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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**FORM 10-Q**

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(MARK ONE)

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

**For the quarterly period ended September 30, 2003 or**

**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 000-0030755**

**CEPHEID**

(Exact name of registrant as specified in its charter)

**California**

**77-0441625**

(State or Other Jurisdiction of Incorporation or Organization)

(I.R.S. Employer Identification Number)

**904 Caribbean Drive**

**Sunnyvale, California 94089-1189**

(Address of principal executive offices including zip code)

**(408) 541-4191**

(Registrant's telephone number, including area code)

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

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

As of November 10, 2003 there were 35,899,222 shares of the registrant's common stock outstanding.

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**CEPHEID**  
**Report On Form 10-Q For The**  
**Quarter Ended September 30, 2003**  
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**PART I - FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

**CEPHEID**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(amounts in thousands)

	<u>September 30,</u> <u>2003</u>	<u>December 31,</u> <u>2002 (1)</u>
	<u>(Unaudited)</u>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$ 15,166	\$ 14,505
Restricted cash .....	1,166	2,296
Accounts receivable .....	3,521	3,044
Inventory .....	4,627	3,850
Prepaid expenses and other current assets .....	1,040	352
Total current assets .....	<u>25,520</u>	<u>24,047</u>
Property and equipment, net .....	7,813	6,144
Other assets .....	50	--
Total assets .....	<u>\$ 33,383</u>	<u>\$ 30,191</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable .....	\$ 2,382	\$ 2,367
Accrued compensation .....	1,480	1,171
Other accrued liabilities .....	2,407	2,092
Current portion of equipment financing .....	1,764	1,423
Current portion of bank loan payable.....	<u>36</u>	<u>32</u>
Total current liabilities .....	8,069	7,085
Equipment financing, less current portion .....	2,094	1,629
Bank loan payable, less current portion.....	374	364
Deferred rent .....	464	355
Commitments		
Shareholders' equity:		
Common stock .....	90,487	75,928
Additional paid-in capital .....	7,490	7,505
Deferred stock-based compensation .....	(6)	(103)
Accumulated foreign exchange translation adjustment.....	(2)	4
Accumulated deficit .....	<u>(75,587)</u>	<u>(62,576)</u>
Total shareholders' equity .....	<u>22,382</u>	<u>20,758</u>
Total liabilities and shareholders' equity .....	<u>\$ 33,383</u>	<u>\$ 30,191</u>

(1) The balance sheet at December 31, 2002 has been derived from the audited financial statements, which are included in the Company's 2002 Annual Report on Form 10-K filed with the Securities and Exchange Commission.

See accompanying notes to Condensed Consolidated Financial Statements

**CEPHEID**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(unaudited)**

**(in thousands, except per share amounts)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Revenues:				
Instrument sales .....	\$ 4,074	\$ 3,315	\$ 9,433	\$ 7,814
Reagents and disposables sales .....	568	450	1,523	949
Total product sales .....	4,642	3,765	10,956	8,763
License and royalty revenue .....	8	71	44	200
Contract revenue .....	717	593	2,250	1,038
Total revenues .....	5,367	4,429	13,250	10,001
Operating costs and expenses:				
Cost of product sales .....	2,768	2,928	6,433	6,672
Research and development.....	4,004	4,546	11,866	13,110
Selling, general and administrative.....	2,503	2,471	7,928	6,311
Restructuring expenses.....	--	262	--	262
Total operating costs and expenses .....	9,275	10,207	26,227	26,355
Loss from operations .....	(3,908)	(5,778)	(12,977)	(16,354)
Interest (expense) income, net .....	7	17	(34)	88
Net loss .....	\$ (3,901)	\$ (5,761)	\$ (13,011)	\$ (16,266)
Net loss per share, basic and diluted.....	\$ (0.11)	\$ (0.20)	\$ (0.40)	\$ (0.59)
Shares used in computing net loss per share, basic and diluted .....	33,985	29,302	32,596	27,342

See accompanying notes to Condensed Consolidated Financial Statements.

**CEPHEID**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(unaudited)**

**(amounts in thousands)**

	Nine Months Ended September 30,	
	2003	2002
<b>OPERATING ACTIVITIES:</b>		
Net loss .....	\$ (13,011)	\$ (16,266)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization .....	1,543	1,561
Amortization of deferred stock-based compensation .....	82	469
Amortization of deferred rent .....	109	202
Changes in operating assets and liabilities:		
Accounts receivable .....	(477)	(880)
Inventory .....	(777)	(3)
Prepaid expenses and other assets .....	(738)	(120)
Accounts payable and other current liabilities .....	324	1,976
Accrued compensation .....	309	1,157
Net cash used in operating activities .....	(12,636)	(11,904)
<b>INVESTING ACTIVITIES:</b>		
Capital expenditures .....	(3,212)	(3,656)
Restricted cash .....	1,130	--
Proceeds from maturities of marketable securities .....	--	8,775
Net cash (used in) provided by investing activities .....	(2,082)	5,119
<b>FINANCING ACTIVITIES:</b>		
Net proceeds from the sale of common shares .....	14,559	9,947
Proceeds from loan arrangements .....	1,900	2,094
Principal payments under loan arrangements .....	(1,080)	(871)
Net cash provided by financing activities .....	15,379	11,170
Net increase in cash and cash equivalents .....	661	4,385
Cash and cash equivalents at beginning of period .....	14,505	15,905
Cash and cash equivalents at end of period .....	\$ 15,166	\$ 20,290

See accompanying notes to Condensed Consolidated Financial Statements.

**CEPHEID**  
**Notes to Condensed Consolidated Financial Statements**  
**(unaudited)**

**1. ORGANIZATION, BUSINESS AND BASIS OF PRESENTATION**

Cepheid (the "Company") was incorporated in the State of California on March 4, 1996. The Company develops, manufactures, and markets fully-integrated systems that enable sophisticated genetic and DNA analysis of patients and organisms by automating complex manual laboratory procedures.

The accompanying unaudited condensed consolidated financial statements have been prepared by management in accordance with generally accepted accounting principles in the United States ("GAAP") for interim financial information and with the instructions for Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include certain information and footnotes normally included in financial statements prepared in accordance with GAAP. In the opinion of management, all adjustments (consisting only of normal recurring entries) considered necessary for a fair presentation have been included. Operating results for the three and nine month periods ended September 30, 2003 are not necessarily indicative of the results that may be expected for the year ending December 31, 2003 or for any other future period. The accompanying financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Form 10-K for the year ended December 31, 2002 filed with the Securities and Exchange Commission.

**2. SIGNIFICANT ACCOUNTING POLICIES**

*Principles of Consolidation*

The condensed consolidated financial statements of the Company include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated.

*Use of Estimates*

The preparation of the condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results could differ from these estimates.

*Revenue Recognition*

We recognize revenue from product sales when goods are shipped, when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collectibility

is reasonably assured. No right of return exists for our products with the exception of damaged goods. We have not experienced any significant returns of our products.

Contract revenues related to research and development agreements and government grants are recognized as the related services are performed based on the performance requirements of the relevant contract. Non-refundable contract fees for which no further performance obligations exist, where there is no continuing involvement required of us are recognized on the earlier of the date the payments are received or when collection is reasonably assured. Under research and development agreements, we are required to perform specific research and development activities and are reimbursed based on the costs associated with each specific contract over the term of the agreement. Milestone related revenues are recognized upon the achievement of the specified milestone provided that the related milestone was at risk at the inception of the arrangement. Deferred revenue is recorded when funds are received in advance of services to be performed.

*Warranty Accrual*

The Company warrants its products against defects for a period of 12 months from the date of sale for material and labor costs to repair the product. Accordingly, a provision for the estimated cost of the warranty is recorded at the time revenue is recognized. The Company's warranty accrual is established using management's estimate for future costs of repairing any instrument failures during the one-year warranty period. The Company's accrued warranty liability at September 30, 2003 and December 31, 2002 was \$0.4 and \$0.6 million, respectively. The activity in the warranty accrual for the nine-month period ended September 30, 2003 consisted of the following (in thousands):

Balance at December 31, 2002.....	\$	634
Cost incurred & charged against reserve.....		(751)
Provision for warranty.....		<u>543</u>
Balance at September 30, 2003.....	\$	<u><u>426</u></u>

The Company generally sells products with a limited indemnification against intellectual property infringement claims related to the Company's products. The Company's policy is to accrue for known indemnification issues if a loss is probable and can be reasonably estimated, and accrues for estimated incurred but unidentified issues based on historical activity. To date, there are no such accruals or related expenses.

*Comprehensive (Income) Loss*

Comprehensive loss includes net loss as well as other comprehensive income or loss. Other comprehensive loss consists of net unrealized gains and losses on available-for-sale marketable securities. Comprehensive loss approximated net loss for the three and nine month periods ended September 30, 2003 and 2002.

### *Stock-Based Compensation*

As permitted by the provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation," (SFAS 123), the Company has elected to continue to apply the intrinsic value method of Accounting Principle Board Opinion No. 25, "Accounting for Stock Issued to Employees," (APB 25) and related interpretations in accounting for its employee stock option plans and the Employee Stock Purchase Plan. Under APB 25, if the exercise price of its employee and director stock options equals or exceeds the fair value of the underlying stock on the date of grant, no compensation expense is recognized.

The presentation of pro forma net loss set forth in this footnote has been determined as if the Company had accounted for its employee stock options granted using the fair value method of SFAS 123. The fair value of these options was estimated at the date of grant using the Black-Scholes option pricing model, with the following weighted-average assumptions: risk free interest rates of 3.14% and 2.87% for the three and nine month periods ended September 30, 2003, respectively, and 4% for grants in the three and nine month periods ended September 30, 2002, respectively; a weighted average expected life of five years; and a dividend yield of zero. The weighted average fair value of options granted during the three and nine month periods ended September 30, 2003 was \$4.46 and \$3.82, respectively, and \$3.73 and \$3.53, respectively for the three and nine month periods ended September 30, 2002. The expected volatility of the Company's common stock used in the pricing model was 1.3 for the three and nine months ended September 30, 2003 and 1.4 for the three and nine months ended September 30, 2002.

For purposes of disclosure pursuant to FAS 123 as amended by SFAS 148, "Accounting for Stock-Based Compensation, Transition and Disclosure," the estimated fair value of options is amortized to expense over the options' vesting period. The following table illustrates the effect on net loss per share as if we had applied the fair value recognition provision of SFAS 123 to stock based employee compensation (in thousands, except per share data):



	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<u>2003</u>	<u>2002</u>	<u>2003</u>	<u>2002</u>
Net loss as reported .....	\$ (3,901)	\$ (5,761)	\$ (13,011)	\$ (16,266)
Deduct: Total stock-based employee compensation determined under the fair value method for all awards, net of tax related effects.....	(898)	(670)	(2,362)	(1,791)
Add: Amortization of deferred stock based compensation.....	5	47	82	469
Pro forma net loss.....	\$ (4,794)	(6,384)	\$ (15,291)	(17,588)
Basic and diluted net loss per share:				
As reported.....	\$ (0.11)	(0.20)	\$ (0.40)	(0.59)
Pro forma.....	\$ (0.14)	(0.22)	\$ (0.47)	(0.64)

### 3. SIGNIFICANT CONCENTRATIONS

The Company distributes its products through its direct sales force and through third-party distributors. For the three and nine month periods ended September 30, 2003, product sales through distributors represented 46% and 53%, respectively, of total product sales (consisting of sales of instruments, reagents, and disposables). The Company's distributors in the United States, the Far East and Europe accounted for 25%, 8%, and 13%, respectively, of total product sales for the three month period ended September 30, 2003, and 33%, 10%, and 10%, respectively, of total product sales for the nine month period ended September 30, 2003. Such distributors accounted for 29%, 11%, and 3%, respectively, of total product sales for the corresponding three month period of the previous year, and 38%, 15%, and 3%, respectively, of total product sales for the corresponding nine month period of the prior year. For the three month period ended September 30, 2003, there was one direct customer that represented 12% of total product sales. For the nine month period ended September 30, 2003, there was no one direct customer that represented greater than 10% of total product sales. For the corresponding three and nine month periods of the prior year, there was no one direct customer that represented greater than 10% of total product sales.

The Company relies on several companies as sole sources for various materials used in its manufacturing process. Any extended interruption in the supply of these materials could result in the failure to meet customer demand.

Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of cash equivalent and debt securities.

### 4. NET LOSS PER COMMON SHARE

Basic net loss per common share has been calculated based on the weighted-average number of

common shares outstanding during the period, less shares subject to the Company's right of repurchase. Common stock equivalents consisting of stock options and warrants (calculated using the treasury stock method) have been excluded from the computation of diluted net loss per share, as their inclusion would be antidilutive.

The following table presents the calculation of basic and diluted net loss per share (in thousands, except per share data):

	<u>Three Months Ended</u> <u>September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2003</u>	<u>2002</u>	<u>2003</u>	<u>2002</u>
Net loss .....	\$ (3,901)	\$ (5,761)	\$ (13,011)	\$ (16,266)
<b>Basic and diluted:</b>				
Weighted-average shares of common stock outstanding .....	34,009	29,419	32,634	27,582
Less: weighted-average shares subject to repurchase .....	<u>(24)</u>	<u>(117)</u>	<u>(38)</u>	<u>(240)</u>
Shares used in computing basic and diluted net loss per share .....	<u>33,985</u>	<u>29,302</u>	<u>32,596</u>	<u>27,342</u>
Basic and diluted net loss per share .....	\$ <u>(0.11)</u>	\$ <u>(0.20)</u>	\$ <u>(0.40)</u>	\$ <u>(0.59)</u>

## 5. INVENTORY

Inventory is stated at the lower of standard cost (which approximates actual cost) or market, with cost determined on the first-in-first-out (“FIFO”) method. The Company maintains a reserve for inventory obsolescence. The inventory reserve is established using management’s estimate of the potential future obsolescence of inventory

The components of inventories (in thousands) are as follows:

	<u>September 30,</u> <u>2003</u>	<u>December 31,</u> <u>2002</u>
Raw materials .....	\$ 2,270	\$ 2,361
Work in process .....	946	988
Finished goods .....	1,411	501
	<u>\$ 4,627</u>	<u>\$ 3,850</u>

## 6. SUBSEQUENT EVENT

On October 16, 2003, the Company received a \$2.0 million option payment from a potential partner in a strategic commercial relationship. If the option is exercised, the payment would be credited towards amounts payable to the Company; if the option is not exercised, the Company would retain the option payment.

On November 7, 2003, the Company completed the sale of 555,556 common shares at \$3.75 for net proceeds of approximately \$2.0 million to an institutional investor. The shares were sold pursuant to an option issued in connection with its common stock offering in August 2003.

On November 6, the Company entered into series of agreements with Infectio Diagnostics, Inc which resulted in the restructuring of our previously existing collaborative relationship. In connection with these agreements, the Aridia joint venture was dissolved.

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

Certain statements in this Form 10-Q, including without limitation the information under the captions entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" contain or refer to forward-looking statements within the meaning of the federal securities laws. We also may provide oral or written forward-looking statements in other materials we release to the public from time to time. Statements that are not statements of historical fact are forward-looking statements. They are based on current expectations. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "expect," "anticipate," "believe," "estimate," "predict," "intend," "potential" or "continue" or the negative of these terms or other comparable terminology. Forward-looking statements involve risks and uncertainties that could cause actual results and the timing of events to differ materially from those anticipated in our forward-looking statements. These risks and uncertainties include the impact of the factors set forth under "Factors That Might Affect Future Results." We assume no obligation to update any of the forward-looking statements after the date of this report or to conform these forward-looking statements to actual results.

### ***OVERVIEW***

We develop, manufacture, and market fully-integrated systems that enable sophisticated genetic and DNA analysis of patients and organisms by automating complex manual laboratory procedures. Based on state-of-the-art microfluidic and microelectronic technologies, our easy-to-use systems analyze complex biological samples in disposable cartridges designed to rapidly and automatically perform all of the steps associated with sophisticated molecular biological procedures. We are focusing our efforts on those applications where rapid genetic and DNA testing is particularly important, such as the infectious disease, biothreat and cancer testing markets. In particular, we have designed our systems to be capable of use in genetic management of disease, performing a broad range of genetic tests that include identifying infectious organisms, evaluating at-risk populations for the early detection of disease such as cancer, determining the stage of the disease and assessing what might be the most effective therapy. We have also designed our systems to rapidly detect food, air and water contaminants through genetic identification of disease causing agents. We are collaborating with strategic partners to co-develop assays, or biological tests, and to provide marketing and sales support across a broad range of markets.

We commenced commercial sales of our first product, the Smart Cyclor, in May 2000. The Smart Cyclor is a DNA amplification and detection system initially directed at the life sciences research market. We began shipping the Smart Cyclor II, which features various enhancements to the Smart

Cycler, in November 2002. We believe our Smart Cycler products allow users to analyze biological samples faster and more efficiently than with any other product currently available.

Our GeneXpert system, currently in the final stages of development, integrates automated sample preparation with our Smart Cycler amplification and detection technology. Following clinical trials and FDA approval, we anticipate commercial launch of the GeneXpert system to the clinical genetic assessment market in the second half of 2005. We believe that the GeneXpert system is the only genetic analysis system that integrates automated sample preparation with genetic analysis, while also offering customers a complete testing system comprised of both instrumentation and disposable cartridges containing all necessary reagents for a particular test.

## **SIGNIFICANT ACCOUNTING POLICIES AND MANAGEMENT JUDGMENTS**

We consider certain accounting policies related to revenue recognition, inventory reserves, and warranty accruals to be critical accounting policies. Inherent in our determination of when to recognize revenue, and in our calculation of our inventory reserve and warranty accrual are a number of estimates, assumptions and judgments. These estimates, assumptions and judgments include deciding whether the elements required to recognize revenue from a particular arrangement are present and estimating the amount of inventory obsolescence and warranty costs associated with shipped products.

Revenue Recognition. We recognize revenue from product sales when goods are shipped, when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collectibility is reasonably assured. No right of return exists for our products with the exception of damaged goods. We have not experienced any significant returns of our products. Contract revenues related to research and development agreements and government grants are recognized as the related services are performed based on the performance requirements of the relevant contract. Non-refundable contract fees for which no further performance obligations exist, where there is no continuing involvement required of us are recognized on the earlier of the date the payments are received or when collection is reasonably assured. Under research and development agreements, we are required to perform specific research and development activities and are reimbursed based on the costs associated with each specific contract over the term of the agreement. Milestone related revenues are recognized upon the achievement of the specified milestone provided that the related milestone was at risk at the inception of the arrangement. Deferred revenue is recorded when funds are received in advance of services to be performed. Determining whether the elements required for us to recognize revenue are present (including, for example, determining whether there is sufficient evidence that an arrangement existing, the collectibility of billings and whether contractual performance obligations and milestones have been met) requires us to make estimates, assumptions and judgments that affect our operating results.

Inventory Reserve and Warranty Accrual. We maintain reserves for inventory obsolescence and warranty costs that we believe are reasonable and that are based on our historical experience and current expectations for future performance of operations. The inventory reserve is established using management's estimate of the potential future obsolescence of inventory. A substantial decrease in demand for our products could lead to excess inventories and could require us to increase our reserve for inventory obsolescence.

Our warranty accrual is established using management's estimate for the future costs of any instrument failures during the one-year warranty period. A significant change in failure rates of our Smart Cyclor system could lead to increased warranty costs and could require us to increase our warranty reserve. If such adverse conditions were to occur, we cannot readily predict what effect on our financial condition or results of operations would result, as any such effect would depend on both future results of operations and the magnitude and timing of the adverse conditions.

## ***RESULTS OF OPERATIONS***

### **THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2003 COMPARED TO THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2002**

#### ***REVENUES***

We derive our revenues principally from sales of our Smart Cyclor system and associated reagents and disposable reaction tubes and, to a lesser extent, from contractual payments for services rendered in research and development arrangements. Total revenues for the three and nine month periods ended September 30, 2003 were \$5.4 million and \$13.3 million respectively, an increase over the corresponding prior year periods of \$0.9 million or 21%, and \$3.2 million or 32%, respectively.

Product sales for the three and nine month periods ended September 30, 2003 were \$4.6 million and \$11.0 million respectively, an increase over the corresponding prior year periods of \$0.9 million or 23%, and \$2.2 million or 25%, respectively. The increase in product sales for the three and nine month periods ended September 30, 2003 resulted primarily from the growth of sales of our Smart Cyclor system, particularly in Europe. The increase in product sales in Europe was due primarily to the establishment of several new distributors in this region through our wholly owned French subsidiary, Cepheid SA. For the three and nine month periods ended September 30, 2003, product sales through distributors represented 46% and 53% of total product sales (including instruments, reagents, and disposables). For the three month period ended September 30, 2003, there was one direct customer that represented 12% of total product sales. For the nine month period ended September 30, 2003, there was no one direct customer that represented greater than 10% of total product sales. For the corresponding three and nine month periods of the prior year, there was no one direct customer that represented greater than 10% of total product sales. For the three month period ended September 30, 2003, product sales in North America, Europe, and the Far East represented 79%, 14%, and 7% respectively, of total product sales, as compared to 85%, 4%, 11% for the corresponding period of 2002. For the nine month period ended September 30, 2003, product sales in North America, Europe, and the Far East represented 76%, 15%, and 9%, respectively, of total product sales as compared to 79%, 6%, and 15% for the corresponding period of 2002. We expect that the percentage of sales contributed by each of the three geographical areas for the nine-month period ended September 30, 2003 will remain relatively constant for the remainder of 2003.

We are part of a Northrop Grumman-led consortium that has been selected by the U.S. Postal Service (USPS) to produce a DNA-based biothreat detection system for installation in USPS mail sorting facilities. We expect to realize approximately 15-17% of the initial contract award of \$175 million, with the majority of the revenue to be recognized in 2004. The contract award includes an option for placement of an additional number of units and associated GeneXpert anthrax test cartridges, which may be exercised in 2004. We also expect to realize continuing demand for GeneXpert anthrax test

cartridges beyond the initial contract awards. However, our participation in the USPS biothreat detection system program is subject to a number of risks and uncertainties, including uncertainties in the timing and decision-making and deployment of the biothreat detection system and sensitivity to changes in national and international priorities and budgets. Accordingly, the program may not yield the revenues we anticipate.

Contract revenues for the three and nine month periods ended September 30, 2003 were \$0.7 million and \$2.3 million respectively, an increase over the corresponding prior year periods of \$0.1 million or 21%, and \$1.2 million or 117%, respectively. Our contract revenues were derived principally from our research and development contract with the United States Military Institute for Infectious Disease (“USAMRIID”). We do not expect to experience a continued increase in quarterly contract revenue in the remainder of 2003 as we continue to focus on increasing our product marketing efforts and shifting our business away from contract research and development.

### ***COST OF PRODUCT SALES***

Cost of product sales consists of raw materials, direct labor, manufacturing overhead, facility and warranty costs. Cost of product sales for the three and nine month periods ended September 30, 2003 were \$2.8 million and \$6.4 million, respectively, a decrease from the corresponding prior year periods of \$0.2 million or 5%, and \$0.2 million or 4%, respectively. Our product gross margin percentage for the three and nine month periods ended September 30, 2003 was 40% and 41%, respectively as compared to 22% and 24% for the corresponding prior year periods. The increase in product gross margin percentage for the three and nine month periods ended September 30, 2003, as compared to the corresponding prior year periods, was due primarily to improved product pricing and increased manufacturing economies of scale. For the three month period ended September 30, 2003, improved product pricing accounted for 6%, decreased warranty costs accounted for 6%, and improved manufacturing economies of scale accounted for the remaining 6% of the improvement in gross margin percentage as compared to the prior year quarter. In the third quarter of the prior year, we incurred approximately \$0.4 million in warranty costs to enhance the reliability of the Smart Cyclor system which are not included in the three and nine month periods of the prior year. For the nine month period ended September 30, 2003, improved product pricing accounted for 8% while improved manufacturing economies of scale accounted for the remaining 9% improvement in product gross margin percentage as compared to the prior year period. We expect our quarterly gross margin percentage to remain essentially unchanged from the nine month period ended September 30, 2003 for the remainder of 2003.

### ***RESEARCH AND DEVELOPMENT EXPENSES***

Research and development expense consists of salaries, deferred stock compensation, research and development materials, and facility costs. Research and development expense for the three and nine month periods ended September 30, 2003 was \$4.0 million and \$11.9 million, respectively, a decrease from the corresponding prior year periods of \$0.5 million or 12% and \$1.2 million or 9%, respectively. The primary reason for the decrease for the three and nine month periods ended September 30, 2003, as compared to the corresponding prior year periods was a reduction in force that we completed in September 2002. Specifically, the decrease for the three month period ended September 30, 2003 as compared to the corresponding prior year period was comprised of a \$0.1 million decrease in wages and other personnel-related expenses, a \$0.1 million decrease in outside engineering and consulting

costs, a \$0.1 million decrease in non-cash deferred stock compensation, a \$0.4 decrease in facilities allocation, offset partially by a \$0.2 million increase in depreciation expenses. The decrease for the nine month period ended September 30, 2003 as compared to the corresponding prior year period was comprised of a \$0.4 million decrease in wages and other personnel-related expenses, a \$0.5 million decrease in outside engineering and consulting costs, and a \$0.3 million decrease in non-cash deferred compensation expense. We expect that our quarterly research and development expenses will increase slightly in the fourth quarter of 2003 as we continue our product development efforts, particularly with respect to developing assays for the Smart Cyclor and GeneXpert systems.

### ***SELLING, GENERAL AND ADMINISTRATIVE EXPENSES***

Selling, general and administrative expenses consist of salaries, deferred stock compensation, severance costs, accounting and other professional fees, facilities costs, and human resources expenses. Selling, general and administrative expense for the three and nine month periods ended September 30, 2003 was \$2.5 million and \$7.9 million, respectively, an increase over the corresponding prior year periods of \$0.032 million or 1.3%, and \$1.6 million or 26%, respectively. The primary reason for the increase for the three and nine month periods ended September 30, 2003, as compared to the prior year periods, was the organization and establishment of our wholly owned French subsidiary, Cepheid SA, in the fourth quarter of 2002, and other increases in sales and marketing headcount. The increase for the nine month period ended September 30, 2003 was comprised of a \$0.5 million increase in salaries and personnel-related expenses resulting primarily from increased sales and marketing and executive headcount, a \$0.3 million increase in travel expenses due to the increased sales force headcount, a \$0.2 million increase in legal and accounting costs, a \$0.3 million increase in consulting costs, a \$0.2 million increase in advertising costs, and a \$0.2 million increase in insurance costs, partially offset by a \$0.1 million decrease in non-cash deferred stock compensation. We expect that our quarterly selling general and administrative expense will increase slightly in fourth quarter of 2003 as we continue to make additional investments in sales and marketing.

### ***OTHER INCOME***

Other income (expense) for the three and nine month periods ended September 30, 2003 was \$7,000 and (\$34,000), respectively, representing a decrease in other income from the corresponding prior year periods of \$10,000 or 59% and \$122,000 or 139%, respectively. The decrease for both periods was due to a decrease in our cash balances, decreased investment yield due to lower interest rates, and increased interest expense due to increased equipment financing borrowings

### ***LIQUIDITY AND CAPITAL RESOURCES***

As of September 30, 2003, we had \$16.3 million in cash, cash equivalents and short-term investments, (including \$1.1 million in restricted cash) as compared to \$16.8 million (including \$2.3 million in restricted cash) as of December 31, 2002. Net cash used for operating activities was \$12.6 million for the nine month period ended September 30, 2003 as compared to \$11.9 million for the corresponding prior year period. The \$0.7 million increase in net cash used in operating activities for the nine month period ended September 30, 2003 as compared to the corresponding prior year period included a \$3.5 million increased investment in working capital including accounts receivable, inventory, and prepaid assets, a \$0.4 million decrease in non-cash deferred stock compensation, and a \$0.1 million decrease in amortization of deferred rent partially offset by a \$3.3 million decrease in net loss.

Through September 30, 2003, we had received net proceeds of approximately \$90.5 million from sales of common and convertible preferred stock since inception, including our initial public offering and recent offerings pursuant to our shelf registration statement. Through September 30, 2003, we had financed equipment, land and building purchases and leasehold improvements totaling approximately \$8.6 million. As of September 30, 2003, we had \$3.9 million in equipment financing obligations under an equipment financing agreement. These obligations are secured by the financed equipment, bear interest at a weighted average fixed rate of 9.2% per year and are due in monthly installments through September 2006. Under the equipment financing agreement, a balloon payment is due at the end of each individual lease term of the underlying equipment. As additional security for our obligations under this agreement, we provided a letter of credit in the amount of \$1.1 million to the creditor in October 2002, and our ability to draw down additional funding under our agreement was suspended. In September 2003, the creditor waived the letter of credit and we were permitted to draw down additional amounts under the equipment financing agreement.

In December 2002, we purchased land and a building for approximately \$0.4 million for our newly formed subsidiary in France. We financed the purchase with a ten-year mortgage loan, which bears interest at 4.75% per year and is secured by the land and building. Additionally, the loan is guaranteed by the Company through a standby letter of credit in the amount of \$0.5 million. The collateral for this standby letter of credit is classified as a component of restricted cash at September 30, 2003.

For the nine month period ended September 30, 2003, net cash used in investing activities consisted of \$3.2 million in capital expenditures for property and equipment partially offset by a \$1.1 million decrease in restricted cash, while, for the nine month period ended September 30, 2002, net cash provided by investing activities consisted of proceeds from maturities of marketable securities of \$8.8 million, partially offset by capital expenditures of \$3.7 million. The decrease in capital expenditures for the nine month period ended September 30, 2003, as compared to the corresponding prior year period, was primarily the result of capital expenditures made for leasehold improvements to our new headquarter facility during the nine month period ended September 30, 2002. Nominal capital expenditures for leasehold improvements were made during the nine month period ended September 30, 2003.

Net cash provided by financing activities for the nine month period ended September 30, 2003 consisted of \$14.6 million in net proceeds from sales of common stock under our shelf registration statement and our stock option and employee stock purchase plans and \$1.9 million in amounts financed under our equipment financing arrangement, partially offset by \$1.1 million in principal payments under our equipment financing arrangements. Net cash provided by financing activities for the nine month period ended September 30, 2002 consisted of \$2.1 million in amounts borrowed pursuant to loan arrangements and, \$9.9 million in net proceeds from sales of common shares under our shelf registration statement and stock option and employee stock purchase plans partially offset by \$0.9 million in principle payments under the loan arrangements.

Our contractual obligations for the next five years, and thereafter, are currently as follows as of December 31, 2002 (in thousands):



<u>CONTRACTUAL OBLIGATIONS(1)</u>	<u>LESS THAN 1 YEAR</u>	<u>1-3 YEARS</u>	<u>4-5 YEARS</u>	<u>AFTER 5 YEARS</u>	<u>TOTAL</u>
Equipment and mortgage loans.....	\$ 1,681	\$ 1,889	\$ 100	\$ 196	\$ 3,866
Operating leases.....	1,352	4,304	3,089	5,372	14,117
Research funding.....	117	49	--	--	166
Minimum royalty payments.....	<u>260</u>	<u>844</u>	<u>620</u>	<u>3,031</u>	<u>4,755</u>
Total contractual cash obligations.....	<u>\$ 3,410</u>	<u>\$ 7,086</u>	<u>\$ 3,809</u>	<u>\$ 8,599</u>	<u>\$ 22,904</u>

We expect to have negative cash flow from operations through at least the end of 2004. For the nine month period ended September 30, 2003, total cash used was \$0.5 million or \$14.5 million excluding the approximately \$4.7 million in net proceeds received from our March 2003 common stock offering and approximately \$9.3 million in net proceeds from our August 2003 common stock offering. After the net proceeds of approximately \$9.3 million from our August 2003 common stock offering, the receipt in October 2003 of a \$2.0 million option payment from a prospective partner in connection with a potential collaboration agreement, and the receipt of net proceeds of \$2.0 million in November 2003 from the sale of common shares, we anticipate that our existing capital resources will enable us to maintain our currently planned levels of operations through the first nine months of 2004. This expectation is based on our current operating plan and may change as a result of many factors, including our future capital requirements and our ability to reduce expenses, which, in many instances, depend on a number of factors outside our control. For example, our future cash use will depend on, among other things, market acceptance of our products, the resources we devote to developing and supporting our products, continued progress of our research and development of potential products, the need to acquire licenses to new technology or to use our technology in new markets, and the availability of other financing. Announcements of potential strategic commercial relationships, including the potential relationship discussed above, are not an assurance that any such relationship will arise, and options to participate in such relationships may never be exercised or otherwise lead to additional revenues. Consequently, we may need additional funding sooner than anticipated. We currently have no credit facility or committed sources of capital.

To the extent our capital resources are insufficient to meet future capital requirements, we expect that we will need to raise additional capital or incur indebtedness to fund our operations. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. In December 2001, we filed a shelf registration statement for the issuance of up to \$35.0 million in debt and/or equity securities. After our common stock offering in August 2003, we have approximately \$9.4 million still available for sale under this registration statement. There can be no assurance that additional debt or equity financing will be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate our research and development programs, reduce our commercialization effort or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to technologies or products that we might otherwise seek to develop or commercialize. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in dilution to our shareholders. In addition, such securities may be sold at a discount from the market price of our common stock, and may include rights, preferences or privileges senior to those of our common stock.

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

*You should carefully consider the risks described below, together with all of the other information included in this report, in considering our business and prospects. The risks and uncertainties described below are not the only ones facing Cepheid. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. The occurrence of any of the following risks could harm our business, financial condition or results of operations.*

***If we fail to raise additional capital, our ability to fund our operations and advance our development programs would be impaired and our business would be adversely affected.***

We expect to have negative cash flow from operations through the end of 2004. Although we anticipate that our existing capital resources will enable us to maintain our currently planned levels of operations through the first nine months of 2004, this expectation is based on our current operating plan and may change as a result of many factors, including our future capital requirements and our ability to reduce expenses, which, in many instances, depend on a number of factors outside our control. For example, our future cash use will depend on, among other things, market acceptance of our products, the resources we devote to developing and supporting our products, continued progress of our research and development of potential products, the need to acquire licenses to new technology or to use our technology in new markets, and the availability of other financing. Consequently, we may need additional funding sooner than anticipated. We currently have no credit facility or committed sources of capital.

To the extent our capital resources are insufficient to meet future capital requirements, we expect that we will need to raise additional capital or incur indebtedness to fund our operations. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. There can no assurance that additional debt or equity financing will be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate our research and development programs, reduce our commercialization effort or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to technologies or products that we might otherwise seek to develop or commercialize. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in dilution to our shareholders. In addition, such securities may be sold at a discount from the market price of our common stock, and may include right preferences or privileges senior to those of our common stock.

***We may not achieve or maintain profitability and may be unable to continue our operations.***

We have experienced significant operating losses each year since our inception and expect to have negative cash flow from operations through at least the end of 2004. We experienced net losses of approximately \$14.8 million in 2000, \$15.5 million in 2001, \$19.7 million in 2002 and \$13.0 million for the first nine months of 2003. As of September 30, 2003, we had an accumulated deficit of approximately \$75.6 million. Our ability to become profitable will depend on our revenue growth, which depends on a number of factors including market acceptance of our products, the success of the USPS BDS program in which we are participating, and global economic and political conditions. Our

ability to become profitable also depends on our expense levels and product costs, which are also influenced by a number of factors, including the resources we devote to developing and supporting our products, to continued progress of our research, and to development of potential products, and the need to acquire licenses to new technology or to use our technology in new markets, including the potentially significant ongoing royalty payments associated with such licenses. If we fail to grow our revenue and manage our expenses and product costs, we may never achieve profitability.

***Our participation in the U.S. Postal Service bio-threat detection program evaluation and other similar programs may not result in predictable contracts or revenues.***

Our participation in governmental contracting programs, including the USPS biothreat detection system program, inevitably involves significant uncertainties in the timing of decision-making and deployment and is highly sensitive to changes in national and international priorities and budgets. We cannot be certain that actual funding, deployment and operating parameters, or product purchases, will be at currently expected levels. In addition, we cannot be sure that we will be able to sufficiently ramp up our manufacturing and implementation capacity to meet, in a timely fashion, the demands that will be placed on us when we are requested to enter full-scale production of the components of the BDS that we supply. In this and any similar future programs, there may be no obligation on the part of the eventual customer to buy a minimum number of units or tests, so, even if we are awarded a production contract, we may be subject to our customer's future spending patterns and budgetary cycles. Furthermore, if we participate in any other collaborations bidding for government contracts, the bidding and evaluation process could be lengthy and involve significant expense, and may never result in a contract or a contract with acceptable terms. Accordingly, our participation in the USPS biothreat detection system program and other similar programs are subject to a number of risks and uncertainties and may never yield significant revenues.

***Delays in the time it takes for us to finalize instrument sales can cause variability and unpredictability in our operating results.***

In recent periods, we have begun to experience longer sales cycles for our products, which makes it more difficult for us to accurately forecast revenues in a given period, and may cause revenues and operating results to vary significantly from period to period. Over the first nine months of 2003, we have encountered growing delays between the initial decision to purchase our instruments and final approval of such purchases by our customers's purchasing departments. We believe that this increase has resulted mostly from delays in government funding to research institutions. As a result, we may expend considerable resources on unsuccessful sales efforts or we may not be able to complete transactions on the schedule anticipated. If this trend continues, we may not recognize revenues in the timeframe we anticipate, harming our operating results.

***If we cannot successfully commercialize our GeneXpert system, we may never achieve profitability.***

Our GeneXpert system is in the final stages of development. We anticipate that for the foreseeable future our ability to achieve profitability will depend in part on the successful commercialization of GeneXpert. Many factors may affect the market acceptance and commercial success of our GeneXpert system, including:

- Availability of assays for use in the GeneXpert system;

- timely completion of the GeneXpert system for commercial sale;
- cost-effective commercial scale production of the GeneXpert system;
- the timing of market entry of our GeneXpert system relative to competitive products;
- our ability to convince our potential customers of the advantages and economic value of our GeneXpert systems over competing technologies and products;
- the extent and success of our marketing and sales efforts, including our ability to enter into successful collaborations with marketing partners; and
- publicity concerning our GeneXpert system or any similar products.

If the GeneXpert system does not gain market acceptance, we will be unable to generate significant sales, which will prevent us from achieving profitability. If the GeneXpert system is not accepted in the marketplace, this could have a negative effect on our ability to sell subsequent systems.

***We may require licenses for new product features and products, and our strategic plans and growth could be impaired if we are unable to obtain such licenses.***

We will need to introduce new products and product features in order to market our products to a broader customer base. Our products typically require licenses from third-party suppliers in order to be sold. Accordingly, our introduction of new products and product features could require us to obtain additional licenses. Furthermore, for certain markets, we intend to manufacture reagents for use with our Smart Cycler and GeneXpert systems to offer a more complete solution for the detection and analysis of DNA. However, we will require additional licenses for many reagents. We believe that manufacturing reagents for use in our Smart Cycler and GeneXpert systems is important to our business and growth prospects. We may not be able to obtain licenses for a given product or product feature, or for certain reagents, on commercially reasonable terms, if at all. Some of these licenses may include significant upfront and ongoing royalty payments. Some of our competitors have rights to technologies and reagents that we have not yet obtained. Our failure to obtain similar rights would limit our ability to offer a system that includes certain product features or reagents and would adversely affect our competitive position and our performance.

***We expect that our operating results will fluctuate significantly, and any failure to meet financial expectations may disappoint securities analysts or investors and result in a decline in our stock price.***

We expect that our quarterly operating results will fluctuate in the future as a result of many factors, some of which are outside of our control. Because our revenue and operating results are difficult to predict, we believe that period-to-period comparisons of our results of operations are not a good indication of our future performance. We expect our gross profit to fluctuate depending upon the timing of introduction and acceptance of our products. In addition, our operating results may be affected by the inability of some of our customers to consummate anticipated purchases of our products, whether due to changes in internal priorities or, in the case of governmental customers, problems with the appropriations process. It is possible that in some future quarter or quarters our operating results will be below the expectations of securities analysts or investors. In this event, the

market price of our common stock may fall abruptly and significantly.

Broad market fluctuations in our stock price could result in the loss of market makers for our common stock, which could, in turn, result in a decline in the price of our common stock. To maintain our eligibility for listing on Nasdaq, we must maintain a minimum number of market makers and meet and maintain other eligibility requirements, including a minimum trading value of our common stock. A prolonged decline in the price of our common stock could effect the operation of our business by severely limiting our ability to raise capital or to use our common stock in connection with acquisitions. In addition if the price of our common stock is below \$5.00 per share, broker dealers may have to follow specific disclosure and suitability requirements, which could limit the marketability of our common stock.

If revenue declines in a quarter, whether due to a delay in recognizing expected revenue or otherwise, our earnings will decline because many of our expenses are relatively fixed. In particular, research and development and selling, general and administrative expenses are not significantly affected by variations in revenue.

***The regulatory approval process is expensive, time-consuming, and uncertain and may prevent us from obtaining required approvals for the commercialization of some of our products.***

Some of our products, depending upon their intended use, will be subject to approval or clearance by the Food and Drug Administration or foreign governmental entities prior to their marketing for commercial use. Products, such as the Smart Cyclor and, when it is launched commercially, the GeneXpert system, when used for clinical diagnostic purposes will require such approval. To date, we have only received FDA approval for use of the group B streptococcus assay for Smart Cyclor that was developed through our collaboration with Infectio Diagnostics, Inc. We have not sought approval from the FDA or any other governmental body for other assays for the Smart Cyclor, and we have not received any such approvals. The process of obtaining necessary FDA or foreign clearance or approvals can be lengthy, expensive and uncertain. We generally expect to rely on our collaborators to direct the regulatory approval process for our products. There are no assurances that such collaborators will timely and diligently pursue such process, or that they or we can obtain any required clearance or approval. Any such failure, or any material delay in obtaining the clearance or approval, could harm our business, financial condition and results of operations.

In addition, our failure or the failure of our collaborators to comply with regulatory requirements applicable to our products could result in significant sanctions, including:

- injunctions;
- recall or seizure of products;
- withdrawal of marketing clearances or approvals; and
- fines, civil penalties and criminal prosecutions.

***If we fail to respond to changing technologies, demand for our products and our ability to enhance our revenues will suffer.***

If we do not continue to improve our products and develop new products that keep pace with competitive product introductions and technological developments, satisfy diverse and rapidly evolving customer requirements and achieve market acceptance; we might be unable to attract new customers. The development of proprietary technology and necessary service enhancements entails significant technical and business risks and requires substantial expenditures and lead-time. We may also need to modify our manufacturing processes with respect to changes in product design or new product introductions. We might not be successful in developing and marketing product enhancements and new products that respond to technological advances and market changes, on a timely or cost-effective basis. In addition, even if these products are developed and released, they might not achieve market acceptance.

***If our competitors and potential competitors develop superior products and technologies our competitive position and results of operations would suffer.***

We face intense competition from a number of companies that offer products in our targeted application areas. These competitors include:

- companies developing and marketing sequence detection systems for life sciences research products;
- healthcare companies that manufacture laboratory-based tests and analyzers;
- diagnostic and pharmaceutical companies;
- companies developing drug discovery technologies; and
- companies developing or offering biothreat detection technologies.

We also face competition from both established and development-stage companies that continually enter these markets. Several companies are currently making or developing products that may or will compete with our products. Our competitors may succeed in developing, obtaining FDA approval for, or marketing technologies or products that are more effective or commercially attractive than our potential products, or that render our technologies and potential products obsolete. As these companies develop their technologies, they may develop proprietary positions that prevent us from successfully commercializing our products.

We also need to compete effectively with companies developing their own microfluidics technologies and products. Microfluidic technologies have undergone and are expected to continue to undergo rapid and significant change. Rapid technological development may result in our products or technologies becoming obsolete. Products we offer could be made obsolete either by less expensive or more effective products based on similar or other technologies. Our future success will depend on our ability to establish and maintain a competitive position in these and future technologies. We also compete against universities and public and private research institutions. While these organizations primarily have educational or basic research objectives, they may develop proprietary technology and acquire patents that we need for the development of our products. Licenses to this proprietary

technology may not be available to us on acceptable terms, if at all.

In many instances particularly in the clinical genetic assessment area, our competitors have substantially greater financial, technical, research and other resources, and larger, more established marketing, sales, distribution and service organizations than we have. Moreover, these competitors may offer broader product lines and tactical discounts and have greater name recognition. If we fail to compete effectively against these and other competitors, we will lose sales and our business will be harmed.

***If our products do not perform as expected, or the reliability of the technology on which our products are based is questioned, we could experience lost revenue, delayed or reduced market acceptance of our products, increased costs and damage to our reputation.***

Our success depends on the market's confidence that we can provide reliable, high quality genetic and DNA testing systems. We believe that customers in the life sciences research, biothreat applications and genetic management of disease markets are likely to be particularly sensitive to product defects and errors. Our reputation and the public image of our products or technologies may be impaired for any of the following reasons:

- failure of products to perform as expected;
- governmental, academic or industry concerns regarding the reliability or efficacy of the polymerase chain reaction (PCR) technology on which our systems are based;
- a perception that our products are difficult to use; or
- litigation concerning the performance of our products or our technology.

Even after any underlying concerns or problems are resolved, any widespread concerns regarding our technology or any manufacturing defects or performance errors in our products could result in lost revenue, delay in market acceptance, damage to our reputation, increased service and warranty costs, and claims against us.

***If product liability lawsuits are successfully brought against us, we may face reduced demand for our products and incur significant liabilities.***

We face an inherent risk of exposure to product liability claims if our technologies or systems are alleged to have caused harm, in part because our products are used for sensitive applications. We cannot be certain that we can successfully defend any product liability lawsuit brought against us. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for our products;
- injury to our reputation;
- costs of related litigation; and
- substantial monetary awards to plaintiffs.

If we are the subject of a successful product liability lawsuit that exceeds the limits of any insurance coverage we may have, we may incur substantial liabilities, which would adversely affect our earnings and financial condition.

***The world geopolitical climate has created increased financial expectations that may not materialize.***

The world geopolitical climate in the wake of the September 11, 2001 terrorist attacks has created increased interest in biothreat detection systems. However, we are uncertain what the long-term impact will be on our product sales. To date, we have not generated significant revenues from the market for biothreat detection systems. As a result, we may not ever realize substantial revenues from the use of our products in biothreat detection systems and, even if we do, the amount and timing of such revenues would be subject to substantial uncertainty.

***If we are unable to maintain our relationships with collaborative partners, we may have difficulty selling our products and services.***

We believe that our success in penetrating our target markets and in bidding for certain kinds of contracts depends in part on our ability to develop and maintain collaborative relationships with key companies. However, our collaborative partners may not be able to perform their obligations as expected or devote sufficient resources to the development, supply or marketing of potential products developed under these collaborations. Also, if a key collaborative partner fails to perform its obligations as expected, including, for example, if it becomes insolvent or is acquired by another company with which we have no relationship, we may not be able to develop an adequate alternative in a timely manner.

Currently, our significant collaborative partners include:

- Infectio Diagnostics, Inc. in a collaborative arrangement to develop a line of assays adapted to our systems, including the group B streptococcus assay for Smart Cyclor, which began shipping in the second quarter of 2003;
- Northrop Grumman Corp.'s Automation and Information Systems Division, Sceptor Industries and Smiths Detection, with whom we will jointly install and test bio-threat detection systems for the USPS;
- Applied Biosystems Group, in a collaboration to develop and sell reagents to detect biothreat agents for use with our GeneXpert system and cartridges; and
- Takara Bio, Inc. in a collaboration to manufacture and sell a line of general use PCR enzyme reagents optimized for use on our products.

Relying on these or other collaborative relationships is risky to our future success because, among other things:

- our collaborative partners may not devote sufficient resources to the success of our collaboration;
- our collaborative partners may not obtain regulatory approvals necessary to continue the



collaborations in a timely manner;

- our collaborative partners may develop technologies or components competitive with our products;
- components developed by collaborators could fail to meet specifications, possibly causing us to lose potential projects and subjecting us to liability;
- some agreements with our collaborative partners may terminate prematurely due to disagreements or may result in litigation between the partners;
- our collaborators may not have sufficient capital resources;
- our existing collaborations may preclude us from entering into additional future arrangements; or
- we may not be able to negotiate future collaborative arrangements on acceptable terms.

***If we are unable to manufacture the GeneXpert system and reagents in sufficient quantities and at acceptable costs, we may be unable to meet demand for our products and our ability to generate revenue will be diminished.***

We are in the process of launching our manufacturing process for our GeneXpert system and reagents to support commercial sales. We have limited manufacturing experience, and we cannot assure you that manufacturing or quality control problems will not arise as we attempt to produce our GeneXpert systems or reagents, or that we can scale-up manufacture and quality control in a timely manner or at commercially reasonable costs. If we are unable to manufacture GeneXpert systems or reagents consistently on a timely basis because of these or other factors, our product sales will be negatively affected.

If we launch a diagnostic product, our manufacturing facilities, where we produce the Smart Cycler system and the GeneXpert system, cartridges and reagents, will be subject to periodic regulatory inspections by the FDA and other federal and state regulatory agencies. These facilities would be subject to Quality System Regulation, or QSR, requirements of the FDA. If we fail to maintain these facilities in accordance with the QSR requirements, international quality standards or other regulatory requirements, the manufacturing process could be suspended or terminated, which would impair our business.

***If our direct selling efforts for our products fail, our business expansion plans could suffer and our ability to generate revenue will be diminished.***

We are utilizing a direct sales force to market our products in some markets. We have a relatively small sales force compared to our competitors. Failure to effectively promote and sell our products in these markets could have a negative impact on their market acceptance. If our systems fail to penetrate these expanding markets, this could have a negative effect on our ability to sell subsequent systems and hinder the planned expansion of our business.

***If our distributor relationships are not successful, our ability to market and sell our products in the***

***life sciences research market would be harmed and our financial performance will be adversely affected.***

We are dependent on relationships with distributors for the marketing and sales of our products in the life sciences research market in various geographic regions and we have a limited ability to influence their efforts. For the nine-month period ended September 30, 2003, product sales through distributors represented 53% of total product sales (consisting of sales of instruments, reagents and disposables). The Company's distributors in the United States, the Far East and Europe accounted for 33%, 10%, and 10%, respectively, of total product sales for the nine months ended September 30, 2003. Such distributors accounted for 38%, 15%, and 4%, respectively, of total product sales for the corresponding nine month period of the prior year. Takara Bio, Inc. is the exclusive distributor of Smart Cyclor in the life sciences research market in Japan, South Korea, China and Taiwan and we also rely on various distributors for our sales of Smart Cyclor in the European life sciences research market. Relying on distributors for our sales and marketing is risky to our future for various reasons, including:

- agreements with distributors may terminate prematurely due to disagreements or may result in litigation between the partners;
- our distributors may not devote sufficient resources to the sale of products;
- our distributors may be unsuccessful;
- our existing relationships with distributors may preclude us from entering into additional future arrangements; and
- we may not be able to negotiate future distributor agreements on acceptable terms.

***If we fail to effectively manage our modifications and planned modifications to our distribution network, our sales could decline.***

We are currently in the process of modifying our distribution network, phasing in new distributors, changing our relationships with our existing distributors and increasing our direct sales efforts. These relationships are new and we cannot predict whether they will be successful. Furthermore, we have limited experience and infrastructure for managing a larger network of distributors. If we cannot effectively manage this new broader network of distributors, our sales and marketing efforts in these geographic areas would be adversely affected and our operating results could suffer.

***We may be subject to third- party claims that we require additional licenses for our products, and such claims could interfere with our business.***

Our industry is characterized by a large number of patents, claims of which appear to overlap in many cases. As a result, there is a significant amount of uncertainty regarding the extent of patent protection and infringement. Obtaining licenses to relevant patents could be costly and could materially harm our results of operations and future cash flows. Failing to obtain a license could result in litigation, which may consume our resources and lead to significant damages, royalty payments or an injunction on the sale of our currently existing products. In addition, some of these licenses could result in substantial additional royalties, which could adversely impact our product costs and have an impact on our business.

***If our products infringe on the intellectual property rights of others, we could face costly litigation, which could cause us to pay substantial damages and limit our ability to sell some or all of our products.***

Our market success depends in part on us neither infringing valid, enforceable patents or proprietary rights of third parties, nor breaching any licenses that may relate to our technologies and products. We are aware of third-party patents that may relate to our technology. We plan to seek licenses, as we deem appropriate; however, it is possible that we may unintentionally infringe upon these patents or proprietary rights of third parties. In response, third parties may assert infringement or other intellectual property claims against us. We may consequently be subjected to substantial damages for past infringement or be required to modify our products if it is ultimately determined that our products infringe a third party's proprietary rights. Further, we may be prohibited from selling our products before we obtain a license, which, if available at all, may require us to pay substantial royalties. Even if these claims are without merit, defending a lawsuit takes significant time, may be expensive and may divert management attention from other business concerns. Any public announcements related to litigation or interference proceedings initiated or threatened against us could cause our stock price to decline.

***We may need to initiate lawsuits to protect or enforce our patents, which would be expensive and, if we lose, may cause us to lose some, if not all, of our intellectual property rights, and thereby impair our ability to compete.***

We rely on patents to protect a large part of our intellectual property. To protect or enforce our patent rights, we may initiate patent litigation against third parties, such as infringement suits or interference proceedings. These lawsuits could be expensive, take significant time and divert management's attention from other business concerns. They would also put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. We may also provoke these third parties to assert claims against us. Patent law relating to the scope of claims in the technology fields in which we operate is still evolving and, consequently, patent positions in our industry are generally uncertain. We cannot assure you that we would prevail in any of these suits or that the damages or other remedies awarded, if any, would be commercially valuable. During the course of these suits, there may be public announcements of the results of hearings, motions and other interim proceedings or developments in the litigation. If securities analysts or investors perceive any of these results to be negative, it could cause our stock to decline.

***If we fail to maintain and protect our intellectual property rights, our competitors could use our technology to develop competing products and our business will suffer.***

Our competitive success will be affected in part by our continued ability to obtain and maintain patent protection for our inventions, technologies and discoveries, including intellectual property that we license. Our pending patent applications may lack priority over others' applications or may not result in the issuance of patents. Even if issued, our patents may not be sufficiently broad to provide protection against competitors with similar technologies and may be challenged, invalidated or circumvented.

In addition to patents, we rely on a combination of trade secrets, copyright and trademark laws, nondisclosure agreements, licenses and other contractual provisions and technical measures to

maintain and develop our competitive position with respect to intellectual property. Nevertheless, these measures may not be adequate to safeguard the technology underlying our products. For example, employees, consultants and others who participate in the development of our products may breach their agreements with us regarding our intellectual property and we may not have adequate remedies for the breach. We also may not be able to effectively protect our intellectual property rights in some foreign countries, as many countries do not offer the same level of legal protection for intellectual property as the United States. Furthermore, for a variety of reasons, we may decide not to file for patent, copyright or trademark protection outside of the United States. Our trade secrets could become known through other unforeseen means. Notwithstanding our efforts to protect our intellectual property, our competitors may independently develop similar or alternative technologies or products that are equal or superior to our technology. Our competitors may also develop similar products without infringing on any of our intellectual property rights or design around our proprietary technologies.

***Our international operations and proposed expansion subject us to additional risks and costs.***

Our international operations are subject to a number of difficulties and special costs, including:

- costs of customizing products for foreign countries;
- laws and business practices favoring local competitors;
- dependence on local vendors;
- uncertain regulation of electronic commerce;
- compliance with multiple, conflicting and changing governmental laws and regulations;
- longer sales cycles;
- potential for exchange and currency risks;
- greater difficulty in collecting accounts receivable;
- import and export restrictions and tariffs;
- difficulties staffing and managing foreign operations;
- greater difficulties and expense in enforcing intellectual property rights;
- business risks (including fluctuations in demand for our products and the cost and effort to conduct international operations and travel abroad to promote international distribution) associated with international military operations, and the global economic slowdown;
- multiple conflicting tax laws and regulations; and
- political and economic instability.

We intend to expand our international sales and marketing activities, including through our European

subsidiary, and enter into relationships with additional international distribution partners. We are in the early stages of developing our indirect distribution channels in markets outside the United States. We may not be able to attract distribution partners that will be able to market our products effectively.

Our international operations could also increase our exposure to international laws and regulations. If we cannot comply with foreign laws and regulations, which are often complex and subject to variation and unexpected changes, we could incur unexpected costs and potential litigation. For example, the governments of foreign countries might attempt to regulate our products and services or levy sales or other taxes relating to our activities. In addition, foreign countries may impose tariffs, duties, price controls or other restrictions on foreign currencies or trade barriers, any of which could make it more difficult for us to conduct our business.

The nature of our products may also subject us to export control regulation by the U.S. Department of State and the Department of Commerce. Violations of these regulations can result in monetary penalties and denial of export privileges.

***If our single source suppliers fail to deliver key product components in a timely manner, our manufacturing ability would be impaired and our product sales could suffer.***

We depend on long term delivery contracts with several single source suppliers that supply components used in the manufacture of the Smart Cyclor, the GeneXpert system, disposable reaction tubes, and cartridges. If we need alternative sources for key component parts for any reason, such component parts may not be immediately available. If alternative suppliers are not immediately available, we will have to identify and qualify alternative suppliers, and production of such components may be delayed. We may not be able to find an adequate alternative supplier in a reasonable time period, or on commercially acceptable terms, if at all. Our inability to obtain a key source supplier for the manufacture of our potential products may force us to curtail or cease operations.

***If we fail to obtain an adequate level of reimbursement for our products from third-party payers, our ability to sell products in some markets would be harmed.***

Our ability to sell our products in the clinical diagnostics market will depend in part on the extent to which reimbursement for our products and related treatments will be available from:

- government health administration authorities;
- private health coverage insurers;
- managed care organizations; and
- other organizations.

If appropriate reimbursement cannot be obtained, we could be prevented from successfully commercializing some of our potential products.

There are efforts by governmental and third-party payers to contain or reduce the costs of health care through various means. Additionally, third-party payers are increasingly challenging the price of

medical products and services. If purchasers or users of our products are not able to obtain adequate reimbursement for the cost of using our products, they may forego or reduce their use. Significant uncertainty exists as to the reimbursement status of newly approved health care products and whether adequate third-party coverage will be available.

***If we fail to retain key members of our staff, our ability to conduct and expand our business would be impaired.***

We are highly dependent on the principal members of our management and scientific staff. The loss of services of any of these persons could seriously harm our product development and commercialization efforts. In addition, we will require additional skilled personnel in areas such as microbiology, regulatory, and sales and marketing. Retaining and training personnel with the requisite skills is challenging even in today's economy, and, if general economic conditions improve, is likely to become extremely competitive again, particularly in the Silicon Valley area of California where our main office is located. If at any point we are unable to hire, train and retain a sufficient number of qualified employees to match our growth, our ability to conduct and expand our business could be seriously reduced. The inability to retain and hire qualified personnel could also hinder the planned expansion of our business.

***If a catastrophe strikes our manufacturing facilities, we may be unable to manufacture our products for a substantial amount of time and we would experience lost revenue.***

Our manufacturing facilities are located in Sunnyvale, California. Even though we have business interruption insurance, our facilities and some pieces of manufacturing equipment are difficult to replace and could require substantial replacement lead-time. Various types of disasters, including earthquakes, fires, floods and acts of terrorism, may affect our manufacturing facilities. Earthquakes are of particular significance since the manufacturing facilities are located in an earthquake-prone area. In the event our existing manufacturing facilities or equipment is affected by man-made or natural disasters, we may be unable to manufacture products for sale, meet customer demands or sales projections. If our manufacturing operations were curtailed or ceased, it would seriously harm our business.

***If we acquire companies, products or technologies, we may face risks associated with those acquisitions.***

If we are presented with appropriate opportunities, we may make other investments in complementary companies, products or technologies. We may not realize the anticipated benefit of any acquisition or investment. If we acquire companies or technologies, we will likely face risks, uncertainties and disruptions associated with the integration process, including difficulties in the integration of these operations and services of an acquired company, integration of acquired technology with our products, diversion of our management's attention from other business concerns and the potential loss of key employees or customers of the acquired businesses. If we fail to successfully integrate other companies that we may acquire, our business could be harmed. Furthermore, we may have to incur debt or issue equity securities to pay for any additional future acquisitions or investments, the issuance of which could be dilutive to our existing shareholders or us. In addition, our operating results may suffer because of acquisition-related costs or amortization expenses or charges relating to acquired goodwill and other intangible assets.

***If we become subject to claims relating to improper handling, storage or disposal of hazardous materials, we could incur significant cost and time to comply.***

Our research and development processes involve the controlled storage, use and disposal of hazardous materials, including biological hazardous materials. We are subject to federal, state and local regulations governing the use, manufacture storage, handling and disposal of materials and waste products. We may incur significant costs complying with both existing and future environmental laws and regulations. In particular, we are subject to regulation by the Occupational Safety and Health Administration, or OSHA, and the Environmental Protection Agency, or EPA, and to regulation under the Toxic Substances Control Act and the Resource Conservation and Recovery Act. OSHA or the EPA may adopt regulations that may affect our research and development programs. We are unable to predict whether any agency will adopt any regulations that would have a material adverse effect on our operations.

Although we believe that our safety procedures for handling and disposing of these hazardous materials comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials cannot be eliminated completely. In the event of an accident, we could be held liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of our insurance. We may not be able to maintain insurance on acceptable terms, if at all. We could be required to incur significant costs to comply with current or future environmental laws and regulations.

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

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with fixed interest rate at the then-prevailing rate and the prevailing interest rate later rises, the principal amount of our investment will probably decline. To minimize this risk in the future, we intend to maintain our portfolio of cash equivalents in short term commercial paper and money market funds. Due to the short-term nature of the investments, we believe we have no material exposure to interest rate risk arising from our investments. Therefore we have not included quantitative tabular disclosure in this report on Form 10-Q.

We do not enter into financial investments for speculation or trading purposes and are not a party to financial or commodity derivatives.

We have operated primarily in the United States and the majority of sales to date have been made in U.S. Dollars. Accordingly, we have not made any material exposure to foreign currency rate fluctuations.

### **ITEM 4. CONTROLS AND PROCEDURES**

#### **Evaluation of Disclosure Controls and Procedures**

Regulations under the Securities Exchange Act of 1934 require public companies, including our company, to maintain “disclosure controls and procedures”, which are defined to mean a company’s

controls and procedures that are designed to ensure that information required to be disclosed in the reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. Our Chief Executive Officer and Chief Financial Officer, based on their evaluation of our disclosure controls and procedures as of the end of the period covered by this report, concluded that our disclosure controls and procedures were effective for this purpose.

### **Changes in Internal Controls Over Financial Reporting**

Regulations under the Securities Exchange Act of 1934 require public companies, including our company, to evaluate any change in our "internal control over financial reporting," which is defined as a process to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States. In connection with their evaluation of our disclosure controls and procedures as of the end of the period covered by this report, our Chief Executive Officer and Chief Financial Officer did not identify any change in our internal control over financial reporting during the three-month period ended September 30, 2003 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II**

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

None

### **ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS**

None.

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

### **ITEM 4. SUBMISSION OF MATTERS TO VOTE OF SECURITY HOLDERS**

None

### **ITEM 5. OTHER INFORMATION**

None

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

(a) Exhibits



<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference</u>			<u>Filed Herewith</u>
		<u>Form</u>	<u>File No.</u>	<u>Exhibit</u>	
10.1	Change of Control Agreement dated September 8, 2003 between Cepheid and Ira Marks				X
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*				X
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*				X

\*These certifications “accompany” Cepheid’s quarterly report on Form 10-Q; they are not deemed “filed” for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that Cepheid specifically incorporates it by reference.

(b) Reports on Form 8-K

On July 31, 2003, Cepheid filed a Current Report on Form 8-K reporting under Item 12 Cepheid’s issuance of a press release announcing its preliminary financial results for the three months ended June 30, 2003 and certain other information, and furnishing such press release as an exhibit to such Current Report.; and

On August 14, 2003, Cepheid filed a Current Report on Form 8-K reporting, under Item 5:

- Cepheid’s issuance of a press release announcing its preliminary financial results for the three months ended June 30, 2003 and certain other information and filing such press release as an exhibit to such Current Report; and
- The sales of 2,777,778 shares of its common stock for \$10,000,000.80, with an option to purchase up to an additional 555,556 shares for an additional \$2,083,335, directly to an institutional investor in an offering under Cepheid’s shelf registration statement on Form S-3.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized, in the City of Sunnyvale, State of California on this 13th day of November, 2003.

CEPHEID  
*(Registrant)*

By: /s/ John L. Bishop  
John L. Bishop  
*Chief Executive Officer and Director*  
(Duly Authorized Officer)

By: /s/ John R. Sluis  
John R. Sluis  
*Chief Financial Officer*  
(Principal Accounting Officer)

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