred stock dividend in the second quarter of 2003. The proceeds of the offering were allocated between preferred stock and warrants issued and the \$3.5 million discount was determined by subtracting the effective conversion price of the common stock of \$4.95 from the common stock market value of \$7.12 the day before the closing and multiplying that number by the number of common shares issuable upon conversion of the preferred stock.

**12. RELATED PARTY TRANSACTIONS**

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

**13. STOCK OPTIONS**

The Company maintains two stock option plans whereby nonqualified and incentive stock options may be granted to employees, consultants and directors of the Company. Under these plans, options to purchase common stock are granted at a price determined by the Board of Directors. The options may be exercised during specified future periods and generally vest over four years and generally expire ten years from the date of grant. In 1994, the Company established the 1994 Stock Plan in which 639,249 shares of the Company's common stock are reserved for issuance. In 1995, the shareholders of the Company approved the adoption of the Company's 1995 Stock Plan in which 1,613,150 shares of the Company's common stock are currently reserved for issuance.

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

A summary of the status of the Company's Plans as of December 31, 2003, 2002 and 2001, and changes during the years ending on those dates, including the weighted average exercise price (WAEP) is presented below:

2003

2002

2001

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	<u>Shares</u>	<u>WAEP</u>	<u>Shares</u>	<u>WAEP</u>	<u>Shares</u>	<u>WAEP</u>
Outstanding at beginning of year	1,536,634	\$ 6.21	1,387,167	\$ 6.12	1,311,898	\$ 5.63
Granted	25,000	\$ 5.95	273,015	\$ 6.56	236,992	\$ 8.46
Exercised	(30,574)	\$ 1.80	(82,791)	\$ 4.86	(82,223)	\$ 5.36
Forfeited	(420,991)	\$ 9.19	(40,757)	\$ 8.04	(79,500)	\$ 5.83
Outstanding at end of year	1,110,069	\$ 5.20	1,536,634	\$ 6.21	1,387,167	\$ 6.12
Options exercisable at year-end	850,747	\$ 4.70	907,890	\$ 5.12	854,300	\$ 4.55

The weighted average fair value per share of options granted during the years ended December 31, 2003, 2002 and 2001 was \$4.38, \$4.88 and \$7.71, respectively.

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**Table of Contents****PHARMANETICS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued**

The following table summarizes information about the Plans' stock options, including the weighted average remaining contractual life (Life), at December 31, 2003:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number	Life	WAEP	Number	WAEP
\$ 0.79	261,786	5.4 years	\$ 0.79	261,786	\$ 0.79
\$ 3.75 \$ 5.00	188,597	2.9 years	\$ 4.70	188,597	\$ 4.70
\$ 5.25 \$ 5.95	81,250	6.0 years	\$ 5.43	81,250	\$ 5.43
\$ 6.00 \$ 6.67	365,955	7.2 years	\$ 6.28	174,931	\$ 6.18
\$ 7.00 \$ 9.87	170,481	7.5 years	\$ 8.33	110,933	\$ 8.63
\$10.00 \$15.06	42,000	6.7 years	\$ 12.30	33,250	\$ 12.72
	<u>1,110,069</u>			<u>850,747</u>	

**14. SIGNIFICANT CUSTOMERS AND RELATED PARTY**

During the years ended December 31, 2003, 2002 and 2001 there were sales to customers that exceeded 10% of net consolidated sales. Sales to these customers were:

	2003	2002	2001
Bayer Diagnostics	\$ 5,387,542	\$ 3,862,694	\$ 2,859,130
AstraZeneca		160,000	1,500,000

As of December 31, 2003 and 2002, there were outstanding receivables from the Company's distributor, Bayer Diagnostics, that exceeded 10% of total trade receivables. Receivables from this customer as a percentage of total trade receivables were 90% in 2003 and 96% in 2002.

As of March 12, 2004, the Company has ended its distribution agreement with Bayer Diagnostics.

The Company generated revenue from sales to different geographic areas during 2003, 2002 and 2001 as follows:

	<u>2003</u>	<u>2002</u>	<u>2001</u>
United States	\$ 5,513,526	\$ 3,930,443	\$ 3,038,842
Sweden		160,000	1,500,000
Total sales	<u>\$ 5,513,526</u>	<u>\$ 4,090,443</u>	<u>\$ 4,538,842</u>

#### 15. CONCENTRATION OF CREDIT RISK

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents and accounts receivable. The Company places its cash in accounts with federally insured depository institutions (up to \$100,000). At December 31, 2003 the Company had a majority of its cash and cash equivalents in one financial institution. Concentrations of credit risk with respect to trade receivables exist due to the Company's small customer base. Periodic credit evaluations of customers' financial condition are performed and generally no collateral is required. The Company establishes reserves for expected credit losses and such historical losses, in the aggregate, have not exceeded management's expectations.

#### 16. LICENSE AGREEMENTS

The Company entered into a license agreement with Tokuyama Soda Company, Ltd. ( "TS" ), as amended in December 1995, pursuant to which the Company granted TS exclusive rights to manufacture and sell PT and aPTT tests and analyzers in certain Asian countries. The Company received royalty payments under this agreement of \$38,366, \$43,705, and \$24,000 during the years ended December 31 2003, 2002 and 2001, respectively.

**Table of Contents****PHARMANETICS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued****17. INCOME TAXES**

The Company has not incurred income tax expense for the years ended December 31, 2003, 2002 and 2001. A reconciliation of expected income tax at the statutory U.S. federal rate of 34% with the actual income tax expense for the years ended December 31, 2003, 2002 and 2001 is as follows:

	<u>2003</u>	<u>2002</u>	<u>2001</u>
Expected income tax benefit at federal statutory rate	\$ (4,542,780)	\$ (3,779,457)	\$ (2,923,015)
State tax provision (benefit)	(545,039)	(440,877)	(397,096)
Other	473,540	16,240	669
Research and development credit	(216,664)	(156,107)	(47,057)
Change in valuation allowance	4,830,943	4,360,201	3,366,499
	<u>                    </u>	<u>                    </u>	<u>                    </u>
Net income tax provision	\$	\$	\$

The components of the net deferred tax assets and net deferred tax liabilities as of December 31, 2003 and 2002 were as follows:

	<u>2003</u>	<u>2002</u>
Deferred tax assets:		
Net operating loss carryforward	\$ 22,344,000	\$ 19,071,000
Research and development credits	876,000	659,000
Foreign tax credits	35,000	35,000
Accrued expenses	1,000	34,000
Alternative minimum tax credits	9,000	9,000
Deferred revenue	1,269,000	1,630,000
Inventory reserve	830,000	29,000
Other	289,000	257,000
	<u>                    </u>	<u>                    </u>
Total gross deferred tax assets	25,653,000	21,724,000
Valuation allowance	(25,523,000)	(20,692,000)
	<u>                    </u>	<u>                    </u>
Net deferred tax assets	130,000	1,032,000
Deferred tax liabilities:		
Patents	75,000	179,000
Investment adjustment	484,000	484,000
Fixed assets	(429,000)	369,000

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Total gross deferred tax liabilities	130,000	1,032,000
Net deferred taxes	\$	\$

At December 31, 2003 and 2002, the Company had approximately \$58,318,000 and \$49,828,000, respectively, of combined federal net operating losses. These losses expire in varying amounts beginning in 2004 if not utilized. At December 31, 2003 and 2002 for state income tax purposes, the Company had net operating loss carryforwards of approximately \$55,253,000 and \$46,373,000, respectively. These carryforwards expire in varying amounts beginning in 2008 if not utilized. To the extent that a previously owned subsidiary's net operating losses incurred through 1994 (approximately \$2,000,000 at December 31, 2003) are utilized in the future, the benefit will reduce the excess cost over fair value of net assets acquired. The 2003 and 2002 valuation allowance includes an allowance against net operating losses generated by tax only deductions for stock options for approximately \$140,000, for which the benefit will go directly to shareholders' equity. Due to the Company's history of operating losses and uncertainty regarding its ability to generate taxable income in the future, management has determined that a valuation allowance equal to the amount of net deferred tax assets is required at December 31, 2003 and 2002. As a result of changes in ownership in prior years, as defined by Internal Revenue Code Section 382, the utilization of a previously owned subsidiary's loss carryforwards generated through December 31, 1993 and the Company's consolidated loss carryforwards generated through January 1994 will be subject to an annual limitation of approximately \$175,000 and \$482,000, respectively. An additional change in ownership occurred in 1995 in connection with the Company's initial public offering which subjects the loss carryforwards generated during the period from January 1994 to December 1995 to an incremental annual limitation of approximately \$1,954,000 per year.

**Table of Contents****PHARMANETICS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements Continued****18. LEGAL PROCEEDINGS**

On November 4, 2003, the Company filed a lawsuit in the eastern district court of North Carolina against Aventis Pharmaceuticals, Inc., a wholly-owned subsidiary of French pharmaceutical company Aventis. The lawsuit alleges that Aventis has engaged in false and misleading advertising of its drug Lovenox®, which has damaged sales of the Enox test card, a rapid point-of-care test developed in cooperation with Aventis to enhance the way Lovenox is managed in the cardiac community. The Company is seeking injunctive relief against Aventis to prevent the use of false, misleading and deceptive promotional messages in their advertising and sales activities. The Company also is demanding that Aventis promote the need for monitoring as required in Lovenox s® labeling and as required by the development agreement entered into between the two companies in August 2000. On November 25, 2003, Aventis filed a counterclaim against the Company, alleging libel and slander; trade libel, product disparagement and injurious falsehood; fraud in the inducement; breach of contract; state statutory unfair competition and unfair and deceptive trade practices; and common law unfair competition. The Company has denied all of these allegations and is aggressively defending against Aventis counterclaim. An initial hearing on this matter was held before the court in New Bern, North Carolina on March 22 through March 24th and the parties are awaiting the court s response to these proceedings.

**19. SUMMARY QUARTERLY FINANCIAL DATA (UNAUDITED)**

The following represents a summary of operations for the quarters of 2003 and 2002:

	<b>2003</b>			
	<b>First</b>	<b>Second</b>	<b>Third</b>	<b>Fourth</b>
	<b>Quarter</b>	<b>Quarter</b>	<b>Quarter</b>	<b>Quarter</b>
Total revenues	\$ 1,423,000	\$ 1,915,000	\$ 1,641,000	\$ 1,615,000
Gross profit	479,000	665,000	424,000	23,000
Operating expenses	3,736,000	4,054,000	3,659,000	8,511,000(a)
Net loss before preferred stock charges	(2,344,000)	(2,126,000)	(1,987,000)	(6,904,000)(a)
Net loss attributable to common shareholders	(2,467,000)	(5,830,000)(b)	(2,271,000)	(7,074,000)(a)
Net loss attributable to common shareholders per common share	\$ (0.25)	\$ (0.60)(b)	\$ (0.23)	\$ (0.72)(a)
	<b>2002</b>			
	<b>First</b>	<b>Second</b>	<b>Third</b>	<b>Fourth</b>
	<b>Quarter</b>	<b>Quarter</b>	<b>Quarter</b>	<b>Quarter</b>

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Total revenues	\$ 1,057,000	\$ 937,000	\$ 1,307,000	\$ 1,421,000
Gross profit	37,000	77,000	254,000	227,000
Operating expenses	3,354,000	3,272,000	3,486,000	5,789,000(c)
Net loss before preferred stock charges	(2,255,000)	(2,323,000)	(2,185,000)	(4,353,000)(c)
Net loss attributable to common shareholders	(2,381,000)	(2,426,000)	(2,293,000)	(4,498,000)
Net loss attributable to common shareholders per common share	\$ (0.25)	\$ (0.25)	\$ (0.24)	\$ (0.47)

- (a) Includes \$4.5 million in write-downs of inventory and long-lived assets
- (b) Includes \$3.5 million beneficial conversion feature charge related to issuance of Series B preferred stock
- (c) Includes \$1.3 million non-cash compensation expense related to stock-based compensation

### 20. SUBSEQUENT EVENTS

On January 16, 2004, the Company announced that it had engaged Davenport & Company LLC, an investment banking firm, as its financial advisor to assist the Company in pursuing a potential sale of its manufacturing operations and routine test business as well as review other strategic alternatives.



**Table of Contents****PHARMANETICS, INC.****CONSOLIDATED BALANCE SHEETS**

(In thousands, except share data)

	MARCH 31, 2004 <u>(Unaudited)</u>	DECEMBER 31, 2003
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 5,716	\$ 8,463
Accounts receivable from related party	615	498
Other receivables, net of allowance for doubtful accounts of \$1 and \$2, respectively	46	54
Inventories		567
Other current assets	499	623
<b>Total current assets</b>	<b>6,876</b>	<b>10,205</b>
Property and equipment, net	4,051	4,656
Patents and intellectual property, net	330	403
Other noncurrent assets	3	3
<b>Total assets</b>	<b>\$ 11,260</b>	<b>\$ 15,267</b>
<b>LIABILITIES, CONVERTIBLE REDEEMABLE PREFERRED STOCK, AND SHAREHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 251	\$ 800
Accrued expenses	1,117	538
Deferred revenue, current portion	1,042	1,226
Current portion of long term debt and capital lease obligations	20	514
<b>Total current liabilities</b>	<b>2,430</b>	<b>3,078</b>
Noncurrent liabilities:		
Deferred revenue, less current portion	1,737	2,065
Long term debt and capital lease obligations, less current portion	21	617
<b>Total noncurrent liabilities</b>	<b>1,758</b>	<b>2,682</b>
<b>Total liabilities</b>	<b>4,188</b>	<b>5,760</b>
Series A convertible redeemable preferred stock, no par value; authorized 120,000 shares; 65,000 and 65,500 shares issued and outstanding at March 31, 2004 and December 31, 2003, respectively (aggregate liquidation value at March 31, 2004 of \$6,500,000)	5,401	5,443
Series B convertible redeemable preferred stock, no par value; authorized 130,000 shares; 103,058 and 101,354 shares issued and outstanding at March 31, 2004 and December 31, 2003, respectively (aggregate liquidation value at March 31, 2004 of \$10,305,800)	7,495	7,408
Shareholders equity:		
Common stock, no par value; authorized 40,000,000 shares; 10,068,246 and 10,021,556 shares issued and outstanding at March 31, 2004 and December 31, 2003, respectively	75,653	75,511
Accumulated deficit	(81,477)	(78,855)

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Total shareholders' equity	(5,824)	(3,344)
Total liabilities, redeemable preferred stock and shareholders' equity	\$ 11,260	\$ 15,267

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

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**Table of Contents****PHARMANETICS, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)****(IN THOUSANDS, EXCEPT PER SHARE DATA)**

	<b>THREE MONTHS ENDED</b>	
	<b>MARCH 31,</b>	<b>MARCH 31,</b>
	<b>2004</b>	<b>2003</b>
Net product sales to related party	\$ 1,688	\$ 1,147
Net product sales to third parties	175	15
Development income	261	261
<b>Total revenues</b>	<b>2,124</b>	<b>1,423</b>
Operating expenses:		
Cost of goods sold	1,107	683
General and administrative	2,390	1,062
Sales and marketing	396	728
Research and development	374	1,263
Write-down of inventories	378	
<b>Total operating expenses</b>	<b>4,645</b>	<b>3,736</b>
<b>Operating loss</b>	<b>(2,521)</b>	<b>(2,313)</b>
Other income (expense):		
Interest expense	(25)	(37)
Interest income	17	11
Other income (expense)	94	(5)
<b>Total other income (expense)</b>	<b>86</b>	<b>(31)</b>
<b>Net and comprehensive loss</b>	<b>(2,435)</b>	<b>(2,344)</b>
Dividends on preferred stock	186	123
<b>Net loss applicable to common shareholders</b>	<b>\$ (2,621)</b>	<b>\$ (2,467)</b>
<b>Basic and diluted net loss per common share</b>	<b>\$ (0.26)</b>	<b>\$ (0.25)</b>
<b>Average weighted common shares outstanding</b>	<b>10,022</b>	<b>9,701</b>

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



**Table of Contents****PHARMANETICS, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)**

(In thousands)

	<b>Three Months Ended</b>	
	<b>March 31, 2004</b>	<b>March 31, 2003</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (2,435)	\$ (2,344)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation	615	442
Amortization of intangible and other assets	79	29
Loss (gain) on trading securities	(3)	6
Provision for inventory obsolescence		20
Write-down of inventory to net realizable value	379	
<b>Change in operating assets and liabilities:</b>		
Accounts receivable	(109)	80
Inventories	189	(454)
Other assets	126	59
Accounts payable and accrued expenses	30	(391)
Deferred revenue	(512)	(224)
<b>Net cash used in operating activities</b>	<b>(1,641)</b>	<b>(2,777)</b>
<b>Cash flows from investing activities:</b>		
Payments for purchase of property and equipment	(10)	(63)
Costs incurred to obtain patents and intangibles	(6)	(14)
<b>Net cash used in investing activities</b>	<b>(16)</b>	<b>(77)</b>
<b>Cash flows from financing activities:</b>		
Principal payments on long-term debt and capital lease obligations	(1,090)	(79)
Proceeds from common stock options exercised		37
<b>Net cash used in financing activities</b>	<b>(1,090)</b>	<b>(42)</b>
<b>Net decrease in cash and cash equivalents</b>	<b>(2,747)</b>	<b>(2,896)</b>
Cash and cash equivalents at beginning of period	8,463	9,146
<b>Cash and cash equivalents at end of period</b>	<b>\$ 5,716</b>	<b>\$ 6,250</b>
<b>Supplemental disclosure of noncash investing and financing activities:</b>		
Series A preferred stock dividends paid with common shares	\$ 100	\$ 123
Series B preferred stock dividends paid with preferred shares	86	
Conversion of Series A Preferred Stock into common stock	42	789

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



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**PHARMANETICS, INC.**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

(unaudited)

Note 1. Organization and Basis of Presentation

PharmaNetics, Inc. (the Company) is a holding company incorporated in July 1998 as the parent company of Cardiovascular Diagnostics, Inc. (CVDI). CVDI was incorporated in November 1985 and formerly developed, manufactured and marketed rapid turnaround diagnostics to assess blood clot formation and dissolution. CVDI developed tests based on its proprietary dry chemistry diagnostic test system, known as the Thrombolytic Assessment System (TAS), to provide rapid and accurate evaluation of hemostasis at the point of patient care.

In December 2003, the Company announced that, as a result primarily of the dispute and litigation with Aventis Pharmaceuticals and its impact on the Company's business and prospects, it was seeking a variety of strategic alternatives, including the sale of its manufacturing operations. At that time, the Company also announced that, if a willing and able buyer for the operations is not identified, it would terminate its distribution agreement with its distribution partner, Bayer Diagnostics (Bayer). As required under the distribution agreement with Bayer, the Company provided Bayer 90-day notice that it would terminate this agreement effective March 12, 2004. In addition, the Company provided 90-day notice to PDI, the contractor and provider of the Enox sales and technical support teams, that the sales and technical service personnel would be terminated by March 12, 2004. PharmaNetics believes these steps were and are necessary in order to reduce overhead costs and to conserve cash for the Company's efforts to license and sell assets and its intellectual property as well as to finance its lawsuit against Aventis. Since filing the lawsuit, the Company has implemented personnel reductions and has engaged Davenport & Company LLC (Davenport), an investment banking firm, as its financial advisor. Davenport is currently assisting the Company in pursuing a sale of its manufacturing operations and intellectual property. As of the end of April 2004, no buyer has emerged and the Company has ended its distribution agreement with Bayer and has ceased producing and selling all products. The Company is shifting its corporate strategy from a manufacturing/distribution model to that of a biotech model, whereby revenues, if any, would be tied to royalty streams from future product sales. The Company is actively seeking a buyer for its operating assets and to sell or license its intellectual property with a significant portion of the potential valuation tied to royalties. In essence, if successful in implementing such a potential arrangement, the Company would receive royalties on tests developed and would not be responsible for manufacturing and distribution. This new approach would not preclude the Company from initiating future operations related to new products if circumstances warranted it.

The consolidated financial statements included herein as of any date other than December 31 have been prepared by the Company without audit, pursuant to the rules and regulations of the Securities and Exchange Commission. Financial information as of December 31 has been derived from the audited financial statements of the Company, but does not include all disclosures required by generally accepted accounting principles. In the opinion of management, the accompanying unaudited consolidated financial statements include all adjustments (consisting only of normal recurring adjustments) necessary to fairly state the consolidated financial position, results of operations and cash flows of the Company. For further information regarding the Company's accounting policies, refer to the Consolidated Financial Statements and related notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2003. Because the Company has ceased operations, the results for this interim period, in particular, are not indicative of the results for future interim periods.

Note 2. Revenue Recognition

While in operation, the Company recorded revenue from the sale of products when an arrangement existed, the product had been delivered or services had been rendered (transfer of risk occurs), the price was fixed and determinable and collectibility was reasonably assured. For all

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products except the Enox test, the Company recorded revenue from product sold to Bayer, then our sole distribution partner and largest customer, when the above elements existed and specifically upon transfer of risk (at delivery) to Bayer. Delivery occurred at the point of shipment and title legally passed at that time. Bayer assumed all risk of loss once title passed and took ownership of the finished inventory and held it for resale to hospitals. The Company does not retain any additional performance obligation with respect to the product once the product has been manufactured and transferred to Bayer. The product, except in the case of defects, is not returnable and there has not been a history of defective product returns. A standard pricing model has been in place and the Company does not offer price protection or rights of return. The Company recorded product revenue from the sale of the Enox test upon shipment of the product to the hospital. The Company invoiced Bayer at the shipment date, netting a 10% commission paid to Bayer (for administration and collection services) against the product revenue to be recognized in accordance with EITF 01-09 Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products). Bayer was responsible for invoicing and collecting from the hospital and paid the Company regardless of whether it collected from the hospital. The Company accounts for royalties on an accrual basis. Tokuyama Soda pays the Company royalties based on Tokuyama's net sales of a licensed product. The Company recognizes income under license and development agreements over the anticipated period of the agreements with its collaborators, in accordance with SEC Staff Accounting Bulletin No. 104 (SAB 104). SAB 104 clarifies conditions to be met to recognize up-front non-refundable payments. Such payments are recognized over the life of the

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related agreement unless the payment relates to products delivered or services performed that represent the completion of the earnings process. Payments received but not recognized into income in the year of receipt are deferred and recognized over the period of the respective agreements. For example, the Company received upfront payments for development of the Enoxaparin test card from Aventis. Pursuant to this arrangement, the Company received non-refundable milestone payments for executing the agreement, completing the development, FDA approval, and the first commercial sale of the product. There is a period of four years after the first commercial sale of the test card in which the Company cannot develop a similar test card for another entity. The Company is recognizing the milestone payments over a period of five years, based on the estimated life of the relationship.

## Note 3. Cash Equivalents

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

## Note 4. Inventory

Inventories consisted of the following (in thousands):

	<b>March 31, 2004</b>	<b>December 31, 2003</b>
	<u>          </u>	<u>          </u>
Raw materials	\$ 1,849	\$ 2,013
Work in process		135
Finished goods	502	571
Less: reserve		(179)
Less: write-down to net realizable value	(2,351)	(1,973)
	<u>          </u>	<u>          </u>
	<b>\$</b>	<b>\$ 567</b>
	<u>          </u>	<u>          </u>

As a result of ceasing operations, the Company recorded a write-down in the quarter ended March 31, 2004 to reduce its inventories from standard cost to its estimated net realizable value.

## Note 5. Patents and Intellectual Property

Patents and intellectual property costs are capitalized and are amortized using the straight-line method over their estimated useful lives. Due to events in the fourth quarter of 2003 relating to the Aventis litigation and leading up to the cessation of operations, the estimated useful lives of the patents have been reduced from seventeen years to two years.

## Note 6. Loss Per Common Share

In accordance with Statement of Financial Accounting Standards ( SFAS ) No. 128, Earnings Per Share ( EPS ), the Company is required to present both basic and diluted EPS on the face of the Statement of Operations. Basic EPS excludes dilution and is computed by dividing income (loss) attributable to common shareholders by the weighted average number of common shares outstanding for the period. Diluted EPS is the same as basic EPS for the Company's quarters ended March 31, 2004 and 2003, because, for loss periods, potential common shares (such as options) are not included in computing diluted EPS since the effect would be antidilutive. The number of potential common shares (represented by shares issuable upon the exercise or conversion of outstanding options, warrants and convertible preferred stock) as of March 31, 2004 and 2003 totaled 3,987,141 and 2,587,634, respectively.

Note 7. Preferred Stock

Series A Convertible Redeemable Preferred Stock

During 2000, the Company completed a private placement of 120,000 shares of Series A convertible preferred stock ( Series A ), resulting in net proceeds to the Company of \$11,220,000. The Company also issued five-year warrants to acquire 240,000 shares of common stock at \$10.00 per share. Approximately \$1,275,000 of the net proceeds was allocated to the warrants based on their relative fair value as computed by using the Black-Scholes pricing model. The Series A has an annual dividend of 6% payable quarterly in cash or in shares of common stock at the option of the Company. The number of common stock dividend shares to be issued at each quarterly dividend date are determined using the average of the closing prices (or average of the closing bid or sales prices, whichever is applicable, in the case shares are traded over the counter) of the common stock on the Nasdaq SmallCap Market over the 30-day period ending three days prior to the end of each quarter. The number of shares to be issued is then multiplied by the closing market value of PharmaNetics common stock on the payment date to determine the amount recorded as the dividend in the financial statements. For the quarter ended March 31, 2004, the Series A dividend was paid by issuing 41,690 shares of common stock and was recorded at the fair value of the common stock on the dividend payment date of March 31.

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Each share of the Series A is convertible into ten shares of common stock. The number of common shares reserved for conversion of Series A preferred stock and exercise of warrants held by Series A investors, including the related dividends, is approximately 1,281,000. The Series A is convertible at the option of the holder at any time or may be redeemed at the option of the Company at any time.

The holders of the Series A have a liquidation preference of \$100 per preferred share (totaling \$6,500,000) plus any accrued but unpaid dividends then held, such amounts subject to certain adjustments. The liquidation preference is payable, in preference to the common stock, upon a change in control of the Company, thus the Series A is carried in the mezzanine section of the balance sheet. The holders also have the right to vote together with the common stock on an as-if-converted basis.

On the date of issuance of the Series A, the effective conversion price of the Series A was at a discount to the price of the common stock into which the Series A is convertible. In accordance with EITF 98-5, Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios, this discount totaled \$3,004,000 and was recorded as a preferred stock dividend during 2000.

### Series B Convertible Redeemable Preferred Stock

During May 2003, the Company completed a private placement of 95,800 shares of Series B convertible redeemable preferred stock ( Series B ), resulting in net proceeds to the Company of approximately \$8,700,000. The Company also issued five-year warrants to acquire 542,865 shares of common stock at \$7.20 per share. Approximately \$1,671,000 of the net proceeds was allocated to the warrants based on their relative fair value as computed using the Black-Scholes pricing model. The Series B has an annual dividend of 8.5% payable quarterly for the first nine quarters in additional shares of Series B preferred stock and thereafter quarterly in cash or in shares of common stock at the option of the Company. The number of preferred stock dividend shares to be paid for each full quarterly period will equal 2.125% of the Series B shares outstanding on each dividend date. Any shares of common stock issued in payment of dividends after September 2005 will be valued at 90% of the volume weighted average of the closing prices of the common stock over the 30 days prior to any given quarterly dividend date, as reported on Nasdaq or such other principal exchange on which the Company's common stock is traded. For the quarter ended March 31, 2004, the Series B dividend was paid by issuing 2,154 shares of Series B preferred stock. These shares are convertible into approximately 35,901 shares of common stock, which number is multiplied by the closing market price of PharmaNetics stock on the dividend payment date of March 31, 2004 to determine the amount recorded for accounting purposes as the Series B dividend.

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

The holders of the Series B have the right to require the Company to redeem all or any outstanding Series B preferred upon a change of control event, as defined. Pari passu with the Series A holders, Series B holders have a liquidation preference of the greater of (i) an amount per share that holders would have received if all shares of the Series B preferred had been converted into common stock immediately prior to a liquidation event or (ii) \$100 per preferred share (totaling \$10,305,800) plus any accrued but unpaid dividends then held, such amounts subject to customary adjustments. The liquidation preference is payable upon a liquidating event, including a change in control of the Company, thus the Series B is carried in the mezzanine section of the balance sheet. The holders also have the right to vote together with the common stock with each share of Series B entitled to approximately 14.04 votes.

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On the date of issuance of the Series B, the effective conversion price of the Series B was at a discount to the price of the common stock into which the Series B is convertible. In accordance with EITF 98-5, Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios and EITF 00-27 Application of Issue No. 98-5 to Certain Convertible Instruments, this discount totaled \$3,459,000 and was recorded as a preferred stock dividend in the second quarter of 2003. The proceeds of the offering were allocated between preferred stock and warrants issued and the \$3.5 million discount was determined by subtracting the effective conversion price of the common stock of \$4.95 from the common stock market value of \$7.12 the day before the closing and multiplying the difference by the number of common shares issuable upon conversion of the preferred stock.

### Note 8. Related Party Transactions

In April 2001, Bayer Diagnostics 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%. The Company and Bayer

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formerly maintained a distribution agreement to market and distribute the Company's routine tests worldwide and the Company's enoxaparin test in countries other than the United States. This distribution agreement was terminated in March 2004 and Bayer no longer serves as the Company's distributor.

### Note 9. Accrued Expenses

At March 31, 2004 and December 31, 2003, the Company had accrued \$341,000 and \$130,000 respectively, related to severance payments to employees terminated as a result of the Company ceasing operations. These amounts are included within accrued expenses.

### Note 10. Debt

During the quarter ended March 31, 2004, the Company paid the remaining balance of its outstanding equipment loan from General Electric (GE). Total debt and capital lease paydown, including repaying the remainder of the GE debt, totaled \$1.1 million during the quarter.

### Note 11. Development Income and Deferred Revenue

The Company recognizes development income in accordance with SEC Staff Accounting Bulletin No. 104. Under SAB 104, payments received under collaboration agreements are deferred and recognized as income over the period of the respective agreements. Historically, the Company has received payments as part of collaboration agreements with other entities. Revenue recognized related to collaboration agreements for the quarters ended March 31, 2004 and 2003 were \$261,000. At March 31, 2004, total payments received but deferred to future periods was \$2,779,000. These amounts will be amortized through 2006.

### Note 12. Significant Customers and Related Party

During the quarters ended March 31, 2004 and 2003, the Company had sales to Bayer totaling \$1,688,000 and \$1,147,000, respectively, representing 91% and 99% of total product revenues for the respective periods. At March 31, 2004 and December 31, 2003, outstanding receivables from that customer totaled 93% and 90%, respectively, of total receivables.

### Note 13. Stock Based Compensation

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

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reported had FAS 123 been adopted for recognition purposes as of its effective date. These disclosures are required to be made in annual financial statements and in quarterly information provided to shareholders without regard to whether the entity has adopted FAS 123 for recognition purposes.

For purposes of the proforma disclosures required for the quarter ended March 31, 2004, no stock option grants were made in the first quarter of 2004. For the periods ended March 31, 2004 and 2003, the following table summarizes the net loss and stock-based compensation expense, as reported, compared to pro forma amounts had the fair value method been applied:

	<b>Three Months Ended</b>	<b>Three Months Ended</b>
	<b>March 31, 2004</b>	<b>March 31, 2003</b>
	<u>                    </u>	<u>                    </u>
Net loss attributable to common shareholders, as reported	\$ (2,435,000)	\$ (2,344,000)
Net loss per basic and diluted share, as reported	\$ (0.26)	\$ (0.25)
Stock based compensation based on fair value method	\$ (0)	\$ (274,000)
Pro forma net loss using fair value method	\$ (2,435,000)	\$ (2,618,000)
Pro forma net loss per basic and diluted share	\$ (0.26)	\$ (0.27)

### Note 14. Legal Proceedings

In November 2003, the Company filed a lawsuit in the United States District Court of the Eastern District of North Carolina against Aventis Pharmaceuticals, Inc., the wholly owned subsidiary of French pharmaceutical company, Aventis. The lawsuit alleges that Aventis has engaged in false and misleading advertising of its second largest drug, Lovenox<sup>®</sup>, which has damaged the Company's sales of its Enox test card, a rapid point-of-care test developed in cooperation with Aventis to enhance the way Lovenox is managed in

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the cardiac community. In addition to claims of false advertising, the Company's complaint includes allegations of tortious interference, fraud and breach of contract. As part of the lawsuit, the Company requested that the court enter a preliminary injunction against Aventis to prevent Aventis from falsely advertising Lovenox.

On March 22-24, 2004, the court held a hearing on the Company's motion for a preliminary injunction against Aventis. On April 29, 2004, the court issued an order denying the Company's request for a preliminary injunction, but in denying the Company's motion, the court made a judicial determination that two of Aventis' advertising claims regarding Lovenox were literally false. First, the court found that Aventis' claim that Lovenox reaches therapeutic levels with 1/2 hour of administration to be literally false. Second, the court found literally false Aventis' claim that Lovenox was therapeutic from dose one. Although the court did not grant the Company's request for a preliminary injunction, one of the reasons cited by the court for not enjoining these false advertising messages was that Aventis has discontinued using these false statements in its advertising. In particular, after the Company filed its false advertising lawsuit against Aventis in November 2003, almost immediately thereafter Aventis withdrew these statements from its advertising of Lovenox.

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

Note 15. Recent Accounting Pronouncements

In January 2003, the Financial Accounting Standards Board issued Interpretation No. 46 (FIN 46), Consolidation of Variable Interest Entities, which requires the assets, liabilities and results of operations of variable interest entities (VIE) be consolidated into the financial statements of the company that has controlling financial interest. FIN 46 also provides the framework for determining whether a VIE should be consolidated based on voting interest or significant financial support provided to the VIE. The Company adopted these provisions, as required, with respect to VIEs created after January 31, 2003. The effective date for applying the provisions of FIN 46 for interests held by non-public entities in VIEs or potential VIEs created before February 1, 2003 is January 1, 2005.

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**No one (including any salesman or broker) is authorized to provide oral or written information about this offering that is not included in this prospectus.**

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**2,472,364 SHARES**

**PHARMANETICS, INC.**

**COMMON STOCK**

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**PROSPECTUS**

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June 30, 2004