

PHARMANETICS INC

Form 10-Q

May 14, 2004

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# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

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## FORM 10-Q

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**x**      Quarterly report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934.

For the quarterly period ended March 31, 2004.

**..**      Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission File Number

0-25133

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## PHARMANETICS, INC.

(Exact Name of Registrant as Specified in its Charter)

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North Carolina  
(State or other jurisdiction of

Incorporation or organization)

56-2098302  
(IRS Employer

Identification Number)

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9401 Globe Center Drive, Suite 140

Morrisville, North Carolina  
(Address of Principal Executive Office)

27560  
(Zip Code)

Registrant's Telephone Number, Including Area Code 919-582-2600

\_\_\_\_\_

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

<u>Class</u>	<u>Outstanding as of May 11, 2004</u>
Common Stock, no par value	10,089,245

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

(In thousands, except share data)

	<b>MARCH 31,</b>	<b>DECEMBER 31,</b>
	<b>2004</b>	<b>2003</b>
	<b>(Unaudited)</b>	
<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
	<u>6,876</u>	<u>10,205</u>
Total current assets	6,876	10,205
Property and equipment, net	4,051	4,656
Patents and intellectual property, net	330	403
Other noncurrent assets	3	3
	<u>4,384</u>	<u>5,062</u>
Total assets	\$ 11,260	\$ 15,267
<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
	<u>2,430</u>	<u>3,078</u>
Total current liabilities	2,430	3,078
Noncurrent liabilities:		
Deferred revenue, less current portion	1,737	2,065
Long term debt and capital lease obligations, less current portion	21	617
	<u>1,758</u>	<u>2,682</u>
Total noncurrent liabilities	1,758	2,682
Total liabilities	4,188	5,760
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.

**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
Total revenues	2,124	1,423
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	
Total operating expenses	4,645	3,736
Operating loss	(2,521)	(2,313)
Other income (expense):		
Interest expense	(25)	(37)
Interest income	17	11
Other income (expense)	94	(5)
Total other income (expense)	86	(31)
Net and comprehensive loss	(2,435)	(2,344)
Dividends on preferred stock	186	123
Net loss applicable to common shareholders	\$ (2,621)	\$ (2,467)
Basic and diluted net loss per common share	\$ (0.26)	\$ (0.25)
Average weighted common shares outstanding	10,022	9,701

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>
Cash flows from operating activities:		
Net loss	\$ (2,435)	\$ (2,344)
Adjustments to reconcile net loss to net cash used in operating activities:		
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	
Change in operating assets and liabilities:		
Accounts receivable	(109)	80
Inventories	189	(454)
Other assets	126	59
Accounts payable and accrued expenses	30	(391)
Deferred revenue	(512)	(224)
Net cash used in operating activities	(1,641)	(2,777)
Cash flows from investing activities:		
Payments for purchase of property and equipment	(10)	(63)
Costs incurred to obtain patents and intangibles	(6)	(14)
Net cash used in investing activities	(16)	(77)
Cash flows from financing activities:		
Principal payments on long-term debt and capital lease obligations	(1,090)	(79)
Proceeds from common stock options exercised		37
Net cash used in financing activities	(1,090)	(42)
Net decrease in cash and cash equivalents	(2,747)	(2,896)
Cash and cash equivalents at beginning of period	8,463	9,146
Cash and cash equivalents at end of period	\$ 5,716	\$ 6,250
Supplemental disclosure of noncash investing and financing activities:		
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>
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)
	<b>\$</b>	<b>\$ 567</b>

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**

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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:

	Three Months Ended	Three Months Ended
	March 31, 2004	March 31, 2003
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.

## **ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

This Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements. Our actual results might differ materially from those projected in the forward-looking statements due to any number of factors, including those set forth below under Factors That May Affect Future Results. Additional information concerning factors that could cause actual results to materially differ from those in the forward-looking statements is contained in our other SEC filings, copies of which are available upon request to us.

The following discussion should be read in connection with the unaudited Consolidated Financial Statements and Notes thereto appearing elsewhere in this report. Unless the context indicates otherwise, all references to the Company include our wholly-owned subsidiary, Cardiovascular Diagnostics, Inc., or CVDI.

**BUSINESS**

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

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### **OVERVIEW**

The Company has derived income from the following sources: TAS product sales, interest income, and development income recognized in connection with collaboration agreements. Product sales have mainly consisted of the Company's routine test cards, the PT, aPTT, HMT, HTT, PRT and LHMT tests along with the related controls and analyzers. These products were distributed under a global distribution agreement with Bayer Diagnostics. In August 1998, the Company signed a five-year global distribution agreement, subject to minimum annual sales, with Chiron Diagnostics, now Bayer Diagnostics, to distribute the products. At that time and under a separate purchase agreement, the Company received an up-front investment of \$6 million from Bayer in exchange for 600,000 shares of common stock, all of which were recorded as an increase to stockholder's equity. Under that agreement, Bayer agreed to purchase minimum quantities of the Company's products covered by the agreement at pre-determined prices. The prices charged to Bayer were variable depending on purchase volumes. Subsequently, in April 2001, Bayer purchased 1,450,000 shares of common stock at a negotiated price of \$12 per share, representing a negotiated premium to market price at that time, for \$17.4 million, all of which was recorded as an increase to stockholder's equity. At that time, this investment increased Bayer's ownership percentage in the Company from approximately 7% to 19.9%. In connection with the 2001 investment, the Company entered into an amended distribution agreement with Bayer to replace the previous distribution agreement. Under the terms of the amended agreement, Bayer agreed to purchase, at the same pre-determined prices as in the original distribution agreement, the same products as covered by the original agreement. For these products distributed by Bayer, Bayer would send monthly purchase orders and the Company would transfer ownership of the product to and receive payment from Bayer. As requested by Bayer, and in accordance with Bayer's pre-determined delivery schedule, upon receipt of the committed purchase order, the Company would produce and transfer the product into Bayer's segregated warehouse facility at the Company. The Company did not retain any specific performance obligation with respect to product once it was completed and transferred to the segregated warehouse space. The Company sold this product to Bayer at the pre-determined prices set forth in the amended distribution agreement and Bayer took ownership of and assumed all risk for the inventory upon transfer and then held it for resale. Bayer does not have any right to return unsold product and has no history of requesting return. Assuming full conversion of outstanding preferred stock into common stock, Bayer now owns approximately 17% of the Company's outstanding shares and maintains the right to designate one nominee for election to 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 the amended distribution agreement with Bayer, the Company expanded its relationship with Bayer to cover collaborative distribution and supply of certain theranostic tests in the United States, principally the Enox test. The Company commercially launched this test in January 2003 to detect the anticoagulant effects of enoxaparin sodium, a leading low molecular weight heparin marketed by Aventis. Under the provisions of the amended distribution agreement, Bayer was exclusively responsible for receiving the Enox sales order from the hospital, informing the Company of the order, sending an invoice to the hospital and collecting that resulting receivable, thus assuming the credit and collection risk. For these services, Bayer received a commission of 10% of the price of each card. The Enox test inventories were maintained on the Company's books until shipment and the Company would invoice Bayer for the shipment of Enox tests and record revenue upon shipment of the product to the hospital that placed the order with Bayer, which is when all elements of the Company's revenue recognition policy have been met. The Company offered no price concession to Bayer, received payment therefore directly from Bayer within 30 to 70 days of the invoice date and Bayer's 10% commission was netted and recorded against the revenue in the financial statements.

The Company hired contract sales and technical service personnel to work with Aventis' sales force in promoting the Enox test. However, in November 2003, the Company filed a lawsuit in the eastern district of North Carolina against Aventis. The Company, in cooperation with Aventis, developed the Enox test, which the Company believes enhances the way Lovenox®, a popular anti-blood clotting drug marketed by Aventis, currently is managed. The Company believes the test has the potential to facilitate the drug's use in patients in the cardiac community who stand to benefit from its use. Aventis collaborated with the Company in a multi-million dollar project in which it made milestone payments to the Company to develop and co-promote the test together with Lovenox for targeted patient populations. See Note 14 - Legal Proceedings in the Notes to the Consolidated Financial Statements in this report for more information on the Aventis litigation. The Company intends to aggressively pursue the lawsuit to enforce its rights, and the Company expects the lawsuit could take a year or more to complete and consume significant time and expense.

In December 2003, the Company announced that, primarily as a result of the Aventis litigation and its impact on the Company's business and prospects, it is pursuing a variety of strategic alternatives, including the sale of its manufacturing operations. At that time, the Company also

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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 or sale of assets and the intellectual property as well as to finance its lawsuit against Aventis. Since filing the lawsuit, the Company has implemented significant personnel reductions and has engaged Davenport & Company LLC ( Davenport ), an investment banking firm, as its financial advisor. Davenport is currently assisting the Company in pursuing a sale of its manufacturing operations and intellectual property. As of the end of April 2004, no buyer has yet

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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 this new strategy, under such a potential arrangement, the Company would receive royalties on tests developed and would not be responsible for manufacturing and distribution. This would not preclude the Company from initiating future operations related to new products if circumstances warranted it.

## **CRITICAL ACCOUNTING POLICIES**

The consolidated financial statements have been prepared in accordance with generally accepted accounting principles, which require the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosure of contingent assets and liabilities. The Company evaluates the estimates, judgments and the policies underlying these estimates on a periodic basis as the situation changes, and regularly discuss financial events, policies, and issues with the Company's independent auditors and members of the audit committee. Actual results could differ from these estimates. In addition, as of March 12, 2004, the Company ended its distribution agreement with Bayer and has ceased producing and selling all products.

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

## **REVENUE RECOGNITION**

Revenue from the sale of products is recorded when an arrangement exists, delivery has occurred or services have been rendered, the seller's price is fixed and determinable and collectibility is reasonably assured. Substantially all of the Company's product sales in the quarters ended March 31, 2004 and 2003 were made to the Company's distributor, Bayer. Income under license and development agreements is recognized over the anticipated period of the agreements with the collaborators, in accordance with SEC Staff Accounting Bulletin No. 104 (SAB 104). SAB 104 clarifies conditions to be met to recognize up-front non-refundable payments. Such payments are recognized over the life of the related agreement unless the payment relates to products delivered or services performed that represent the completion of the earnings process. Payments received but not recognized into income in the year of receipt are deferred and recognized over the period of the respective agreements. The Company has recognized revenue related to the development agreement with Aventis. The Company is recognizing revenue related to the Aventis development contract, which was entered into in 2000. Previous milestone payments from Aventis, which are non-refundable, remain deferred because even though the Company's development agreement with Aventis has been terminated, the Company remains under obligation not to develop another test card that would compete with Aventis through November 2006. The Company is recognizing development income from Aventis on a straight-line basis through November 2006.

## **STOCK-BASED COMPENSATION**

The Company has adopted Statement of Financial Accounting Standards No. 123, Accounting for Stock Based Compensation (SFAS No. 123). As permitted by SFAS No. 123, the Company has chosen to continue to apply APB Opinion No. 25 Accounting for Stock Issued to Employees (APB No. 25) and related interpretations in accounting for its stock plans. Accordingly, in each period, the Company has used the intrinsic-value method to record stock based employee compensation. No compensation expense has been recognized for stock options granted to employees with an exercise price equal to or above the trading price per share of the Company's common stock on the grant date.

## **INVENTORIES**

Inventories are stated at the lower of standard cost (which approximates cost on a first-in, first-out basis) or market. The Company assesses its inventory on a periodic basis and recognizes reserves when necessary. In December 2003, the Company notified Bayer of its intention to terminate its distribution agreement in March 2004. Due to the resulting ceasing of sales and production, the Company determined that excess inventories exist at March 31, 2004 that will not be consumed or sold in the ordinary course of business. The Company recorded a write-down of its inventories of \$379,000 in the quarter ended March 31, 2004 to reduce them to their net realizable value of zero.

## **RESULTS OF OPERATIONS**

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

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### **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 ended 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. The Company is recognizing these payments into income over the period of the agreement in accordance with SAB 104.

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. Higher 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 the Company's contract sales and technical service force related to the 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 of 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 the Company.

During the quarters ended March 31, 2004 and 2003, the Company 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 the Company's common stock on the dividend payment date to determine the amount recorded as the dividend for that period. In addition, for the quarter ended March 31, 2004, the Company paid a dividend 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 the Company's stock on the dividend payment date to determine the amount recorded as the Series B dividend of \$86,000.

### **LIQUIDITY AND CAPITAL RESOURCES**



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At March 31, 2004, the Company had cash, cash equivalents and 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 the first quarter ended March 31, 2004, the Company used cash in operating activities of \$1.6 million. The use of cash was due to funding our net operating loss of \$2.4 million, offset by non-cash charges for depreciation expense and write-down of inventory. Inventories were written down during the quarter as a result of the Company ceasing production and sales of products. The deferred revenue balance has decreased due to the normal amortization of previous payments received from Aventis into development income and recognition of revenues for test cards shipped on behalf of The Medicines Company for which the Company had received advanced payments in the second half of 2002. Accounts receivable increased as higher final orders for Bayer were completed during March but were not yet collected by the end of March. Prepaids and other assets decreased due to normal amortization of these assets into expense during the first quarter.

During the first quarter of 2004, the Company made \$16,000 in expenditures related to maintaining the usefulness of its fixed assets and patents.

Cash used in financing activities in the quarter ended March 31, 2004 was due to payments on the Company's debt and capital leases. The Company paid the remaining balance of its 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.

The Company sustained continuing operating losses in 2004 and 2003 and had an accumulated deficit of \$81.5 million as of March 31, 2004. In December 2003, the Company announced that, due to continued legal action against Aventis and the impact of

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that litigation on the Company's operations and prospects, it is seeking strategic alternatives, including the sale of its manufacturing operations. The Company also announced that, if a willing and able buyer for the operations is not identified, it would terminate its distribution agreement with Bayer. As of the end of April 2004, no buyer has yet emerged. The Company terminated its distribution agreement with Bayer and ceased producing and selling all products effective in March 2004. The Company is continuing its search for a buyer and intends to continue seeking a buyer during 2004. The Company intends to pursue the lawsuit with Aventis with its existing funds, which total approximately \$6.0 million as of March 31, 2004. The Company will be eliminating capital and operating leases for office equipment by expending approximately \$200,000. In addition, the Company has terminated substantially all of its employees during the first quarter of 2004, resulting in severance costs of approximately \$638,000. The Company will continue to lease its building in 2004, resulting in anticipated expense in the last nine months of 2004 of approximately \$297,000. The Company believes it has sufficient resources to fund its 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, there can be no assurance that such resources will be sufficient. Pending the outcome of the litigation, presently the Company does not expect to need nor does it intend to seek additional sources of financing.

Barring the receipt of proceeds from a successful completion of the Aventis litigation or revenues and profits from future operations, the holders of the Company's 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 the Company's preferred stockholders had first been satisfied.

## **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.

## **FACTORS THAT MIGHT AFFECT FUTURE RESULTS**

A number of uncertainties exist that might affect the Company's future operating results and stock price. There can be no assurance that the Company will be successful in its lawsuit against Aventis or that it will find a buyer for any of its assets. See Legal Proceedings below for a discussion of the status of the lawsuit with Aventis. The market price of the common stock could be subject to significant fluctuations in response to developments in the litigation as well as other factors which may be unrelated to the Company's performance. The stock market in recent years has experienced extreme price and volume fluctuations that often have been unrelated or disproportionate to the operating performance of and announcements concerning public companies. Such broad fluctuations may adversely affect the market price of the Company's common stock. Securities of issuers having relatively limited capitalization are particularly susceptible to volatility based on short-term trading strategies of some investors.

## **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Not applicable

**ITEM 4. CONTROLS AND PROCEDURES**

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

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

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### **PART II. OTHER INFORMATION**

#### **ITEM 1. LEGAL PROCEEDINGS**

In November 2003, the Company filed a lawsuit in the eastern district of North Carolina against Aventis. The Company, in cooperation with Aventis, has developed the Enox test, which the Company believes enhances the way Lovenox®, a popular anti-blood clotting drug marketed by Aventis, currently is managed. The Company believes the test has the potential to facilitate the drug's use in patients in the cardiac community who stand to benefit from its use. Aventis collaborated with the Company in a multi-million dollar project in which it made milestone payments to the Company to develop and co-promote the test together with Lovenox for targeted patient populations. The lawsuit alleges that Aventis has engaged in false and misleading advertising of Lovenox, which damaged the Company's efforts to market and sell the Enox test card. The lawsuit also alleges that Aventis has failed to fulfill its obligation to promote the test and is systematically and falsely advising physicians that the test is not necessary through its claims that Lovenox requires no monitoring and is therapeutic from dose one. In addition to claims of false advertising, the Company's complaint includes allegations of tortious interference, fraud and breach of contract. 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 ½ hour of administration to be literally false. Second, the court found literally false Aventis' claim that Lovenox was therapeutic from dose one. Although the court did not grant the Company's request for a preliminary injunction, one of the reasons cited by the court for not enjoining these false advertising messages was that Aventis has discontinued using these false statements in its advertising. In particular, after the Company filed its false advertising lawsuit against Aventis in November 2003, almost immediately thereafter Aventis withdrew these statements from its advertising of Lovenox. In addition, the court found that certain disparaging statements made by Aventis representatives concerning the ENOX® test card were also literally false. Although the court elected not to issue a preliminary injunction, the court's order ultimately 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 this case should ultimately be evaluated by a jury. In order to prevail in a jury trial, the Company must prove a variety of factual issues as well as substantiate its calculation of damages. The Company intends to aggressively pursue the lawsuit to enforce its rights, and the Company expects the lawsuit could take a year or more to complete and consume significant time and expense.

#### **ITEM 6. EXHIBITS**

(a) Exhibits.

10.42 Employment agreement with John Funkhouser

31.1 Certification of Chief Executive Officer pursuant to Rule 13a-14(a)

31.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(a)

32.1 Certification by the Chief Executive Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

32.2 Certification by the Chief Financial Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002



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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**PHARMANETICS, INC.**

Date: May 14, 2004

By: /s/ John P. Funkhouser

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John P. Funkhouser  
Chief Executive Officer

/s/ Paul T. Storey

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Paul T. Storey  
Chief Financial Officer  
(Principal Financial Officer)