FORM 10-Q

CEPHEID - CPHD

Filed: November 07, 2008 (period: September 30, 2008)

Quarterly report which provides a continuing view of a company's financial position

Table of Contents

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

FORM 10-Q

(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, 2008

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 000-30755

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 No.)**
904 Caribbean Drive, Sunnyvale, California	**94089-1189**
(Address of Principal Executive Office)	**(Zip Code)**

(408) 541-4191
(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or 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 ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer ☑	Accelerated Filer ☐	Non-Accelerated Filer ☐ (Do not check if smaller reporting company)	Smaller Reporting Company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

☐ Yes ☑ No

As of October 28, 2008 there were 57,647,607 shares of the registrant's common stock outstanding.

REPORT ON FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2008

INDEX

ITEM 1. FINANCIAL STATEMENTS

CEPHEID
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)

	September 30, 2008 (unaudited)	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 24,389	$ 16,476
Marketable securities	—	27,550
Accounts receivable, net	17,883	21,263
Inventory	29,870	23,821
Prepaid expenses and other current assets	3,751	2,565
Total current assets	75,893	91,675
Property and equipment, net	23,412	17,174
Investments	21,023	—
Other non-current assets	422	923
Intangible assets, net	37,163	40,629
Goodwill	17,514	14,844
Total assets	$ 175,427	$ 165,245
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 14,079	$ 10,587
Accrued compensation	6,519	8,573
Accrued royalties	7,442	6,913
Accrued collaboration profit sharing	1,070	522
Accrued and other liabilities	7,563	4,742
Income tax payable	—	213
Deferred revenue	3,146	4,016
Total current liabilities	39,819	35,566
Deferred revenue	1,798	2,054
Other liabilities	3,663	690
Total liabilities	45,280	38,310
Commitments and contingencies		
Shareholders' equity:		
Common stock, no par value; 100,000,000 shares authorized, 57,617,607 and 55,611,398 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively	266,784	254,807
Additional paid-in capital	37,891	26,697
Accumulated other comprehensive income (loss)	(3,784)	340
Accumulated deficit	(170,744)	(154,909)
Total shareholders' equity	130,147	126,935
Total liabilities and shareholders' equity	$ 175,427	$ 165,245

See accompanying notes.

CEPHEID

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Revenues:				
System sales	$ 13,961	$ 15,911	$ 40,708	$ 32,142
Reagent and disposable sales	28,432	18,105	82,558	47,525
Total product sales	42,393	34,016	123,266	79,667
Other revenue	2,522	2,313	8,532	9,379
Total revenues	44,915	36,329	131,798	89,046
Costs and operating expenses:				
Cost of product sales	23,623	19,966	69,479	47,722
Collaboration profit sharing	2,460	2,729	8,970	8,957
Research and development	11,611	8,371	32,473	22,732
Sales and marketing	7,871	6,411	22,246	15,971
General and administrative	5,517	4,445	15,782	12,418
Total costs and operating expenses	51,082	41,922	148,950	107,800
Loss from operations	(6,167)	(5,593)	(17,152)	(18,754)
Other income (expense):				
Interest income	241	621	1,039	2,175
Interest expense	(1)	(5)	(3)	(19)
Other income (expense), net	(1,146)	236	(469)	463
Other income (expense), net	(906)	852	567	2,619
Net loss before income tax benefit	(7,073)	(4,741)	(16,585)	(16,135)
Income tax benefit	614	—	750	—
Net loss	$ (6,459)	$ (4,741)	$ (15,835)	$ (16,135)
Basic and diluted net loss per share	$ (0.11)	$ (0.09)	$ (0.28)	$ (0.29)
Shares used in computing basic and diluted net loss per share	57,538	55,356	56,917	55,174

See accompanying notes.

CEPHEID
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2008	2007
Cash flows from operating activities:		
Net loss	$ (15,835)	$ (16,135)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,569	4,023
Amortization of intangible assets	3,465	3,141
Amortization of prepaid compensation expense	189	247
Stock-based compensation related to employees and consulting services rendered	10,837	7,299
Deferred rent	304	76
Changes in operating assets and liabilities:		
Accounts receivable	3,380	(9,336)
Inventory	(5,692)	(9,540)
Prepaid expenses and other current assets	(1,567)	(709)
Other non-current assets	(178)	210
Accounts payable and other current liabilities	7,391	3,219
Income taxes payable	(213)	—
Accrued compensation	(2,052)	914
Accrued expense for patent-related matter	—	(3,350)
Deferred revenue	(1,119)	759
Net cash provided by (used in) operating activities	3,479	(19,182)
Cash flows from investing activities:		
Capital expenditures	(12,778)	(4,666)
Acquisition of leasehold improvements	327	—
Payments for technology licenses	—	(4,737)
Cost of Sangtec acquisition, net of cash acquired	—	(27,372)
Cost of Actigenics acquisition, net of cash acquired	—	(82)
Proceeds from maturities of marketable securities	2,550	46,500
Proceeds of marketable securities	—	(1,800)
Proceeds from the sale of property and equipment	1,723	24
Transfer to unrestricted cash	517	—
Net cash provided by (used in) investing activities	(7,661)	7,867
Cash flows from financing activities:		
Net proceeds from the issuance of common shares and exercise of stock options	11,977	2,656
Principal payments under equipment financing	—	(316)
Payment of note payable	(4)	(46)
Net cash provided by financing activities	11,973	2,294
Effect of exchange rate change on cash	122	104
Net increase (decrease) in cash and cash equivalents	7,913	(8,917)
Cash and cash equivalents at beginning of period	16,476	17,186
Cash and cash equivalents at end of period	$ 24,389	$ 8,269

See accompanying notes.

CEPHEID

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Organization and Summary of Significant Accounting Policies

Organization and Business

Cepheid (the "Company" or "we") was incorporated in the State of California on March 4, 1996. We are a molecular diagnostics company that develops, manufactures, and markets fully-integrated systems for genetic analysis in the Clinical, Industrial and Biothreat markets. Our systems enable rapid, sophisticated genetic testing for organisms and genetic-based diseases by automating otherwise complex manual laboratory procedures.

The condensed consolidated balance sheet at September 30, 2008, the condensed consolidated statements of operations for the three and nine months ended September 30, 2008 and 2007, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2008 and 2007 are unaudited. In the opinion of management, these condensed consolidated financial statements reflect all adjustments (consisting of normal recurring adjustments) that are necessary for a fair presentation of the results for and as of the periods shown. The accompanying condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States. However, certain information or footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"). The results of operations for such periods are not necessarily indicative of the results expected for the remainder of 2008 or for any future period. The condensed consolidated balance sheet as of December 31, 2007 is derived from audited financial statements as of that date but does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and related notes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007 filed with the SEC. Certain amounts have been reclassified to conform to the current period presentation.

Principles of Consolidation

The condensed consolidated financial statements include our accounts and the accounts of our wholly-owned subsidiaries after elimination of intercompany transactions and balances. In February 2007, we acquired Sangtec Molecular Diagnostics AB ("Sangtec"), which became our Swedish subsidiary, Cepheid AB. The condensed consolidated financial statements include the results of operations of Sangtec subsequent to its acquisition date of February 14, 2007. The functional currency of our French subsidiary, Cepheid SA, is the Euro, and the functional currency of our Swedish subsidiary is the Swedish Krona; accordingly, all gains and losses arising from foreign currency transactions in currencies other than the functional currency are included in the condensed consolidated statements of operations. Adjustments resulting from translating the financial statements of foreign subsidiaries into U.S. Dollars are reported as a separate component of accumulated other comprehensive income (loss) in shareholders' equity.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from these estimates.

Fair Value of Financial Instruments

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 157 ("SFAS 157"), "Fair Value Measurements" ("SFAS 157"), which establishes guidelines for measuring fair value and expands disclosures regarding fair value measurements. SFAS 157 does not require any new fair value measurements but rather eliminates inconsistencies in guidance found in various prior accounting pronouncements and is effective for fiscal years beginning after November 15, 2007. In February 2008, the Financial Accounting Standards Board ("FASB") issued FASB Staff Position No. FAS 157-2, "Effective Date of FASB Statement No. 157", which provides a one year deferral of the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually, until fiscal years beginning after November 15, 2008, and interim periods within those fiscal years. Therefore, we adopted the provisions of SFAS 157 with respect to our financial assets and liabilities only. The partial adoption of SFAS 157 for financial assets and liabilities did not have a material impact on our consolidated financial position, results of operations, or cash flows. See Note 2 for information and related disclosures regarding our fair value measurements.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities — Including an Amendment of FASB Statement No. 115" ("SFAS 159"). The fair value option established by SFAS 159 permits all entities to choose to measure eligible items at fair value at specified election dates. A business entity will report unrealized gains and losses on items for which the fair value option has been elected in earnings (or another performance indicator if the business entity does not report earnings) at each subsequent reporting date. The fair value option: (a) may be applied instrument by instrument, with a few exceptions, such as investments otherwise accounted for by the equity method; (b) is irrevocable (unless a new election date occurs); and (c) is applied only to entire instruments and not to portions of instruments. We adopted SFAS 159 effective January 1, 2008, and the adoption did not affect our condensed consolidated financial statements.

Cash, Cash Equivalents and Investments

Cash and cash equivalents consist of cash on deposit with banks, money market instruments, commercial paper and debt securities with maturities from the date of purchase of 90 days or less. Interest income includes interest, dividends, amortization of purchase premiums and discounts and realized gains and losses on sales of securities.

Our investments are designated as available-for-sale, and realized and unrealized gains and losses on investments are determined on the specific identification method. Unrealized holding gains or losses are reported as a component of accumulated other comprehensive income (loss). Investments with maturities greater than 90 days and less than one year are classified as short-term; otherwise they are classified as long-term.

An impairment charge is recognized in the condensed consolidated statement of operations when the decline in the fair value of a security below the amortized cost basis is determined to be other-than-temporary. We consider various factors in determining whether to recognize an impairment charge, including the duration of time and the severity to which the fair value has been less than our amortized cost basis, any adverse changes in the investees' financial condition and our intent and ability to hold the investment for a period of time sufficient to allow for any anticipated maturity or recovery in market value. To date, we have not recorded any impairment charges on investments related to other-than-temporary declines in market value.

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 method. Accordingly, allocation of fixed production overheads to conversion costs is based on normal capacity of the production. Abnormal amounts of idle facility expense, freight, handling costs and spoilage are expensed as incurred and not included in overhead.

The components of inventory were as follows (in thousands):

	September 30, 2008	December 31, 2007
Raw Materials	$ 11,946	$ 9,956
Work in Process	8,124	7,550
Finished Goods	9,800	6,315
	$ 29,870	$ 23,821

Warranty Reserve

We warrant our systems to be free from defects for a period of 12 to 15 months from the date of sale and our disposable products to be free from defects, when handled according to product specifications, for the stated life of such products. Accordingly, a provision for the estimated cost of warranty repair or replacement is recorded at the time revenue is recognized. Our warranty provision is established using management's estimate of future failure rates and of the future costs of repairing any system failures during the warranty period or replacing any disposable products with defects. The activities in the warranty provision consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Balance at beginning of period	$ 750	$ 408	$ 549	$ 256
Costs incurred and charged against reserve	(449)	(69)	(968)	(163)
Accrual related to current period product sales	603	166	1,270	440
Adjustment to pre-existing warranties	(245)	(42)	(192)	(70)
Balance at end of period	$ 659	$ 463	$ 659	$ 463

Revenue Recognition

In accordance with Staff Accounting Bulletin ("SAB") No. 104, "Revenue Recognition", we recognize revenue from product sales when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable and collectibility is reasonably assured. No right of return exists for our products except in the case of damaged goods. We have not experienced any significant returns of our products. Other revenue includes contract revenues and grant and government sponsored research revenue. Contract revenues include fees for technology licenses and research and development services, royalties under license and collaboration agreements. Contract revenue related to technology licenses is generally fully recognized only after the license period has commenced, the technology has been delivered and no further involvement by us is required. When we have continuing involvement related to a technology license, revenue is recognized over the license term. Royalties are typically based on licensees' net sales of products that utilize our technology. Royalty revenues are recognized as earned in accordance with the contract terms when the royalties can be reliably measured and their collectibility is reasonably assured, such as upon the receipt of a royalty statement from the customer. Grants and government sponsored research revenue and contract revenue related to research and development services are recognized as the related services are performed based on the performance requirements of the relevant contract. Service revenue is recognized when the services have been provided. Shipping and handling costs are expensed as incurred and included in cost of product sales. In those cases where we bill shipping and handling costs to customers, the amounts billed are classified as revenue.

From time to time, we enter into revenue arrangements with multiple deliverables. Multiple element revenue agreements are evaluated under Emerging Issues Task Force ("EITF") Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables" ("EITF 00-21"), to determine whether the delivered item has value to the customer on a stand-alone basis and whether objective and reliable evidence of the fair value of the undelivered item exists. Deliverables in an arrangement that do not meet the separation criteria in EITF 00-21 must be treated as one unit of accounting for purposes of revenue recognition. Advance payments received in excess of amounts earned, such as funds received in advance of products to be delivered or services to be performed, are classified as deferred revenue until earned.

Stock-Based Compensation

We follow the accounting provisions of SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123(R)"), for share-based awards granted to employees and directors, including employee stock option awards, restricted stock awards and employee stock purchases made under our Employee Stock Purchase Plan ("ESPP"), using the estimated grant date fair value method of accounting in accordance with SFAS No. 123(R). We recognize the fair value of our stock option awards on a straight-line basis over the requisite service period of each award, which is generally four years. Stock-based compensation to other than employees is determined in accordance with SFAS No. 123(R) and EITF Issue No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods, or Services".

Net Loss per Share

Basic net loss per share has been calculated based on the weighted-average number of common shares outstanding during the period. Shares used in diluted net loss per share calculations exclude anti-dilutive common stock equivalent shares, consisting of stock options. These anti-dilutive common stock equivalent shares totaled 9,027,084 and 8,923,332 at September 30, 2008 and 2007, respectively.

Comprehensive Loss

Comprehensive loss includes net loss as well as other comprehensive income (loss). Other comprehensive income (loss) consists of foreign currency translation adjustments and unrealized gains (losses) on available-for-sale securities. The following table presents the calculation of comprehensive loss, including components of other comprehensive loss (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Net loss	$ (6,459)	$ (4,741)	$ (15,835)	$ (16,135)
Other comprehensive income (loss):				
Foreign currency translation adjustments	(435)	349	(147)	286
Unrealized loss on investments	(960)	—	(3,977)	—
Comprehensive loss	$ (7,854)	$ (4,392)	$ (19,959)	$ (15,849)

Reclassifications

Certain amounts have been reclassified to conform to the current period presentation.

Recent Accounting Pronouncements

In April 2008, the FASB issued FSP 142-3, "Determining the Useful Life of Intangible Assets" ("FSP 142-3"). FSP 142-3 amends the factors to be considered in determining the useful life of intangible assets. Its intent is to improve the consistency between the useful life of an intangible asset and the period of expected cash flows used to measure its fair value. FSP 142-3 is effective for fiscal years beginning after December 15, 2008. We are currently assessing the impact of FSP 142-3 on our consolidated financial statements.

In May 2008, FASB issued SFAS No. 162, *"*The Hierarchy of Generally Accepted Accounting Principles*"*. This statement identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles (GAAP) in the United States (the GAAP hierarchy). This statement will not result in a change in current practice. This statement is effective 60 days following the Securities and Exchange Commission's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, "The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles". The adoption of this statement is not expected to have a material effect on our financial position, cash flows or results of operations.

2. Fair Value

SFAS 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and requires enhanced disclosures about fair value measurements. Fair value is defined under SFAS 157 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under SFAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the third unobservable that may be used to measure fair value. The three levels of inputs are the following:

- Level 1 - Quoted prices in active markets for identical assets or liabilities.
- Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

In accordance with SFAS 157, the following table represents the fair value hierarchy for our financial assets (cash equivalents and investments) measured at fair value on a recurring basis as of September 30, 2008 (in thousands):

	Level 1	Level 2	Level 3	Total
Cash equivalent - money market funds	$ 12,119	$ —	$ —	$ 12,119
Investments - taxable auction variable rate notes	—	—	21,023	21,023
	$ 12,119	$ —	$ 21,023	$ 33,142

Level 3 assets consist of auction rate securities whose underlying assets are student loans, most of which are guaranteed by the federal government. In February 2008, auctions began to fail for these securities, and each auction since then has failed. Based on the overall failure rate of these auctions, the frequency of the failures, and the underlying maturities of the securities, a portion of which are greater than 30 years, we have classified auction rate securities as long-term assets on our condensed consolidated balance sheet as of September 30, 2008. These investments were valued at fair value as of September 30, 2008. The following table provides a summary of changes in fair value of our auction rate securities for the three and nine-month periods as of September 30, 2008 (in thousands):

	Level 1	Level 3
Balance at January 1, 2008	$ 27,550	$ —
Net settlements	(2,550)	—
Transfer	(25,000)	25,000
Unrealized loss included in accumulated other comprehensive loss	—	(2,144)
Balance at March 31, 2008	—	22,856
Unrealized loss included in accumulated other comprehensive loss	—	(873)
Balance at June 30, 2008	—	21,983
Unrealized loss included in accumulated other comprehensive loss	—	(960)
Balance at September 30, 2008	$ —	$ 21,023

Our investment portfolio of auction rate securities is structured with short-term interest rate reset dates of generally less than 90 days, but with contractual maturities that are well in excess of ten years. Our auction rate securities consist of investments that are backed by pools of student loans, which are principally guaranteed by the Federal Family Educational Loan Program (“FFELP”), or insured. We believe that the credit quality of these securities is high based on these guarantees. We determined the fair market values of our financial instruments based on the fair value hierarchy established in SFAS 157, which requires an entity to maximize the use of observable inputs (Level 1 and Level 2 inputs) and minimize the use of unobservable inputs (Level 3 inputs) when measuring fair value. Until the first quarter of 2008, the fair values of our auction rate securities were determinable by reference to frequent successful Dutch auctions of such securities, which settled at par. Therefore, at the adoption date, we had categorized our investments in auction rate securities as Level 1. Given the current failures in the auction markets to provide quoted market prices of the securities, as well as the lack of any correlation of these instruments to other observable market data, we valued these securities using a discounted cash flow methodology with the most significant input categorized as Level 3. Significant inputs that went into the model were the credit quality of the issuer, the percentage and the types of guarantees, the timing and probability of the auction succeeding or the security being called and discount factors.

Based on an analysis of other-than-temporary impairment factors, we have recorded cumulative temporary impairments within other accumulated comprehensive loss of approximately $4.0 million as of September 30, 2008 related to these auction rate securities. We believe we have the ability to hold these investments until maturity or recovery. However, the funds associated with failed auctions will not be accessible until a successful auction occurs, a buyer is found outside of the auction process, or the underlying securities mature, are refinanced or are recalled by the issuer. Given the recent disruptions in the credit markets and the fact that the liquidity for these types of securities remains uncertain, we have classified all of our auction rate securities as long-term assets in our condensed consolidated balance sheet as our ability to liquidate such securities in the foreseeable future is uncertain. In October 2008, UBS, the fund manager with which we hold these securities, announced a proposed comprehensive settlement for its clients holding auction rate securities. Under the proposal, UBS will issue auction rate securities rights to us. These rights will enable us to sell the auction rate securities held in our accounts with UBS to UBS at par value during a two year period beginning in June 2010. In exchange, we would be required to release UBS from claims we have for damages related to the securities other than consequential damages, and granting UBS the right to sell or otherwise dispose of our auction rate securities on our behalf (so long as we are paid the par value of the securities upon any disposition). The proposal was made by UBS after September 30, 2008. Accordingly, no settlement has been reached as of September 30, 2008. We will continue to evaluate the accounting for our auction rate securities quarterly.

3. Intangible Assets

Intangible assets related to licenses are recorded at cost, less accumulated amortization. Intangible assets related to technology acquired in acquisitions and other intangible assets are recorded at fair value at the date of acquisition, less accumulated amortization. Intangible assets are amortized over their estimated useful lives, ranging from 3 to 20 years, on a straight-line basis, except for intangible assets acquired in the acquisition of Sangtec, which are amortized on the basis of economic useful life. Amortization of intangible assets is primarily included in cost of product sales in the accompanying condensed consolidated statements of operations.

The recorded value and accumulated amortization of major classes of intangible assets at September 30, 2008 were as follows (in thousands):

	Recorded Value	Accumulated Amortization	Net Book Value
Licenses	$ 40,885	$ 12,769	$ 28,116
Technology acquired in acquisitions	8,613	755	7,858
Other	2,170	981	1,189
	$ 51,668	$ 14,505	$ 37,163

Included in licenses was $19.9 million in connection with a patent license agreement with F. Hoffman-La Roche Ltd., effective July 1, 2004. The net book value of this license was $14.5 million and $15.5 million at September 30, 2008 and December 31, 2007, respectively.

Amortization expense of intangible assets was $1.2 million and $1.1 million for the three months ended September 30, 2008 and 2007, respectively, and $3.5 million and $3.1 million for the nine months ended September 30, 2008 and 2007, respectively. The expected future annual amortization expense of intangible assets recorded on our condensed consolidated balance sheet as of September 30, 2008 is as follows, assuming no impairment charges (in thousands):

For the Years Ending December 31,	Amortization Expense
2008 (remaining three months)	$ 1,155
2009	4,927
2010	4,886
2011	4,792
2012	4,686
Thereafter	16,717
Total expected future annual amortization	$ 37,163

4. Segment and Significant Concentrations

We and our wholly owned subsidiaries operate in one business segment.

We currently sell our products through our direct sales force and through third-party distributors. There was one direct customer that accounted for 21% and 27% of total product sales for the three months ended September 30, 2008 and 2007, respectively and 26% and 38% of total product sales for the nine months ended September 30, 2008 and 2007, respectively. We have distribution agreements with several companies to distribute products in the U.S. and have several regional distribution arrangements throughout Europe, Japan, South Korea, China, Mexico and other parts of the world. There was one customer whose accounts receivable balance represented 2% and 22% of total receivables as of September 30, 2008 and December 31, 2007, respectively. The following table provides a breakdown of product sales by geographic region:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
	(As a percent of total product sales)			
Product Sales Geographic information:				
North America	85%	81%	79%	80%
International	15%	19%	21%	20%
Total product sales	100%	100%	100%	100%

No single country outside of the United States represented more than 10% of our total revenues or total assets in any period presented.

5. Collaboration Profit Sharing

Collaboration profit sharing represents the amount that we pay to Applied Biosystems Group under our collaboration agreement to develop reagents for use in the Biohazard Detection System developed for the United States Postal Service. Under the agreement, computed gross margin on anthrax cartridge sales are shared equally between the two parties. As of September 30, 2008 and December 31, 2007, the accrued profit sharing liability was $1.1 million and $0.5 million, respectively. Collaboration profit sharing expense was $2.5 million and $2.7 million for the three months ended September 30, 2008 and 2007, respectively, and $9.0 million for each of the nine months ended September 30, 2008 and 2007. The total revenues and cost of product sales related to these cartridge sales are included in the respective balances in the condensed consolidated statement of operations.

6. Stock-Based Compensation Expense

The stock-based compensation expense in the condensed consolidated statement of operations was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Cost of product sales	$ 419	$ 229	$ 1,015	$ 531
Research and development	1,485	1,319	4,162	3,110
Sales and marketing	868	703	2,623	1,498
General and administrative	1,097	750	3,038	2,161
Total stock-based compensation expense	$ 3,869	$ 3,001	$ 10,838	$ 7,300

The impact on basic and diluted net loss per share resulting from the adoption of SFAS 123(R) was $0.07 and $0.05 for the three months ended September 30, 2008 and 2007, respectively, and $0.06 and $0.13 for the nine months ended September 30, 2008 and 2007. In addition, stock-based compensation cost of approximately $1.1 million and $0.5 million was included in inventory as of September 30, 2008 and December 31, 2007, respectively.

The fair value of our stock options granted to employees and shares purchased by employees under the ESPP was estimated using the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
OPTION SHARES:				
Expected Term (in years)	4.46	5.00	4.51	5.00
Volatility	0.60	0.62	0.60	0.67
Expected Dividends	0.00%	0.00%	0.00%	0.00%
Risk Free Interest Rates	3.03%	4.46%	2.94%	4.57%
Estimated Forfeitures	7.74%	6.76%	7.42%	6.76%
ESPP SHARES:				
Expected Term (in years)	1.25	1.25	1.25	1.25
Volatility	0.70	0.46	0.61	0.47
Expected Dividends	0.00%	0.00%	0.00%	0.00%
Risk Free Interest Rates	2.26%	4.78%	2.19%	4.95%

The weighted average fair value of our stock options granted to employees was $10.94 and $9.89 for the three months ended September 30, 2008 and 2007, respectively, and $10.98 and $7.18 for the nine months ended September 30, 2008 and 2007, respectively. Also, the weighted average fair value for our shares purchased by employees under the ESPP was $7.60 and $5.38 for the three months ended September 30, 2008 and 2007, respectively and $9.42 and $3.94 for the nine months ended September 30, 2008 and 2007, respectively.

7. Income Taxes

We have had no U.S. federal or state income tax provision for any period prior to the three months ended September 30, 2008, as we have incurred operating losses in all periods. The net income tax benefit was $0.6 million and $0.8 million for the three months and nine months ended September 30, 2008, respectively, relates to research and development tax credits associated with our French subsidiary and our United States estimated refundable research and development tax credits under the Housing Rescue bill passed in 2008, less foreign withholding tax expense.

We utilize the liability method of accounting for income taxes as set forth in SFAS No. 109, Accounting for Income Taxes. Under the liability method, deferred taxes are determined based on the temporary differences between the financial statement and tax bases of assets and liabilities using enacted tax rates. A valuation allowance is recorded when it is more likely than not that some of the deferred tax assets will not be realized. We have established deferred tax liabilities of $2.7 million and increased goodwill by the same amount during the third quarter of 2008 in connection with the acquisition of the assets and licensed intellectual properties of Sangtec, which we acquired in February 2007. The effect of this adjustment is not material to the current period or any other prior periods.

We have substantially concluded all U.S. federal income tax matters for years through December 31, 2004. For federal income tax purposes, the open years are 1996 through 2007 due to net operating loss carryforwards relating to these years. Substantially all material state, local and foreign income tax matters have been concluded for years through December 31, 2002. For California state income tax purposes, the open years are 1997 through 2007 due to either research credit carryovers or net operating loss carryforwards.

We anticipate that the total unrecognized tax benefits will not significantly change due to the settlement of audits and the expiration of statute of limitations prior to December 31, 2008.

Effective January 1, 2007, we adopted the provisions of Financial Accounting Standards Interpretation No. 48, “Accounting for Uncertainty in Income Taxes - An Interpretation of FASB Statement No. 109”, or FIN 48. The Company’s policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense.

We recognize interest and penalties related to uncertain tax positions in income tax expense. For the periods presented, we did not recognize any interest or penalties related to uncertain tax positions in the condensed consolidated statements of operations, and at September 30, 2008 and December 31, 2007, we had no accrued interest or penalties.

Our total unrecognized tax benefit as of the January 1, 2007 adoption date and as of December 31, 2007 was $0.2 million and $3.7 million, respectively. Although unrecognized tax benefits for individual tax positions may have increased or decreased during the nine months ended September 30, 2008, we do not currently believe that it is reasonably possible that there will be a significant increase or decrease in unrecognized tax benefits.

No changes to deferred tax assets for unrecognized tax benefits were recorded in the three and nine months ended September 30, 2008.

8. Commitments and Contingencies

In 2008, we entered into long-term operating lease obligations for additional facilities in Sunnyvale, California. The lease terms range from May 1, 2008 through December 31, 2013, with total lease payments of $4.2 million, which include annual increases of between approximately 3% and 4%. Rent expense for all operating leases for the three months ended September 30, 2008 and 2007 was $0.9 million and $0.7 million, respectively, and for the nine months ended September 30, 2008 and 2007 was $2.5 million and $1.9 million, respectively.

In March 2008, we entered into an agreement to purchase $8.9 million of certain material used in production. As of September 30, 2008, the purchase commitment consisted of $1.3 million, $3.2 million and $3.5 million for the remainder of 2008, 2009 and 2010, respectively.

We have certain royalty commitments associated with the shipment and licensing of certain products. Royalty expense is generally based on a dollar amount per unit shipped or a percentage of the underlying revenue.

In the normal course of business, we provide indemnifications of varying scope to customers against claims of intellectual property infringement made by third parties arising from the use of our products. Historically, costs related to indemnification provisions have not been significant and we are unable to estimate the maximum potential impact of these indemnification provisions on our future results of operations.

To the extent permitted under California law, we have agreements whereby we indemnify our directors and officers for certain events or occurrences while the director or officer is, or was serving, at our request in such capacity. The indemnification period covers all pertinent events and occurrences during the director’s or officer’s service. The maximum potential amount of future payments we could be required to make under these indemnification agreements is not specified in the agreements; however, we have director and officer insurance coverage that reduces our exposure and enables us to recover a portion of any future amounts paid. We believe the estimated fair value of these indemnification agreements in excess of applicable insurance coverage is minimal.

We respond to claims arising in the ordinary course of business. In certain cases, management has accrued estimates of the amounts it expects to pay upon resolution of such matters, and such amounts are included in other accrued liabilities. Should we not be able to secure the terms it expects, these estimates may change and will be recognized in the period in which they are identified. Although the ultimate outcome of such claims is not presently determinable, management believes that the resolution of these matters will not have a material adverse effect on our financial position, results of operations and cash flows.

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

Forward-Looking Statements

This Quarterly Report on Form 10-Q, including this Management's Discussion and Analysis of Financial Condition and Results of Operations, contains forward-looking statements that are based upon current expectations. These statements are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "should", "expect", "plan", "anticipate", "believe", "estimate", "intend", "potential" or "continue" or the negative of these terms or other comparable terminology. Forward-looking statements are based upon current expectations that involve risks and uncertainties. Our actual results and the timing of events could differ materially from those anticipated in our forward-looking statements as a result of many factors, including, but not limited to, the following: continued market acceptance of our methicillin resistant staphylococcus aureus ("MRSA") and other healthcare associated infection products; changes in the protocols, best practices or level of testing for MRSA and other healthcare associated infections; development and manufacturing problems; the need for additional intellectual property licenses for new tests and other products and the terms of such licenses; our ability to successfully sell additional products in the Clinical market; lengthy sales cycles in certain markets; the performance and market acceptance of our new products; our ability to obtain regulatory approvals and introduce new products into the Clinical market; the level of testing at existing clinical customer sites; the mix of products sold, which can affect gross margins; our reliance on distributors to market, sell and support our products; the occurrence of unforeseen expenditures, asset impairments, acquisitions or other transactions; our ability to integrate the businesses, technologies, operations and personnel of acquired companies; the scope and timing of actual United States Postal Service ("USPS") funding of the Biohazard Detection System ("BDS") in its current configuration; the rate of environmental testing using the BDS conducted by the USPS, which will affect the amount of consumable products sold; our success in increasing our direct sales; the impact of competitive products and pricing; our ability to manage geographically-dispersed operations; our ability to continue to realize manufacturing efficiencies, which are an important factor in improving gross margins; underlying market conditions worldwide; and the other risks set forth under "Risk Factors" and elsewhere in this report. 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 are a broad-based molecular diagnostics company that develops, manufactures, and markets fully-integrated systems for testing in the Clinical, Industrial and Biothreat markets. Our systems enable rapid, sophisticated molecular testing for organisms and genetic-based diseases by automating otherwise complex manual laboratory procedures. Molecular testing involves a number of complicated and time-intensive steps, including sample preparation, DNA amplification and detection. Our easy-to-use systems integrate these steps and analyze complex biological samples in our proprietary test cartridges. We are currently the only company to have obtained Clinical Laboratory Improvement Amendments (CLIA) moderate complexity categorization for an amplified molecular test system and an associated specific infectious disease test on the market in the United States. Our efforts are currently focused on those applications where rapid molecular testing is particularly important, such as identifying infectious diseases and cancer in the Clinical market; food, agricultural and environmental testing in the Industrial market; and identifying bio-terrorism agents in the Biothreat market.

Our two principal systems are the GeneXpert and SmartCycler systems. The GeneXpert system integrates sample preparation in addition to DNA amplification and detection. The GeneXpert system is designed for a broad range of user types ranging from reference laboratories and hospital central laboratories to satellite testing locations, such as emergency departments and intensive care units within hospitals and doctors' offices. The SmartCycler system integrates DNA amplification and detection to allow rapid analysis of a sample.

The GeneXpert system represents a paradigm shift in the automation of molecular analysis, producing accurate results in a timely manner with minimal risk of contamination. Our GeneXpert system can provide rapid results with superior test specificity and sensitivity over comparable systems on the market today that are integrated but have open architectures.

We currently have available a broad and expanding menu of tests and reagents for use on our systems. Our reagents and tests are marketed along with our systems on a worldwide basis.

Sales Channels

Sales for products within our specific markets are conducted through both direct sales and indirect distribution channels worldwide. Clinical market sales in the United States and the United Kingdom are handled primarily on a direct basis, while sales in all other markets are handled primarily through indirect distribution. As international Clinical markets continue to develop, we expect to expand our direct sales efforts. Our marketing programs are managed on a direct basis.

Revenues

Currently, we derive our revenues primarily from the sales of our two systems and associated reagents and disposables in the Clinical, Industrial, and Biothreat markets, and to a lesser extent from contract and government sponsored research.

Research and Development

The objective of our research and development programs is to develop high-value test applications for the GeneXpert and/or SmartCycler systems for the Clinical, Biothreat, and Industrial testing markets. We focus our research efforts on four main areas: a) systems engineering efforts to extend the multiplexing capabilities of our systems and to develop new low and high throughput systems, b) chemistry research in our Bothell, Washington facility to develop innovative and proprietary methods to design and synthesize oligonucleotide primers, probes, and dyes to optimize the speed, performance and ease-of-use of our assays, c) assay development efforts to design, optimize, and produce specific tests that leverage the systems and chemistry we have developed, and d) target discovery research to identify novel micro RNA targets to be used in the development of future assays. Our development efforts focus primarily on the development of clinical diagnostic products that encompass many of the new technologies that are developed with our research programs.

CRITICAL ACCOUNTING POLICIES, ESTIMATES AND ASSUMPTIONS

Except as discussed below, management believes that there have been no significant changes during the nine months ended September 30, 2008 to the items that we disclosed as our critical accounting policies and estimates in Management's Discussion and Analysis of Financial Condition and Results of Operation in our 2007 Annual Report on Form 10-K filed with the Securities and Exchange Commission. For a description of those critical accounting policies, please refer to our 2007 Annual Report on Form 10-K.

Our investments at cost of $25.0 million at September 30, 2008 consisted of auction rate securities. Auction rate securities are securities that are structured with short-term interest rate reset dates of generally less than 90 days but with contractual maturities that can be well in excess of ten years. Since March 2008, all of our auction rate securities failed at auction. Our auction rate securities consist of investments that are backed by pools of student loans, which are principally guaranteed by the Federal Family Educational Loan Program ("FFELP"), or insured. We believe that the credit quality of these securities is high based on these guarantees and insurance. We determine the fair market values of our financial instruments based on the fair value hierarchy established in SFAS 157, which requires an entity to maximize the use of observable inputs (Level 1 and Level 2 inputs) and minimize the use of unobservable inputs (Level 3 inputs) when measuring fair value. Given the current failures in the auction markets to provide quoted market prices of the securities, as well as the lack of any correlation of these instruments to other observable market data, we valued these securities using a discounted cash flow methodology with the most significant inputs categorized as Level 3. Significant inputs that went into the model were the credit quality of the issuer, the percentage and the types of guarantees, the timing and probability of the auction succeeding or the security being called and discount factors. We also considered various factors in determining whether to recognize an other-than-temporary impairment charge in the condensed consolidated statement of operations, including the duration of time and the severity to which the fair value has been less than our amortized cost basis, any adverse changes in the investees' financial condition and our intent and ability to hold the investment for a period of time sufficient to allow for any anticipated maturity or recovery in market value. At September 30, 2008, the value of our auction rate securities was $21.0 million, all of which have failed to settle at auction since March 2008. After careful consideration of the various factors involved in the valuation of our auction rate securities, as of September 30, 2008 we have recorded cumulative unrealized losses of $4.0 million, which are included in accumulated other comprehensive loss in the condensed consolidated balance sheet. Changes in the assumptions of our model based on the dynamic market conditions could have a significant impact on the valuation of these securities, which may lead us in the future to take an impairment charge for these securities. While we presently do not intend to liquidate these investments, in the event that we did liquidate these investments prior to their scheduled maturities and there were no changes in market interest rates, we could be required to recognize a realized loss on those investments when we liquidate. Furthermore, if this situation were to persist despite our ability to hold such investments until maturity or recovery, we may be required to record an impairment charge at a future date, which would adversely affect our reported results of operations in such period. In October 2008, UBS, the fund manager with which we hold our auction rate securities, announced a comprehensive settlement arrangement for its clients holding auction rate securities. Under the proposal, UBS will issue auction rate securities rights to us. These rights will enable us to sell the auction rate securities held in our accounts with UBS to UBS at par value during a two year period beginning in June 2010. In exchange, we would be required to release UBS from claims we have for damages related to the securities other than consequential damages, and grant UBS the right to sell or otherwise dispose of our auction rate securities on our behalf (so long as we are paid the par value of the securities upon any disposition). We have until November 14, 2008 to accept this offer from UBS. If we participate in the program, we would also be eligible to receive no net cost loans for up to 75% of the market value of our auction rate securities. No settlement has been reached as of September 30 2008.

RESULTS OF OPERATIONS

Comparison of the Three and Nine Months Ended September 30, 2008 and 2007

Revenues

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2007	% Change	2008	2007	% Change
	(Amounts in thousands)			(Amounts in thousands)		
Revenues:						
System sales	$ 13,961	$ 15,911	(12)%	$ 40,708	$ 32,142	27%
Reagent and disposable sales	28,432	18,105	57%	82,558	47,525	74%
Total product sales	42,393	34,016	25%	123,266	79,667	55%
Other revenue	2,522	2,313	9%	8,532	9,379	(9)%
Total revenues	$ 44,915	$ 36,329	24%	$ 131,798	$ 89,046	48%

We operate in three market areas: Clinical, Industrial and Biothreat. The following table illustrates product sales in the three market areas as a percentage of total product sales:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
	(As a % of total product sales)			
Product sales by market:				
Core Clinical	66%	48%	55%	35%
Clinical Partner	4%	13%	11%	14%
Total clinical	70%	61%	66%	49%
Biothreat	20%	26%	25%	37%
Industrial	10%	13%	9%	14%
Total product sales	100%	100%	100%	100%

Within the Clinical market, we have core clinical sales to laboratories and hospitals and non-core clinical sales to partners. Non-core clinical partner sales include sales of our SmartCycler System to Becton Dickinson as well as OEM sales of selected tests to Roche. The increase in product sales of 25% to $42.4 million for the third quarter of 2008 from $34.0 million for the third quarter of 2007 was driven by an increase of 47% in North America, primarily due to an increase of approximately $10.2 million of our Xpert MRSA disposable tests to approximately $14 million. The increase in product sales of 55% to $123.3 million for the nine months ended September 30, 2008 from $79.7 million for the same period in 2007 was driven by increases of 94% in North America, excluding sales to the USPS, and 63% in Europe, primarily due to an increase in overall GeneXpert system sales in the Core Clinical market and Xpert MRSA disposable test sales. The increase in system sales was primarily driven by a 51% increase in GeneXpert System sales for the Core Clinical market for healthcare associated infections. The increase in reagent and disposable sales was primarily due to sales of approximately $33.0 million of our Xpert MRSA disposable tests, as compared to approximately $4 million for the nine months ended September 30, 2007. We expect our Core Clinical product sales to continue to increase during the remainder of 2008 with the continued expansion of the healthcare associated infections market and we expect that our Clinical Partner product sales will continue to decrease during the remainder of 2008 due to our contract with Becton Dickinson expiring in November 2008 and the cancellation by Roche of certain contracted purchases. We also expect our Biothreat sales to decrease during the remainder of 2008 as we expect the USPS to purchase contractually minimum levels of product.

The following table provides a breakdown of our product sales by geographic regions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
	(As a % of total product sales)			
Product Sales by Geographic Regions:				
North America	85%	81%	79%	80%
International	15%	19%	21%	20%
Total product sales	100%	100%	100%	100%

The change in product sales by geographic regions for the three months ended September 30, 2008 compared to the same period in 2007 was primarily due to an increase in Xpert MRSA disposable test sales, predominately in North America, offset by a decrease in International Clinical Partner sales of selected tests to Roche. The change in product sales by geographic regions for the nine months ended September 30, 2008 compared to the same period in 2007 was primarily due to slower Biothreat growth in North America compared to overall Clinical growth.

No single country outside of the United States represented more than 10% of our total revenues in any period presented.

Other revenue of $2.5 million in the three months ended September 30, 2008 increased 9% from $2.3 million for the same period in 2007, primarily due to increases in the programs for the National Institutes of Health and the Foundation for Innovative New Diagnostics, partially offset by a decrease in revenue associated with the termination of the Centers for Disease Control and Prevention program in the third quarter of 2007. Other revenue of $8.5 million for the nine months ended September 30, 2008 decreased 9% from $9.4 million for the same period in 2007, primarily due to the termination of the Centers for Disease Control program in the third quarter of 2007, which had higher program revenues in the nine months ended September 30, 2007 than in the same period of 2008. We expect that our quarterly other revenue will decrease during the remainder of 2008 as certain of our collaboration projects reach transition levels in their lifecycles.

Costs and Operating Expenses

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2007	% Change	2008	2007	% Change
	(Amounts in thousands)			(Amounts in thousands)		
Costs and operating expenses:						
Cost of product sales	$ 23,623	$ 19,966	18%	$ 69,479	$ 47,722	46%
Collaboration profit sharing	2,460	2,729	(10)%	8,970	8,957	0%
Research and development	11,611	8,371	39%	32,473	22,732	43%
Sales and marketing	7,871	6,411	23%	22,246	15,971	39%
General and administrative	5,517	4,445	24%	15,782	12,418	27%
Total costs and operating expenses	$ 51,082	$ 41,922	22%	$ 148,950	$ 107,800	38%

Cost of Product Sales

Cost of product sales consists of raw materials, direct labor and stock-based compensation expense, manufacturing overhead, facility costs and warranty costs. Cost of product sales also includes royalties on product sales and amortization of intangible assets related to technology licenses and intangibles acquired in the purchase of Sangtec. As a result of the increased product sales discussed above, cost of product sales increased 18% to $23.6 million for the third quarter of 2008 compared to $20.0 million for the third quarter of 2007 and increased 46% to $69.5 million from $47.7 million for the first nine months of 2008 and 2007, respectively. Our product gross margin percentage was 44% for the third quarter of 2008 compared to 41% for the third quarter of 2007 and 44% for the nine months ended September 30, 2008 as compared to 40% for the same period in 2007. The increase in product gross margin percentage in the three and nine months ended September 30, 2008 versus the same period in 2007 was primarily due to a shift in product mix to higher margin products, such as clinical reagents, and increased manufacturing efficiencies resulting from automation of our manufacturing processes and increased volumes. For the nine months ended September 30, 2008, these increases were partially offset by costs associated with a production issue related to a GeneXpert cartridge part during the second quarter of 2008.

Collaboration Profit Sharing

Collaboration profit sharing represents the amount that we pay to Applied Biosystems Group under our collaboration agreement to develop reagents for use in the USPS BDS program. Under the agreement, computed gross margin on anthrax cartridge sales are shared equally between the two parties. The collaboration profit sharing expense was $2.5 million and $2.7 million for the third quarter of 2008 and 2007, respectively, and $9.0 million for each of the nine months ended September 30, 2008 and 2007. The slight decrease in collaboration profit sharing for the third quarter of 2008 as compared to the third quarter of 2007 was the result of decreased anthrax cartridge sales under the USPS BDS program, and this expense will remain proportional to the sales of anthrax cartridges under the USPS BDS program, which we expect will decrease during the remainder of 2008.

Research and Development Expenses

Research and development expenses consist of salaries and employee-related expenses, which include stock-based compensation, clinical trials, research and development materials, facility costs and depreciation. Research and development expenses increased 39% to $11.6 million for the third quarter of 2008 from $8.4 million for the third quarter of 2007. The increase in research and development expenses of $3.2 million is primarily due to a $0.9 million increase in salaries and employee-related expenses, inclusive of a $0.2 million increase in stock-based compensation. Other increases included a $0.6 million increase in clinical trial costs, a $0.7 million increase in supplies used in research activities and a $0.3 million increase in contractor costs. Research and development expenses increased 43% to $32.5 million for the nine months ended September 30, 2008 from $22.7 million for the same period of 2007. The increase in research and development expenses of $9.7 million is primarily due to a $3.5 million increase in salaries and employee-related expenses, inclusive of a $1.2 million increase of stock-based compensation. Other increases included a $1.7 million increase in clinical trial costs, a $1.5 million increase in supplies used in research activities, a $0.4 million increase in contractor costs and a $0.3 million increase in lab supplies. We expect that our research and development expenses will remain relatively flat as a percentage of total revenues during the remainder of 2008.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of salaries and employee-related expenses, which include commissions and stock-based compensation, travel, facility-related costs and marketing and promotion expenses. Sales and marketing expenses increased 23% to $7.9 million for the third quarter of 2008 from $6.4 million for the third quarter of 2007. The increase of $1.5 million included a $0.5 million increase in salaries and employee-related expenses, inclusive of a $0.2 million increase in stock-based compensation, a $0.5 million increase in trade-show and travel-related expenses and a $0.1 million increase in contractor costs. Sales and marketing expenses increased 39% to $22.2 million for the nine months ended September 30, 2008 from $16.0 million for the same period of 2007. The increase of $6.2 million included a $4.0 million increase in salaries and employee-related expenses, inclusive of a $1.2 million increase in stock-based compensation, a $1.2 million increase in trade-show and travel-related expenses, a $0.2 million increase in advertising expense and a $0.2 million increase in contractor costs. These increases reflect the increase in sales and marketing headcount and expanded efforts in the Clinical market, including Europe. We expect our sales and marketing expenses to increase during the remainder of 2008 as a result of the continuing expansion of our direct sales force in the UK and our marketing team both in the United States and Europe, and as we continue to expand our efforts in the Clinical market, with particular emphasis on pursuing the market opportunities for our Xpert MRSA test and other healthcare associated infections products, but we believe these expenses will remain relatively constant as a percentage of total revenues as compared to the first nine months of fiscal 2008.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and employee-related expenses, which include stock-based compensation, travel, facility, legal, accounting and other professional fees. General and administrative expenses increased 24% to $5.5 million for the third quarter of 2008 from $4.4 million for the third quarter of 2007. The increase of $1.1 million is primarily due to a $0.9 million increase in salaries and employee-related expenses, inclusive of a $0.3 million increase in stock-based compensation expense, which reflects an increase in headcount. In addition, legal, accounting, and other professional expenses increased $0.2 million in the third quarter of 2008 as compared to the same period of 2007. General and administrative expenses increased 27% to $15.8 million for the nine months ended September 30, 2008 from $12.4 million for the same period of 2007. The increase of $3.4 million is primarily due to a $1.9 million increase in salaries and employee-related expenses, inclusive of a $0.9 million increase in stock-based compensation expense, which reflects an increase in headcount. In addition, legal, accounting, and other professional expenses increased $0.8 million in the first nine months of the year in 2008 as compared to the same period of 2007. We expect our general and administrative expenses to remain relatively flat as a percentage of total revenues during the remainder of 2008.

Other Income (Expense), Net

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2007	% Change	2008	2007	% Change
	(Amounts in thousands)			(Amounts in thousands)		
Other income (expense), net:						
Interest income	$ 241	$ 621	(61)%	$ 1,039	$ 2,175	(52)%
Interest expense	(1)	(5)	80%	(3)	(19)	84%
Other income (expense)	(1,146)	236	(586)%	(469)	463	(201)%
Total other income (expense), net	$ (906)	$ 852	(206)%	$ 567	$ 2,619	(78)%

Other income (expense), net consists of interest income, interest expense and other income (expense). Interest income decreased to $0.2 million for the third quarter of 2008 from $0.6 million for the third quarter of 2007 and decreased to $1.0 million for the nine months ended September 30, 2008 from $2.2 million for the same period in 2007. The decrease is primarily due to lower interest rates in 2008 than in 2007 and lower average cash balances generating interest income, as cash has been used to fund operations in addition to the Sangtec acquisition in the second quarter of 2007. Other income (expense) decreased to a $1.1 million loss from a $0.2 million gain, primarily due to foreign currency losses reflecting strengthening of the U.S. Dollar during the third quarter of 2008. The decrease in other income (expense) to $0.5 million expense for the nine months ended September 30, 2008 from $0.5 million income for the same period in 2007 was primarily from foreign currency losses, reflecting the overall strengthening of the U.S. Dollar since the third quarter of 2007.

LIQUIDITY AND CAPITAL RESOURCES

Cash and Cash Flow

As of September 30, 2008, we had $24.4 million in cash and cash equivalents. The total cash, cash equivalents and marketable securities increase in the nine months ended September 30, 2008 was $7.9 million, which primarily consisted of $12.0 million provided by financing activities and $3.5 million provided by operating activities offset by $7.6 million used in investing activities.

Net cash provided by operating activities was $3.5 million for the nine months ended September 30, 2008, versus net cash used in operating activities of $19.2 million for the nine months ended September 30, 2007. For the nine months ended September 30, 2008, net cash used in operating activities primarily consisted of a $15.8 million net loss, which was offset by $8.0 million of depreciation expense and amortization of intangible assets, $10.8 million of stock based compensation and $0.3 million of deferred rent. In addition, the increase of $0.1 million attributable to changes in operating assets and liabilities primarily consisted of increases in inventory of $5.7 million, prepaid expenses of $1.5 million and $0.2 million of other non-current assets and decreases in receivables of $3.4 million, accrued compensation of $2.1 million and deferred revenue of $1.1 million, which were partially offset by an increase in accounts payable and other current liabilities and income taxes payable of $7.2 million.

Net cash used in investing activities was $7.6 million for the nine months ended September 30, 2008, versus net cash provided by investing activities of $7.9 million for the nine months ended September 30, 2007. For the nine months ended September 30, 2008, net cash used in investing activities consisted of $12.4 million in net capital expenditures, which was partially offset by $2.6 million in proceeds from the sale of marketable securities, $1.7 million in proceeds from the sale of fixed assets and $0.5 million related to the transfer to unrestricted cash.

Net cash provided by financing activities was $12.0 million and $2.3 million for the nine months ended September 30, 2008 and 2007, respectively. For the nine months ended September 30, 2008, cash provided by financing activities primarily consisted of $12.0 million in net proceeds from the sale of common stock under our employee equity incentive plans.

At September 30, 2008, we had $21.0 million invested in auction rate securities, all of which have failed to settle at auction since March 2008. We continue to collect interest on the investments that failed to settle at auction at the maximum contractual rate. At September 30, 2008, all but two of our auction rate securities continue to carry at least an AAA rating by at least one of the rating agencies; two carrying an AA rating. Our auction rate securities consist of investments that are backed by pools of student loans, which are principally guaranteed by the Federal Family Educational Loan Program (“FFELP”), or insured. We currently anticipate that our existing cash resources, exclusive of our holdings in auction rate securities, are sufficient to meet our anticipated working capital needs and fund our business plan. We have the ability and intent to hold these investments until the market recovers. However, there is no assurance as to when the market for auction rate securities will stabilize.

In October 2008, UBS, the fund manager with which we hold our auction rate securities, announced a comprehensive settlement arrangement for its clients holding auction rate securities. Under the proposal, UBS will issue auction rate securities rights to us.

These rights will enable us to sell the auction rate securities held in our accounts with UBS to UBS at par value during a two year period beginning in June 2010. In exchange, we would be required to release UBS from claims we have for damages other than consequential damages, and grant UBS the right to sell or otherwise dispose of our auction rate securities on our behalf (so long as we are paid the par value of the securities upon any disposition). We have until November 14, 2008 to accept this offer from UBS. If we participate in the program, we would also be eligible to receive no net cost loans for up to 75% of the market value of our auction rate securities.

Off-Balance-Sheet Arrangements

As of September 30, 2008, we did not have any off-balance-sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K promulgated under the Securities Act of 1933.

Financial Condition Outlook

We plan to continue to make expenditures to expand our manufacturing capacity and to support our activities in sales and marketing and research and development. We plan to continue to support our working capital needs and anticipate that our existing cash resources will enable us to maintain currently planned operations. This expectation is based on our current and long-term operating plan and may change as a result of many factors, including our future capital requirements and our ability to increase revenues and reduce expenses, which, in many instances, depend on a number of factors outside our control including the general decline in global economic conditions. 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, expansion through acquisitions and the availability of other financing.

In the future, we may seek additional funds to support our strategic business needs and may seek to raise such additional funds through private or public sales of securities, strategic relationships, bank debt, lease financing arrangements, or other available means. If additional funds are raised through the issuance of equity or equity-related securities, stockholders may experience additional dilution, or such equity securities may have rights, preferences, or privileges senior to those of the holders of our common stock. If adequate funds are not available or are not available on acceptable terms to meet our business needs, our business may be harmed.

Please see Note 8 to our financial statements included herein for a description of certain changes to our commitments and contingencies.

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. In addition, we do not enter into financial investments for speculation or trading purposes and are not a party to financial or commodity derivatives. Our investments in interest-bearing assets are subject to interest rate 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 a fixed interest rate at the then-prevailing rate and the prevailing interest rate later rises, the principal amount of our investment will probably decline.

Our investments at cost of $25.0 million at September 30, 2008 consisted of auction rate securities. Auction rate securities are securities that are structured with short-term interest rate reset dates of generally less than 90 days, but with contractual maturities that can be well in excess of ten years. Since March 2008, all of our auction rate securities failed at auction. Our auction rate securities consist of investments that are backed by pools of student loans, which are principally guaranteed by the Federal Family Educational Loan Program (“FFELP”), or insured. We believe that the credit quality of these securities is high based on these guarantees and insurance, and we continue to earn interest on the investments that failed to settle at auction at the maximum contractual rate. We determined the fair market values of our financial instruments based on the fair value hierarchy established in SFAS 157, which requires an entity to maximize the use of observable inputs (Level 1 and Level 2 inputs) and minimize the use of unobservable inputs (Level 3 inputs) when measuring fair value. Given the current failures in the auction markets to provide quoted market prices of the securities, as well as the lack of any correlation of these instruments to other observable market data, we valued these securities using a discounted cash flow methodology with the most significant inputs categorized as Level 3. Significant inputs that went into the model were the credit quality of the issuer, the percentage and the types of guarantees and insurance, the timing and probability of the auction succeeding or the security being called and discount factors. We also considered various factors in determining whether to recognize an other-than-temporary impairment charge in the condensed consolidated statement of operations, including the duration of time and the severity to which the fair value has been less than our amortized cost basis, any adverse changes in the investees’ financial condition and our intent and ability to hold the investment for a period of time sufficient to allow for any anticipated maturity or recovery in market value. After careful consideration of the various factors involved in the valuation

of our auction rate securities, as of the third quarter of 2008 we have recorded cumulative unrealized losses of $4.0 million, which are included in accumulated other comprehensive loss in the condensed consolidated balance sheet at September 30, 2008. Changes in the assumptions of our model based on the dynamic market conditions could have a significant impact on the valuation of these securities, which may lead us in the future to take an impairment charge for these securities. As discussed above, in October 2008, UBS has offered a program for us to sell our auction rate securities to UBS, commencing in June 2010.

We operate primarily in the United States and a majority of our revenue, cost, expense and capital purchasing activities are transacted in U.S. Dollars. As a corporation with international as well as domestic operations, we are exposed to changes in foreign exchange rates. These exposures may change over time and could have a material adverse impact on our financial results. We recorded losses in foreign currency of $1.2 million and $0.5 million for the third quarter of 2008 and the nine months ended September 30, 2008, respectively. During the nine months ended September 30, 2008 and the fiscal year ended December 31, 2007, we did not utilize foreign currency forward contracts to manage the risk of exchange rate fluctuations. We will continue to monitor and evaluate our internal processes relating to foreign exchange, including the potential use of hedging strategies.

ITEM 4. CONTROLS AND PROCEDURES

EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES

Regulations under the Securities Exchange Act of 1934 (the “Exchange Act”) require public companies, including our company, to maintain “disclosure controls and procedures”, which are defined to mean a company’s controls and other procedures that are designed to ensure that information required to be disclosed in the reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in the Securities and Exchange Commission’s rules and forms. Our Chief Executive Officer and our Chief Financial Officer, based on their evaluation of our disclosure controls and procedures as of the end of the period covered by of this report, concluded that our disclosure controls and procedures were effective for this purpose.

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

Regulations under the Exchange Act 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 accounting principles generally accepted 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 nine months ended September 30, 2008, that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

ITEM 1A. RISK FACTORS

You should carefully consider the risks and uncertainties 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.

We may not achieve profitability.

We have incurred operating losses in each period since our inception. We experienced net losses of approximately $26.0 million in 2006, $11.4 million in 2007 and $15.8 million for the first nine months of 2008. As of September 30, 2008, we had an accumulated deficit of approximately $170.7 million. Our ability to become profitable will depend on our ability to continue to increase our revenues, which is subject to a number of factors including our ability to continue to successfully penetrate the Clinical market, our ability to successfully market the GeneXpert system and develop effective GeneXpert tests, continued growth in sales of our Xpert MRSA tests , the extent of our participation in the USPS BDS program and the operating parameters of the USPS BDS program, which will affect the rate of our consumable products sold, the success of our other collaborative programs, our ability to compete effectively against current and future competitors, global economic and political conditions and the impact of Statement of Financial Accounting Standards No. 123 (revised 2004), “Share-Based Payment”. Our ability to become profitable also depends on our expense levels and product gross margin, which are also influenced by a number of factors, including the resources we devote to developing and supporting our products, the continued progress of our research and development of potential products, the ability to gain FDA clearance for our products, our ability to improve manufacturing efficiencies, license fees or royalties we may be required to pay, our ability to integrate acquired businesses and technologies, acquisition-related costs and expenses and the potential need to acquire licenses to new technology or to use our technology in new markets, which could require us to pay unanticipated license fees and royalties in connection with these licenses. Our expansion efforts may prove more expensive than we currently anticipate, and we may not succeed in increasing our revenues to offset higher expenses. These expenses, among other things, may cause our net income and working capital to decrease. If we fail to grow our revenue and manage our expenses and improve our product gross margin, we may never achieve profitability. If we fail to do so, the market price of our common stock will likely decline.

We expect that our operating results will fluctuate significantly, and any failure to meet financial expectations may 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, such as those described elsewhere in this section, many of which are beyond 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 indicator of our future performance. Our operating results may be affected by the inability of some of our customers to consummate anticipated purchases of our products, whether due to the global economic downturn, changes in internal priorities or, in the case of governmental customers, problems with the appropriations process and variability and timing of orders, changes in procedures or protocols with respect to testing or manufacturing inefficiencies. If revenue declines in a quarter, whether due to a delay in recognizing expected revenue, unexpected costs or otherwise, our results of operations will be harmed because many of our expenses are relatively fixed. In particular, research and development, sales and marketing and general and administrative expenses are not significantly affected by variations in revenue. If our quarterly operating results fail to meet or exceed the expectations of securities analysts or investors, our stock price could drop suddenly and significantly.

Our sales cycle can be lengthy, which can cause variability and unpredictability in our operating results.

The sales cycles for our systems products can be lengthy, 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. For example, sales of our products involving our corporate accounts within the Clinical market and those within the Industrial market often involve purchasing decisions by large public and private institutions, and any purchases can require many levels of pre-approval. In addition, certain industry sales may depend on these institutions receiving research grants from various federal agencies, which grants vary considerably from year to year in both amount and timing due to the political process. 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. In addition, Clinical Partner sales to companies such as Becton Dickinson and Roche can vary significantly from period to period.

If we cannot successfully commercialize our products, our business could be harmed.

If our tests for use on the GeneXpert and SmartCycler systems do not gain continued market acceptance, we will be unable to generate significant sales, which will prevent us from achieving profitability. While we have received FDA clearance for our Xpert GBS, Xpert EV, Xpert MRSA, Xpert MRSA SA/SSTI and Xpert MRSA SA/BC tests, these products may not continue to experience increased sales. Many factors may affect the market acceptance and commercial success of our products, including:

- timely development of a menu of tests and reagents;
- the results of clinical trials needed to support any regulatory approvals of our tests;
- our ability to obtain requisite FDA or other regulatory clearances or approvals for our tests under development on a timely basis;
- demand for the tests and reagents we are able to introduce;
- the timing of market entry for various tests for the GeneXpert and the SmartCycler systems;
- our ability to convince our potential customers of the advantages and economic value of our systems and tests over competing technologies and products;
- the breadth of our test menu relative to competitors;
- changes to policies, procedures or what are considered best practices for detecting and preventing healthcare associated infections;
- the extent and success of our marketing and sales efforts;
- level of reimbursement for our products by third-party payers; and
- publicity concerning our systems and tests.

In particular, we believe that the success of our business will depend in large part on our ability to continue to increase sales of our Xpert MRSA tests and our ability to introduce additional tests for the Clinical market. We believe that successfully expanding our business in the Clinical market is critical to our long-term goals and success. We have limited ability to forecast future demand for our products in this market. In addition, we have committed substantial funds to licenses that are required for us to compete in the Clinical market. If we cannot successfully penetrate the Clinical market to fully exploit these licenses, these investments may not yield significant returns, which could harm our business.

Current uncertainty in global economic conditions makes it particularly difficult to predict product demand and other related matters and makes it more likely that our actual results could differ materially from expectations.

Our operations and performance depend on worldwide economic conditions, which have recently deteriorated significantly in the United States and other countries, and may remain depressed for the foreseeable future. These conditions make it difficult for our customers and potential customers to accurately forecast and plan future business activities, and could cause our customers and potential customers to slow or reduce spending on our products. Furthermore, during challenging economic times, our customers may face issues gaining timely access to sufficient credit, which could result in their unwillingness to purchase products or an impairment of their ability to make timely payments to us. If that were to occur, we may experience decreased sales, be required to increase our allowance for doubtful accounts and our days sales outstanding would be negatively impacted. We cannot predict the timing, strength or duration of any economic slowdown or subsequent economic recovery, worldwide, in the United States, or in our industry. These and other economic factors could have a material adverse effect on demand for our products and on our financial condition and operating results.

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.

In the Clinical market, our products are regulated as medical device products by the FDA and comparable agencies of other countries. In particular, FDA regulations govern activities such as product development, product testing, product labeling, product storage, premarket clearance or approval, manufacturing, advertising, promotion, product sales, reporting of certain product failures

and distribution. Some of our products, depending on their intended use, will require premarket approval ("PMA") or 510(k) clearance from the FDA prior to marketing. The 510(k) clearance process usually takes from three to six months from submission but can take longer. The PMA process is much more costly, lengthy and uncertain and generally takes from six months to one year or longer from submission. Clinical trials are generally required to support both PMA and 510(k) submissions. Certain of our products for use on our GeneXpert and SmartCycler systems, when used for clinical purposes, may require PMA, and all such tests will most likely, at a minimum, require 510(k) clearance. We are planning clinical trials for other proposed products. Clinical trials are expensive and time-consuming. In addition, the commencement or completion of any clinical trials may be delayed or halted for any number of reasons, including product performance, changes in intended use, changes in medical practice and issues with evaluator Institutional Review Boards.

Failure to comply with the applicable requirements can result in, among other things, warning letters, administrative or judicially imposed sanctions such as injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal to grant premarket clearance or PMA for devices, withdrawal of marketing clearances or approvals, or criminal prosecution. With regard to future products for which we seek 510(k) clearance or PMA from the FDA, any failure or material delay to obtain such clearance or approval could harm our business. If the FDA were to disagree with our regulatory assessment and conclude that approval or clearance is necessary to market the products, we could be forced to cease marketing the products and seek approval or clearance. With regard to those future products for which we will seek 510(k) clearance or PMA from the FDA, any failure or material delay to obtain such clearance or approval could harm our business. In addition, it is possible that the current regulatory framework could change or additional regulations could arise at any stage during our product development or marketing, which may adversely affect our ability to obtain or maintain approval of our products and could harm our business.

Our manufacturing facilities located in Sunnyvale, California, Bothell, Washington and Bromma, Sweden, where we assemble and produce the GeneXpert and SmartCycler systems, cartridges and other molecular diagnostic kits and reagents, are subject to periodic regulatory inspections by the FDA and other federal and state regulatory agencies. For example, these facilities are subject to Quality System Regulations ("QSR") of the FDA and are subject to annual inspection and licensing by the States of California and Washington and European regulatory agencies. If we fail to maintain these facilities in accordance with the QSR requirements, international quality standards or other regulatory requirements, our manufacturing process could be suspended or terminated, which would prevent us from being able to provide products to our customers in a timely fashion and therefore harm our business.

We rely on licenses of key technology from third parties and may require additional licenses for many of our new product candidates.

We rely on third-party licenses to be able to sell many of our products, and we could lose these third-party licenses for a number of reasons, including, for example, early terminations of such agreements due to breaches or alleged breaches by either party to the agreement. If we are unable to enter into a new agreement for licensed technologies, either on terms that are acceptable to us or at all, we may be unable to sell some of our products or access some geographic or industry markets. We also need to introduce new products and product features in order to market our products to a broader customer base and grow our revenues, and many new products and product features could require us to obtain additional licenses and pay additional license fees and royalties. Furthermore, for some markets, we intend to manufacture reagents and tests for use on our systems. We believe that manufacturing reagents and developing tests for our systems is important to our business and growth prospects but may require additional licenses, which may not be available on commercially reasonable terms or at all. Our ability to develop, manufacture and sell products, and our strategic plans and growth, could be impaired if we are unable to obtain these licenses or if these licenses are terminated or expire and cannot be renewed. We may not be able to obtain or renew licenses for a given product or product feature or for some reagents on commercially reasonable terms, if at all. Furthermore, some of our competitors have rights to technologies and reagents that we do not have which may put us at a competitive disadvantage in certain circumstances and could adversely affect our performance.

We enter into collaborations with third parties that may not result in the development of commercially viable products or the generation of significant future revenues.

In the ordinary course of our business, we enter into collaborative arrangements to develop new products or to pursue new markets. These collaborations may not result in the development of products that achieve commercial success, and these collaborations could be terminated prior to developing any products. In addition, our collaboration partners may not necessarily purchase the volume of products that we expect. Accordingly, we cannot be assured that any of our collaborations will result in the successful development of a commercially viable product or result in significant additional future revenues in the future.

Our participation in the USPS BDS program may not result in predictable revenues in the future.

Our participation in the USPS BDS program involves significant uncertainties related to governmental decision-making and timing of deployment and is highly sensitive to changes in national priorities and budgets. Budgetary pressures may result in reduced allocations to government agencies such as the USPS, sometimes without advanced notice. We cannot be certain that actual funding and operating parameters, or product purchases, will occur at currently expected levels or in the currently expected timeframe.

We may face risks associated with acquisitions of companies, products and technologies, and our business could be harmed if we are unable to address these risks.

If we are presented with appropriate opportunities, we intend to acquire or make other investments in complementary companies, products or technologies. We may not realize the anticipated benefit of any acquisition or investment. We will likely face risks, uncertainties and disruptions associated with the integration process, including difficulties in the integration of the operations and services of an acquired company, integration of acquired technology with our products, diversion of our management's attention from other business concerns, the potential loss of key employees or customers of the acquired businesses and impairment charges if future acquisitions are not as successful as we originally anticipate. If we fail to successfully integrate other companies, products or technologies that we 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. In addition, our operating results may suffer because of acquisition-related costs or amortization expenses or charges relating to acquired intangible assets.

If we are unable to manufacture our products in sufficient quantities and in a timely manner, our operating results will be harmed and our ability to generate revenue could be diminished.

Our revenues and other operating results will depend in large part on our ability to manufacture and assemble our products in sufficient quantities and in a timely manner. Any interruptions we experience in the manufacturing or shipping of our products could delay our ability to recognize revenues in a particular quarter. Manufacturing problems can and do arise, and as demand for our products increases, any such problems could have an increasingly significant impact on our operating results. For example, during the second quarter of 2008, we experienced a manufacturing issue with respect to our cartridges, which caused us to experience increased costs and negatively affected our gross margin for the period. In the past, we have experienced problems and delays in production that have impacted our product yield and caused delays in our ability to ship finished products, and we may experience such delays in the future. We may not be able to react quickly enough to ship products and recognize anticipated revenues for a given period if we experience significant delays in the manufacturing process. In addition, we must maintain sufficient production capacity in order to minimize such delays, which carries fixed costs that we may not be able to offset if orders slow, which would adversely affect our operating margins. If we are unable to manufacture our products consistently and on a timely basis, our revenues from product sales, gross margins and our other operating results will be materially and adversely affected.

If certain 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 certain single source suppliers that supply some of the components used in the manufacture of our systems and our disposable reaction tubes and cartridges. If we need alternative sources for key component parts for any reason, these component parts may not be immediately available to us. If alternative suppliers are not immediately available, we will have to identify and qualify alternative suppliers, and production of these 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. Shipments of affected products have been limited or delayed as a result of such problems in the past, and similar problems could occur in the future. Our inability to obtain our key source supplies for the manufacture of our products may require us to delay shipments of products, harm customer relationships or force us to curtail or cease operations.

If certain of our products fail to obtain an adequate level of reimbursement from third-party payers, our ability to sell products in the Clinical market would be harmed.

Our ability to sell our products in the Clinical market will depend in part on the extent to which reimbursement for tests using our products will be available from:

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

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 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 target markets. These competitors include:

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

Several companies provide systems and reagents for DNA amplification or detection. ABI and Roche sell systems integrating DNA amplification and detection (sequence detection systems) to the commercial market. Roche, Abbott Laboratories, Becton, Dickinson and Company, Qiagen, Celera and GenProbe sell sequence detection systems, some with separate robotic batch DNA purification systems and sell reagents to the Clinical market. Other companies, including Siemens, Hologic, and bioMerieux, offer molecular tests.

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 molecular test systems. We believe that customers in our target 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 if our products fail to perform as expected or our products are perceived as difficult to use. Despite testing, defects or errors could occur in our products or technologies. Furthermore, with respect to the BDS program, our products are incorporated into larger systems that are built and delivered by others; we cannot control many aspects of the final system.

In the future, if our products experience a material defect or error, this could result in loss or delay of revenues, delayed market acceptance, damaged reputation, diversion of development resources, legal claims, increased insurance costs or increased service and warranty costs, any of which could harm our business. Furthermore, any failure in the overall BDS, even if it is unrelated to our products, could harm our business. 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, delayed market acceptance, damaged 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 or do not perform in accordance with specifications, in part because our products are used for sensitive applications. We cannot be certain that we would be able to 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.

Although we carry product liability insurance, if we become the subject of a successful product liability lawsuit, our insurance may not cover all substantial liabilities, which could harm 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 have a relatively small sales force compared to our competitors. If our direct sales force is not successful, or new additions to our sales team fail to gain traction among our customers, we may not be able to increase market awareness and sales of our products. If we fail to establish our systems in the marketplace, it 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 would be harmed and our financial performance will be adversely affected.

We depend on relationships with distributors for the marketing and sales of our products in the Industrial and Clinical markets in various geographic regions, and we have a limited ability to influence their efforts. We expect to continue to rely substantially on our distributor relationships for sales into other markets or geographic regions, which is key to our long-term growth potential. Relying on distributors for our sales and marketing could harm our business for various reasons, including:

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

We may be subject to third-party claims that require additional licenses for our products and 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 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. Companies may have pending patent applications, which are typically confidential for the first eighteen months following filing, that cover technologies we incorporate in our products. Accordingly, we may be subjected to substantial damages for past infringement or be required to modify our products or stop selling them if it is ultimately determined that our products infringe a third party's proprietary rights. Moreover, from time to time, we receive correspondence and other communications from companies that ask us to evaluate the need for a license of patents they hold, and indicating or suggesting that we need a license to their patents in order to offer our products and services or to conduct our business operations. Even if we are successful in defending against claims, we could incur substantial costs in doing so. Any litigation related to claims of patent infringement could consume our resources and lead to significant damages, royalty payments or an injunction on the sale of certain products. Any additional licenses to patented technology could obligate us to pay substantial additional royalties, which could adversely impact our product costs and harm our business.

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 our intellectual property that includes technologies that we license. Our ability to do so will depend on, among other things, complex legal and factual questions. We have patents related to some of our technology and have licensed some of our technology under patents of others. Our patents and licenses may not successfully preclude others from using our technology. Our pending patent applications may lack priority over applications submitted by third parties 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. Furthermore, any efforts to enforce our proprietary rights could result in disputes and legal proceedings that could be costly and divert attention from our business.

The United States Government has certain rights to use and disclose some of the intellectual property that we license and could exclusively license it to a third party if we fail to achieve practical application of the intellectual property.

Aspects of the technology licensed by us under agreements with third party licensors may be subject to certain government rights. Government rights in inventions conceived or reduced to practice under a government-funded program may include a non-exclusive, royalty-free worldwide license to practice or have practiced such inventions for any governmental purpose. In addition, the U.S. government has the right to require us or our licensors (as applicable) to grant licenses which would be exclusive under any of such inventions to a third party if they determine that: (1) adequate steps have not been taken to commercialize such inventions in a particular field of use; (2) such action is necessary to meet public health or safety needs; or (3) such action is necessary to meet requirements for public use under federal regulations. Further, the government rights include the right to use and disclose, without limitation, technical data relating to licensed technology that was developed in whole or in part at government expense. At least one of our technology license agreements contains a provision recognizing these government rights.

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. Any public announcements related to these suits could cause our stock price to decline.

Our international operations subject us to additional risks and costs.

Our international operations have expanded recently. These operations are subject to a number of difficulties and special costs, including:

- compliance with multiple, conflicting and changing governmental laws and regulations;
- laws and business practices favoring local competitors;
- foreign exchange and currency risks;
- difficulty in collecting accounts receivable or longer payment cycles;
- import and export restrictions and tariffs;
- difficulties staffing and managing foreign operations;
- 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 and overall global economic conditions;
- multiple conflicting tax laws and regulations; and
- political and economic instability.

We intend to expand our international sales and marketing activities, including through our subsidiary in France and our direct sales force in the United Kingdom, and enter into relationships with additional international distribution partners. We may not be able to attract international 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.

We have reformatted certain of our products affected by the U.S. Food and Drug Administration final guidance governing the sale of Analyte Specific Reagent ("ASR") products which could negatively impact our sales of these products.

In September 2007, the FDA published final guidance clarifying the FDA's regulations governing the sale of ASR products. The guidance became effective on September 15, 2008. ASRs are a class of products that do not require regulatory clearance or approval but do require compliance with the FDA's Good Manufacturing Practice Regulations. The final guidance contains more specific ASR regulations with regard to which products may be characterized as ASRs. The final ASR guidance has caused us to implement modifications of some of our ASR products in order for us to continue selling them. We have no assurances that the reformatted products will achieve market acceptance. The final guidance has curtailed our interest in developing any new products that would previously have qualified as ASRs.

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

Our sales to customers outside the United States are subject to government export regulations that require us to obtain licenses to export such products internationally. In particular, we are required to obtain a new license for each purchase order of our biothreat products that are exported outside the United States. Delays or denial of the grant of any required license, or changes to the regulations that make such delays or denials more likely or frequent, could make it difficult to make sales to foreign customers and could adversely affect our revenue. In addition, we could be subject to fines and penalties for violation of these export regulations if we were found in violation. Such violation could result in penalties, including prohibiting us from exporting our products to one or more countries, and could materially and adversely affect our business.

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 require skilled personnel in areas such as microbiology, clinical and sales, marketing and finance. Attracting, retaining and training personnel with the requisite skills remains challenging, and, could become increasingly competitive, 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.

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 foreign, 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 ("OSHA") and the Environmental Protection Agency ("EPA"), and to regulation under the Toxic Substances Control Act and the Resource Conservation and Recovery Act in the United States. 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.

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 workers' compensation insurance. We may not be able to maintain insurance on acceptable terms, if at all.

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, Bromma, Sweden, and Bothell, Washington. Although 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 our primary manufacturing facilities in California are located in an earthquake-prone area. In the event our existing manufacturing facilities or equipment are affected by man-made or natural disasters, we may be unable to manufacture products for sale or meet customer demands or sales projections. If our manufacturing operations were curtailed or ceased, it would seriously harm our business.

Funds associated with certain of our auction rate securities may not be accessible for in excess of 12 months, and our auction rate securities may experience an other than temporary decline in value, which would adversely affect our income.

Our investments of $25.0 million, with a fair value of $21.0 million, at September 30, 2008 consisted of auction rate securities. Auction rate securities are securities that are structured with short-term interest rate reset dates of generally less than 90 days, but with contractual maturities that can be well in excess of ten years. Since March 2008, all of our auction rate securities failed at auction. Our auction rate securities consist of investments that are backed by pools of student loans, which are principally guaranteed by the Federal Family Educational Loan Program (“FFELP”), or insured. We believe that the credit quality of these securities is high based on these guarantees and insurance. Based on an analysis of other-than-temporary impairment factors, we have recorded cumulative temporary impairments within other accumulated comprehensive loss of approximately $4.0 million as of September 30, 2008 related to these auction rate securities. The funds associated with failed auctions will not be accessible until a successful auction occurs, a buyer is found outside of the auction process, or the underlying securities mature, are refinanced or are recalled by the issuer. Given the recent disruptions in the credit markets and the fact that the liquidity for these types of securities remains uncertain, we have classified all of our auction rate securities as long-term assets in our condensed consolidated balance sheet as our ability to liquidate such securities in the foreseeable future is uncertain. While we presently do not intend to liquidate these investments, in the event that we did liquidate these investments prior to their scheduled maturities and there were no changes in market interest rates, we could be required to recognize a realized loss on those investments. Furthermore, if this situation were to persist despite our ability to hold such investments until maturity or recovery, we may be required to record an impairment charge at a future date, which would adversely affect our reported results of operations in such period. Additionally, if we were to require additional cash to fund our operations or for other corporate purposes, we may not have access to the funds invested in these auction rate securities.

In October 2008, UBS, the fund manager with which we hold our auction rate securities, announced a comprehensive settlement arrangement for its clients holding auction rate securities. Under the proposal, we can elect to receive auction rate securities rights from UBS, which would give us the right to sell our auction rate securities to UBS at par value at our option during a two year period beginning in June 2010. If we elect to participate in this program, given the substantial dislocation in the financial markets and among financial services companies, we cannot assure you that UBS will ultimately have the ability to repurchase our auction rate securities at par, or at any other price, as these rights will be an unsecured contractual obligation of UBS. In addition, as a condition of accepting the auction rate securities rights, we would be required to sign a release of claims against UBS, which would prevent us from making claims against UBS related to our investment in auction rate securities, other than claims for consequential damages.

We might require additional capital to support business growth, and such capital might not be available.

We may need to engage in additional equity or debt financing to support business growth and respond to business challenges, which include the need to develop new products or enhance existing products, conduct clinical trials, enhance our operating infrastructure and acquire complementary businesses and technologies. Equity and debt financing, however, might not be available when needed or, if available, might not be available on terms satisfactory to us. In addition, 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, these 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. If we are unable to obtain adequate financing or financing on terms satisfactory to us, our ability to continue to support our business growth and to respond to business challenges could be significantly limited.

We rely on relationships with collaborative partners and other third parties for development, supply and marketing of certain products and potential products, and such collaborative partners or other third parties could fail to perform sufficiently.

We believe that our success in penetrating our target markets depends in part on our ability to develop and maintain collaborative relationships with other companies. Relying on collaborative relationships is risky to our future success for these products 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 be acquired by another company and decide to terminate our collaborative partnership or become insolvent;
- 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;
- disagreements with collaborators could result in the termination of the relationship or litigation;
- collaborators may not have sufficient capital resources;
- collaborators may pursue tests or other products that will not generate significant volume for us, but may consume significant research and development and manufacturing resources; and
- we may not be able to negotiate future collaborative arrangements, or renewals of existing collaborative agreements, on acceptable terms.

Because these and other factors may be beyond our control, the development or commercialization of these products may be delayed or otherwise adversely affected.

If we or any of our collaborative partners terminate a collaborative arrangement, we may be required to devote additional resources to product development and commercialization or we may need to cancel some development programs, which could adversely affect our product pipeline and business.

Compliance with regulations governing public company corporate governance and reporting is complex and expensive.

Many laws and regulations, notably those adopted in connection with the Sarbanes-Oxley Act of 2002 by the SEC and the NASDAQ Global Market, impose obligations on public companies, such as ours, which have increased the scope, complexity, and cost of corporate governance, reporting, and disclosure practices. Our implementation of these reforms and enhanced new disclosures has required and will continue to require substantial management time and oversight and requires us to incur significant additional accounting and legal costs.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Not Applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not Applicable.

ITEM 4. SUBMISSION OF MATTERS TO VOTE OF SECURITY HOLDERS

Not Applicable.

ITEM 5. OTHER INFORMATION

Not Applicable.

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference			Filing Date	Filed Herewith
		Form	File No.	Exhibit		
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a), as adopted 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, as 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, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*					X

* This certification accompanying this Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933 or the Securities Exchange Act of 1934 (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

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 7th day of November 2008.

CEPHEID
(Registrant)

/s/ JOHN L. BISHOP
John L. Bishop
Chief Executive Officer and Director
(Principal Executive Officer)

/s/ ANDREW D. MILLER
Andrew D. Miller
Senior Vice President, Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit Index

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* This certification accompanying this report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933 or the Securities Exchange Act of 1934 (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

Exhibit 31.1

Certification of Chief Executive Officer
Pursuant to Section 302 of the
Sarbanes-Oxley Act of 2002

I, John L. Bishop, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cepheid;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in the Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2008

/s/ JOHN L. BISHOP
John L. Bishop
Chief Executive Officer

Exhibit 31.2

Certification of Chief Financial Officer
Pursuant to Section 302 of the
Sarbanes-Oxley Act of 2002

I, Andrew D. Miller, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cepheid;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in the Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2008

/s/ ANDREW D. MILLER
Andrew D. Miller
Senior Vice President, Chief Financial Officer

Exhibit 32.1

Certification of Chief Executive Officer Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Cepheid (the Company) on Form 10-Q for the quarter ended September 30, 2008, as filed with the Securities and Exchange Commission on the date hereof (the Report), I, John L. Bishop, as Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 7, 2008

/s/ JOHN L. BISHOP
John L. Bishop
Chief Executive Officer

This certification accompanies this Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933 or the Securities Exchange Act of 1934 (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

Certification of Chief Financial Officer Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Cepheid (the Company) on Form 10-Q for the quarter ended September 30, 2008, as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Andrew D. Miller, as Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 7, 2008

/s/ Andrew D. Miller
Andrew D. Miller
Senior Vice President, Chief Financial Officer

This certification accompanies this Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933 or the Securities Exchange Act of 1934 (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.