QUIDEL CORP /DE/
Form 10-Q
August 09, 2004

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2004

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 July 30, 2004, 31,600,977 shares of common stock were outstanding.

QUIDEL CORPORATION
FORM 10-Q
FOR THE QUARTER ENDED
June 30, 2004

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PART I FINANCIAL INFORMATION

ITEM 1. Financial Statements

QUIDEL CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	June 30, 2004 (unaudited)	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 35,267	$ 25,627
Accounts receivable, net	8,098	24,143
Inventories, net	12,132	9,495
Other current assets	8,093	6,651
Total current assets	63,590	65,916
Property and equipment, net	21,210	20,830
Intangible assets, net	21,507	22,635
Other non-current assets	8,076	8,044
Total assets	$ 114,383	$ 117,425
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,647	$ 5,233
Accrued royalties	746	3,450
Current portion of obligations under capital leases	554	519
Other accrued liabilities	4,080	7,185
Total current liabilities	10,027	16,387
Deferred rent	1,751	1,581
Capital leases, net of current portion	9,388	9,677
Stockholders' equity:		
Common stock	32	31
Additional paid-in capital	152,355	146,836
Accumulated other comprehensive earnings	1,114	1,199
Accumulated deficit	(60,284)	(58,286)
Total stockholders' equity	93,217	89,780
Total liabilities and stockholders' equity	$ 114,383	$ 117,425

See accompanying notes.

QUIDEL CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data; unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
REVENUES				
Net sales	$ 13,706	$ 18,334	$ 32,839	$ 42,260
Research contracts, license fees and royalty income	576	544	1,179	1,013
Total revenues	14,282	18,878	34,018	43,273
COSTS AND EXPENSES				
Cost of sales	7,408	9,288	16,809	20,413
Research and development	2,936	1,895	5,433	4,338
Sales and marketing	3,564	4,406	7,336	8,940
General and administrative	3,832	2,414	6,643	5,213
Restructuring charge		832		832
Amortization of intangibles	519	517	1,037	1,020
Total costs and expenses	18,259	19,352	37,258	40,756
Earnings (loss) from operations	(3,977)	(474)	(3,240)	2,517
OTHER INCOME (EXPENSE)				
Interest income	94	26	175	33
Interest expense	(223)	(291)	(448)	(519)
Other	224	112	127	161
Total other income (expense)	95	(153)	(146)	(325)
Earnings (loss) before provision for income taxes	(3,882)	(627)	(3,386)	2,192
Provision (benefit) for income taxes	(1,592)	(260)	(1,388)	869
Net earnings (loss)	$ (2,290)	$ (367)	$ (1,998)	$ 1,323
Basic earnings (loss) per share	$ (0.07)	$ (0.01)	$ (0.06)	$ 0.05
Diluted earnings (loss) per share	$ (0.07)	$ (0.01)	$ (0.06)	$ 0.04
Weighted shares used in basic per share calculation	31,595	29,002	31,266	28,953
Weighted shares used in diluted per share calculation	31,595	29,002	31,266	29,480

See accompanying notes.

QUIDEL CORPORATION CONDENSED
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands; unaudited)

	Six months ended June 30,	
	2004	**2003**
OPERATING ACTIVITIES:		
Net cash provided by operating activities	$ 6,724	$ 10,952
INVESTING ACTIVITIES:		
Acquisition of property and equipment	(2,536)	(1,099)
Other	(53)	78
Net cash used for investing activities	(2,589)	(1,021)
FINANCING ACTIVITIES:		
Payments on obligations under capital leases	(254)	(222)
Net proceeds from issuance of common stock and warrants	5,520	581
Net cash provided by financing activities	5,266	359
Effect of exchange rate fluctuations on cash and cash equivalents	239	111
Net increase in cash and cash equivalents	9,640	10,401
Cash and cash equivalents, beginning of period	25,627	2,910
Cash and cash equivalents, end of period	$ 35,267	$ 13,312
Supplemental disclosures of cash flow information:		
Cash paid during the period for interest	$ 300	$ 434
Cash paid during the period for income taxes	$ 435	$ 650

See accompanying notes.

Quidel Corporation
Notes to Condensed Consolidated Financial Statements
(Unaudited)

Note 1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of Quidel Corporation and its subsidiaries (the "Company") have been prepared in accordance with generally accepted accounting principles 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 June 30, 2004, and for the three and six months ended June 30, 2004 and 2003, is unaudited. Operating results for the six months ended June 30, 2004 are not necessarily indicative of the results that may be expected for the year ending December 31, 2004. For further information, refer to the consolidated financial statements and footnotes thereto for the year ended December 31, 2003 included in the Company's 2003 Annual Report on Form 10-K.

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, the calendar quarter end date is used herein.

Note 2. Comprehensive Earnings

The components of comprehensive earnings (loss) are as follows (in thousands; unaudited):

	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
Net earnings (loss)	$ (2,290)	$ (367)	$ (1,998)	$ 1,323
Foreign currency translation adjustment	(3)	434	(85)	605
Comprehensive earnings (loss)	$ (2,293)	$ 67	$ (2,083)	$ 1,928

Note 3. Stock Compensation

The Company has elected to follow Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," and related Interpretations, in accounting for its employee and director stock options. In accordance with APB No. 25, because the exercise price of the Company's employee and director stock options equals or exceeds the market price of the underlying stock on the date of grant, no compensation expense has been recognized.

The fair value of each option grant was estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions used for grants for the three and six months ended June 30, 2004 and 2003:

	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
Risk-free interest rate	3.0%	3.8%	3.0%	3.8%
Expected option life (years)	5.3	6.0	5.3	6.0
Volatility	0.81	0.84	0.81	0.84
Dividend rate	0%	0%	0%	0%

The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. Because the Company's employee and director stock option plans have characteristics significantly different from those of traded options, the resulting pro forma compensation cost may not be representative of the compensation cost expected in future years. Had compensation cost for the Company's stock option plans been determined based on the fair value at the grant date for awards for the six months ended June 30, 2004 and 2003, consistent with the provisions of SFAS No. 123, the Company's net earnings (loss) and earnings (loss) per share would have been as indicated below (in thousands, except per share data; unaudited):

	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
Net earnings (loss) as reported	$ (2,290)	$ (367)	$ (1,998)	$ 1,323
Net loss pro forma	(3,019)	(1,362)	(3,286)	(449)
Basic earnings (loss) per share as reported	(0.07)	(0.01)	(0.06)	0.05
Diluted earnings (loss) per share as reported	(0.07)	(0.01)	(0.06)	0.04
Basic and diluted loss per share pro forma	(0.10)	(0.05)	(0.11)	(0.02)

Note 4. Computation of Earnings Per Share

Basic earnings per share was computed by dividing net earnings 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 earnings were divided by the weighted-average number of common shares and potentially dilutive common shares from outstanding stock options. Potential dilutive common shares were calculated using the treasury stock method and represent incremental shares issuable upon exercise of the Company's outstanding stock options. Potentially dilutive shares have not been included for the three months ended June 30, 2004 and 2003 and the six months ended June 30, 2004, as their inclusion would be antidilutive.

The following table reconciles the weighted average shares used in computing basic and diluted earnings per share in the respective periods (in thousands; unaudited):

	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
Shares used in basic earnings (loss) per share (weighted average common shares outstanding)	31,595	29,002	31,266	28,953
Effect of dilutive stock options				527
Shares used in diluted earnings (loss) per share calculation	31,595	29,002	31,266	29,480

Note 5. Inventories

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

	June 30, 2004	December 31, 2003
	(unaudited)	
Raw materials	$ 4,488	$ 3,442
Work-in-process	4,356	3,541
Finished goods	3,288	2,512
	$ 12,132	$ 9,495

Note 6. Deferred Revenue

During the quarter ended June 30, 2004, the Company entered into a joint development agreement with another company. In connection with this agreement, the Company received approximately $1.6 million in upfront fees, which has been recorded as deferred revenue and included in other accrued liabilities in the accompanying balance sheet. This amount will be recognized as contract revenue ratably over the period of development, which is expected to be through December 2005.

Note 7. Income Taxes

A valuation allowance of $13.3 million had been established against a portion of the Company's deferred tax assets at December 31, 2002. As of December 31, 2003, the Company believed it was more likely than not that it would be able to realize the majority of its deferred tax asset through expected future taxable profits, and released approximately $13.3 million of the valuation allowance in the fourth quarter of 2003. As of June 30, 2004, the Company recorded a valuation allowance of $1.9 million related to deferred tax assets created by the exercise and/or disposition of employee stock options in recent periods. Any tax benefits realized from the reduction of this valuation allowance will be recorded to additional paid-in capital. As of June 30, 2004, the Company assessed its deferred tax asset. While the Company's revenues and related earnings for the six months ended June 30, 2004 were lower than expected, it does not believe a valuation allowance is necessary. The Company will continue to assess its deferred tax asset in the third and fourth quarters of 2004. The Company may propose a valuation allowance if it determines that its future earnings, among other factors, do not support the deferred tax asset. Should the Company determine that it would not be able to realize all or part of its other components of the 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. As of June 30, 2004, we had $13.6 million in net deferred tax assets.

The Company also reserves for taxes that may become payable as a result of audits in future periods with respect to previously filed tax returns. The Company establishes the reserves based on its assessment of exposure associated with permanent tax differences, tax credits and interest expense applied to temporary difference adjustments. The tax reserves are analyzed periodically and adjustments are made as events occur to warrant adjustment to the reserve.

Note 8. Stockholders' Equity

During the six months ended June 30, 2004, 1,176,219 shares of common stock were issued due to the exercise of common stock options and 18,316 shares of common stock were issued in connection with the Company's employee stock purchase plan, resulting in proceeds to the Company of approximately $5.5 million.

Note 9. Industry and Geographic Information

The Company operates in one reportable segment. Sales to customers outside the U.S. represented 30% and 42% of total sales for the six months ended June 30, 2004 and 2003, respectively. As of June 30, 2004 and December 31, 2003, balances due from foreign customers were $2.9 million and $11.5 million, respectively.

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

	Six months ended June 30,	
	2004	2003
Customer:		
A	15%	13%
B	13%	3%
C	10%	7%
D	8%	26%

As of June 30, 2004, accounts receivable from customers with a balance due in excess of 10% of total accounts receivable totaled $4.6 million while at December 31, 2003, accounts receivable from customers with balances due in excess of 10% of total accounts receivable totaled $16.2 million.

The following presents net sales for the six months ended June 30, 2004 and 2003 and long-lived assets as of June 30, 2004 and December 31, 2003 by geographic territory (in thousands):

	Long-Lived Assets		Net Sales Six months ended June 30,	
	June 30, 2004	December 31, 2003	2004	2003
United States operations:				
Domestic	$ 20,942	$ 20,467	$ 22,960	$ 24,467
Foreign			9,346	14,412
Foreign operations	268	363	533	3,381
Total	$ 21,210	$ 20,830	$ 32,839	$ 42,260

Note 10. Restructuring

In April 2003, the Company announced and implemented a restructuring plan (the "Restructuring Plan"). The Restructuring Plan was primarily driven by manufacturing automation in the Company's San Diego facility, completion of certain research and development projects, implementation of the Company's BaaN enterprise resource planning system in its Santa Clara facility, and the transition of the Company's foreign sales and support offices to independent distributors. The Restructuring Plan included a workforce reduction of 63 positions (18% of the Company's total workforce at such time) and closure of the Company's sales and support offices in Heidelberg, Germany and Milan, Italy. The Company recorded a restructuring charge of approximately $2.2 million during 2003. The significant components of the restructuring charge in 2003 were $1.3 million for employee severance costs, $0.5 million for contractual lease and commercial contract terminations, $0.3 million for professional fees and $0.1 million for impairment charges related to assets that were deemed obsolete due to restructuring activities. As of June 30, 2004, the entire $2.2 million of the restructuring charge has been paid.

The following table provides information regarding our liabilities relating to our restructuring activity (in thousands; unaudited):

	Severance	Facilities Consolidation and Contract Termination	Professional Fees	Asset Impairments	Total
Liability at December 31, 2003	$ 200	$ 200	$	$	$ 400
Cash payments	(200)	(200)			(400)
Liability at June 30, 2004	$	$	$	$	$

Note 11. Patent Litigation

On February 20, 2004, the Company filed a lawsuit (the "Action") in the U.S. District Court, Southern District of California (the "Court") against Inverness Medical Innovations Inc., Inverness Medical Switzerland GmbH, and Applied Biotech, Inc. (collectively "Inverness") as well as against Armkel LLC, for infringement of our U.S. Patent No. 4,943,522 (the "522 Patent"), which relates to lateral-flow technology, and for declaratory relief. The Company is seeking damages and injunctive relief against Inverness products that infringe its patented technology. The Company's claim for declaratory relief relates to nine Inverness-owned and Inverness-licensed patents (U.S. Patent Nos. 6,485,982: 5,989,921; 5,714,389; 6,352,862; 6,228,660; 6,187,598; 5,656,503; 5,622,871; and 5,602,040), and requests the Court to conclude that its lateral-flow products do not infringe these patents, and that the patents are invalid and unenforceable.

On March 9, 2004, Inverness and a related party filed, in the U.S. District Court, Southern District of California, denials of the Company's allegations of infringement in the Action, allegations that the Company's "522 Patent is invalid and unenforceable, as well as counterclaims for patent infringement against the Company. On March 12, 2004, Armkel LLC filed, in the U.S. District Court, Southern District of California, an answer to the Company's request for declaratory relief and counterclaims for patent infringement against the Company. The counterclaims by Inverness and the related parties and by Armkel LLC allege that the Company's immunoassay test products, including its tests for influenza, pregnancy, strep, and H pylori, infringe eight of the nine Inverness patents that the Company identified in the Action. In addition, Inverness Medical Switzerland GmbH, Wampole Laboratories, LLC, and Applied BioTech, Inc. filed a separate complaint against the Company alleging that its immunoassay test devices also infringe a ninth patent owned by Inverness, U.S. Patent No. 6,534,320. The relief requested in these claims and counterclaims against the Company includes damages and preliminary

and permanent injunctive relief to the effect that if this relief is granted, the Company would be required to cease and desist from manufacturing, selling, marketing, using, and inducing others to use products that represent a substantial majority of its revenues.

On May 6, 2004, the Company filed responses to Inverness' claims and counterclaims, and filed claims for declaratory relief that three additional Inverness-owned patents (U.S. Patents Nos. 5,120,643; 5,578,577; and 4,956,302) are not infringed by the Company's lateral flow products and are invalid and unenforceable. On June 8, 2004, Inverness filed a motion to dismiss the Company's claims for declaratory relief. The motion is currently pending.

From May 17-20, 2004, the Court began conducting a Markman hearing regarding four of the patents at issue in the Action. The Court construed terms in Inverness U.S. Patent No. 6,485,982, and construed one term of the Company's "522 Patent. The Markman hearing continued on July 27-28, 2004, and the Court construed additional terms of the Company's "522 Patent. The Markman hearing will continue in the future to interpret remaining terms of the Company's "522 Patent and other patents.

On February 17, 2004, the Company's German affiliate Quidel Deutschland GmbH was provided with a copy of a lawsuit that Inverness Medical Switzerland GmbH, another Inverness subsidiary, and Preymed had apparently filed on or about February 4, 2004 in District Court in Düsseldorf, Germany, which names the Company, Quidel Deutschland GmbH, and its distributor, Progen Biotechnik GmbH, as defendants. The lawsuit alleges that the Company and the other defendants are infringing two Inverness-owned European patents, EP 0 291 194 and EP 0 560 411, and is directed at the Company's lateral flow test devices, including its tests for pregnancy, strep, H pylori, and Chlamydia. The suit seeks injunctive relief, an accounting, damages and annulment. If the Court grants injunctive relief, the Company will be required to cease and desist from manufacturing, selling, marketing, using, and importing its lateral flow products in Germany.

The Company is also aware of Inverness's active participation in suing other third parties for patent infringement on the basis that it allegedly owns, or has an exclusive license to, patent rights covering aspects of current lateral flow technology. The Company believes that it has various defenses to claims that have been made or might be made, but no assurances can be given that the Company will prevail. Because of the Company's current use of lateral flow technology and the fact that a substantial majority of its revenues are from products impacted by these disputes, the Company's business would be materially and adversely affected if it is unable to successfully prosecute and/or defend against any such patent infringement allegations or to obtain a commercially reasonable license from Inverness.

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, intellectual property, product liability, environmental and other litigation, required patent license fee payments not currently reflected in our costs, seasonality, the length and severity of cold and flu seasons, 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 (the "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 Securities and Exchange Commission (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. We undertake no obligation to publicly release the results of any revision of these forward-looking statements.

Overview

We are a worldwide leader in developing, manufacturing and marketing point-of-care ("POC") rapid diagnostic tests for the detection and management of a variety of medical conditions and illnesses. Our current product areas include pregnancy, infectious diseases, autoimmune diseases, osteoporosis and urinalysis, for professional and research use. In the U.S., we lead the professional market in several POC product categories for sales through medical product distributors. This leadership position includes an estimated 50%, 49% and 43% professional market share in influenza, pregnancy and Group A Strep products, respectively, as of March 31, 2004. Our products provide healthcare professionals with accurate and cost-effective diagnostic information at the POC. We sell our products to professionals for use in physician offices, hospitals, clinical laboratories and wellness screening centers. We focus our products substantially on women's and family health in areas such as reproduction, infectious diseases, general health screening and diseases associated with the elderly.

We commenced our operations in 1979 and launched our first products, dipstick-based pregnancy tests, in 1984. Our product base and technology platforms have expanded through internal development and acquisitions of other products and technologies.

We market our products in the U.S. through a network of national and regional distributors, supported by a direct sales force. In the rest of the world, we sell and market through distributors in Asia-Pacific, Europe, the Middle East, Africa and Latin America and in other international locations by channeling products through distributor organizations and sales agents.

Results of Operations

Net Sales

Net sales decreased 25% to $13.7 million for the three months ended June 30, 2004 from $18.3 million for the three months ended June 30, 2003 and decreased 22% to $32.8 million for the six months ended June 30, 2004 from $42.3 million for the six months ended June 30, 2003. The decrease for the three months ended June 30, 2004 as compared to the three months ended June 30, 2003 was, we believe, primarily due to our sales being adversely impacted by a drop off in orders for Strep A test products as a result of distributor confusion or concern created by ongoing intellectual property litigation. In addition, we did not receive an expected order from one of our domestic distributors for our new influenza A+B product and the launch of our influenza A+B product in Japan was delayed. The decrease for the six months ended June 30, 2004 as compared to the six months ended June 30, 2003 was primarily the result of a weak flu season in Japan as well as the factors noted above in the second quarter.

Distribution Developments and Trends

Our sales estimates for future periods are closely based on estimated end-user demand for our products. Sales to our distribution partners would fall short of expectations if distributor inventories increase because of less than estimated end-user consumption or if distributor concerns over the

intellectual property litigation increase. A significant portion of our international sales includes sales of our influenza tests through our distribution partner in Japan. Due to a weak flu season in Japan which ended abruptly in the first quarter of 2004, our Japanese distributor has significant quantities of our influenza A/B test in its distribution channel. Given current estimates of these quantities, we believe that the launch of our new influenza A+B test in Japan will be delayed until the fourth quarter of 2004 after the sale of the remaining influenza A/B product.

Research Contracts, License Fees and Royalty Income

Research contracts, license fees and royalty income increased to $0.6 million for the three months ended June 30, 2004 from $0.5 million for the three months ended June 30, 2003 and increased to $1.2 million for the six months ended June 30, 2004 from $1.0 million for the six months ended June 30, 2003. The revenue for all periods principally relates to royalties received on our patented technologies utilized by third parties. The agreement covering these royalty payments extends through November 2009, the expiration date of the patents. For the three months ended June 30, 2004, we also recognized $0.2 million of contract revenue for milestone achievments related to a joint development agreement entered into during the period.

Cost of Sales and Gross Profit From Net Sales

Gross profit decreased to $6.3 million for the three months ended June 30, 2004 from $9.0 million for the three months ended June 30, 2003 and decreased to $16.0 million for the six months ended June 30, 2004 from $21.8 million for the six months ended June 30, 2003. Gross profit as a percentage of net sales decreased to 46% for the three months ended June 30, 2004 from 49% for the three months ended June 30, 2003 and decreased to 49% for the six months ended June 30, 2004 from 52% for the six months ended June 30, 2003. The decreases for both the three and six months ended June 30, 2004 as compared to the three and six months ended June 30, 2003 were primarily due to lower sales of our Strep A and higher margin influenza tests and a less favorable product mix, partially offset by cost savings relating to our restructuring activities during 2003.

Research and Development Expense

Research and development expense increased to $2.9 million for the three months ended June 30, 2004 from $1.9 million for the three months ended June 30, 2003 and increased to $5.4 million for the six months ended June 30, 2004 from $4.3 million for the six months ended June 30, 2003. Research and development expense as a percentage of net sales increased to 21% for the three months ended June 30, 2004 from 10% for the three months ended June 30, 2003 and increased to 17% for the six months ended June 30, 2004 from 10% for the six months ended June 30, 2003. The absolute dollar increases for both the three and six months ended June 30, 2004 as compared to the three and six months ended June 30, 2003 were primarily due to additional employees and project supplies related to our continued focus on our LTF ("Layered Thin Film") technology, partially offset by cost savings relating to our restructuring activities during 2003. We believe that the LTF immunoassay feasibility will be completed during 2004.

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 decreased to $3.6 million for the three months ended June 30, 2004 from $4.4 million for the three months ended June 30, 2003 and to $7.3 million for the six months ended June 30, 2004 from $8.9 million for the six months ended June 30, 2003. Sales and marketing expense as a percentage of net sales increased to 26% for the three months ended June 30, 2004 from

24% for the three months ended June 30, 2003 and increased to 22% for the six months ended June 30, 2004 from 21% for the six months ended June 30, 2003. The absolute dollar decreases for both the three and six months ended June 30, 2004 as compared to the three and six months ended June 30, 2003 were primarily due to cost savings relating to our restructuring activities during 2003, including the closure of our sales and support offices in Germany and Italy.

General and Administrative Expense

General and administrative expense increased to $3.8 million for the three months ended June 30, 2004 from $2.4 million for the three months ended June 30, 2003 and increased to $6.6 million for the six months ended June 30, 2004 from $5.2 million for the six months ended June 30, 2003. General and administrative expense as a percentage of net sales increased to 28% for the three months ended June 30, 2004 from 13% for the three months ended June 30, 2003 and increased to 20% for the six months ended June 30, 2004 from 12% for the six months ended June 30, 2003. The absolute dollar increases for both the three and six months ended June 30, 2004 were primarily due to increased legal fees associated with our intellectual property litigation, partially offset by higher professional fees during 2003 related to the re-audit of our fiscal 2001 financial statements and certain tax consulting projects and by cost savings relating to our restructuring activities during 2003.

Amortization of Intangibles

On January 1, 2002, we adopted SFAS No. 141, "Business Combinations," ("SFAS No. 141") and SFAS No. 142, "Goodwill and Other Intangible Assets" ("SFAS No. 142,") which eliminated the amortization of goodwill. SFAS No. 142 also requires periodic evaluations for impairment of goodwill balances. We completed our annual evaluation for impairment of goodwill in December 2003, and determined that there was no impairment as of December 31, 2003. A significant decline in our projected revenue or earnings growth or cash flows, a significant decline in our stock price or the stock price of comparable companies, loss of legal ownership or title to an asset, and any significant change in our strategic business objectives and utilization of our assets are among many factors that could result in an impairment charge that could have a material negative impact on our operating results. Our revenues and related earnings were adversely impacted for the six months ended June 30, 2004 as compared to the six months ended June 30, 2003. We believe this was primarily due to our sales being adversely impacted by a drop off in orders for Strep A test products as a result of distributor confusion or concern created by ongoing intellectual property litigation. In addition, we did not receive an expected order from one of our domestic distributors for our new influenza A+B product, there was a weak flu season in Japan, and the launch of our influenza A+B product in Japan was delayed. We believe the revenue decline relating to influenza sales was seasonal in nature and the revenue decline relating to Strep A test sales was primarily related to short-term distributor confusion or concern created by ongoing intellectual property litigation and we do not believe there was any impairment as of June 30, 2004. Our other intangible assets, which are being amortized over a period of three to 12 years, include purchased technology, license agreements, patents, trademarks and a favorable lease.

Amortization of intangibles was $0.5 million for both the three months ended June 30, 2004 and 2003 and $1.0 million for both the six months ended June 30, 2004 and 2003.

Other Income and Expense

Other income was $0.1 million for the three months ended June 30, 2004 compared to other expense of $0.2 million for the three months ended June 30, 2003 and other expense decreased to $0.1 million for the six months ended June 30, 2004 from $0.3 million for the six months ended June 30, 2003. The activity for the three months ended June 30, 2004 includes receipt of a one-time payment of $0.1 million related to the sale of our allergy business. The balance for all periods primarily

relates to interest expense paid on obligations under capital leases, which are primarily related to our San Diego facility, partially offset by interest income associated with an increased cash balance.

Income Taxes

Income tax benefit was $1.6 million for the three months ended June 30, 2004 as compared to $0.3 million for the three months ended June 30, 2003 and income tax benefit was $1.4 million for the six months ended June 30, 2004 as compared to an income tax provision of $0.9 million for the six months ended June 30, 2003.

Liquidity and Capital Resources

Our principal source of liquidity has historically been cash flow from operations. Our principal requirements for cash currently are for the funding of operations and capital expenditures.

At June 30, 2004, we had cash and cash equivalents of approximately $35.3 million compared to $25.6 million at December 31, 2003.

The net increase in cash and cash equivalents for the six months ended June 30, 2004 was $9.6 million, the significant components of which are discussed below. The cash generated from operating activities of $6.7 million is largely comprised of our net loss of $3.4 million, non-cash expenses of $3.2 million related to depreciation and amortization and a decrease in accounts receivables of $16.0 million, partially offset by increases in inventories of $2.7 million and decreases in accounts payable, accrued royalties and other accrued liabilities of $0.6 million, $2.7 million and $3.0 million, respectively. Another source of cash during the period was $5.5 million in proceeds from issuance of common stock in connection with our employee stock purchase plan and the exercise of outstanding options under our stock option plans. Our primary uses of cash for the six months ended June 30, 2004 were acquisitions of manufacturing equipment related to our LTF product line and assets related to information technology of $2.5 million, as well as payments on obligations under capital leases totaling $0.3 million.

We have a $10 million term loan facility which matures in 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 matured in July 2004. At our request, the line of credit has been extended for a period of 90 days while we negotiate the terms of a new credit facility. At our option, the current credit facility 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 agreements governing our line of credit and term loan facilities contain 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 June 30, 2004, there were no borrowings outstanding under either the line of credit or the term loan. As of June 30, 2004, we had $10 million of availability both under the line of credit and term loan, and we were in compliance with all covenants.

We currently have planned approximately $3.6 million in capital expenditures for the remainder of 2004. The primary purpose for our capital expenditures is to acquire manufacturing equipment and information technology. We plan to fund these capital expenditures with cash flow from operations. We have approximately $1.4 million of firm purchase commitments with respect to such planned expenditures as of the date of this filing. These commitments largely relate to manufacturing equipment for our LTF product line.

We also intend to continue evaluation of acquisition and technology licensing candidates. As such, we may need to incur additional debt, or sell additional equity, to successfully complete these

acquisitions. Cash requirements fluctuate as a result of numerous factors, such as the extent to which we generate cash from 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 12 months.

Off-Balance Sheet Arrangements

At June 30, 2004 and December 31, 2003, we did not have any other relationships with unconsolidated entities or financial partners, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in such relationships.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. 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 revenues from product sales. These revenues are recorded net of rebates and other discounts which are estimated at the time of sale, and are largely driven by various customer program offerings, including special pricing agreements, promotions and other volume-based incentives. 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 FOB destination and at the time of shipment when the sales terms are FOB shipping point. We also earn income from the licensing of technology and earn income for performing services under joint development agreements. Royalty income from the grant of license rights is recorded during the period the cash is received from the licensee. Milestone payments are recognized when earned, as evidenced by written acknowledgment from the collaborator or other persuasive evidence that the milestone has been achieved, provided that (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement, and (ii) our performance obligations after the milestone achievement will continue to be funded by the collaborator at a level comparable to before the milestone achievement. If both of these criteria are not met, the milestone payment is recognized over the remaining minimum period of our performance obligations under the agreement. Income earned from licensing and distribution activities are classified under revenues in the accompanying consolidated statements of operations.

We maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. Our allowance for doubtful accounts is based on our

assessment of the collectibility of specific customer accounts, the aging of accounts receivable, our history of bad debts, and the general condition of the industry. If a major customer's credit worthiness deteriorates, or our customers' actual defaults exceed our historical experience, our estimates could change and adversely impact our reported results.

Our policy is to value inventories at the lower of cost or market on a part-by-part basis. This policy requires us to make estimates regarding the market value of our inventories, including an assessment of excess or obsolete inventories. We determine excess and obsolete inventories based on an estimate of the future demand for our products within a specified time horizon, generally 12 months. The estimates we use for demand are also used for near-term capacity planning and inventory purchasing and are consistent with our revenue forecasts. If our demand forecast is greater than our actual demand, we may be required to take additional excess inventory charges, which would decrease gross margin and adversely impact net operating results in the future.

Intangible assets with definite lives are amortized over their estimated useful lives. Useful lives are based on the expected number of years the asset will generate revenue or otherwise be used by us. On January 1, 2002, we adopted SFAS No. 142, which requires that goodwill and other intangible assets that have indefinite lives not be amortized but instead be tested at least annually for impairment, or more frequently when events or changes in circumstances indicate that the asset might be impaired. Examples of such events or circumstances include:

- 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 an asset;
- significant changes in our strategic business objectives and utilization of our assets; and
- the impact of significant negative industry or economic trends.

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.

For indefinite-lived intangible assets, impairment is tested by comparing the carrying value of the assets to the fair value of the reporting unit to which they are assigned. For goodwill, a two-step test is used to identify the potential impairment and to measure the amount of impairment, if any. The first step is to compare the fair value of a reporting unit with its carrying amount, including goodwill. If the fair value of a reporting unit exceeds its carrying amount, goodwill is considered not impaired; otherwise, goodwill is impaired and the loss is measured by performing step two. Under step two, the impairment loss is measured by comparing the implied fair value of the reporting unit with the carrying amount of goodwill. We completed our annual evaluation for impairment of goodwill in December 2003, and have also determined there was no impairment as of June 30, 2004.

A valuation allowance of $13.3 million had been established against a portion of our deferred tax assets at December 31, 2002. As of December 31, 2003, we believed it was more likely than not that we would be able to realize the majority of our deferred tax asset through expected future taxable profits, and released approximately $13.3 million of the valuation allowance in the fourth quarter of 2003. As of June 30, 2004, we recorded a valuation allowance of $1.9 million related to deferred tax assets created by the exercise and/or disposition of employee stock options in recent periods. Any tax benefits realized from the reduction of this valuation allowance will be recorded to additional paid-in capital. As of June 30, 2004, we assessed our deferred tax asset. While our revenues and related earnings for the six months ended June 30, 2004 were lower than expected, we do not believe a valuation allowance is necessary. We will continue to assess our deferred tax asset in the third and fourth quarters of 2004. We may propose a valuation allowance if we determine our future earnings, among other factors, do not support our deferred tax asset. Should we determine that we would not be able to realize all or part of our other components of the 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. As of June 30, 2004, we had $13.6 million in net deferred tax assets.

We also reserve for taxes that may become payable as a result of audits in future periods with respect to previously filed tax returns. We establish the reserves based on our assessment of exposure associated with permanent tax differences, tax credits and interest expense applied to temporary difference adjustments. The tax reserves are analyzed periodically and adjustments are made as events occur to warrant adjustment to the reserve.

RISK FACTORS

Risks Related to Our Business

We are involved in pending, and may become involved in future, intellectual property infringement disputes, which are costly and could limit or eliminate our ability to use certain of our core technologies in the future and sell our products.

There are a large number of patents and patent applications in our product areas, and we believe, based on experience and published reports, that additional patents may issue to third parties relating to our product areas, and that litigation in our industry regarding patent and other intellectual property rights is prevalent and will continue.

On February 20, 2004, we filed a lawsuit (the "Action") in the U.S. District Court, Southern District of California (the "Court") against Inverness Medical Innovations, Inc., Inverness Medical Switzerland GmbH, and Applied Biotech, Inc. (collectively "Inverness"), as well as against Armkel LLC, for infringement of our U.S. Patent No. 4,943,522 (the "522 Patent"), which relates to lateral-flow technology, and for declaratory relief. We are seeking damages and injunctive relief against Inverness products that infringe our patented technology. Our claim for declaratory relief relates to nine Inverness-owned and Inverness-licensed patents (U.S. Patent Nos. 6,485,982: 5,989,921; 5,714,389; 6,352,862; 6,228,660; 6,187,598; 5,656,503; 5,622,871; and 5,602,040), and requests the Court to conclude that our lateral-flow products do not infringe these patents, and that the patents are invalid and unenforceable.

On March 9, 2004, Inverness and a related party filed, in the U.S. District Court, Southern District of California, denials of our allegations of infringement in the Action, allegations that our "522 Patent is invalid and unenforceable, as well as counterclaims for patent infringement against us. On March 12, 2004, Armkel LLC filed, in the U.S. District Court, Southern District of California, an answer to our request for declaratory relief and counterclaims for patent infringement against us. The counterclaims by Inverness and the related parties and by Armkel LLC allege that our immunoassay test products, including our tests for influenza, pregnancy, strep, and H pylori, infringe eight of the nine Inverness patents that we identified in the Action. In addition, Inverness Medical Switzerland GmbH, Wampole Laboratories, LLC, and Applied BioTech, Inc. filed a separate complaint against us alleging that our immunoassay test devices also infringe a ninth patent owned by Inverness, U.S. Patent No. 6,534,320. The relief requested in these claims and counterclaims against us includes damages and preliminary and permanent injunctive relief to the effect that if this relief is granted, we would be required to cease and desist from manufacturing, selling, marketing, using, and inducing others to use products that represent a substantial majority of our revenues.

On May 6, 2004, we filed responses to Inverness' claims and counterclaims, and filed claims for declaratory relief that three additional Inverness-owned patents (U.S. Patents Nos. 5,120,643; 5,578,577; and 4,956,302) are not infringed by our lateral flow products and are invalid and unenforceable. On June 8, 2004, Inverness filed a motion to dismiss our claims for declaratory relief. The motion is currently pending.

From May 17-20, 2004, the Court began conducting a Markman hearing regarding four of the patents at issue in the Action. The Court construed terms in Inverness U.S. Patent No. 6,485,982, and construed one term of our "522 Patent. The Markman hearing continued on July 27-28, 2004, and the Court construed additional terms of our "522 Patent. The Markman hearing will continue in the future to interpret remaining terms of our "522 Patent and other patents.

On February 17, 2004, our German affiliate Quidel Deutschland GmbH was provided with a copy of a lawsuit that Inverness Medical Switzerland GmbH, another Inverness subsidiary, and Preymed had apparently filed on or about February 4, 2004 in District Court in Düsseldorf, Germany, which names us, Quidel Deutschland GmbH, and our distributor, Progen Biotechnik GmbH, as defendants. The

lawsuit alleges that we and the other defendants are infringing two Inverness-owned European patents, EP 0 291 194 and EP 0 560 411, and is directed at our lateral flow test devices, including our tests for pregnancy, strep, H pylori, and Chlamydia. The suit seeks injunctive relief, an accounting, damages and annulment. If the Court grants injunctive relief, we will be required to cease and desist from manufacturing, selling, marketing, using, and importing our lateral flow products in Germany.

We are also aware of Inverness's active participation in suing other third parties for patent infringement on the basis that it allegedly owns, or has an exclusive license to, patent rights covering aspects of current lateral flow technology. We believe that we have various defenses to claims that have been made or might be made, but no assurances can be given that we will prevail. Because of our current use of lateral flow technology and the fact that a substantial majority of our revenues are from products impacted by these disputes, our business would be materially and adversely affected if we are unable to successfully prosecute and/or defend against any such patent infringement allegations or to obtain a commercially reasonable license from Inverness.

In addition, and as separate matters, two other industry participants have sent us letters during the third quarter of 2003 and the first quarter of 2004 suggesting that we obtain a sublicense to patents for which they are a licensee, with royalty amounts to be negotiated. We do not currently believe we will be required to pay royalties to these industry participants or other owners of intellectual property with a resulting material increase in our product cost, and an adverse effect on our profits; however, no assurance can be given that we would be able to obtain any license to third-party intellectual property under commercially reasonable terms, if at all.

As a more general matter, our involvement in litigation to determine rights in proprietary technology could adversely affect our net sales and business because:

- as is common with major litigation, it would likely consume a substantial portion of managerial and financial resources;
- its outcome would be uncertain and a court may find the third-party patent claims valid and infringed by our products;
- an adverse outcome could subject us to significant liability in the form of past royalty payments, penalties, special and punitive damages, or future royalty payments significantly 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
- a court could award a preliminary and/or permanent injunction which would prevent us from selling our current or future products.

Our operating results may fluctuate adversely as a result of many factors that are outside our control.

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. For example, total revenues decreased 22% to $32.8 million for the six months ended June 30, 2004, as compared to $42.3 million for the six months ended June 30, 2003. We believe this was primarily due to our sales being adversely impacted by a drop off in orders for Strep A test products as a result of distributor confusion or concern created by ongoing intellectual property litigation. In addition, we did not receive an expected order from one of our domestic distributors for our new influenza A+B product, there was a weak flu season in Japan, and the launch of our influenza A+B product in Japan was delayed. Our sales estimates for future periods are closely based on estimated end-user demand for our products. Sales to our distribution partners would fall short of expectations if distributor inventories increase because of less than estimated end-user consumption or if distribution concerns over the

intellectual property litigation increase. A significant portion of our international sales includes sales of our influenza tests through our distribution partner in Japan. Due to a weak flu season in Japan, which ended abruptly in the first quarter of 2004, our Japanese distributor has significant quantities of our influenza A/B test in its distribution channel. Given current estimates of these quantities, we believe that the launch of our new influenza A+B test in Japan will be delayed until the fourth quarter of 2004 after the sale of the remaining influenza A/B product.

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 quarters and higher operating results in the first and fourth calendar quarters;
- the length and severity of the influenza and strep seasons;
- changes in the level of competition, such as would occur if one of our larger and better financed competitors introduced a new or lower priced 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;
- 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 not reduce costs by the same proportion, and hence could cause operating losses;
- significant quantities of our product in our distributors inventories or distribution channels; and
- changes in distributor buying patterns.

In order to remain competitive and profitable, we must expend considerable resources to introduce new products and develop new markets. Our failure to successfully introduce new technologies, new products and develop new markets could have a material adverse effect on our business and prospects.

We devote a significant amount of financial resources to researching and developing new technologies, new products and new markets. The development, manufacture and sale of diagnostic products require a significant investment of resources. Moreover, no assurances can be given that our efforts to develop new technologies or products, including our efforts relating to the LTF technology platform and migration of products to that platform, will be successful. The development of new markets also requires a substantial investment of resources, such as new employees, offices and manufacturing facilities. As a result, we are likely to 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 other third parties; 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. Similarly, if adequate financial, personnel, equipment or real estate resources are not available, we may be required to delay or scale back market developments. Our operations will be adversely affected if our net sales and gross profits do not correspondingly increase or if our product and market development efforts are unsuccessful or delayed. Furthermore, our failure to successfully introduce new products and develop new markets could have a material adverse effect on our business and prospects.

We rely on a limited number of key distributors which account for over half of our net sales. The loss of any key distributor 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. Four of our distributors, which are considered to be among the market leaders, accounted for approximately 46% and 49% of our net sales for the six months ended June 30, 2004 and 2003, respectively. 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, some 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. If net sales to these or any of our other significant distributors were to decrease in any material amount in the future, our business, operating results and financial condition could be materially and adversely affected.

As an alternative, we could expand our efforts to distribute and market our products directly. This, however, would require substantial 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, because we do not have experience in direct distribution and marketing, our direct distribution efforts may not be successful. If we were to make the substantial investment to directly distribute and market our products and were unsuccessful, our net sales and profits could be materially and adversely affected.

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. Clinical reference laboratories and hospital-based laboratories are significant competitors for our products and provide a majority of the diagnostic tests used by physicians and other healthcare providers. Our future sales depend on, among other matters, capture of sales from these laboratories by achieving market acceptance of POC testing 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 against our POC diagnostic products in order to maintain and expand their existing dominance of the overall diagnostic 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 to POC tests. Our failure to achieve market acceptance from physicians and healthcare providers with respect to the use of our POC diagnostic products would have a negative effect on our future sales growth.

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. As of March 31, 2004, our estimated U.S. professional market share

for some of our key POC products was 50% in influenza, 49% for pregnancy and 43% for Group A Strep tests. There are, however, a large number of multinational and regional competitors making investments in competing technologies and products, including several large pharmaceutical and diversified healthcare companies. These competitors include Beckman Coulter Primary Care Diagnostics, Becton, Dickinson and Company, Genzyme Diagnostics Corporation and Inverness. We also face competition from our distributors since some have created, and others may decide to create, their own products to compete with ours. 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 acquire market share from our products through more effective marketing or competitive pricing, 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 own 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.

Our ability to obtain patents and licenses, and their benefits, is uncertain. We have 242 issued patents and approximately 59 patent applications pending. Our patents have expiration dates ranging from 2004 to 2020 and 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 Australia, Austria, Belgium, Canada, France, Germany, Italy, Japan, Korea, Lithuania, The Netherlands, Norway, Spain, South Africa, Sweden, Switzerland and the United Kingdom. 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 and required to produce our products on commercially reasonable terms.

Our products are highly regulated by various governmental agencies. Any changes to the existing laws and regulations may adversely impact our ability to manufacture and market our products.

The testing, manufacture and sale of our products are subject to regulation by numerous governmental authorities in the U.S., principally the FDA and corresponding state and foreign regulatory agencies. The FDA regulates most of our products, which are all Class I or II devices. The U.S. Department of Agriculture regulates our veterinary products. 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. Regulatory approval 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 our products.

Furthermore, in the ordinary course of business, we must frequently make subjective judgments with respect to compliance with applicable laws and regulations. If regulators subsequently disagree with the manner in which we have sought to comply with these regulations, we could be subjected to substantial civil and criminal penalties, as well as product recall, seizure or injunction with respect to the sale of our products. The assessment of any civil and criminal penalties against us could severely impair our reputation within the industry and any limitation on our ability to manufacture and market our products could have a material adverse effect on our business.

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 or laws regulating any of our businesses are added, the costs of compliance with these laws could substantially increase our costs. 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. 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 but not limited to chemicals and biological materials such as dimethyl sulfate, sodium nitrite, acetaldehyde, acrylamide, potassium bromate and radionuclides. 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 already 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 additional, and possibly 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 sizeable fines, penalties or damages in the event of noncompliance with environmental laws. Any environmental violation or remediation requirement could also partially or completely shut down our research and manufacturing facilities and operations, which would have a material adverse effect on our business. The risk of accidental contamination or injury from these hazardous materials cannot be completely eliminated and exposure of individuals to these materials could result in substantial fines, penalties or damages as well.

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

The end-users of our products are primarily physicians and other healthcare providers. Use of our products would be adversely impacted if physicians do not receive reimbursement for the cost of our products by their patients' healthcare insurers or payors. Our net sales could also 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 who 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. 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.

Unexpected 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 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 adversely 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 and profitability.

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. Some raw materials require significant ordering lead time and some are currently obtained from a sole supplier or a limited group of suppliers. We have long-term supply agreements with these suppliers, but these long-term agreements involve risks for us, such as our potential inability to obtain an adequate supply of raw materials and components and our reduced control over pricing, quality and timely delivery. It is also possible that one or more of these suppliers may become unwilling or unable to deliver materials to us. Any shortfall in our supply of raw materials and components, and our inability to obtain alternative sources for this supply, could have a material adverse effect on our net sales or cost of sales.

Our inability to meet customer demand for our products, whether as a result of manufacturing problems or supply shortfalls, could harm our customer relationships and impair our reputation within the industry. This, in turn, could have a material adverse effect on our business and prospects.

If one of our products proves to be defective, we could be subject to claims of liability that could adversely affect our business.

A defect in the design or manufacture of our products could have a material adverse effect on our reputation in the industry and subject us to claims of liability for injuries and otherwise. Any substantial underinsured loss resulting from such a claim would have a material adverse effect on our profitability and the damage to our reputation in the industry could have a material adverse effect on our business.

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

Our business strategy contemplates further growth in 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 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

have a relatively small executive staff, future growth may also divert management's attention from other aspects of our business, and will place a strain on existing management and 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 San Diego and Santa Clara where our headquarters and the majority of our operations are located. In addition, we expect to further grow our operations, and our needs for additional management and other key personnel may increase. If we are not able to retain existing key personnel, or identify and hire additional qualified personnel to meet expected growth, our business could be negatively impacted.

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

Claims may be made against us for types of damages, or for amounts of damages, that are not covered by our insurance. For example, although we currently carry product liability insurance for liability losses, there is a risk that product liability 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 currently in effect, or may not be renewed at all. If we are held liable for a claim against which we are not insured 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 adverse effect on our results of operations and profitability.

We face risks relating to our international sales and foreign operation, 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. We currently sell and market through distributors in Asia-Pacific, Europe, the Middle East, Africa and Latin America and in other international locations by channeling products through distributor organizations and sales agents. Sales to foreign customers accounted for approximately 30% and 42% of our net sales for the six months ended June 30, 2004 and 2003, respectively, and are expected to continue to account for a significant percentage of our net sales. We also manufacture our urinalysis products in Marburg, Germany. International sales and manufacturing operations are subject to inherent economic, political and regulatory risks, which could increase our operating costs, result in shipment delays and impede our international growth. These foreign risks include:

- exposure to currency exchange fluctuations, such as the 4% decrease in the value of the Euro against the U.S. dollar for the six months ended June 30, 2004 and the 20% increase in the value of the Euro against the U.S. dollar for the year ended December 31, 2003;

- longer payment cycles and greater difficulty in accounts receivable collection;

- compliance with new and changing registration requirements, tariffs or other barriers as we continue to expand into new countries and geographic regions;

- reduced protection for, and enforcement of, intellectual property rights, particularly as we seek to expand our international business beyond Europe and Japan;
- 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. In order to maintain a competitive price for our products in Europe and Japan, we may have to provide discounts or otherwise effectively reduce our prices, resulting in a lower margin on products sold in these geographical territories. Continued change in the values of the Euro and other foreign currencies could have a negative impact on our business, financial condition and results of operations. We do not currently hedge against exchange rate fluctuations, which means that we will be fully exposed to exchange rate losses.

Risks Related to Our Common Stock

Our stock price has been highly volatile, and an investment in our stock could suffer a significant decline in value, adversely affecting the value of those shares.

The market price of our common stock has been highly volatile and has fluctuated substantially in the past. For example, between June 30, 2003 and June 30, 2004, the price of our common stock, as reported on the Nasdaq National Market System, has ranged from a low of $5.05 to a high of $13.98. We expect our common stock to continue to be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- litigation or threat of litigation;
- 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 quarters 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 or lower priced 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;
- 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 not reduce costs by the same proportion, and hence could cause operating losses;
- declines in orders from major distributors as a result of lower than expected end-user demand, whether as a result of a light cold and flu season or otherwise;
- our failure to achieve, or changes in, financial estimates by securities analysts and comments or opinions about us by securities analysts or major stockholders;
- additions or departures of our key personnel;
- sales of our common stock and limited daily trading volume; and

economic and other external factors, disasters or crises.

In addition, the stock market in general, and the Nasdaq National Market System and the market for technology companies in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of the relevant companies. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. A securities class action suit against us could result in substantial costs, potential liabilities and the diversion of management's attention and resources.

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 common stock. As of June 30, 2004:

- Approximately 31.6 million shares of our common stock had been issued in registered offerings and are freely tradable in the public markets.

- In addition, approximately 4.0 million shares of our common stock were issuable upon exercise of stock options outstanding as of June 30, 2004 under our various stock option plans at a weighted average exercise price of $5.05 per share.

- We had in effect registration statements under the Securities Act of 1933 registering approximately 6.1 million shares of common stock reserved under our stock option and employee stock purchase plans.

We are unable to estimate the number of shares of our common stock that may actually be resold in the public market since this will depend on the market price for our 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 one or more of 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 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to the risk of future currency exchange rate fluctuations, which are accounted for as an adjustment to stockholders' equity. Exchange gains and losses arising from transactions denominated in foreign currencies are recorded in operations and have historically not been material. Nonetheless, 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 we report, and such effect may be material in any individual reporting period.

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. A hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would not materially affect the fair value of our interest-sensitive financial instruments at June 30, 2004. Based on our market risk sensitive instruments outstanding at June 30, 2004, and December 31, 2003, we have determined that there was no material market risk exposure to our consolidated financial position, results of operations or cash flows as of such dates.

ITEM 4. Controls and Procedures

As of the end of the period covered by this quarterly report on Form 10-Q, 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-15 or 15d-15. Based on 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 were no changes in our internal control over financial reporting during the period covered by this quarterly report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1. Legal Proceedings

On February 20, 2004, we filed the Action in the U.S. District Court, Southern District of California against Inverness, as well as against Armkel LLC, for infringement of our "522 Patent, which relates to lateral-flow technology, and for declaratory relief. We are seeking damages and injunctive relief against Inverness products that infringe our patented technology. Our claim for declaratory relief relates to nine Inverness-owned and Inverness-licensed patents (U.S. Patent Nos. 6,485,982: 5,989,921; 5,714,389; 6,352,862; 6,228,660; 6,187,598; 5,656,503; 5,622,871; and 5,602,040), and requests the Court to conclude that our lateral-flow products do not infringe these patents, and that the patents are invalid and unenforceable.

On March 9, 2004, Inverness and a related party filed, in the U.S. District Court, Southern District of California, denials of our allegations of infringement in the Action, allegations that our "522 Patent is invalid and unenforceable, as well as counterclaims for patent infringement against us. On March 12, 2004, Armkel LLC filed, in the U.S. District Court, Southern District of California, an answer to our request for declaratory relief and counterclaims for patent infringement against us. The counterclaims by Inverness and the related parties and by Armkel LLC allege that our immunoassay test products, including our tests for influenza, pregnancy, strep, and H pylori, infringe eight of the nine Inverness patents that we identified in the Action. In addition, Inverness Medical Switzerland GmbH, Wampole Laboratories, LLC, and Applied BioTech, Inc. filed a separate complaint against us alleging that our immunoassay test devices also infringe a ninth patent owned by Inverness, U.S. Patent No. 6,534,320. The relief requested in these claims and counterclaims against us includes damages and preliminary and permanent injunctive relief to the effect that if this relief is granted, we would be required to cease and desist from manufacturing, selling, marketing, using, and inducing others to use products that represent a substantial majority of our revenues.

On May 6, 2004, we filed responses to Inverness' claims and counterclaims, and filed claims for declaratory relief that three additional Inverness-owned patents (U.S. Patents Nos. 5,120,643; 5,578,577; and 4,956,302) are not infringed by our lateral flow products and are invalid and unenforceable. On June 8, 2004, Inverness filed a motion to dismiss our claims for declaratory relief. The motion is currently pending.

From May 17-20, 2004, the Court began conducting a Markman hearing regarding four of the patents at issue in the Action. The Court construed terms in Inverness U.S. Patent No. 6,485,982, and construed one term of our "522 Patent. The Markman hearing continued on July 27-28, 2004, and the Court construed additional terms of our '522 Patent. The Markman hearing will continue in the future to interpret remaining terms of our "522 Patent and other patents.

On February 17, 2004, our German affiliate Quidel Deutschland GmbH was provided with a copy of a lawsuit that Inverness Medical Switzerland GmbH, another Inverness subsidiary, and Preymed had apparently filed on or about February 4, 2004 in District Court in Düsseldorf, Germany, which names us, Quidel Deutschland GmbH, and our distributor, Progen Biotechnik GmbH, as defendants. The

lawsuit alleges that we and the other defendants are infringing two Inverness-owned European patents, EP 0 291 194 and EP 0 560 411, and is directed at our lateral flow test devices, including our tests for pregnancy, strep, H pylori, and Chlamydia. The suit seeks injunctive relief, an accounting, damages and annulment. If the Court grants injunctive relief, we will be required to cease and desist from manufacturing, selling, marketing, using, and importing our lateral flow products in Germany.

We are also aware of Inverness's active participation in suing other third parties for patent infringement on the basis that it allegedly owns, or has an exclusive license to, patent rights covering aspects of current lateral flow technology. We believe that we have various defenses to claims that have been made or might be made, but no assurances can be given that we will prevail. Because of our current use of lateral flow technology and the fact that a substantial portion of our revenues are from products impacted by these disputes, our business would be materially and adversely affected if we are unable to successfully prosecute and/or defend against any such patent infringement allegations or to obtain a commercially reasonable license from Inverness.

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

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Our Annual Meeting of Stockholders was held on May 26, 2004. All of the directors nominated for election as stated in our Proxy Statement were elected as follows:

DIRECTOR NOMINEE	VOTES IN FAVOR	VOTES WITHHELD
Thomas A. Glaze	22,866,713	6,826,435
Douglas S. Harrington, M.D.	28,905,353	787,795
S. Wayne Kay	28,816,053	877,095
Mary Lake Polan, M.D., Ph.D., M.P.H.	28,814,853	878,295
Mark A. Pulido	28,815,553	877,595
Faye Wattleton	28,457,098	1,236,050

In addition, the only other proposal presented at the Annual Meeting, as stated in our Proxy Statement, was approved as follows:

To approve the amendment of the Quidel Corporation 2001 Equity Incentive Plan to increase the number of shares of common stock available for issuance by 2,000,000 shares.

VOTES IN FAVOR	VOTES AGAINST	VOTES ABSTAINING	NON-VOTES
14,449,523	5,395,718	51,225	9,796,682

ITEM 5. OTHER EVENTS

On June 2, 2004 the Company announced that Mark A. Pulido, 51, has been elected non-executive chairman of our board of directors.

On May 26, 2004, Andre dé Bruin retired from our Board of Directors.

On July 13, 2004, the Company announced that S. Wayne Kay, our President, Chief Executive Officer and director, is leaving but currently intends to remain until a successor has been named. In addition, we announced that Mark E. Paiz, previously Senior Vice President, Technology and Business Development, has been promoted to Chief Operating Officer.

On July 19, 2004, Matthew T. Heindel, our Senior Vice President, Global Sales and Marketing, resigned.

ITEM 6. Exhibits and Reports on Form 8-K

(a) Exhibits

Exhibit Number	
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 Registrant'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 Registrant's Current Report on Form 8-K filed on May 29, 2002.)
10.1(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(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.)
10.3(1)	Registrant's 1996 Non-Employee's Director Plan. (Incorporated by reference to Registrant's Proxy Statement filed on September 27, 1996.)
10.4(1)	Registrant's 1998 Stock Incentive Plan. (Incorporated by reference to Registrant's Proxy Statement filed on July 8, 1998.)
10.5(1)	Registrant's Amended and Restated 2001 Equity Incentive Plan. (Incorporated by reference to Appendix A to Registrant's Proxy Statement filed on April 20, 2004.)
10.6(1)	Registrant's General Nonstatutory Stock Option Plan, as amended December 11, 2000 (Incorporated by reference to Exhibit 10.7 to the Registrant's Form 10-K filed on March 31, 2003.).
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	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.)
10.9	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.)
10.10	Rosenstein License Agreement effective April 1, 1997 between the Registrant and Becton Dickinson and Company. (Incorporated by reference to Exhibit 0.20 to the Registrant's Form 10-K for the year ended March 31, 1997.)

10.11(1)	Employment Agreement dated September 9, 1998 between Registrant and André de Bruin. (Incorporated by reference to Exhibit 10.23 to the Registrant's Form 10-Q for the quarter ended September 30, 1998.)
10.12(1)	Stock Option Agreement dated September 9, 1998 between Registrant and André de Bruin. (Incorporated by reference to Exhibit 10.24 to the Registrant's Form 10-Q for the quarter ended September 30, 1998.)
10.13(1)	Amendment No. 1 to the 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.)
10.14(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.)
10.15(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.)
10.16(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.)
10.17(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.)
10.18(1)	Employment Agreement dated as of August 28, 2003 between the Registrant and Matthew T. Heindel. (Incorporated by reference to Exhibit 10.19 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003.)
10.19	Master Revolving Note dated August 29, 2002 by Quidel Corporation in favor of Comerica Bank California. (Incorporated by reference to Exhibit 10.22 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)
10.20	Variable Rate Single Payment Note dated August 29, 2002 by Registrant in favor of Comerica Bank California. (Incorporated by reference to Exhibit 10.23 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)
10.21	Security Agreement dated as of August 29, 2002 between Registrant and Comerica Bank California. (Incorporated by reference to Exhibit 10.24 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)
10.22	Business Loan Agreement dated of August 29, 2002 between Registrant and Comerica Bank California. (Incorporated by reference to Exhibit 10.25 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)
10.23	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.)
10.24	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.)
10.25	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.)

10.26	Form of Indemnification Agreement Corporate Officer and/or Director. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 10-Q for he quarter ended September 30, 2000.)
10.27(1)	Change in Control Agreement dated February 27, 2003 between the Registrant and S. Wayne Kay. (Incorporated by reference to Exhibit 10.32 to the Registrant's Form 10-Q for quarter ended March 31, 2003)
10.28(1)*	Amendment No. 1 to Change in Control agreement dated February 27, 2003 between the Registrant and S. Wayne Kay.
10.29(1)	Change in Control Agreement dated February 28, 2003 between the Registrant and Paul E. Landers. (Incorporated by reference to Exhibit 10.33 to the Registrant's Form 10-Q, period ended March 31, 2003)
10.30(1)*	Amendment No. 1 to Change in Control agreement dated February 28, 2003 between the Registrant and Paul E. Landers.
10.31(1)	Change in Control Agreement dated April 13, 2003 between the Registrant and Mark E. Paiz. (Incorporated by reference to Exhibit 10.34 to the Registrant's 10-Q, March 31, 2003)
10.32(1)*	Amendment No. 1 to Change in Control agreement dated April 13, 2003 between the Registrant and Mark E. Paiz.
10.33(1)	Change in Control Agreement dated as of September 15, 2003 between the Registrant and Matthew T. Heindel. (Incorporated by reference to Exhibit 10.31 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003.)
10.34(1)*	Change in Control Agreement dated July 19, 2004 between the Registrant and Scot M. McLeod.
10.35(1)*	Change in Control Agreement dated July 19, 2004 between the Registrant and Michael J. Beck.
31.1*	Certification by Chief Executive Officer of Registrant pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification by Chief Financial Officer of Registrant pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certifications by Chief Executive Officer and Chief Financial Officer of Registrant pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith.

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

(b) Reports on Form 8-K filed or furnished in the quarter ended June 30, 2004

On April 20, 2004, we furnished a current report on Form 8-K to the Securities and Exchange Commission regarding the issuance of a press release announcing the expected revenues for our first fiscal quarter of 2004 and revised full-year 2004 financial guidance.

On April 30, 2004, we furnished a current report on Form 8-K to the Securities and Exchange Commission regarding the issuance of a press release announcing the financial results for our first fiscal quarter of 2004.

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.

Date: August 9, 2004

QUIDEL CORPORATION

/s/ S. WAYNE KAY

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

/s/ PAUL E. LANDERS

Paul E. Landers
Senior Vice President, Finance and Administration, Chief Financial Officer and Secretary (Principal Financial Officer and Accounting Officer)

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