QUIDEL CORP /DE/
Form 10-Q/A
March 31, 2003

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q/A

Amendment No. 1

(Mark One)

ý **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2002
or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission File Number: 0-10961

QUIDEL CORPORATION

(Exact name of Registrant as specified in its charter)

Delaware	**94-2573850**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

10165 McKellar Court, San Diego, California 92121
(Address of principal executive offices)

(858) 552-1100
(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 ý No o

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes ý No o

As of October 31, 2002, 28,888,804 shares of common stock were outstanding.

QUIDEL CORPORATION
FORM 10-Q/A
FOR THE QUARTER ENDED
September 30, 2002

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Introductory Note

We issued a press release on February 10, 2003, announcing our intention to restate our financial statements for the year ended December 31, 2001, for each quarter in the year ended December 31, 2001 and for each quarter in the nine month period ended September 30, 2002. The condensed consolidated financial statements and Part 1 Item 1 of this Form 10-Q/A (Amendment No. 1) have been amended to give effect to the restatement discussed in Note 2 to the condensed consolidated financial statements.

This amendment incorporates certain revisions to historical financial data and related descriptions but is not intended to update other information presented in this quarterly report as originally filed, except where specifically noted.

PART I FINANCIAL INFORMATION

ITEM 1. Financial Statements

QUIDEL CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	September 30, 2002 (unaudited) (restated)	December 31, 2001 (restated)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,885	$ 3,396
Accounts receivable, net	12,444	15,657
Inventories, net	9,303	9,145
Prepaid expenses and other current assets	1,141	922
Total current assets	27,773	29,120
Property and equipment, net	22,692	22,652
Intangible assets, net	25,337	26,866
Deferred tax asset	2,180	2,684
Other assets	1,086	1,071
Total assets	$ 79,068	$ 82,393
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,881	$ 4,008
Accrued payroll and related expenses	1,323	987
Line of credit		2,650
Current portion of obligations under capital leases	439	424
Other accrued liabilities	1,695	3,261
Total current liabilities	6,338	11,330
Deferred rent	1,097	662
Capital leases, net of current portion	10,314	10,654
Stockholders' equity:		
Common stock	30	30
Additional paid-in capital	140,356	139,578
Accumulated other comprehensive loss	(128)	(632)
Accumulated deficit	(78,939)	(79,229)

	September 30, 2002	December 31, 2001
Total stockholders' equity	61,319	59,747
Total liabilities and stockholders' equity	$ 79,068	$ 82,393

See accompanying notes to condensed consolidated financial statements.

QUIDEL CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data, unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2002	2001	2002	2001
	(restated)	(restated)	(restated)	(restated)
REVENUES				
Net sales	$ 14,126	$ 16,117	$ 52,253	$ 51,185
Research contracts, license fees and royalty income	382	451	1,256	1,317
Total revenues	14,508	16,568	53,509	52,502
COSTS AND EXPENSES				
Cost of sales	8,019	8,205	27,381	25,649
Research and development	1,644	1,484	4,747	4,768
Sales and marketing	4,366	3,374	12,171	10,765
General and administrative	1,992	1,949	6,494	6,638
Restructuring charge				550
Amortization of intangibles	483	1,099	1,460	3,246
Total costs and expenses	16,504	16,111	52,253	51,616
Earnings (loss) from operations	(1,996)	457	1,256	886
OTHER (INCOME) EXPENSE				
Interest income	(3)	(2)	(9)	(43)
Interest expense	238	328	722	1,010
Other	(86)	(78)	(251)	(262)
Total other expense	149	248	462	705
Earnings (loss) before income taxes	(2,145)	209	794	181

	Three months ended September 30,		Nine months ended September 30,	
Provision (benefit) for income taxes	(811)	449	504	1,202
Net earnings (loss)	$ (1,334)	$ (240)	$ 290	$ (1,021)
Basic and diluted earnings (loss) per share	$ (0.05)	$ (0.01)	$ 0.01	$ (0.04)
Weighted shares used in basic per share calculation	28,850	28,302	28,802	28,202
Weighted shares used in diluted per share calculation	28,850	28,302	29,912	28,202

See accompanying notes to condensed consolidated financial statements.

QUIDEL CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands, unaudited)

	Nine months ended September 30,	
	2002	2001
OPERATING ACTIVITIES:		
Net cash provided by operating activities	$ 6,215	$ 4,996
INVESTING ACTIVITIES:		
Acquisition of property and equipment	(2,927)	(4,706)
Proceeds from sale of assets		550
Other	(106)	42
Net cash used for investing activities	(3,033)	(4,114)
FINANCING ACTIVITIES:		
Line of credit, net	(2,650)	(800)
Payments on obligations under capital leases	(325)	(364)
Proceeds from issuance of common stock and exercise of warrants	778	968
Net cash used for financing activities	(2,197)	(196)
Effect of exchange rate fluctuations on cash and cash equivalents	504	(369)
Net increase in cash and cash equivalents	1,489	317
Cash and cash equivalents, beginning of period	3,396	1,901
Cash and cash equivalents, end of period	$ 4,885	$ 2,218

	Nine months ended September 30,	
Supplemental disclosures of cash flow information:		
Cash paid during the period for interest	$ 734	$ 1,011
Cash paid during the period for income taxes	$	$

See accompanying notes to condensed consolidated financial statements.

Quidel Corporation

Notes to Condensed Consolidated Financial Statements

(Unaudited)

Note 1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of Quidel Corporation (the "Company") have been prepared in accordance with generally accepted accounting principles in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the U.S. for complete financial statements. In the opinion of management, all adjustments considered necessary for a fair presentation (consisting of normal recurring accruals) have been included. The information at September 30, 2002, and for the three and nine months ended September 30, 2002 and 2001, is unaudited. Operating results for the nine months ended September 30, 2002 are not necessarily indicative of the results that may be expected for the year ending December 31, 2002. For further information, refer to the consolidated financial statements and footnotes thereto for the year ended December 31, 2001 included in the Company's 2001 Annual Report on Form 10-K.

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

The Company's first, second and third fiscal quarters end on the Sunday closest to March 31, June 30 and September 30, respectively. For ease of reference, such quarter end date is used herein.

Note 2. Restatement of Financial Statements

The Company has restated its consolidated balance sheets as of September 30, 2002 and December 31, 2001 and its consolidated statements of operations for the three and nine months ended September 30, 2002 and 2001 as described below. The restatement adjustment was required to reflect the appropriate accounting treatment for a lease obligation. In January 2001, the Company entered into a nine-year lease agreement for its manufacturing facility in Santa Clara, California, whereby the agreement included scheduled rent increases in each succeeding year. The Company had originally accounted for the lease payments based on cash paid. SFAS No. 13, "Accounting for Leases", requires that operating leases which include scheduled rent increases be accounted for on a straight-line basis.

Key financial data as of September 30, 2002 and December 31, 2001 and for the three and nine month periods ended September 30, 2002 and 2001, as previously reported and as restated, are as follows (in thousands, except per share data):

	As Previously Reported		As Restated	
	Three months ended	Nine months ended	Three months ended	Nine months ended

	As Previously Reported				As Restated			
	September 30,		September 30,		September 30,		September 30,	
	2002	2001	2002	2001	2002	2001	2002	2001
Statements of Operations:								
Revenue	$ 14,126	$ 16,117	$ 52,253	$ 51,185	$ 14,126	$ 16,117	$ 52,253	$ 51,185
Cost of sales	7,903	8,072	27,033	25,250	8,019	8,205	27,381	25,649
General and administrative expenses	1,963	1,917	6,407	6,540	1,992	1,949	6,494	6,638
Net earnings (loss)	(1,189)	(75)	725	(524)	(1,334)	(240)	290	(1,021)
Basic net earnings (loss) per share	(0.04)	0.00	0.03	(0.02)	(0.05)	(0.01)	0.01	(0.04)
Diluted net earnings (loss) per share	(0.04)	0.00	0.02	(0.02)	(0.05)	0.01	0.01	(0.04)

	As Previously Reported		As Restated	
	September 30, 2002	December 31, 2001	September 30, 2002	December 31, 2001
Balance Sheets:				
Deferred rent	$	$	$ 1,097	$ 662
Accumulated deficit	(77,842)	(78,567)	(78,939)	(79,229)

Note 3. Comprehensive Gain (Loss)

The components of comprehensive gain (loss) are as follows (in thousands, unaudited):

	Three months ended September 30,		Nine months ended September 30,	
	2002	2001	2002	2001
Net earnings (loss)	$ (1,334)	$ (240)	$ 290	$ (1,021)
Foreign currency translation adjustment	(138)	355	504	(369)
Comprehensive gain (loss)	$ (1,472)	$ 115	$ 794	$ (1,390)

Note 4. Computation of Earnings (Loss) Per Share

Basic earnings (loss) per share was computed by dividing net earnings (loss) by the weighted average number of common shares outstanding during the period. Diluted earnings per share reflects the potential dilution that could occur if the income were divided by the weighted-average number of common shares and potentially dilutive common shares from outstanding stock options and warrants. Potential dilutive common shares were calculated using the treasury stock method and represent incremental shares issuable upon exercise of the Company's outstanding options and warrants. Potentially dilutive shares have not been included for the three months ended September 30, 2002 and 2001, and nine months ended September 30, 2001, as their inclusion would be antidilutive.

Note 5. Inventories

Inventories are recorded at the lower of cost (first-in, first-out) or market and consist of the following (in thousands):

	September 30, 2002	December 31, 2001
	(unaudited)	

	September 30, 2002	December 31, 2001
Raw materials	$ 2,885	$ 2,588
Work-in-process	2,046	1,549
Finished goods	4,372	5,008
	$ 9,303	$ 9,145

Note 6. Stockholders' Equity

During the nine months ended September 30, 2002, 178,892 shares of common stock were issued for the exercise of common stock options and 28,320 shares of common stock were issued in connection with the Company's Employee Stock Purchase Plan (the "ESPP"), resulting in proceeds to the Company of approximately $0.8 million.

Note 7. Accounting Changes

In June 2001, the Financial Accounting Standards Board (the "FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 141 "Business Combinations," and SFAS No. 142, "Goodwill and Other Intangible Assets." SFAS No. 141 addresses the accounting for acquisitions of businesses and is effective for acquisitions occurring on or after July 1, 2001. SFAS No. 142 addresses the method of identifying and measuring goodwill and other intangible assets acquired in a business combination, eliminates further amortization of goodwill, and requires periodic evaluations of impairment of goodwill balances. In addition, the useful lives of recognized intangible assets acquired in transactions completed before July 1, 2001 are to be reassessed and the remaining amortization periods adjusted accordingly. SFAS No. 142 is effective January 1, 2002.

Effective January 1, 2002, the Company has adopted SFAS No. 142. With this adoption, we have reclassified the net book value assigned to the assembled workforce intangible at December 31, 2001 to goodwill, which totaled approximately $0.1 million, and then ceased to amortize approximately $13.3 million of goodwill. Based on the current values assigned to goodwill and assembled workforce, the elimination of goodwill amortization had a positive impact on reported net earnings of approximately $1.8 million for the nine months ended September 30, 2002 as compared to the results reported for the nine months ended September 30, 2001; and the Company expects the positive impact to be approximately $2.5 million for the year ended December 31, 2002 as compared to the year ended December 31, 2001. We completed our review for impairment of goodwill during the first quarter of 2002 and no such impairment existed.

In August 2001, the FASB issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. SFAS No. 144 replaces SFAS No. 121, *Accounting for the Impairment of Long Lived Assets and for Long-Lived Assets to be Disposed Of*. The FASB issued SFAS No. 144 to establish a single accounting model, based on the framework established in SFAS 121, as SFAS No. 121 did not address the accounting for a segment of a business accounted for as a discontinued operation under Accounting

Principles Board Opinion No. 30, *Reporting the Results of Operations Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary Unusual and Infrequently Occurring Events and Transactions*. SFAS No. 144 also resolves significant implementation issues related to SFAS No. 121. Companies are required to adopt SFAS No. 144 for fiscal years beginning after December 15, 2001, but early adoption is permitted. The adoption of this standard is not expected to have a material impact on the Company's results of operations and financial position.

In June 2002, the FASB issued SFAS No. 146, "*Accounting for Costs Associated with Exit or Disposal*". SFAS No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies EITF Issue No. 94-3, "*Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)*" ("EITF 94-3"). The principal difference between SFAS No. 146 and EITF 94-3 relates to SFAS No. 146's requirements for recognition of a liability for a cost associated with an exit or disposal activity. SFAS No. 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Under EITF 94-3, a liability for an exit cost as generally defined in EITF 94-3 was recognized at the date of an entity's commitment to an exit plan. The provisions of SFAS No. 146 are effective for exit or disposal activities that are initiated after December 31, 2002, with early application encouraged. The Company does not expect that the adoption of SFAS No. 146 will have a material impact on the financial statements.

Note 8. Industry and Geographic Information

The Company operates in one reportable segment. Sales to customers outside the United States (primarily Asia and Europe) represented 28% and 23% for the nine months ended September 30, 2002 and September 30, 2001, respectively. As of September 30, 2002 and December 31, 2001, balances due from foreign customers were $6.0 million and $6.4 million, respectively.

The Company had sales to individual customers in excess of 10% of net sales, as follows:

	Nine months ended September 30,	
	2002	2001
	(unaudited)	
Customer:		
A	20%	19%
B	11%	13%

As of September 30, 2002, accounts receivable from three customers with balances due in excess of 10% of total accounts receivable totaled $5.8 million while at December 31, 2001, accounts receivable from three customers with balances due in excess of 10% of total accounts receivable totaled $7.0 million.

The following presents net sales for the nine months ended September 30, 2002 and 2001 and long-lived assets as of September 30, 2002 and December 31, 2001 by geographic territory:

	Long-Lived Assets		Net Sales	
			Nine months ended September 30,	
	September 30, 2002	December 31, 2001	2002	2001
	(unaudited)		(unaudited)	
United States operations:				
Domestic	$ 22,491	$ 22,458	$ 37,624	$ 39,435
Foreign			9,690	6,819
Foreign operations	201	194	4,939	4,931
Total	$ 22,692	$ 22,652	$ 52,253	$ 51,185

Note 9. Restructuring

In the first quarter of 2001, the Company implemented an expense reduction plan (the "Reduction Plan") of certain of its operations. The Reduction Plan included a workforce reduction of approximately 15 employees and closure of the Company's facilities in the United Kingdom ("U.K."). In the first quarter of 2001, the Company recorded a restructuring charge of approximately $0.6 million related to the Reduction Plan. The significant components of the Reduction Plan were $0.5 million for employee severance costs and $0.1 million in closing costs related to the U.K. facility. As of September 30, 2002 all amounts had been paid.

ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

In this quarterly report, all references to "we," "our" and "us" refer to Quidel Corporation and its subsidiaries.

Future Uncertainties

This discussion contains forward-looking statements within the meaning of the federal securities laws that involve material risks and uncertainties. Many possible events or factors could affect our future financial results and performance, such that our actual results and performance may differ materially. As such, no forward-looking statement can be guaranteed. Differences in operating results may arise as a result of a number of factors, including, without limitation, seasonality, adverse changes in the competitive and economic conditions in domestic and international markets, actions of our major distributors, manufacturing and production delays or difficulties, adverse actions or delays in product reviews by the United States Food and Drug Administration ("FDA"), and the lower acceptance of our new products than forecast. Forward-looking statements typically are identified by the use of terms such as "may," "will," "should," "might," "believe," "expect," "anticipate," "estimate" and similar words, although some forward-looking statements are expressed differently. The risks described in this report and in other reports and registration statements filed with the SEC from time to time should be carefully considered. The following should be read in conjunction with the unaudited condensed consolidated financial statements and notes thereto included elsewhere in this Form 10-Q.

Overview

We commenced our operations in 1979 and launched our first products, dipstick-based pregnancy tests, in 1984. The product base has expanded through internal development and acquisitions of other products. Our primary product areas are pregnancy and ovulation, infectious diseases, autoimmune diseases, osteoporosis and urinalysis. We discover, develop, manufacture and market rapid diagnostic products for point-of-care ("POC") detection. These products provide simple, accurate and cost-effective diagnoses for acute and chronic medical conditions. Products are sold worldwide to professionals in the physician's office and clinical laboratories, and to consumers through organizations that provide private label, store brand products.

Results of Operations

Net Sales

Net sales decreased 12% to $14.1 million for the three months ended September 30, 2002 from $16.1 million for the three months ended September 30, 2001 and increased 2% to $52.3 million for the nine months ended September 30, 2002 from $51.2 million for the nine months ended September 30, 2001. The decrease for the three months ended September 30, 2002 as compared to the three months ended September 30, 2001 was primarily due to certain distributors not making expected quarter-end purchases and changes in distributors' inventory management practices, which primarily impacted our pregnancy, Group A Strep and H.pylori products, partially offset by an increase in our influenza products. The increase for the nine months ended September 30, 2002 was primarily due to an increase in our influenza products, offset by a smaller decrease in pregnancy, Group A Strep and H.pylori product sales.

Research Contracts, License Fees and Royalty Income

Research contracts, license fees and royalty income decreased to $0.4 million for the three months ended September 30, 2002 from $0.5 million for the three months ended September 30, 2001 and was constant at $1.3 million for both the nine months ended September 30, 2002 and September 30, 2001.

The revenue for all periods is primarily related to royalties received on our patented technologies utilized by third-parties.

Cost of Sales and Gross Profit From Net Sales

Gross profit decreased to $6.1 million for the three months ended September 30, 2002 from $7.9 million for the three months ended September 30, 2001 and decreased to $24.9 million for the nine months ended September 30, 2002 from $25.5 million for the nine months ended September 30, 2001. Gross profit as a percentage of net sales decreased to 43% for the three months ended September 30, 2002 from 49% for the three months ended September 30, 2001, and decreased to 48% for the nine months ended September 30, 2002 from 50% for the nine months ended September 30, 2001. The decrease in the gross margin percentage for the three and nine months ended September 30, 2002 as

compared to the three and nine months ended September 30, 2001 is primarily attributable to a decrease in net sales volume for the three months ended September 30, 2002, underutilization of manufacturing capacity and costs resulting from lower production volumes in our Marburg, Germany facility, higher royalties associated with increased influenza product sales, pricing pressures related to our core products and charges related to outsourcing our packaging line, as well as a write-off of certain expired urinalysis products in the first quarter of 2002.

Research and Development Expense

Research and development expense increased to $1.6 million for the three months ended September 30, 2002 from $1.5 million for the three months ended September 30, 2001 and decreased to $4.7 million for the nine months ended September 30, 2002 from $4.8 million for the nine months ended September 30, 2001. Research and development expense as a percentage of net sales, increased to 12% for the three months ended September 30, 2002 from 9% for the three months ended September 30, 2001 and remained constant at 9% for both the nine months ended September 30, 2002 and September 30, 2001. While research and development costs have been constant for the three and nine months ended September 30, 2002 as compared to the three and nine months ended September 30, 2001, we have increased our costs related to the development of new products for the layered thin film platform ("LTF"), offset by efficiencies of integrating our resources in our northern California operations. We anticipate that we will continue to devote a significant amount of financial resources to research and development for the foreseeable future.

Sales and Marketing Expense

Sales and marketing expense increased to $4.4 million for the three months ended September 30, 2002 from $3.4 million for the three months ended September 30, 2001 and to $12.2 million for the nine months ended September 30, 2002 from $10.8 million for the nine months ended September 30, 2001. Sales and marketing expense as a percentage of net sales increased to 31% for the three months ended September 30, 2002 from 21% for the three months ended September 30, 2001 and increased to 23% for the nine months ended September 30, 2002 from 21% for the nine months ended September 30, 2001. The increases for the three and nine months ended September 30, 2002 as compared to the three and nine months ended September 30, 2001 relate primarily to costs associated with the launch of our infectious vaginitis products, bone ultrasonometer and urinalysis instrument, including infrastructure, public relations, advertising and consulting fees.

General and Administrative Expense

General and administrative expense increased to $2.0 million for the three months ended September 30, 2002 from $1.9 million for the three months ended September 30, 2001 and decreased to $6.5 million for the nine months ended September 30, 2002 from $6.6 million for the nine months ended September 30, 2001.

Restructuring Charge

In the first quarter of 2001, we implemented an expense reduction plan (the "Reduction Plan"). The Reduction Plan included a workforce reduction of approximately 15 employees and the closure of our facilities in the U.K. In the first quarter of 2001, we recorded a restructuring charge of approximately $0.6 million. The significant components of the Reduction Plan were $0.5 million for employee severance costs and $0.1 million in closing costs related to the U.K. facility. As of September 30, 2001 all amounts had been paid.

Amortization of Intangibles

Amortization of intangibles decreased to $0.5 million for the three months ended September 30, 2002 from $1.1 million for the three months ended September 30, 2001 and to $1.5 million for the nine months ended September 30, 2002 from $3.2 million for the nine months ended September 30, 2001. This decrease was primarily due to the adoption of Statement of Financial and Accounting Standards No. 142 ("SFAS No. 142") in January 2002 and the resulting elimination of goodwill amortization.

Interest Expense

Interest expense decreased to $0.2 million for the three months ended September 30, 2002 from $0.3 million for the three months ended September 30, 2001 and to $0.7 million for the nine months ended September 30, 2002 from $1.0 million for the nine months ended September 30, 2001. These decreases relate primarily to a decrease in the average borrowing outstanding under our line of credit.

Income Taxes

Income tax benefit was $0.8 million for the three months ended September 30, 2002 compared to an income tax provision of $0.4 million for the three months ended September 30, 2001 and an income tax provision of $0.5 million for the nine months ended September 30, 2002 compared to $1.2 million for the nine months ended September 30, 2001.

Liquidity and Capital Resources

Our principal sources of liquidity have historically been cash flow from operations and borrowings under our line of credit. Our principal requirements for cash currently are for the funding of operations and capital expenditures.

Cash provided by operating activities was $6.2 million and $5.0 million for the nine months ended September 30, 2002 and 2001, respectively and consisted of funding our working capital, less non-cash amortization and depreciation of $4.5 million and $6.4 million for the nine months ended September 30, 2002 and 2001, respectively, a decrease in receivables of $3.2 million for the nine months ended September 30, 2002 compared to an increase of $0.7 million for the nine months ended September 30, 2001, an increase in inventories of $0.2 million for the nine months ended September 30, 2002 compared to a decrease of $1.0 million for the nine months ended September 30, 2001, an increase in prepaid and other assets of $0.2 million and $0.9 million for the nine months ended September 30, 2002 and 2001, respectively, a decrease in accounts payable of $1.1 million and $1.4 million for the nine months ended September 30, 2002 and 2001, respectively, an increase in accrued payroll and related expenses of $0.3 million for the nine months ended September 30, 2002 compared to a decrease of $0.2 million for the nine months ended September 30, 2001, a decrease in accrued royalties of $0.5 million for the nine months ended September 30, 2002 compared to an increase of $0.1 million for the nine months ended September 30, 2001, a decrease in other accrued liabilities of $1.0 million for the nine months ended September 30, 2002 compared to an increase of $0.5 million in other accrued liabilities for the nine months ended September 30, 2001 and an increase

in deferred rent liability of $0.4 million and $0.5 million for the nine months ended September 30, 2002 and 2001, respectively.

Cash used for investing activities was $3.0 million for the nine months ended September 30, 2002 and $4.1 million for the nine months ended September 30, 2001. For the nine months ended September 30, 2002 and 2001, the amount consisted primarily of cash used in connection with purchases of property and equipment of $2.9 million and $4.1 million, respectively. The amount consisted primarily of cash used in connection with purchases of property and equipment offset by proceeds from sale of certain assets of $0.6 million for the nine months ended September 30, 2001. Cash used for financing activities was $2.2 million for the nine months ended September 30, 2002 and $0.2 million for the nine months ended September 30, 2001. For the nine months ended September 30, 2002 the amount consisted primarily of net payments under our line of credit of $2.7 million, offset by proceeds from issuance of common stock of $0.8 million. For the nine months ended September 30, 2001 the amount consisted of the net payments on our line of credit of $0.8 million, offset by proceeds from issuance of common stock of $1.0 million.

As of September 30, 2002, our outstanding indebtedness included $10.8 million under capital leases (primarily our San Diego facility). We have a $10 million term loan facility which matures in July 2008 and which bears interest at a rate equal to the lender's base rate minus one quarter of one percent. We also have a $10 million line of credit facility which matures in July 2004 and, at our option, bears interest at a rate equal to the lender's base rate minus one quarter of one percent or at the London InterBank Offering Rate plus two and one quarter percent. The agreement governing our line of credit and term loan facilities contains certain customary covenants restricting our ability to, among other matters, incur additional indebtedness, create liens or other encumbrances, pay dividends or make other restricted payments, make investments, loans and guarantees or sell or otherwise dispose of a substantial portion of assets to, or merge or consolidate with, another entity. As of September 30, 2002 there were no borrowings outstanding under either the line of credit or the term loan and we believe we were in compliance with all material covenants.

We plan approximately $1.0 million in capital expenditures for the remainder of the year. The primary purpose for our capital expenditures is procuring manufacturing equipment, facilities improvements and information technology. We plan to fund these capital expenditures with cash flow from operations and borrowings under our existing credit facilities. We have no material commitments with respect to such planned expenditures as of the date of this filing.

We also intend to continue searching for acquisition and technology licensing candidates. As such, we may need to incur additional debt or sell additional equity to fund these acquisitions. Cash requirements fluctuate as a result of numerous factors, such as the extent to which we generate cash in operations, progress in research and development projects, competition and technological developments and the time and expenditures required to obtain governmental approval of our products. Based on the current cash position and the current assessment of future operating results, we believe that our existing sources of liquidity will be adequate to meet operating needs during the next twelve months.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to customer programs and incentives, bad debts, inventories, intangible assets, income taxes, restructuring and contingencies and litigation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the

circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

We record estimated reductions to revenue for customer programs and incentive offerings including special pricing agreements, price protection, promotions and other volume-based incentives. While we have increased customer incentive programs for the nine months ended September 30, 2002 and 2001, if market conditions were to decline, we may take actions to further increase customer incentive offerings, possibly resulting in an incremental reduction of revenue and gross margin at the time the incentive is offered. We record revenues from product sales, net of related rebates and discounts at the time the sale is recognized. We recognize an allowance for pricing rebates based upon the estimated amounts of rebates that will be claimed by the customers. Revenue from product sales are recorded upon passage of title and risk of loss to the customer. Title to the product and recognition of revenue passes upon delivery to the customer when sales terms are free on board ("FOB") destination and at the time of shipment when the sales terms are FOB shipping point. We also earn income for performing services under joint development agreements and licensing of technology. Milestone payments are considered to be payments received for the accomplishment of a discrete, substantive earnings event. The non-refundable payment arising from the achievement of a defined milestone is recognized as revenue when the performance criteria for that milestone have been met when substantive effort is required to achieve the milestone, the amount of the milestone payments appears reasonable and commensurate with the effort expended and collection of the payment is reasonably assured. Income from the grant of distribution rights is recorded when the event triggering payment to us has occurred as specified by the terms of the related distribution agreements and collectibility is reasonably assured.

We maintain allowances for doubtful accounts for estimated losses resulting from the inability or unwillingness of our customers to make required payments. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.

We write down our inventory for estimated obsolescence or unmarketable inventory equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required.

We periodically assess the impairment of goodwill, intangible and other long-lived assets, which requires us to make assumptions and judgments regarding the carrying value of these assets. The assets are considered to be impaired if we determine that the carrying value may not be recoverable based upon our assessment of the following events or changes in circumstances:

- the asset's ability to continue to generate income from operations and positive cash flow in future periods;
- any volatility or significant decline in our stock price and market capitalization compared to our net book value;
- loss of legal ownership or title to the asset;
- significant changes in our strategic business objectives and utilization of the asset(s); or

the impact of significant negative industry or economic trends.

If the assets are considered to be impaired, the impairment we recognize is the amount by which the carrying value of the assets exceeds the fair value of the assets. In addition, we base the useful lives and related amortization or depreciation expense on our estimate of the period that the assets will generate revenues or otherwise be used by us. If a change were to occur in any of the above-mentioned factors or estimates, the likelihood of a material change in our reported results would increase.

In 2002, SFAS No. 142, "Goodwill and Other Intangible Assets," became effective and, as a result, we ceased to amortize goodwill and indefinite-lived intangible assets. We currently expect that the elimination of goodwill and indefinite-lived amortization will have a positive impact on net earnings for the year ended December 31, 2002 of approximately $2.5 million. In lieu of amortization, we are required to perform an initial impairment review of our goodwill in 2002 and an annual impairment review thereafter. We completed our review during the first quarter of 2002 and concluded there was no impairment of our goodwill. In a future review, we cannot assure you a material impairment charge will not be recorded.

We record a valuation allowance to reduce our deferred tax asset to the amount that we believe is more likely than not to be realized. While we have considered future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for the valuation allowance, in the event we were to determine that we would be able to realize our deferred tax assets in the future in excess of our net recorded amount, an adjustment to the deferred tax asset would increase earnings in the period such determination was made. Likewise, should we determine that we would not be able to realize all or part of our net deferred tax asset in the future, an adjustment to the deferred tax asset would be charged to earnings in the period such determination were made.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to the risk of future currency exchange rate fluctuations, which is accounted for as an adjustment to stockholders' equity. Therefore, changes from reporting period to reporting period in the exchange rates between various foreign currencies and the U.S. dollar have had and will continue to have an impact on the accumulated other comprehensive loss component of stockholders' equity reported by us, and such effect may be material in any individual reporting period. We currently are not a party to derivative contracts or other arrangements that may reduce exchange rate risk.

The fair market value of floating interest rate debt is subject to interest rate risk. Generally, the fair market value of floating interest rate debt will vary as interest rates increase or decrease. Based on our market risk sensitive instruments outstanding at September 30, 2002 and December 31, 2001, we believe that there was no material market risk exposure to our consolidated financial position, results of operations or cash flows as of such dates.

Risk Factors

Our operating results may fluctuate as a result of factors that are outside our control, and this could have a negative effect on the price of our common stock.

Fluctuations in our operating results, for any reason, that decrease sales or profitability could cause our growth or operating results to fall below the expectations of investors and securities analysts, and this could cause our stock price to decline. The market price of our common stock has fluctuated substantially in the past. Between September 30, 2001 and September 30, 2002, the price of our common stock, as reported on the Nasdaq National Market, has ranged from a low of $3.33 to a high of $8.75. We expect the market price of our common stock to continue to experience significant fluctuations in the future in response to a variety of factors, including fluctuation in our operating results.

For the nine months ended September 30, 2002, total revenues increased 2% to $52.3 million from $51.2 million for the nine months ended September 30, 2001. We had net earnings of $0.3 million for the nine months ended September 30, 2002 compared to a net loss of $1.0 million for the nine months ended September 30, 2001. The increase in earnings for the nine months ended September 30, 2002 is primarily due to an increase in our influenza products, as well as the elimination of goodwill amortization in 2002 offset by decreases in some our core products due to certain distributors not making expected quarter-end purchases and changes in distributors' inventory management practices during the three

months ended September 30, 2002. We may not continue our revenue growth or continue to achieve profitability. Operating results may continue to fluctuate, in a given quarter or annual period, or from prior periods as a result of a number of factors, many of which are outside of our control.

Other factors that are beyond our control and that could affect our operating results in the future include:

- seasonal fluctuations in our sales of Group A Strep and influenza tests, which are generally highest in fall and winter, thus resulting in generally lower operating results in the second and third calendar quarter and higher operating results in the first and fourth calendar quarters;

- changes in the level of competition, such as would occur if one of our larger and better financed competitors introduced a new product to compete with one of our products;

- changes in economic conditions in our domestic and international markets, such as economic downturns, reduced consumer demand, inflation and currency fluctuations, particularly as we expand into markets outside Western Europe where economic conditions may differ from those prevailing at given times among developed nations;

- delays in shipments of our products to customers or from suppliers which could result in manufacturing difficulties or from unexpected large customer orders which could strain our manufacturing resources; and

- changes in sales levels, since a significant portion of our costs are fixed costs with the result that relatively higher sales could likely increase profitability but relatively lower sales would reduce revenue but would not reduce costs by the same proportion, and hence could cause operating losses.

Our operating results may also fluctuate as a result of factors that we do control, such as efforts in introducing new products or developing new markets. We may have to expend considerable resources in order to pursue these steps, and this could have a negative effect on our profits.

We must change the mix of products we sell from time to time. For example, while we do not believe that we currently have major products that are nearing the end of their life cycle, we may in the future be required to replace aging products. We also attempt to focus development efforts on products with relatively higher margins. The development, manufacture and sale of our diagnostic products require a significant investment of resources. We may incur increased operating expenses as a result of our increased investment in sales and marketing activities, manufacturing scale-up and new product development associated with our efforts to:

- expand our business line;

- expand the LTF technology platform menu of analytes;

- develop products with higher margins internally, or in collaborations with the external pharmaceutical community; and

- expand our business geographically.

The funds for these projects have in the past come primarily from our business operations and a working capital line of credit. If our business slows and we become less profitable, and as a result have less money available to fund research and development, we will have to decide at that time which programs to cut, and by how much. This decision will be based on a number of factors, including the amount of the funding shortfall, how promising a particular project appears to be, and how close the project is to being commercially available. Our operations will be adversely affected if our net sales and gross profits do not correspondingly increase, or if our product development efforts are unsuccessful or delayed. Development of new markets also requires a substantial investment of resources, such as new employees, offices and

manufacturing facilities, and, if adequate financial, personnel, equipment or real estate resources are not available, we may be required to delay or scale back market developments.

Unexpected significant increases in demand for our products could require us to spend considerable resources to meet the demand, or harm our customer relationships if we are unable to meet demand.

If we experience unexpected significant increases in the demand for our products, we may be required to expend additional capital resources to meet these demands. These capital resources could involve the cost of new machinery, or even the cost of new manufacturing facilities. This would increase our capital costs, which could affect our earnings. If we are unable to develop necessary manufacturing capabilities in a timely manner, our net sales could be adversely affected. Failure to cost-effectively increase production volumes, if required, or lower than anticipated yields or production problems encountered as a result of changes that we may make in our manufacturing processes to meet increased demand, could result in shipment delays as well as increased manufacturing costs, which could also have a material adverse effect on our net sales.

Unexpected increases in demand for our products could also require us to obtain additional raw materials in order to manufacture products to meet the demand. The majority of raw materials and purchased components used to manufacture our products are readily available. However, some raw materials require significant ordering lead time and/or are currently obtained from a sole supplier or a limited group of suppliers. We have long-term supply agreements with these vendors. The reliance on sole or limited suppliers and the failure to maintain long-term agreements with other suppliers involve several risks, including the inability to obtain an adequate supply of raw materials and components and reduced control over pricing, quality and timely delivery. Although we attempt to minimize our supply risks by maintaining an inventory of raw materials and continuously evaluating other sources, any interruption in supply could have a material adverse effect on our net sales or cost of sales.

The loss of key distributors or an unsuccessful effort to directly distribute our products could lead to reduced sales.

Although we have distribution agreements with approximately 80 distributors, the market is dominated by a small group of these distributors. Five of our distributors, which are considered to be among the market leaders, accounted for approximately 52% and 49% of our net sales for the nine months ended September 30, 2002 and September 30, 2001, respectively. While we believe our relationship with our distributors is good, the loss of a major distributor may have an adverse effect on our net sales. The loss or termination of our relationship with any of these key distributors could significantly disrupt our business unless suitable alternatives can be timely found. Finding a suitable alternative may pose challenges in our industry's competitive environment, and another suitable distributor may not be found on satisfactory terms. For instance, many distributors already have exclusive arrangements with our competitors, and others do not have the same level of penetration into our target markets as our existing distributors. We could expand our efforts to distribute and market our products directly; however, this would require an investment in additional sales and marketing resources, including hiring additional field sales personnel, which would significantly increase our future

selling, general and administrative expenses. In addition, our direct sales, marketing and distribution efforts may not be successful.

We may not achieve market acceptance of our products among physicians and other healthcare providers, and this would have a negative effect on future sales growth.

A large part of our business is based on the sale of rapid POC diagnostic tests that physicians and other healthcare providers can administer in their own facilities without sending samples to laboratories. Thus, clinical reference laboratories and hospital-based laboratories are significant competitors for our products, and provide many of the diagnostic tests used by physicians and other healthcare providers. Our estimated market share in fiscal 2001 for some of our key products was 56% in pregnancy, 50% in Group A Strep and 36% for influenza tests. Our future sales depend on, among other matters, capture of sales from these laboratories by achieving market acceptance from physicians and other healthcare providers. If we do not capture sales at the levels we have budgeted for, our net sales may not grow as much as we hope and the costs we have incurred will be disproportionate to our sales levels. We expect that these laboratories will compete vigorously to maintain their dominance of the testing market. Moreover, even if we can demonstrate that our products are more cost-effective or save time, physicians and other healthcare providers may resist changing their established source for these tests.

Intense competition with other manufacturers of POC diagnostic products may reduce our sales.

In addition to competition from laboratories, our POC diagnostic tests compete with similar products made by our competitors. We have a large number of multinational and regional competitors making investments in competing technologies, including several large pharmaceutical

and diversified healthcare companies. These competitors include Abbott Laboratories, Beckman Coulter Primary Care Diagnostics, Becton Dickinson and Genzyme. In November 1999, Abbott Laboratories ceased manufacturing certain diagnostic products in its primary manufacturing facility in conjunction with a consent decree from the FDA. Currently we are not aware of a date at which Abbott Laboratories may re-enter the market. A number of our competitors have a potential competitive advantage because they have substantially greater financial, technical, research and other resources, and larger, more established marketing, sales, distribution and service organizations than we have. Moreover, some competitors offer broader product lines and have greater name recognition than we have. If our competitors' products are more effective than ours, or are cheaper, our net sales could be adversely affected. Competition also has the effect of limiting the prices we can charge for our products.

To remain competitive, we must continue to develop or obtain proprietary technology rights; otherwise, other companies may increase their market share by selling products that compete with our products.

Our competitive position is heavily dependent on obtaining and protecting our proprietary technology or obtaining licenses from others. Our ability to compete successfully in the diagnostic market depends on continued development and introduction of new proprietary technology and the improvement of existing technology. If we cannot continue to obtain and protect proprietary technology, our net sales and gross profits could be adversely affected. Moreover, our current and future licenses may not be adequate for the operation of our business.

We have a license agreement with Becton Dickinson related to our pregnancy and Group A Strep products, which products account for 53% and 63% of our net sales during the nine months ended September 30, 2002 and September 30, 2001, respectively. The license agreement expires in 2004. Our ability to obtain patents and licenses, and their benefits, are uncertain. We have 192 issued patents and approximately 70 applications are pending. Our patents have expiration dates from 2002 to 2020. There are no patents that are expiring in the near term which we consider material to our business. However, our pending patent applications may not result in the issuance of any patents, or if issued, the patents

may not have priority over others' applications or may not offer protection against competitors with similar technology. Moreover, any patents issued to us may be challenged, invalidated or circumvented in the future. In addition to the U.S., we have patents issued in Canada, Germany, France, U.K., Italy, Spain, Australia, Belgium, Korea, Norway, Lithuania, The Netherlands, Austria, Switzerland, Sweden and South Africa. Therefore, third parties can make, use and sell products covered by our patents in any country in which we do not have patent protection. We license the right to use our products to our customers under label licenses that are for research purposes only. These licenses could be contested, and, because we cannot monitor all potential unauthorized uses of our products around the world, we might not be aware of an unauthorized use and might not be able to enforce the license restrictions in a cost-effective manner. Also, we may not be able to obtain licenses for technology patented by others or on commercially reasonable terms.

We may be involved in intellectual property infringement disputes which are costly and could limit our ability to use some technologies in the future.

There are a large number of patents and patent applications in our product areas, and we believe, based on experience and published reports, that litigation in our industry regarding patent and other intellectual property rights is prevalent and will continue. We are not currently involved in any litigation in this area, but our involvement in litigation to determine rights in proprietary technology could adversely affect our net sales because:

- in common with any major litigation, it would likely consume a substantial portion of managerial and financial resources;
- of the developing state of the law in this area, in the U.S. and around the world, its outcome would be uncertain and a court may find the third-party claims valid and that we have no successful defense to such claims;
- an adverse outcome could subject us to significant liability in the form of penalties, special and punitive damages, or future royalty payments affecting our future earnings;
- failure to obtain a necessary license upon an adverse outcome could prevent us from selling our current products or other products we may develop; and

of the developing state of the law, protection of our rights may not be available under the law or may be inadequate.

The uncertainty and cost of regulatory approval for our products may have a negative effect on our profitability.

The testing, manufacture and sale of our products are subject to regulation by numerous governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies. The FDA regulates all of our products except our veterinary products, which are regulated by the U.S. Department of Agriculture. Our future performance depends on, among other matters, our estimates as to when and at what cost we will receive regulatory approval for new products. However, complying with laws and regulations of these regulatory agencies can be a lengthy, expensive and uncertain process making the timing and costs of approvals difficult to predict. Our net sales would be negatively affected by delays in the receipt of or failure to receive approvals or clearances, the loss of previously received approvals or clearances or the placement of limits on the use of the products.

We are subject to numerous government regulations in addition to FDA regulation, and compliance with changes could increase our costs.

In addition to the FDA and other regulations described previously, numerous laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard

control and disposal of hazardous or potentially hazardous substances impact our business operations. If these laws change, are amended, or are added to, the costs of compliance with these laws could substantially increase our costs. While we believe that we currently comply with these laws in all material respects, compliance with any future modifications of these laws or laws regulating the manufacture and marketing of our products could result in substantial costs and loss of sales or customers. Because of the number and extent of the laws and regulations affecting our industry, and the number of governmental agencies whose actions could affect our operations, it is impossible to reliably predict the full nature and impact of future legislation or regulatory developments relating to our industry. We do not estimate that we will have material capital expenditures for environmental control facilities for the remainder of our current fiscal year or the succeeding fiscal year. To the extent the costs and procedures associated with meeting new requirements are substantial, our business and results of operations could be adversely affected.

We use hazardous materials in our business that may result in unexpected and substantial claims against us relating to handling, storage or disposal.

Our research and development and manufacturing activities involve the controlled use of hazardous materials, including chemicals and biological materials such as dimethyl sulfate, sodium nitrite, acetaldehyde, acrylamide, potassium bromate and radionuclides. The risk of accidental contamination or injury from these materials cannot be completely eliminated. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. These regulations include federal statutes popularly known as CERCLA, RCRA and the Clean Water Act. Compliance with these laws and regulations is expensive. If any governmental authorities were to impose new environmental regulations requiring compliance in addition to that required by existing regulations, these future environmental regulations could impair our research, development or production efforts by imposing substantial costs on our business. In addition, because of the nature of the penalties provided for in some of these environmental regulations, we could be required to pay substantial fines, penalties or damages in the event of noncompliance with environmental laws or the exposure of individuals to hazardous materials. Further, any accident could partially or completely shut down our research and manufacturing facilities and operations.

Our net sales could be affected by third-party reimbursement policies and potential cost constraints.

We sell many of our products to physicians and other healthcare providers. They will not use our products if they do not get reimbursed for the cost by their patients' healthcare insurers or payors, such as Blue Cross, Blue Shield, Medicare, or other public or private healthcare programs. Our net sales could be adversely affected by changes in reimbursement policies of these governmental or private healthcare payors. In the U.S., healthcare providers such as hospitals and physicians that purchase diagnostic products generally rely on third-party payors, principally private health insurance plans, federal Medicare and state Medicaid, to reimburse all or part of the cost of the procedure. We believe that the overall escalating cost of medical products and services has led to and will continue to lead to increased pressures on the healthcare industry, both foreign and domestic, to reduce the cost of products and services, including our products. Given the efforts to control and reduce healthcare costs in the U.S. in recent years, currently available levels of reimbursement may not continue to be available in the future for our existing products or products under development. Third-party reimbursement and coverage may not be available or adequate in either U.S. or foreign markets, current reimbursement amounts may be decreased in the future and future legislation, regulation or reimbursement policies of third-party payors may reduce the demand for our products or our ability to sell our products on a profitable basis.

If we are not able to manage our growth strategy, and if we experience difficulties integrating acquired companies or technologies after the acquisition, our earnings may be adversely affected.

During 1999 and 2000, we acquired three businesses, Litmus Concepts, Inc., Metra Biosystems Inc. and the urine test strip business from Dade Behring. Our business strategy contemplates further increased growth in the number of employees, the scope of operating and financial systems and the geographic area of our operations, including further expansion outside the U.S., as new products are developed and commercialized. We may experience difficulties integrating our own operations with those of companies or technologies that we have acquired or we may acquire, and as a result we may not realize our anticipated benefits and cost savings within our expected time frame, or at all. Because we do not have a large executive staff, future growth may also divert management's attention from other aspects of our business, and will place a strain on existing management, as well as on our operational, financial and management information systems. Furthermore, we may expand into markets in which we have less experience or incur higher costs. Should we encounter difficulties in managing these tasks, our growth strategy may suffer and our net sales and gross profits could be adversely affected.

Our business could be negatively affected by the loss of key personnel or our inability to hire qualified personnel.

Our future success depends in part on our ability to retain our key technical, sales, marketing and executive personnel and our ability to identify and hire additional qualified personnel. Competition for these personnel is intense, both in the industry in which we operate and also in the geographic area (Northern San Diego County) where our headquarters and many of our operations are located. If we are not able to retain existing key personnel, or identify and hire additional qualified personnel, our business could be negatively impacted. In addition, we expect to further grow our operations, and our needs for additional management and other key personnel will increase.

We are exposed to business risks which, if not covered by insurance, could have an adverse effect on our profits.

We maintain insurance that we believe is appropriate to protect us against the kinds of insurable risks, such as product liability claims or business interruptions, that companies of our size and companies in our industry typically insure against. However, there is a risk that claims may be made against us for types of damages, or for amounts of damages, that are not covered by our insurance. For example, there is a risk of product liability claims arising from our testing, manufacturing and marketing of medical diagnostic devices, both those currently being marketed as well as those under development. We currently have a product liability policy providing coverage up to $10 million, and our claims to date have not been material. However, it is possible that potential product liability or other claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of our policy. Also, if we are held liable, our existing insurance may not be renewed at the same cost and level of coverage as presently in effect, or may not be renewed at all. If we are held liable for a claim against which we are not indemnified or for damages exceeding the limits of our insurance coverage, whether arising out of product liability matters or from some other matter, that claim could have a material negative effect on our results of operations.

We face risks relating to our international sales and foreign operations, including the risk of currency fluctuations, which could increase our costs or stifle our growth opportunities.

Our products are sold internationally, primarily to customers in Japan and Europe, including Germany, Italy and Poland. Sales to foreign customers accounted for 28% and 23% of our net sales for the nine months ended September 30, 2002 and 2001, respectively, and are expected to continue to account for a significant percentage of our net sales. In December 2001, we began manufacturing our

urinalysis products in Marburg, Germany. Any delays or problems encountered in the integration of this process could result in shipment delays and increased manufacturing costs and could have a material adverse effect on our results of operations. International sales and manufacturing operations are subject to inherent risks which could increase our costs and stifle our growth opportunities. These risks include:

- exposure to currency exchange fluctuations, such as the 10% increase in the value of the Euro against the U.S. dollar for the nine months ended September 30, 2002 and the 6% drop in the value of the German and Italian currencies against the U.S. dollar during fiscal 2001;

longer payment cycles and greater difficulty in accounts receivable collection;

compliance with multiple foreign laws, tariffs or other barriers as we continue to expand into new countries and geographic regions;

difficulties in obtaining export licenses;

reduced protection for, and enforcement of, intellectual property rights, particularly as we expand our business beyond Europe;

political and economic instability in some of the regions that we may expand into in the future; and

potentially adverse tax consequences.

Even that portion of our international sales which is negotiated for and paid in U.S. dollars is subject to currency risks, since changes in the values of foreign currencies relative to the value of the U.S. dollar can render our products comparatively more expensive. These exchange rate fluctuations could negatively impact international sales of our products and our anticipated foreign operations, as could changes in the general economic conditions in those markets. For the nine months ended September 30, 2002, for example, the value of the Euro increased 10% against the U.S. dollar, while in fiscal 2001, the value of the German and Italian currencies dropped 6% against the U.S. dollar. To date, we have not reflected that change in currency value in our selling prices. In order to maintain a competitive price for our products in Europe, however, we may have to provide discounts or otherwise effectively reduce our prices, resulting in a lower margin on products sold in Europe. During 2002, Economic Monetary Union countries in Europe adopted the Euro as their single currency. As of yet, we have not seen any unusual costs associated with the use of the Euro, but we continue to monitor its impact on our operations. Continued change in the values of European currencies or changes in the values of other foreign currencies could have a negative impact on our business, financial condition and results of operations. Although we do not currently hedge against exchange rate fluctuations, any measures we take to hedge against exchange rate fluctuations may not adequately protect us from their potential harm.

We rely on a continuous power supply to conduct our operations, and California's energy crisis could disrupt our operations and increase our expenses.

California has recently experienced an energy crisis that could have disrupted our operations and significantly increased our expenses. In the event of an acute power shortage, that is, when power reserves for the State of California fall below 1.5%, California has on some occasions implemented, and may in the future continue to implement, rolling blackouts throughout California. We currently have a backup generator with limited capacity. We have no alternate source of power in the event of a blackout, and our current insurance does not provide coverage for any damages that we or our customers may suffer as a result of any interruption in our power supply. If blackouts interrupt our power supply, we would be temporarily unable to continue operations at our facilities. Any such interruption in our ability to continue operations at our facilities could damage our reputation, harm

our ability to retain existing customers and to obtain new customers, and could result in lost revenue, any of which could substantially harm our business and results of operations. Furthermore, our utility expenses have increased substantially and could continue to be negatively impacted by the California energy crisis.

Future sales by existing stockholders could depress the market price of our common stock and make it more difficult for us to sell stock in the future.

Sales of our common stock in the public market, or the perception that such sales could occur, could negatively impact the market price of our securities and impair our ability to complete equity financings. We currently have outstanding the following shares of common stock:

Approximately 28.9 million shares of common stock that have been issued in registered offerings and are freely tradable in the public markets.

In addition, approximately 5.7 million shares of common stock are issuable upon exercise of stock options outstanding as of September 30, 2002 under our various stock option plans at a weighted average exercise price of $4.64 per share.

We have in effect registration statements under the Securities Act registering approximately 6.5 million shares of common stock reserved under our employee stock option and purchase plans.

We are unable to estimate the number of shares of common stock that may actually be resold in the public market since this will depend on the market price for the common stock, the individual circumstances of the sellers and other factors. We also have a number of institutional stockholders that own significant blocks of our common stock. If these stockholders sell large portions of their holdings in a relatively short time, for liquidity or other reasons, the prevailing market price of our common stock could be negatively affected.

Item 4. Controls and Procedures

Within the 90 days prior to the date of this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-14. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in timely alerting them to material information (including information about our consolidated subsidiaries) required to be included in our periodic SEC reports. There have been no significant changes in our internal controls or in other factors that could significantly affect these internal controls subsequent to the date of our most recent evaluation.

PART II OTHER INFORMATION

ITEM 1. Legal Proceedings

We received a letter dated April 24, 1992 from the United States Environmental Protection Agency (the "EPA") notifying us that we are a potentially responsible party for cleanup costs at a federal Superfund site, the Marco of Iota Drum Site (the "Marco Site"), near Iota, Louisiana. Documents gathered in response to such letter indicate that we sent a small amount of hazardous waste to facilities in Illinois. It is possible that, subsequently, such waste could have been shipped to the Marco Site. The EPA letter indicates that a similar notice regarding the Marco Site was sent by the EPA to over 500 other parties. At this time, we do not know how much of our waste may have reached the Marco Site, the total volume of waste at the Marco Site or the likely site remediation costs. There is, as in the case of most environmental litigation, the theoretical possibility of joint and several liability being imposed upon us for damages that may be awarded.

We are involved in litigation matters from time to time in the ordinary course of business. Management believes that any and all such actions, in the aggregate, will not have a material adverse effect on us. We maintain insurance, including coverage for product liability claims, in amounts which management believes appropriate given the nature of our business.

ITEM 5. OTHER EVENTS

Effective as of August 28, 2002, Mark A. Pulido was appointed to our board of directors, thereby filling the vacancy caused by the resignation of Richard C.E. Morgan in June 2002.

Our Audit Committee did not pre-approve any non-audit services by our independent auditors during the period covered by this report.

ITEM 6. Exhibits and Reports on Form 8-K

(a)

Exhibits

Exhibit Number	
2.1	Agreement and Plan of Merger, as amended, dated as of October 30, 2000, among Litmus Concepts, Inc., Quidel Corporation and Litmus Acquisition Corporation (Incorporated by reference to Exhibit 2.1 to the Registrant's Form 8-K filed on December 22, 2000.)
3.1	Certificate of Incorporation, as amended. (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on February 26, 1991.)
3.2	Amended and Restated Bylaws. (Incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K dated November 8, 2000.)
4.1	Certificate of Designations of Series C Junior Participating Preferred Stock as filed with the State of Delaware on December 31, 1996 (incorporated by reference to Exhibit 1(A) to the Company's Registration Statement on Form 8-A filed on January 14, 1997.)
4.2	Amended and Restated Rights Agreement dated as of May 24, 2002 between Quidel Corporation and American Stock Transfer and Trust Company, as Rights Agent (incorporated by reference to Exhibit 1 to the Company's current report on Form 8-K filed on May 29, 2002).

10.1	Registrant's 1983 Employee Stock Purchase Plan, as amended. (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated February 26, 1991.)
10.2	Form of Warrant Agreement between Registrant and American Stock Transfer & Trust Company. (Incorporated by reference to Exhibit 10.3 to the Registrant's Form 10-K for the year ended March 31, 1995.)
10.3[(1)]	Registrant's 1990 Employee Stock Option Plan. (Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1990.)
10.4[(1)]	Registrant's 1990 Director Option Plan. (Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1990.)
10.5	Form of Registration Rights Agreement of the Registrant. (Incorporated by reference to Appendix C to the final Joint Proxy Statement/Prospectus dated January 4, 1991 included within Amendment No. 2 to the Registrant's Registration Statement No. 33-38324 on Form S-4 filed on January 4, 1991.)
10.6	Assumption Agreement dated January 31, 1991. (Incorporated by reference to Exhibit 10.52.1 to the Registrant's Form 8-K dated February 26, 1991.)
10.7	Trademark License Agreement dated October 1, 1994 between the Registrant and Becton Dickinson and Company regarding the Q-Test trademark. (Incorporated by reference to Exhibit 10.15 to the Registrant's Form 10-K for the year ended March 31, 1995.)
10.8	Stock Purchase Agreement dated January 5, 1995 between Registrant and Eli Lilly & Company for the sale of all the outstanding capital stock of Pacific Biotech, Inc. (Incorporated by reference to Exhibit 2.1 to the Registrant's Form 8-K dated January 5,

1995.)

10.9 Settlement Agreement effective April 1, 1997 between the Registrant and Becton Dickinson and Company. (Incorporated by reference to Exhibit 10.18 to the Registrant's Form 10-K for the year ended March 31, 1997.)

10.10 Campbell License Agreement effective April 1, 1997 between the Registrant and Becton Dickinson and Company. (Incorporated by reference to Exhibit 10.19 to the Registrant's Form 10-K for the year ended March 31, 1997.)

10.11 Rosenstein License Agreement effective April 1, 1997 between the Registrant and Becton Dickinson and Company. (Incorporated by reference to Exhibit 10.20 to the Registrant's Form 10-K for the year ended March 31, 1997.)

10.12(1) Amended Employment and Stock Option Agreement effective August 13, 2001 between the Registrant and André de Bruin. (Incorporated by reference to Exhibit 10.12 to the Registrant's Form 10-K for the year ended December 31, 2001.)

10.13(1) Employment agreement effective January 1, 2001 between the Registrant and S. Wayne Kay. (Incorporated by reference to Exhibit 10.13 to the Registrant's Form 10-K for the year ended December 31, 2001.)

10.14(1) Stock option agreement effective January 1, 2001 between the Registrant and S. Wayne Kay. (Incorporated by reference to Exhibit 10.14 to the Registrant's Form 10-K for the year ended December 31, 2001.)

10.15(1) Amended employment agreement effective August 13, 2001 between the Registrant and S. Wayne Kay. (Incorporated by reference to Exhibit 10.15 to the Registrant's Form 10-K for the year ended December 31, 2001.)

10.16(1) Stock option agreement effective August 13, 2001 between the Registrant and S. Wayne Kay. (Incorporated by reference to Exhibit 10.16 to the Registrant's Form 10-K for the year ended December 31, 2001.)

10.17 Offer to Purchase for Cash all outstanding shares of common stock of Metra Biosystems, Inc. by MBS Acquisition Corporation, a wholly-owned subsidiary of Quidel Corporation at $1.78 net per share. (Incorporated by reference to Metra's Schedule 14D-1 dated June 9, 1999.)

10.18 Form of Asset Sale Agreement Rapignost® Urine Test Strip Business. (Incorporated by reference to Exhibit 10.5 to the Registrant's Form 8-K filed on December 15, 1999.)

10.19 Form of Purchase and Sale Agreement and Escrow Instructions. (Incorporated by reference to Exhibit 10.6 to the Registrant's Form 8-K filed on January 4, 2000.)

10.20 Form of Single Tenant Absolute Net Lease. (Incorporated by reference to Exhibit 10.7 to the Registrant's Form 8-K filed on January 4, 2000.)

10.21 Form of Indemnification Agreement Corporate Officer and/or Director. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 10-Q for the quarter ended June 30, 2000.)

10.22 Master Revolving Note dated August 29, 2002 by Quidel Corporation in favor of Comerica Bank California.

10.23 Variable Rate Single Payment Note dated August 29, 2002 by Quidel Corporation in favor of Comerica Bank California.

10.24	Security Agreement dated as of August 29, 2002 between Quidel Corporation and Comerica Bank California.
10.25	Business Loan Agreement dated as of August 29, 2002 between Comerica Bank California and Quidel Corporation.
99.1	Certification by the President and Chief Executive Officer and Senior Vice President, Chief Financial Officer and Secretary of the Company pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Indicates a management plan or compensatory plan or arrangement.

(b) Reports on Form 8-K filed in the quarter ended September 30, 2002

None

SIGNATURE

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.

QUIDEL CORPORATION

Date: March 31, 2003

/s/ S. Wayne Kay

S. Wayne Kay
President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION

I, S. Wayne Kay, certify that:

1. I have reviewed this quarterly report on Form 10-Q/A of Quidel Corporation;

2. Based on my knowledge, this quarterly 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 quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly report;

4.

The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

a) Designed such disclosure controls and procedures 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 quarterly report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

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

a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 31, 2003

/s/ S. WAYNE KAY

S. Wayne Kay
President and Chief Executive Officer
Quidel Corporation

CERTIFICATION

I, Paul E. Landers, certify that:

1. I have reviewed this quarterly report on Form 10-Q/A of Quidel Corporation;

2. Based on my knowledge, this quarterly 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 quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

a) Designed such disclosure controls and procedures 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 quarterly report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

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

a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 31, 2003

/s/ PAUL E. LANDERS

Paul E. Landers
Senior Vice President, Chief Financial Officer and Secretary
Quidel Corporation

QUIDEL CORPORATION FORM 10-Q/A FOR THE QUARTER ENDED September 30, 2002
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