

PHARMANETICS INC
Form 10-Q
August 13, 2002
Table of Contents

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

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 June 30, 2002.**
- .. **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. For the transition period from to .**

Commission File Number
0-25133

PHARMANETICS, INC.
(Exact Name of Registrant as Specified in its Charter)

North Carolina
(State or other jurisdiction of
Incorporation or organization)

56-2098302
(IRS Employer
Identification Number)

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

Class	Outstanding as of August 6, 2002
Common Stock, no par value	9,570,638

Table of Contents

PHARMANETICS, INC.

INDEX TO FORM 10-Q

			<u>PAGE</u>
PART I.	FINANCIAL INFORMATION		
	Item 1.	Financial Statements	
		<u>Consolidated Balance Sheets as of June 30, 2002 (unaudited) and December 31, 2001</u>	3
		<u>Consolidated Statements of Operations for the Three Months and Six Months ended June 30, 2002 and 2001 (unaudited)</u>	4
		<u>Consolidated Statements of Cash Flows for the Six Months ended June 30, 2002 and 2001 (unaudited)</u>	5
		<u>Notes to Unaudited Consolidated Financial Statements</u>	6
	Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	8
PART II.	OTHER INFORMATION		
	Item 4.	<u>Submission of Matters to a Vote of Security Holders</u>	12
<u>SIGNATURES</u>			13

Table of Contents**PHARMANETICS, INC.****CONSOLIDATED BALANCE SHEETS**
(In thousands, except share data)

	JUNE 30, 2002	DECEMBER 31, 2001
	(UNAUDITED)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 9,489	\$ 14,883
Accounts and other receivables	647	462
Inventories	2,288	2,223
Other current assets	389	242
	12,813	17,810
Total current assets	12,813	17,810
Property and equipment, net	8,410	8,503
Patents and intellectual property, net	540	551
Other noncurrent assets	110	150
	21,873	27,014
Total assets	\$ 21,873	\$ 27,014
LIABILITIES, REDEEMABLE PREFERRED STOCK, CONTINGENTLY REDEEMABLE COMMON STOCK AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 544	\$ 741
Accrued expenses	216	723
Deferred revenue, current portion	647	487
Current portion of long-term debt and capital lease obligations	24	23
	1,431	1,974
Total current liabilities	1,431	1,974
Noncurrent liabilities:		
Deferred revenue, less current portion	1,101	1,346
Long-term debt and capital lease obligations, less current portion	55	66
	1,156	1,412
Total noncurrent liabilities	1,156	1,412
	2,587	3,386
Total liabilities	2,587	3,386
Series A convertible redeemable preferred stock, no par value; authorized 120,000 shares; 90,500 shares issued and outstanding at June 30, 2002 and December 31, 2001, respectively (aggregate liquidation value at June 30, 2002 of \$9,050,000)	7,520	7,520
Contingently redeemable common stock	13,232	8,538
Shareholders' equity:		
Common stock, no par value; authorized 40,000,000 shares; 9,577,738 and 9,485,294 issued and outstanding at June 30, 2002 and December 31, 2001, respectively	52,957	57,186
Accumulated deficit	(54,423)	(49,616)
	(1,466)	7,570
Total shareholders' equity	(1,466)	7,570
	21,873	27,014
Total liabilities, redeemable preferred stock, contingently redeemable common stock and shareholders' equity	\$ 21,873	\$ 27,014

Edgar Filing: PHARMANETICS INC - Form 10-Q

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		SIX MONTHS ENDED	
	JUNE 30 2002	JUNE 30 2001	JUNE 30 2002	JUNE 30 2001
Net sales	\$ 798	\$ 1,322	\$ 1,741	\$ 2,124
Cost of goods sold	721	1,112	1,627	1,858
Gross profit	77	210	114	266
Operating expenses:				
General and administrative	899	1,351	1,802	2,226
Sales and marketing	250	364	534	592
Research and development	1,402	931	2,663	1,750
Total operating expenses	2,551	2,646	4,999	4,568
Operating loss	(2,474)	(2,436)	(4,885)	(4,302)
Other income (expense):				
Interest expense	(2)	(40)	(5)	(67)
Interest income	36	130	80	210
Grant/royalty income	25	12	25	12
Development income	114	50	228	100
Other expense	(22)	(49)	(21)	(47)
Total other income	151	103	307	208
Net and comprehensive loss	(2,323)	(2,333)	(4,578)	(4,094)
Dividends on preferred stock	103	144	228	291
Net loss applicable to common shareholders	(\$ 2,426)	(\$ 2,477)	(\$ 4,806)	(\$ 4,385)
Basic and diluted net loss per common share	(\$ 0.25)	(\$ 0.28)	(\$ 0.50)	(\$ 0.53)
Average weighted common shares outstanding	9,554,325	8,846,101	9,539,105	8,351,631

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)

	Six Months Ended	
	June 30, 2002	June 30, 2001
Cash flows from operating activities:		
Net loss	(\$ 4,578)	(\$ 4,094)
Adjustments to reconcile net loss to net cash used in operating activities:		
(Gain) Loss on sale of assets	(1)	49
Depreciation	748	555
Amortization of intangible and other assets	74	91
Amortization of discount on investments		(31)
Provision for inventory obsolescence	138	75
Change in operating assets and liabilities:		
Accounts receivable	(185)	(586)
Inventories	(203)	(667)
Other assets	(146)	(121)
Accounts payable and accrued expenses	(704)	(514)
Deferred revenue	(84)	884
Net cash used in operating activities	(4,941)	(4,359)
Cash flows from investing activities:		
Payments for purchase of property and equipment	(662)	(2,872)
Disposal of property and equipment	7	
Costs incurred to obtain patents and intangibles	(24)	(43)
Purchases of investments		(90)
Proceeds from maturities of investments		3,935
Net cash (used in) provided by investing activities	(679)	930
Cash flows from financing activities:		
Principal payments on long-term debt and capital lease obligations	(11)	(853)
Proceeds from issuance of common stock, net of offering costs		17,360
Proceeds from common stock options exercised	306	39
Repurchase of common stock	(69)	
Net cash provided by financing activities	226	16,546
Net (decrease) increase in cash and cash equivalents	(5,394)	13,117
Cash and cash equivalents at beginning of period	14,883	5,344
Cash and cash equivalents at end of period	\$ 9,489	\$ 18,461
Supplemental disclosure of noncash investing and financing activities:		
Preferred stock dividends paid with common shares	\$ 228	\$ 291
Purchase of property and equipment through capital lease	\$	\$ 72

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

Table of Contents

PHARMANETICS, INC.
NOTES TO 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, 2001. 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. 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 3. Inventory

Inventories consisted of the following (in thousands):

	June 30, 2002	December 31, 2001
Raw materials, net of allowance	\$ 1,949	\$ 1,820
Finished goods	339	403
	<u>\$ 2,288</u>	<u>\$ 2,223</u>

Note 4. 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 5. Loss Per Common Share

In accordance with Statement of Financial Accounting Standards (SFAS) No. 128, Earnings Per Share (EPS), the Company is required to present both basic and diluted EPS on the face of the Statement of Operations. Basic EPS excludes dilution and is computed by dividing income (loss) attributable to common shareholders by the weighted average number of common shares outstanding for the period. Diluted EPS is the same as basic EPS for the Company's quarters ended June 30, 2002 and 2001, 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 June 30, 2002 and 2001 totaled 2,500,634 and 2,603,175, respectively.

Table of Contents

Note 6. 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. The Series A has a dividend of 6% payable quarterly in cash or in shares of common stock at the option of the Company. For the quarter ended June 30, 2002, the Series A dividend was paid by issuing 20,827 shares of common stock.

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

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

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.

Note 7. Common Stock

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.

The 2001 common stock purchase agreement with Bayer contains a provision that, upon the occurrence of a change in control, as defined in the agreement, the Company may be required to compensate Bayer, in cash or shares of common stock, for any difference between per share prices originally paid by Bayer and the amount of consideration received by the Company's shareholders pursuant to the change of control transaction. In accordance with the implementation requirements of Emerging Issues Task Force Abstract No. 00-19, the Company has transferred from permanent equity to temporary equity an amount equal to the potential change in control payment called for by the purchase agreement assuming a change in control transaction yielding a payment to common shareholders equal to the fair market value of our common stock, as measured by reference to the closing sale price of our common stock on the NASDAQ National Market, at the end of the reporting period. Under the accounting guidelines, this temporary transfer is required only for those reporting periods in which the price per share paid by Bayer is higher than the fair market value of a common share. This provision expires on December 31, 2002.

Note 8. 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 June 30, 2002 and 2001 were \$114,000 and \$50,000 respectively. At June 30, 2002, total payments received but deferred to future periods was \$1,748,000.

Table of Contents

Note 9. Significant Customers

During the quarters ended June 30, 2002 and 2001, the Company had sales to one customer totaling \$760,000 and \$796,000, respectively. At June 30, 2002 and December 31, 2001, outstanding receivables from that customer totaled 96% of total receivables.

Note 10. Recent Accounting Pronouncements

In April, the Financial Accounting Standards Board (FASB) issued Statement No. 145 (FAS 145), Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections. This Statement rescinds FASB Statement No. 4, Reporting Gains and Losses from Extinguishment of Debt, an amendment of that Statement, FASB Statement No. 64, Extinguishments of Debt Made to Satisfy Sinking-Fund Requirements and FASB Statement No. 44, Accounting for Intangible Assets of Motor Carriers. This Statement also amends FASB Statement No. 13, Accounting for Leases, to eliminate an inconsistency between the required accounting for sale-leaseback transactions and the required accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions. FAS 145 also amends other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions.

In June, the FASB issued Statement No. 146 (FAS 146), Accounting for Exit or Disposal Activities. FAS 146 addresses significant issues regarding the recognition, measurement, and reporting of costs that are associated with exit and disposal activities, including restructuring activities that are currently accounted for pursuant to the guidance set forth in Emerging Issues Task Force Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring). The scope of FAS 146 includes (1) costs related to terminating a contract that is not a capital lease (2) termination benefits received by employees who are involuntarily terminated under the terms of a one-time benefit arrangement that is not an ongoing benefit arrangement or an individual deferred-compensation contract and (3) costs to consolidate facilities or relocate employees. FAS 146 will be effective for exit or disposal activities that are initiated after December 31, 2002.

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, at the point of patient care, rapid and accurate evaluation of hemostasis. The Company is also establishing itself in the emerging field of theranostics, or rapid near-patient testing, in which the diagnostic results may influence treatment decisions. Current tests and tests under development are used in the treatment of angina, heart attack, stroke, deep vein thrombosis and pulmonary and arterial emboli. The TAS technology is used at the point of patient care which provides many potential benefits, including faster results for better treatment of patients, reduced usage of blood products for bleeding complications, quicker patient transfers from costly critical care settings and reduced hospital costs due to less paperwork and personnel time in processing blood samples.

Table of Contents

The Company currently derives income from the following sources: TAS product sales, interest income, and development income recognized in connection with collaboration agreements. Currently, product sales mainly consist of the Company's routine test cards, the PT, aPTT and HMT tests along with the related controls and analyzers. Upon introduction of these products in 1993 and 1995, the Company distributed these routine products through a direct sales force. However, given a consolidating hospital industry, CVDI determined that distribution arrangements, rather than a direct sales force, were needed to penetrate the market. Thus, CVDI has signed a global distribution agreement with Bayer Diagnostics to distribute its products. Bayer's strength is in critical care areas of the hospital, which the Company believes should facilitate the placement of the TAS technology.

In addition, the Company's business strategy has evolved towards becoming more focused on theranostics, the development of specialty tests for drugs, some with narrow ranges between over- and under-dosage. Rapid diagnostic capabilities might improve patient care and turnover, and there is a market trend to obtain diagnostic information faster in order to affect therapy sooner. The Company believes that physicians are beginning to see the need for drug management tools and, consequently, the Company is seeking greater involvement of physician thought leaders during development of new test cards. The Company also believes that these trends should allow the Company to obtain higher pricing of these specialty tests. As a result, the Company has exhibited the flexibility of the TAS platform and the potential to expand its menu of specialty tests by signing development agreements with major pharmaceutical companies to monitor the effects of certain new drugs that are in clinical trials or currently being marketed. Increased placement of specialty tests might also further demand for analyzers and routine anticoagulant tests. The Company believes it is well positioned in its development efforts to expand its menu of tests to monitor developmental drugs where rapid therapeutic intervention is needed.

CRITICAL ACCOUNTING POLICIES

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 June 30, 2002 and 2001 were made to the Company's distributor, Bayer. Income under license and development agreements is recognized over the anticipated period of the agreements with the collaborators, in accordance with SEC Staff Accounting Bulletin No. 101 (SAB 101). SAB 101 clarifies conditions to be met to recognize up-front non-refundable payments. Such payments are recognized over the life of the related agreement unless the payment relates to products delivered or services performed that represent the completion of the earnings process. Payments received but not recognized into income in the year of receipt are deferred and recognized over the period of the respective agreements. The Company has recognized revenue related to the development agreement with Aventis. The Company is recognizing revenue related to the Aventis contract, which was entered into in 2000, over the agreement period of five years.

EQUITY

In April 2001, the Company and Bayer entered into an amended distribution agreement to replace the previous distribution agreement between the parties entered into during 1998. The 2001 common stock purchase agreement with Bayer contains a provision that, upon the occurrence of a change in control, as defined in the agreement, the Company may be required to compensate Bayer, in cash or shares of common stock, for any difference between per share prices originally paid by Bayer and the amount of consideration received by the Company's shareholders pursuant to a change of control transaction. In accordance with the implementation requirements of Emerging Issues Task Force Abstract No. 00-19, the Company has transferred from permanent equity to temporary equity an amount equal to the potential change in control payment called for by the purchase agreement assuming a change in control transaction yielding a payment to common shareholders equal to the fair market value of our common stock, as measured by reference to the closing sale price of our common stock on the NASDAQ National Market, at the end of the reporting period. Under the accounting guidelines, this temporary transfer is required only for those reporting periods in which the price per share paid by Bayer is higher than the fair market value of a common share. This provision expires on December 31, 2002.

STOCK-BASED COMPENSATION

The Company applies the provisions of 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

Table of Contents

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 its stock plans. Accordingly, 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.

RESULTS OF OPERATIONS

THREE MONTHS ENDED JUNE 30, 2002 VS JUNE 30, 2001

Net sales for the quarter ended June 30, 2002 were \$798,000 compared to \$1,322,000 in the same period in 2001, the decrease mainly attributable to specialty card revenue. In the second quarter of 2001, the Company received a \$1.5 million payment from AstraZeneca of which \$500,000 was recognized as revenue in that quarter. No such revenue was recognized in the second quarter of 2002. Routine test card revenue for the second quarter of 2002 declined approximately \$160,000 compared to the same period in 2001 but this decline was substantially offset by increases in analyzer and control revenue.

Cost of goods sold for the quarter ended June 30, 2002 was \$721,000 compared to \$1,112,000 in the comparable period in 2001. The decrease was due to lower manufacturing overhead costs for supplies, facility and personnel compared to the second quarter of 2001 when the Company incurred increased costs associated with maintaining two facilities during our move to a new location. In addition, as a result of a new accounting software system, production overhead costs in the second quarter of 2002 of approximately \$262,000 have been classified as research and development expense in the statement of operations based on test cards produced and consumed in research and development activities.

Total operating expenses for the quarter ended June 30, 2002 were \$2.5 million compared to \$2.6 million in the second quarter of 2001. General and administrative expenses decreased due to lower facility costs, fewer personnel and lower technology infrastructure costs. Sales and marketing expenses decreased due to reduced training and promotion costs compared to the same period in 2001. Research and development expenses increased mainly due to higher project costs compared to 2001, chiefly in the ENOX and TIM II projects, because of increased development materials, experimental test cards and clinical trial costs associated with these projects.

Other income (expense) for the quarter ended June 30, 2002, which is composed of interest income, interest expense and development income, was a net other income of \$151,000 compared to a net other income of \$103,000 in the second quarter of 2001. Interest income decreased due to much lower interest rates and lower average cash balances during the second quarter of 2002 compared to the same period in 2001. Development income in both periods was recognized related to the collaboration with Aventis Pharmaceuticals entered into during 2000 that is being recognized over the period of the development agreement.

SIX MONTHS ENDED JUNE 30, 2002 VS JUNE 30, 2001

Net sales for the six months ended June 30, 2002 were \$1,741,000 compared to \$2,124,000 for the same period in 2001. This decrease was mainly due to decreased specialty card revenue of \$500,000 during the second quarter as discussed above. This decrease was partially offset by higher sales of analyzers and controls to our distributor compared to 2001.

Cost of goods sold for the six months ended June 30, 2002 was \$1,627,000 compared to \$1,858,000 for the same period in 2001. Cost of goods sold decreased in 2002 as a result of lower manufacturing facility, supply and personnel costs compared to 2001, when the Company moved to a new facility. In addition, as a result of a new accounting software system, production overhead costs in the six months of 2002 of approximately \$550,000 have been classified as research and development expense in the statement of operations based on test cards produced and consumed in research and development activities.

Total operating expenses for the six months ended June 30, 2002 were \$4,999,000 compared to \$4,568,000 for the same period in 2001. General and administrative expenses decreased due to lower personnel costs, lower facility costs and lower technology infrastructure costs. Sales and marketing expenses decreased due to lower promotion and other marketing expenses. These decreases were offset by increased research costs related to budgeted personnel cost increases and higher costs in on-going development projects for supplies, experimental test cards and clinical trials.

Table of Contents

Other income (expense) for the six months ended June 30, 2002 increased \$99,000 over the prior year. Lower net interest income was offset by increased development income from the collaboration agreement with Aventis.

LIQUIDITY AND CAPITAL RESOURCES

At June 30, 2002, the Company had cash and cash equivalents of \$9.5 million and working capital of \$11.4 million, as compared to \$14.9 million and \$15.8 million, respectively, at December 31, 2001. During the six months ended June 30, 2002, the Company used cash in operating activities of \$4.9 million. The use of cash was principally due to funding the Company's net operating loss of \$4.5 million as well as funding working capital.

During the first six months of 2002, the Company purchased and installed software to continue the upgrade of its technology infrastructure. In 2001, the Company purchased new equipment and completed leasehold improvements to its new facility. Given the completion of the Company's move during 2001, the Company expects capital expenditures in 2002 to be lower than in 2001 and to range from \$750,000 to \$1,100,000.

Cash provided by financing activities of \$226,000 in the six months ended June 30, 2002 was attributable to stock option exercises. This inflow was reduced by common stock repurchases of \$69,000 and repayments of debt and leases.

In April 2001, the Company and Bayer entered into an amended distribution agreement to replace the previous distribution agreement between the parties entered into during 1998. The 2001 common stock purchase agreement with Bayer contains a provision that, upon the occurrence of a change in control, as defined in the agreement, the Company may be required to compensate Bayer, in cash or shares of common stock, for any difference between per share prices originally paid by Bayer and the amount of consideration received by the Company's shareholders pursuant to a change of control transaction. In accordance with the implementation requirements of Emerging Issues Task Force Abstract No. 00-19, the Company has transferred from permanent equity to temporary equity an amount equal to the potential change in control payment called for by the purchase agreement assuming a change in control transaction yielding a payment to common shareholders equal to the fair market value of our common stock, as measured by reference to the closing sale price of our common stock on the NASDAQ National Market, at the end of the reporting period. Under the accounting guidelines, this temporary transfer is required only for those reporting periods in which the price per share paid by Bayer is higher than the fair market value of a common share. This provision expires on December 31, 2002.

The Company has sustained continuing operating losses in 2002 and had an accumulated deficit of \$54 million as of June 30, 2002. The Company expects to incur operating losses until product revenues reach a sufficient level to support ongoing operations. In addition to the capital expenditures noted above, the Company expects to incur additional operating losses during the remainder of 2002. The Company's working capital requirements will depend on many factors, primarily the volume of subsequent orders of TAS products from distributors, primarily Bayer, and from sales of specialty test cards such as the Enoxaparin test. In addition, the Company expects to incur costs associated with clinical trials for new test cards. The Company might acquire other products, technologies or businesses that complement the Company's existing and planned products, although the Company currently has no understanding, commitment or agreement with respect to any such acquisitions. In addition, the Company might consider a joint venture or the sale of manufacturing rights to complete the commercialization of its routine anticoagulant monitoring tests. Management believes that its existing capital resources and cash flows from operations, including that from its distribution agreement with Bayer, will be adequate to satisfy its planned liquidity and cash requirements through 2002 and into 2003. If additional liquidity becomes necessary in the future, the Company will consider external sources of financing as needed. These financings, if available, may take the form of equity financings such as a private placement of common or preferred stock, a follow-on public offering of common stock or additional equity infusions from collaborative partners. Given the Company's low amount of debt at June 30, 2002, the Company may also consider debt financings such as a working capital line of credit or a term loan.

RECENT ACCOUNTING PRONOUNCEMENTS

In April, the Financial Accounting Standards Board (FASB) issued Statement No. 145 (FAS 145), Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections. This Statement rescinds FASB Statement No. 4, Reporting Gains and Losses from Extinguishment of Debt, an amendment of that Statement, FASB Statement No. 64, Extinguishments of Debt Made to Satisfy Sinking-Fund Requirements and FASB Statement No. 44, Accounting for Intangible Assets of Motor Carriers. This Statement also amends FASB Statement No. 13, Accounting for Leases, to eliminate an inconsistency between the required accounting for sale-leaseback transactions and the required accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions.

Table of Contents

FAS 145 also amends other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions.

In June, the FASB issued Statement No. 146 (FAS 146), *Accounting for Exit or Disposal Activities*. FAS 146 addresses significant issues regarding the recognition, measurement, and reporting of costs that are associated with exit and disposal activities, including restructuring activities that are currently accounted for pursuant to the guidance set forth in Emerging Issues Task Force Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)*. The scope of FAS 146 includes (1) costs related to terminating a contract that is not a capital lease (2) termination benefits received by employees who are involuntarily terminated under the terms of a one-time benefit arrangement that is not an ongoing benefit arrangement or an individual deferred-compensation contract and (3) costs to consolidate facilities or relocate employees. FAS 146 will be effective for exit or disposal activities that are initiated after December 31, 2002.

FACTORS THAT MAY AFFECT FUTURE RESULTS

A number of uncertainties exist that might affect the Company's future operating results and stock price. There can be no assurance that new tests, particularly specialty tests, can be developed, receive regulatory approval, and be commercialized and accepted in the market. Other risks include: market acceptance of TAS; the Company's continuing losses and the resulting potential need for additional capital in the future; managed care and continuing market consolidation, which may result in price pressure, particularly on routine tests; competition within the diagnostic testing industry and FDA regulations and other regulatory guidelines affecting the Company and/or its collaborators. The market price of the common stock could be subject to significant fluctuations in response to variations in the Company's quarterly operating results as well as other factors which may be unrelated to the Company's performance. The stock market in recent years has experienced extreme price and volume fluctuations that often have been unrelated or disproportionate to the operating performance of and announcements concerning public companies. Such broad fluctuations may adversely affect the market price of the Company's common stock. Securities of issuers having relatively limited capitalization are particularly susceptible to volatility based on short-term trading strategies of certain investors.

PART II. OTHER INFORMATION**Item 4. *Submission of Matters to a Vote of Security Holders***

The Annual Meeting of Shareholders of the Company was held on May 7, 2002. The following is a description of the matters voted upon at the meeting and the numbers of affirmative votes and negative votes cast with respect to each matter.

(a) The following persons were elected to the Company's Board of Directors. The votes for, against (withheld) and abstentions were as follows:

Nominee	Votes For	Votes Withheld	Votes Abstained
John P. Funkhouser	8,671,770	315,895	0
John K. Pirotte	8,672,577	315,088	0
Stephen R. Puckett	8,127,834	859,831	0
Philip R. Tracy	8,672,777	314,888	0
Frances L. Tuttle	8,752,177	235,488	0
James B. Farinholt Jr.	8,389,534	598,131	0

(b) The shareholders ratified the proposal to reserve 425,000 additional shares for issuance to employees, consultants and directors under the 1995 Stock Plan with 7,598,163 shares voting for, 1,352,652 shares voting against and 36,850 shares abstaining.

(c) The shareholders ratified the appointment of PricewaterhouseCoopers LLP as the independent auditors of the Company for the year ending December 31, 2002 with 8,826,294 shares voting for, 136,767 shares voting against and 7,825 shares abstaining.

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 each of the undersigned thereunto duly authorized, who certify to their knowledge that this report fully complies with the requirements of Section 13(a) or 15(d) of that Act and that the information contained in this report fairly presents, in all material respects, the financial condition and results of operations of the registrant as of and for the period ended June 30, 2002.

By: /s/ JOHN P. FUNKHOUSER

By: /s/ JAMES A. MCGOWAN

By: /s/ PAUL T. STOREY

15