

PHARMANETICS INC  
Form 10-Q  
November 13, 2003  
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## SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

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### FORM 10-Q

**x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15 (D) OF THE SECURITIES EXCHANGE ACT OF 1934.**

For the quarterly period ended September 30, 2003.

**.. 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)

North Carolina  
(State or other jurisdiction of

Incorporation or organization)

9401 Globe Center Drive, Suite 140

56-2098302  
(IRS Employer Identification Number)

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Morrisville, North Carolina  
(Address of Principal Executive Office)

27560  
(Zip Code)

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

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

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

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 November 6, 2003</u>
Common Stock, no par value	9,855,657

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**PHARMANETICS, INC.**

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

(In thousands, except share data)

	SEPTEMBER 30, 2003 <u>(UNAUDITED)</u>	DECEMBER 31, 2002 <u></u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 10,197	\$ 9,146
Accounts receivable from related party	497	543
Other receivables, net	238	112
Inventories	3,068	2,453
Other current assets	360	503
	<u>14,360</u>	<u>12,757</u>
Total current assets	14,360	12,757
Property and equipment, net	7,303	8,292
Patents and intellectual property, net	635	580
Other noncurrent assets	104	72
	<u>7,303</u>	<u>8,292</u>
Total assets	<u>\$ 22,402</u>	<u>\$ 21,701</u>
<b>LIABILITIES, REDEEMABLE PREFERRED STOCK AND SHAREHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 610	\$ 1,277
Accrued expenses	530	461
Deferred revenue, current portion	1,283	1,089
Current portion of long-term debt and capital lease obligations	503	482
	<u>2,926</u>	<u>3,309</u>
Total current liabilities	2,926	3,309
Noncurrent liabilities:		
Deferred revenue, less current portion	2,333	3,139
Long-term debt and capital lease obligations, less current portion	751	1,095
	<u>3,084</u>	<u>4,234</u>
Total noncurrent liabilities	3,084	4,234
Total liabilities	6,010	7,543
Series A convertible redeemable preferred stock, no par value; authorized 120,000 shares; 76,000 and 90,500 shares issued and outstanding at September 30, 2003 and December 31, 2002, respectively (aggregate liquidation value at September 30, 2003 of \$7,600)	6,315	7,520
Series B convertible redeemable preferred stock, no par value; authorized 130,000 shares; 99,245 and 0 shares issued and outstanding at September 30, 2003 and December 31, 2002, respectively (aggregate liquidation value at September 30, 2003 of \$9,925)	7,342	

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Shareholders' equity:

Common stock, no par value; authorized 40,000,000 shares; 9,838,650 and 9,630,872 issued and outstanding at September 30, 2003 and December 31, 2002, respectively	74,517	67,852
Accumulated deficit	(71,782)	(61,214)
	<u>                    </u>	<u>                    </u>
<b>Total shareholders' equity</b>	<b>2,735</b>	<b>6,638</b>
	<u>                    </u>	<u>                    </u>
<b>Total liabilities, redeemable preferred stock and shareholders' equity</b>	<b>\$ 22,402</b>	<b>\$ 21,701</b>
	<u>                    </u>	<u>                    </u>

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)**

	THREE MONTHS ENDED		NINE MONTHS ENDED	
	SEPTEMBER 30 2003	SEPTEMBER 30 2002	SEPTEMBER 30 2003	SEPTEMBER 30 2002
<b>Revenues</b>				
Net product sales to related party	\$ 1,342	\$ 978	\$ 4,114	\$ 2,703
Net product sales to third parties	38	198	62	215
Grant/royalty income			20	25
Development income	261	131	782	359
<b>Total revenues</b>	<b>1,641</b>	<b>1,307</b>	<b>4,978</b>	<b>3,302</b>
<b>Operating expenses:</b>				
Cost of goods sold	956	922	2,608	2,548
General and administrative	883	808	2,888	2,610
Sales and marketing	992	281	2,630	816
Research and development	828	1,475	3,322	4,139
<b>Total operating expenses</b>	<b>3,659</b>	<b>3,486</b>	<b>11,448</b>	<b>10,113</b>
<b>Operating loss</b>	<b>(2,018)</b>	<b>(2,179)</b>	<b>(6,470)</b>	<b>(6,811)</b>
<b>Other income (expense):</b>				
Interest income	25	25	62	105
Interest expense	(31)	(2)	(102)	(7)
Other income (expense)	37	(29)	52	(51)
<b>Total other income (expense)</b>	<b>31</b>	<b>(6)</b>	<b>12</b>	<b>47</b>
<b>Net and comprehensive loss</b>	<b>(1,987)</b>	<b>(2,185)</b>	<b>(6,458)</b>	<b>(6,764)</b>
Dividends on preferred stock	284	108	652	337
Amortization of beneficial conversion feature on Series B convertible, redeemable preferred stock			3,459	
<b>Net loss applicable to common shareholders</b>	<b>\$ (2,271)</b>	<b>\$ (2,293)</b>	<b>\$ (10,569)</b>	<b>\$ (7,101)</b>
<b>Basic and diluted net loss per common share</b>	<b>\$ (0.23)</b>	<b>\$ (0.24)</b>	<b>\$ (1.08)</b>	<b>\$ (0.74)</b>
<b>Average weighted common shares outstanding</b>	<b>9,815,957</b>	<b>9,577,961</b>	<b>9,766,308</b>	<b>9,552,200</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)

	NINE MONTHS ENDED	
	SEPTEMBER 30,	SEPTEMBER 30,
	2003	2002
Cash flows from operating activities:		
Net loss	\$ (6,458)	\$ (6,764)
Adjustments to reconcile net loss to net cash used in operating activities:		
(Gain) Loss on sale of assets		(1)
Depreciation	1,338	1,136
Amortization of intangible and other assets	96	110
(Gain) Loss on trading securities	(19)	53
Provision for inventory obsolescence	267	303
Change in operating assets and liabilities:		
Accounts receivable	(81)	(363)
Inventories	(882)	(514)
Other assets	35	(165)
Accounts payable and accrued expenses	(639)	(318)
Deferred revenue	(612)	1,132
Net cash used in operating activities	(6,955)	(5,391)
Cash flows from investing activities:		
Payments for purchase of property and equipment	(314)	(1,013)
Disposal of property and equipment	5	7
Costs incurred to obtain patents and intangibles	(85)	(60)
Sale of investments	30	
Net cash used in investing activities	(364)	(1,066)
Cash flows from financing activities:		
Principal payments on long-term debt and capital lease obligations	(322)	(17)
Proceeds from issuance of long-term notes payable		12
Proceeds from issuance of Series B convertible redeemable preferred stock, net of offering costs	8,655	
Proceeds from common stock options exercised	37	403
Repurchase of common stock		(103)
Net cash provided by financing activities	8,370	295
Net increase (decrease) in cash and cash equivalents	1,051	(6,162)
Cash and cash equivalents at beginning of period	9,146	14,883
Cash and cash equivalents at end of period	\$ 10,197	\$ 8,721



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### Supplemental disclosure of noncash investing and financing activities:

Series A preferred stock dividends paid with common shares	\$ 348	\$ 337
Series B preferred stock dividends paid with preferred shares	\$ 304	
Amortization of beneficial conversion feature on Series B convertible, redeemable preferred stock	\$ 3,459	

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 develops, manufactures and markets rapid turnaround diagnostics to assess blood clot formation and dissolution. CVDI 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 hemostasis at the point of patient care. 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, 2002. Results for the interim period are not necessarily indicative of the results for any other interim period or for the full fiscal year.

Note 2. Revenue Recognition

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 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.

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### 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):

	September 30, 2003	December 31, 2002
Raw materials, net of allowance	\$ 2,003	\$ 1,794
Work in process	99	280
Finished goods	966	379
	<u>\$ 3,068</u>	<u>\$ 2,453</u>

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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, generally 17 years. Periods of amortization are evaluated periodically to determine whether later events and circumstances warrant revised estimates of useful lives.

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 and nine month periods ended September 30, 2003 and 2002, 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 outstanding options, warrants and convertible preferred stock) as of September 30, 2003 and 2002 totaled 4,694,115 and 2,467,634, 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 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 quarter ended September 30, 2003, the Series A dividend was paid by issuing 22,942 shares of common stock and was recorded at the fair value of the common stock on the dividend payment date of September 30.

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.

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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.

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, exercisable beginning November 1, 2003, 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 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 quarter ended

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September 30, 2003, the Series B dividend was paid by issuing 2,065 shares of Series B preferred stock. These shares are convertible into approximately 34,417 shares of common stock, which number is multiplied by the closing market value of PharmaNetics stock on the dividend payment date of September 30 to determine the amount recorded as the Series B dividend.

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

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

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

### Note 8. 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%. The Company and Bayer entered into an amended distribution agreement to replace the previous distribution agreement between the parties entered into during 1998. Bayer currently markets and distributes the Company's routine tests worldwide and the Company's enoxaparin test in countries other than the United States.

### Note 9. Development Income and Deferred Revenue

The Company recognizes development income in accordance with SEC Staff Accounting Bulletin No. 101. Under SAB 101, payments received under collaboration agreements are deferred and recognized as income over the period of the respective agreements. In the past, the Company has received payments as part of collaboration agreements with other entities. Revenue recognized related to collaboration agreements for the quarters ended September 30, 2003 and 2002 were \$261,000 and \$131,000, respectively. At September 30, 2003, total payments received but deferred to future periods was \$3,616,000.

Note 10. Significant Customers and Related Party

During the quarters ended September 30, 2003 and 2002, the Company had sales to Bayer totaling \$1,342,000 and \$978,000, respectively, representing 97% and 83% of total product revenues for the respective periods. At September 30, 2003 and December 31, 2002, outstanding receivables from that customer totaled 83% and 96%, respectively, of total receivables.

Note 11. Stock Based Compensation

On December 31, 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 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

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shareholders without regard to whether the entity has adopted FAS 123 for recognition purposes. 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 required for the quarter and nine months ended September 30, 2003, no stock option grants were made in the third quarter of 2003. For the period ended September 30, 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 September 30, 2003	Three Months Ended September 30, 2002	Nine Months Ended September 30, 2003	Nine Months Ended September 30, 2002
Net loss attributable to common shareholders, as reported	\$ (2,271,000)	\$ (2,293,000)	\$ (10,569,000)	\$ (7,101,000)
Net loss per basic and diluted share, as reported	\$ (0.23)	\$ (0.24)	\$ (1.08)	\$ (0.74)
Stock based compensation based on fair value method	\$ (266,396)	\$ (242,936)	\$ (947,365)	\$ (808,535)
Pro forma net loss using fair value method	\$ (2,537,396)	\$ (2,535,936)	\$ (11,516,365)	\$ (7,909,535)
Pro forma net loss per basic and diluted share	\$ (0.26)	\$ (0.26)	\$ (1.18)	\$ (0.83)

## Note 12. Legal Proceedings

On November 4, 2003, the Company filed a lawsuit 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<sup>®</sup>, which has damaged the Company's sales of its Enox test card, a rapid point-of-care test developed in cooperation with Aventis to enhance the way Lovenox is managed in the cardiac community. 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 wants Aventis' advertising to 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.

## Note 13. 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



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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.

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.

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

**INTRODUCTION**

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 us include our wholly-owned subsidiary, Cardiovascular Diagnostics, Inc., or CVDI.

PharmaNetics, Inc., through its wholly-owned subsidiary Cardiovascular Diagnostics, Inc. (CVDI), develops, manufactures and markets rapid turnaround diagnostics to assess blood clot formation and dissolution. CVDI's products are a proprietary analyzer and dry chemistry tests, known as the Thrombolytic Assessment System, or TAS, that provide a physician, at the point of patient care, rapid and accurate evaluation of blood clot formation or dissolution. We are also establishing ourselves in the field of theranostics, or rapid near-patient testing in which the diagnostic results may influence treatment decisions. Our current tests and tests under development are 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. The TAS technology is used at the point of patient care which provides many potential benefits, including faster results for better treatment of patients, reduced usage of blood products for bleeding complications, quicker patient transfers from costly critical care settings and reduced hospital costs due to less paperwork and personnel time in processing blood samples.

We currently derive income from the following sources: product sales from test cards, analyzers and controls; interest income; and development income recognized in connection with collaboration agreements. Currently, product sales consist of: routine test cards, the PT, aPTT, HMT and LHMT tests; theranostic (specialty) test cards, the ECT, ENOX, PRT and HTT tests; quality controls used with the test cards; and analyzers. The PT, aPTT, HMT, LHMT, PRT and HTT tests, along with the related controls and analyzers are distributed pursuant to our global distribution agreement with Bayer Diagnostics (Bayer). In August 1998, we signed a five-year global distribution agreement, subject to minimum annual sales, with Chiron Diagnostics, now Bayer Diagnostics, to distribute our 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 common stock, all of which we 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 we recorded as an increase to stockholder's equity. At that time, this investment increased Bayer's ownership percentage in us 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 sends us monthly purchase orders and we 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 produces and transfers the product into Bayer's segregated warehouse facility at the Company. The Company does not retain any specific performance obligation with respect to product once it has been completed and transferred to the segregated warehouse space. The Company sells this product to Bayer at the pre-determined prices set forth in the amended distribution agreement and Bayer takes ownership of and assumes all risk for the inventory upon transfer and then holds 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.

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In October 2003, the amended distribution agreement with Bayer, originally scheduled to terminate on December 31, 2003, was extended by agreement of both parties to December 31, 2004. We have the right to terminate the amended agreement on ninety days advance written notice in the event our Board of Directors determines to conclude and eliminate our routine test manufacturing operations. The amended agreement can also be terminated if (1) Bayer fails to make payments when due to us, (2) Bayer fails to maintain sales to end users or (3) a distributor appointed by Bayer sells products which are competitive with us. Either party may terminate the Agreement upon the occurrence of any of the following: (1) the insolvency of the other party; (2) material breach of the Bayer agreement by the other party which is not cured; or (3) certain types of change-in-control transactions by the other party. Bayer also markets TAS products in Europe and other foreign countries such as Australia and Canada as our exclusive distributor in these territories.

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Our business strategy has evolved towards becoming more focused on our theranostic tests whereby the diagnostic test and drug therapy are integrated. Rapid diagnostic capabilities might improve patient care and turnover, and there is a market trend to obtain diagnostic information faster in order to affect therapy sooner. We believe that physicians are beginning to see the need for drug management tools and, consequently, we are seeking greater involvement of physician thought leaders during development of new test cards. We also believe that these trends should allow us to obtain higher pricing of these specialty tests. In furtherance of that objective, we commercially launched the Enox test in January 2003 to detect the anticoagulant effects of enoxaparin sodium, a leading low molecular weight heparin marketed by Aventis Pharmaceuticals (Aventis). We have hired our own contract sales and technical service personnel to promote and market this test in the United States. Sales of the Enox test are currently not significant compared to total sales. See Item 1 Legal Proceedings under Part II of this report for a discussion of the litigation we initiated against Aventis Pharmaceuticals in which we allege, among other things, that Aventis has engaged in false and misleading advertising of its drug, which has damaged our sales of the Enox test card. Even if we are successful in this litigation, we might not be able to achieve our sales objectives, timely or at all, with respect to the Enox test card.

Upon entering the amended distribution agreement with Bayer, we expanded our relationship 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 is 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 receives a commission of 10% of the price of each card. The Enox test inventories are maintained on our books until shipment and we 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. PharmaNetics offers no price concession to Bayer, receives payment therefor directly from Bayer within 30 to 70 days of the invoice date and Bayer's 10% commission is netted and recorded against the revenue in the financial statements. If Bayer failed to meet its new responsibilities, we would have to initiate order taking and credit and collection procedures ourselves for these sales, which would potentially require additional personnel and associated costs.

We believe the TAS platform is flexible and that our menu of specialty tests can be expanded to monitor the effects of certain new drugs that are in clinical trials or currently being marketed. Increased placement of specialty tests might also further demand for analyzers and routine anticoagulant tests.

## **CRITICAL ACCOUNTING POLICIES**

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

## **REVENUE RECOGNITION**

We record revenue from the sale of products when an arrangement exists, the product has been delivered or services have been rendered (transfer of risk occurs), our price is fixed and determinable and collectibility is reasonably assured. For all products except the Enox test, we record 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. We do 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 we do not have a

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history of defective product returns. We have a standard pricing model in place and do not offer discounts, price protection, or rights of return. We record product revenue from the sale of the Enox test upon shipment of the product to the hospital. We invoice Bayer at the shipment date, netting a 10% commission paid to Bayer (for administrative and collection services) against the product revenue. Bayer is responsible for invoicing and collecting from the hospital and must pay us regardless of whether it collects from the hospital. We account for royalties on an accrual basis. Tokuyama Soda pays us royalties based on Tokuyama's net sales of a licensed product. We recognize income under license and development agreements over the anticipated period of the agreements with our 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, we received upfront payments for development of the Enoxaparin test card from Aventis. Pursuant to this arrangement, we received non-refundable milestone payments for executing the agreement, completing the

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development, FDA approval, and the first commercial sale of the product. We have a period of four years after the first commercial sale of the test card in which we cannot develop a similar test card for another entity. We are recognizing the milestone payments over a period of five years, based on the estimated life of the relationship.

## **STOCK-BASED COMPENSATION**

We apply the provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock Based Compensation ( SFAS No. 123 ) and Statement of Financial Accounting Standards No. 148, Accounting for Stock Based Compensation Transition and Disclosure (SFAS No. 148) in accounting for and disclosing stock based compensation. 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 its related interpretations, including Interpretation No. 44, ( FIN 44 ) Accounting for Certain Transactions Involving Stock Compensation An Interpretation of APB 25 , in accounting for our stock plans. Accordingly, we have recognized no compensation expense 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.

## **RESULTS OF OPERATIONS**

### **THREE MONTHS ENDED SEPTEMBER 30, 2003 VS SEPTEMBER 30, 2002**

Net product sales for the quarter ended September 30, 2003 increased 17% to \$1,380,000 compared to \$1,176,000 in the same period in 2002. Sales to Bayer represented 97% and 83% of our product sales in the quarters ended September 30, 2003 and 2002, respectively. Revenues from routine test cards increased \$314,000 due to higher unit sales of routine cards to Bayer. An increase of \$125,000 in revenue from sales of PRT, HTT, ECT and Enox specialty test cards during the third quarter of 2003 were offset by a \$160,000 decrease in revenue from TIM II test cards compared to the same period in 2002, when TIM II cards were sold into clinical trials. Revenue from the quality controls used with the test cards increased \$73,000 and revenues from TAS analyzers and Accents decreased \$154,000 from the prior period as a result of changes in the volume of Bayer orders. Revenues from Bayer have increased as Bayer has sold more of our products to its customers. We believe Bayer will generally maintain its current level of orders of routine tests, but might decrease its orders of PRT and HTT tests, as well as TAS and Accents, during the remainder of 2003 as it seeks to work down its current inventory levels of those products. As the Enox test is placed in more hospitals, we expect sales of this product to increase during the remainder of 2003, although we expect our litigation with Aventis could hinder our sales efforts with regard to the Enox test.

Development income was \$261,000 in the third quarter of 2003 compared to \$131,000 in the comparable quarter of 2002. All of the development income recognized in the third quarter of 2003 relates 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. We are recognizing these payments into income over the period of the agreement in accordance with SAB 101. Thus, a portion of the \$3 million received was recognized into income in this quarter. Because the second milestone payment was received after September 30, 2002, only a portion of the first \$1.5 million payment was recognized in development income in the third quarter of 2002.

Cost of goods sold for the quarter ended September 30, 2003 was \$956,000 compared to \$922,000 in the comparable period in 2002. This increase is attributable to slightly higher materials and overhead costs related to increased sales volume of cards and controls during the third quarter of 2003 compared to the same period in the prior year. The improved gross margin is due to increased sales of the PRT, HTT and Enox specialty test cards, which are sold at higher prices than our routine test cards, as well as lower costs per unit sold as our fixed production costs are being spread over higher production levels.

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General and administrative expenses were \$883,000 in the third quarter of 2003 compared to \$808,000 for the comparable period in 2002. These expenses were higher primarily due to a \$42,000 increase in budgeted compensation and benefit costs changes and a \$38,000 increase in fees related to transferring the company's stock listing from the Nasdaq National Market to the Nasdaq SmallCap Market during the third quarter 2003. Sales and marketing expenses increased to \$992,000 in the third quarter of 2003 from \$281,000 in the same period in 2002 due to higher compensation and travel expenses of approximately \$575,000 and higher promotional expenses of \$44,000 in connection with our 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 as we implemented new information systems related to managing sales in the first quarter of 2003. Research and development expenses decreased to \$828,000 in the third quarter of 2003 mainly due to lower project costs of \$461,000, primarily related to the completion of the clinical trials in the development of the enoxaparin test card during the third quarter of 2002. In addition, compensation and benefit costs decreased by \$173,000 compared to 2002 resulting from the termination of nine employees and departmental restructuring during the second quarter of 2003.

Net interest and other income (expense) for the quarter ended September 30, 2003, which is composed of interest income, interest expense and other income, was a net income of \$31,000 compared to a net expense of \$6,000 in the third quarter of 2002. During the third quarter 2003, we recognized income of \$31,000 related to an insurance reimbursement for the sales value of finished goods lost due to a power outage during the quarter.

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During the quarters ended September 30, 2003 and 2002, we paid a dividend to Series A preferred shareholders by issuing 22,942 and 22,182, respectively, shares of common stock, representing a total of \$114,000 and \$108,000, 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 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 common stock on the dividend payment date to determine the amount recorded as the dividend for that period. In addition, for the quarter ended September 30, 2003, we paid a dividend to Series B preferred shareholders by issuing 2,065 shares of Series B preferred stock. These shares are convertible into approximately 34,417 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 \$170,000.

## **NINE MONTHS ENDED SEPTEMBER 30, 2003 VS SEPTEMBER 30, 2002**

Net product sales for the nine months ended September 30, 2003 were \$4,176,000 compared to \$2,918,000 for the same period in 2002. Sales to Bayer represented 99% and 93% of our product sales for the year-to-date periods ended September 30, 2003 and 2002, respectively. Revenues from routine test cards increased \$641,000 due to higher unit sales of routine cards to Bayer. Revenues from specialty tests increased \$303,000 mainly attributable to higher sales of PRT and HTT tests in 2003 compared to 2002 and the sale of Enox test cards which were launched in January 2003. Revenue from the quality controls used with the test cards increased \$119,000 and revenues from analyzers and accents increased \$168,000 as the volume of orders from Bayer increased.

Development income was \$782,000 for the first nine months of 2003 compared to \$359,000 in the comparable year-to-date period of 2002. All of the development income recognized 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. We are recognizing these payments into income over the period of the agreement in accordance with SAB 101. Thus, a portion of the \$3 million received was recognized into income for each of the nine months ended September 30, 2003 and 2002. Because the second milestone payment was received after September 30, 2002, development income increased in the nine months ended September 30, 2003 compared to 2002. License and royalty income was essentially unchanged from the prior-year period.

Cost of goods sold for the nine months ended September 30, 2003 was \$2,608,000 compared to \$2,548,000 for the same period in 2002. Increased material and labor costs of \$439,000 associated with higher unit sales of all products were largely offset by lower overhead costs of \$379,000. In connection with the enoxaparin test card launch beginning in January 2003 and in response to higher card and analyzer sales to Bayer, we increased our production volumes of test cards and analyzers in 2003 compared to 2002, leading to decreased overhead costs per unit sold in 2003. These increased volumes, along with higher sales of specialty test cards which are sold at higher prices than the routine test cards, led to an improved gross margin.

General and administrative expenses were \$2,888,000 for the nine months ended September 30, 2003 compared to \$2,610,000 in the comparable period of 2002. This increase was due to budgeted personnel cost increases of approximately \$170,000 and also higher professional fees related to insurance, legal, accounting and public relation services provided to us, as well as increased costs to transfer our stock listing on Nasdaq. Sales and marketing expenses increased to \$2,630,000 for the nine months ended September 30, 2003 compared to \$816,000 in the comparable period of 2002. This increase was due to higher compensation and travel expenses of approximately \$1,483,000 and higher promotional expenses of \$95,000 in connection with our 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 as we implemented new information systems related to managing sales in the first quarter of 2003. Research and development expenses decreased to \$3,322,000 in the first nine months of 2003, mainly due to lower project costs of \$834,000 compared to 2002, chiefly in the Enox, TIM and LHMT test card projects that incurred development and trials expenses in 2002 that were not incurred in 2003 because research and development in these projects had been substantially completed. In addition, compensation and benefit costs decreased as a result of decreased compensation and benefit costs related to corporate downsizing and departmental restructuring during the second quarter of 2003.



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Net interest and other income (expense) for the nine months ended September 30, 2003 was a net income of \$12,000 compared to net income of \$47,000 for the comparable period of 2002. This change was principally due to higher interest expense paid by us in 2003 under the new \$1.5 million loan obtained from General Electric Capital in December 2002.

For the year-to-date period ended September 30, 2003 and 2002, we paid a dividend to Series A preferred shareholders by issuing 55,177 and 60,286, respectively, shares of common stock, representing a total of \$348,000 and \$337,000 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 the nine months ended September 30, 2003, we paid dividends to Series B preferred shareholders by issuing 3,445 shares of Series B preferred stock. These shares are convertible into

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approximately 57,418 shares of common stock, which number 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 of \$304,000.

## **LIQUIDITY AND CAPITAL RESOURCES**

At September 30, 2003, we had cash, cash equivalents and investments of \$10.3 million and working capital of \$11.4 million, as compared to \$9.3 million and \$9.4 million, respectively, at December 31, 2002. During the nine months ended September 30, 2003, we used cash in operating activities of \$7 million. The use of cash was due to funding our net operating loss of \$6.5 million as well as funding working capital. Inventories increased in the nine months ended September 30, 2003 as we have prepared for anticipated higher sales of specialty products as well as increased sales of routine cards, controls and analyzers. The deferred revenue balance has decreased due to the normal amortization of payments from Aventis into development income and recognition of revenues for ECT cards shipped on behalf of The Medicines Company for which we had received advanced payments for in the second half of 2002. Accounts payable have also decreased to lower levels during the nine months of 2003 because high payables at December 31, 2002 related to fixed asset purchases, trial expenses related to enoxaparin and the timing of professional service expenses which were paid early in 2003.

During the first nine months of 2003, we incurred additional costs for equipment to support manufacturing and operations. We also made information technology purchases to support general company operations as well as the sales and marketing efforts related to enoxaparin. We do not anticipate significant capital expenditures for the remainder of 2003.

Cash provided by financing activities of \$8.4 million in the nine months ended September 30, 2003 was attributable to the completion of a private placement of 95,800 shares of Series B convertible redeemable preferred stock. See a discussion of the terms of the Series B preferred stock in Note 7 Preferred Stock of the Notes to the Consolidated Unaudited Financial Statements. This cash inflow was offset by payments of approximately \$307,000 on debt with GE Capital and by payments of approximately \$15,000 on capital leases. We obtained a three-year \$1.5 million equipment loan from GE Capital in December 2002. The loan has an interest rate of 9.5% and is collateralized by existing fixed assets. The loan includes customary covenants related to, among other things, maintenance of the collateral, but does not contain financial covenants. As of September 30, 2003, the outstanding balance under the loan was approximately \$1,202,000.

We have sustained continuing operating losses in 2003 and had an accumulated deficit of \$71.8 million as of September 30, 2003. We expect to incur operating losses until product revenues reach a sufficient level to support ongoing operations and expect these operating losses to occur during the remainder of 2003 and into 2004. Our cash flow from operations will be substantially affected by the sales of the Enox test card launched in the first quarter of 2003. In November, we filed a lawsuit against Aventis alleging that Aventis has engaged in false and misleading advertising of its drug Lovenox<sup>®</sup>, which has damaged our sales of the Enox test card. Our dispute with Aventis might reduce or delay our revenue opportunities and increase our expenses, thereby accelerating our liquidity needs in 2003 and 2004. Because of the potential strategic and economic significance of the development agreement for the Enox test, we are continuing to review all strategic alternatives, including a possible sale of our manufacturing and routine test business in order to reduce overhead, preserve cash and keep our technology and manufacturing capability intact. We plan to aggressively pursue our claims against Aventis. While we cannot currently estimate the legal costs related to this matter, it could be material to our cash flows.

Our expected liquidity needs through the end of 2004 also include approximately \$700,000 to repay capital leases and our debt with GE Capital. We do not expect our capital expenditures in 2004 to be significant. Our working capital requirements will depend on many factors, primarily the volume of subsequent orders of TAS products from Bayer and from sales of the Enox test card. We expect levels of receivables, inventories and payables for the next 12 months to be approximately the same as those at September 30, 2003 if product sales do not significantly increase. If product sales do significantly increase and levels of receivables, inventories and payables rise, we would consider seeking a working capital line of credit to fund expenses associated with these potential increases, if necessary.

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Our revenue and projected cash flows are heavily dependent on our relationship with our principal distributor, Bayer, which accounted for approximately 94% of our revenues in 2002 and 99% of our revenues in the nine months ended September 30, 2003. In October 2003, the Company and Bayer agreed to extend the amended distribution agreement for another year, to December 31, 2004. If Bayer failed to satisfy its obligations under our distribution agreement or purchased less product, our revenues and cash flows would be negatively impacted.

To meet our liquidity requirements, we will consider sources of funding such as the sale of the routine manufacturing and distribution rights, equity financings such as another private placement of common or preferred stock or additional funds from current or potential collaborative partners. We cannot be certain these sources of funding will be available to us. Our sources of liquidity also could be affected by our dependence and reliance on Bayer as our exclusive distributor, the outcome of the Aventis litigation, our achievement

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of market acceptance in the developing market for theranostic products, particularly related to the Enox test card, compliance with regulations, as well as other factors described under [Factors that May Affect Future Results](#) and [Critical Accounting Policies](#) .

## **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 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 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 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. 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 approval and implementation of FIN 46 did not have a material impact on the consolidated financial statements.

## **FACTORS THAT MAY AFFECT FUTURE RESULTS**

A number of uncertainties exist that might affect our future operating results and stock price. There can be no assurance that new tests, particularly specialty tests, can be developed, receive regulatory approval, and be commercialized and accepted in the market. To increase sales of the Enox specialty test, it is important for us to favorably resolve our dispute with Aventis. There can be no assurance that we will favorably resolve our dispute with Aventis and if we do not, sales of the Enox test would be affected. Specific risks related to the Aventis litigation include: material monetary costs associated with the litigation, even if successful; uncertainty of obtaining a favorable outcome; the potentially significant harm to our business and financial condition and prospects if we are not successful in timely prosecuting the litigation; jeopardizing

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strategic relationships with other existing or potential collaborative partners; harmful delays in meeting sales objectives, even if the litigation is successful; and disruption of management time and resources to pursue the litigation. Other risks include: market acceptance of TAS and our other products; our continuing losses and the resulting potential need for additional capital in the future; managed care and continuing market consolidation, which may result in price pressure, particularly on routine tests; competition within the diagnostic testing industry and FDA regulations and other regulatory guidelines affecting us and/or our collaborators. The market price of the 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.

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

Not applicable

**ITEM 4. CONTROLS AND PROCEDURES**

(a) 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 (as defined in Rule 13a-15(e)) 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.

(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.

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

On November 4, 2003, we 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<sup>®</sup>, which has damaged our 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. We are seeking injunctive relief against Aventis to prevent the use of false, misleading and deceptive promotional messages in their advertising and sales activities. We also are demanding that Aventis promote the need for monitoring as required in Lovenox<sup>®</sup> labeling and as required by the development agreement entered into between the two companies in August 2000.

**ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K**

(a) Exhibits.

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

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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

- (b) We filed current reports on Forms 8-K: (1) on August 5, 2003 disclosing the contents of a press release issued on that date announcing our second quarter results; (2) on September 19, 2003 disclosing that we had received approval from Nasdaq to transfer the listing of its shares of common stock from the Nasdaq National Market to the Nasdaq SmallCap Market.

