

QUIDEL CORP /DE/
Form 10-Q
October 26, 2007

[QuickLinks](#) -- Click here to rapidly navigate through this document

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2007

or

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

For the transition period from _____ to _____
Commission File Number: 0-10961

QUIDEL CORPORATION

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

10165 McKellar Court, San Diego, California 92121

(Address of principal executive offices)

94-2573850
(I.R.S. Employer
Identification No.)

(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 No

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

Large accelerated filer Accelerated filer Non-accelerated

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of October 24, 2007, 32,679,222 shares of common stock were outstanding.

INDEX

PART I FINANCIAL INFORMATION	3
ITEM 1. Financial Statements (unaudited)	3
Consolidated Balance Sheets as of September 30, 2007 and December 31, 2006	3
Consolidated Statements of Income for the three and nine months ended September 30, 2007 and 2006	4
Consolidated Statements of Cash Flows for the nine months ended September 30, 2007 and 2006	5
Notes to Consolidated Financial Statements	6
ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	11
ITEM 3. Quantitative and Qualitative Disclosures about Market Risk	19
ITEM 4. Controls and Procedures	19
PART II OTHER INFORMATION	20
ITEM 1. Legal Proceedings	20
ITEM 1A. Risk Factors	20
ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds	20
ITEM 5. Other Information	20
ITEM 6. Exhibits	21
Signatures	22

PART I FINANCIAL INFORMATION

ITEM 1. Financial Statements

QUIDEL CORPORATION
CONSOLIDATED BALANCE SHEETS
(in thousands; unaudited)

	September 30, 2007	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 35,268	\$ 36,625
Accounts receivable, net	16,955	18,139
Inventories	11,608	9,625
Deferred tax asset - current	1,590	1,590
Prepaid expenses and other current assets	1,966	1,690
	<u>67,387</u>	<u>67,669</u>
Total current assets	67,387	67,669
Property, plant and equipment, net	19,386	20,058
Intangible assets, net	15,347	18,797
Deferred tax asset - non-current	17,257	20,065
Other non-current assets	475	459
	<u>119,852</u>	<u>127,048</u>
Total assets	\$ 119,852	\$ 127,048
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,519	\$ 3,832
Payroll and related expenses	4,788	4,868
Accrued royalties	2,316	3,559
Current portion of obligations under capital leases	741	675
Other current liabilities	2,428	1,672
	<u>13,792</u>	<u>14,606</u>
Total current liabilities	13,792	14,606
Capital leases, net of current portion	7,197	7,764
Deferred rent	1,173	1,402
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$.001 par value per share; 5,000 shares authorized, none issued or outstanding at September 30, 2007 and December 31, 2006		
Common stock, \$.001 par value per share; 50,000 shares authorized, 32,679 and 33,530 issued and outstanding at September 30, 2007 and December 31, 2006, respectively	33	33
Additional paid-in capital	143,499	155,357
Accumulated deficit	(45,842)	(52,114)
	<u>97,690</u>	<u>103,276</u>
Total stockholders' equity	97,690	103,276
Total liabilities and stockholders' equity	\$ 119,852	\$ 127,048

See accompanying notes.

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

	Three months ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Revenues	\$ 27,570	\$ 23,720	\$ 80,084	\$ 67,241
Costs and expenses				
Cost of sales (excludes amortization of intangible assets)	11,159	10,344	33,427	29,527
Research and development	3,128	3,126	9,774	9,903
Sales and marketing	4,667	4,080	14,051	12,312
General and administrative	3,546	3,322	10,359	9,547
Amortization of intangibles	1,329	849	4,151	2,979
Total costs and expenses	23,829	21,721	71,762	64,268
Operating income	3,741	1,999	8,322	2,973
Other income (expense)				
Interest income	440	346	1,372	1070
Interest expense	(182)	(188)	(558)	(573)
Other		(14)	(4)	(48)
Total other income	258	144	810	449
Income before taxes	3,999	2,143	9,132	3,422
Provision for income taxes	1,579		3,607	
Net income	\$ 2,420	\$ 2,143	\$ 5,525	\$ 3,422
Basic earnings per share	\$ 0.08	\$ 0.07	\$ 0.17	\$ 0.10
Diluted earnings per share	0.07	0.06	0.17	0.10
Shares used in basic per share calculation	31,784	32,551	32,031	33,060
Shares used in diluted per share calculation	32,762	33,744	33,024	34,400

See accompanying notes.

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

	Nine months ended September 30,	
	2007	2006
OPERATING ACTIVITIES:		
Net income	\$ 5,525	\$ 3,422
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	7,483	6,146
Stock-based compensation expense	3,416	2,535
Deferred income taxes	3,521	
Changes in assets and liabilities:		
Accounts receivable	1,184	516
Inventories	(1,983)	(881)
Prepaid expenses and other current assets	(276)	(228)
Accounts payable	(313)	(959)
Accrued payroll and related expenses	(80)	281
Accrued royalties	(1,243)	(1,222)
Other accrued liabilities	567	(707)
Net cash provided by operating activities	17,801	8,903
INVESTING ACTIVITIES:		
Acquisition of property, plant and equipment	(2,449)	(3,680)
Acquisition of intangibles	(850)	
Other assets	(85)	132
Net cash used for investing activities	(3,384)	(3,548)
FINANCING ACTIVITIES:		
Payments on capital lease obligation	(501)	(495)
Payments to acquire common stock	(17,854)	(11,558)
Proceeds from issuance of stock under stock plans	2,581	2,340
Net cash used for financing activities	(15,774)	(9,713)
Effect of exchange rate changes on cash and cash equivalents		22
Net decrease in cash and cash equivalents	(1,357)	(4,336)
Cash and cash equivalents, beginning of period	36,625	34,930
Cash and cash equivalents, end of period	\$ 35,268	\$ 30,594
Supplemental disclosures of cash flow information:		
Cash paid during the period for interest	\$ 558	\$ 573
Cash paid during the period for income taxes	\$ 294	\$

See accompanying notes.

Quidel Corporation
Notes to Consolidated Financial Statements
(Unaudited)

Note 1. Basis of Presentation

The accompanying unaudited consolidated financial statements of Quidel Corporation and its subsidiaries (the "Company") have been prepared in accordance with generally accepted accounting principles in the U.S. for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the U.S. for complete financial statements. In the opinion of management, all adjustments considered necessary for a fair presentation (consisting of normal recurring accruals) have been included. The information at September 30, 2007, and for the three and nine months ended September 30, 2007 and 2006, is unaudited. Operating results for the three and nine months ended September 30, 2007 are not necessarily indicative of the results that may be expected for the year ending December 31, 2007. For further information, refer to the consolidated financial statements and footnotes thereto for the year ended December 31, 2006 included in the Company's 2006 Annual Report on Form 10-K.

The Company's fiscal quarters end on the Sunday closest to the last day of each calendar quarter. For ease of reference, the calendar quarter end date is used herein. The three and nine month periods ended September 30, 2007 included 13 weeks and 39 weeks, respectively, while the three and nine month periods ended September 30, 2006 included 13 weeks and 38 weeks, respectively.

Reclassification Certain amounts from the prior year have been reclassified to conform to the September 30, 2007 financial statement presentation.

Note 2. Comprehensive Income

The components of comprehensive income are as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Net income	\$ 2,420	\$ 2,143	\$ 5,525	\$ 3,422
Foreign currency translation adjustment		3		22
Comprehensive income	\$ 2,420	\$ 2,146	\$ 5,525	\$ 3,444

Note 3. Computation of Earnings Per Share

Basic earnings per share were computed by dividing net earnings by the weighted-average number of common shares outstanding, including vested restricted stock awards, during the period. Diluted earnings per share reflects the potential dilution that would occur if net earnings were divided by the weighted-average number of common shares and potentially dilutive common shares from outstanding stock options as well as unvested, time-based restricted stock awards. Potentially dilutive common shares were calculated using the treasury stock method and represent incremental shares issuable upon exercise of the Company's outstanding stock options and unvested, time-based restricted stock awards. The Company has awarded restricted stock with both time-based as well as performance-based vesting provisions. Stock awards based on performance only (as of September 30, 2007, 387,481 of performance only stock awards were outstanding) are not included in the calculation of basic or diluted earnings per share until the performance criteria are met. For periods in which the Company incurs losses,

potentially dilutive shares are not considered in the calculation of net loss per share, as their impact would be anti-dilutive. For periods in which the Company has earnings, out-of-the-money stock options (*i.e.*, the average stock price during the period is below the exercise price of the stock option) are not included in diluted earnings per common share as their effect is anti-dilutive.

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 September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Shares used in basic earnings per share (weighted-average common shares outstanding)	31,784	32,551	32,031	33,060
Effect of dilutive stock options and restricted stock awards	978	1,193	993	1,340
Shares used in diluted earnings per share calculation	32,762	33,744	33,024	34,400

Note 4. Inventories

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

	September 30, 2007	December 31, 2006
Raw materials	\$ 5,125	\$ 4,296
Work-in-process	3,348	2,692
Finished goods	3,135	2,637
	\$ 11,608	\$ 9,625

Note 5. Income Taxes

On July 13, 2006, the Financial Accounting Standards Board ("FASB") issued Financial Interpretation No. 48, "*Accounting for Uncertainty in Income Taxes*" ("FIN 48"), which modifies the accounting for uncertainty in income taxes recognized in a company's financial statements in accordance with FASB Statement No. 109, "*Accounting for Income Taxes*." The interpretation prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The interpretation also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

The Company adopted FIN 48 on January 1, 2007 and recognized a cumulative-effect adjustment of \$0.7 million, increasing retained earnings. As of January 1, 2007, the Company had \$6.0 million of unrecognized tax benefits. If recognized, approximately \$4.9 million, net of federal tax benefits, would be recorded as a component of income tax expense. For the nine months ended September 30, 2007, unrecognized tax benefits increased by \$0.1 million. While the Company's interest and penalties related

to unrecognized tax benefits is immaterial, the Company's policy is to recognize such expenses as tax expense.

The Company is subject to periodic audits by domestic and foreign tax authorities. The Company's tax years for 1993 and forward are subject to examination by the U.S. authorities due to the carryforward of unutilized net operating losses and research and development credits. With few exceptions, the Company's tax years for 1999 and forward are subject to examination by state and foreign tax authorities. The Company believes that it has appropriate support for the income tax positions taken on its tax returns and that its accruals for tax liabilities are adequate for all open years based on an assessment of many factors, including past experience and interpretations of tax law applied to the facts of each matter.

Note 6. Line of Credit

The Company amended its \$30.0 million credit facility ("the Senior Credit Facility") as of September 27, 2007. The Company amended the Senior Credit Facility to amend certain material terms as follows: (i) extend the maturity date through June 30, 2009; (ii) eliminate the security interests on the Company's assets; (iii) eliminate covenants regarding earnings before interest, taxes, depreciation and amortization ("EBITDA") and maximum operating lease covenants; (iv) increase the dollar limit for certain permitted acquisitions; and (v) allow for an increase in the amount of shares that the Company may repurchase under its current stock repurchase program. The maximum borrowing permitted under the Senior Credit Facility remained at \$30.0 million and there were no borrowings as of September 30, 2007.

Note 7. Stockholders' Equity

During the nine months ended September 30, 2007, 393,700 shares of restricted stock were awarded, 467,341 shares of common stock were issued due to the exercise of stock options and 21,801 shares of common stock were issued in connection with the Company's employee stock purchase plan ("ESPP"), resulting in proceeds to the Company of approximately \$2.6 million. Additionally, during the nine months ended September 30, 2007, 1,589,143 shares of outstanding common stock were repurchased for approximately \$17.9 million, which primarily consisted of shares repurchased under the Company's share repurchase program, but also included shares repurchased in connection with payment of minimum tax withholding obligations relating to the lapse of restrictions on certain restricted stock awards during the nine months ended September 30, 2007.

Note 8. Stock-Based Compensation

The Company's net income for the three months ended September 30, 2007 and 2006 includes \$1.0 million and \$0.9 million, respectively, of compensation expense related to the Company's stock-based compensation plans. Compensation costs capitalized to inventory and compensation expense related to the Company's ESPP were not material for the three months ended September 30, 2007 and 2006. The compensation expense related to the Company's stock-based compensation plans included in the statement of income for the three months ended September 30, 2007 and 2006 is as follows: cost of sales of \$0.1 million for both periods; research and development of \$0.2 million for both periods; sales

and marketing of \$0.0 and \$0.1 million, respectively; and general and administrative of \$0.7 million and \$0.5 million, respectively.

The Company's net income for the nine months ended September 30, 2007 and 2006 includes \$3.4 million and \$2.5 million, respectively, of compensation expense related to the Company's stock-based compensation plans. Compensation costs capitalized to inventory and compensation expense related to the Company's ESPP were not material for the nine months ended September 30, 2007 and 2006. The compensation expense related to the Company's stock-based compensation plans included in the statement of income for the nine months ended September 30, 2007 and 2006 is as follows: cost of sales of \$0.3 million and \$0.2 million, respectively; research and development of \$0.5 million for both periods; sales and marketing of \$0.2 million and \$0.4 million, respectively; and general and administrative of \$2.4 million and \$1.4 million, respectively.

Stock Options

Compensation expense related to stock options granted is recognized ratably over the service vesting period for the entire option award. The total number of stock option awards expected to vest is adjusted by estimated forfeiture rates. The estimated fair value of each option award was determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions for the option grants:

	Nine months ended September 30,	
	2007	2006
Expected option life (in years)	4.61	4.55
Volatility rate	0.68	0.75
Risk-free interest rate	4.72%	4.64%
Forfeiture rate	12.7%	12.7%
Dividend rate	0%	0%

The computation of the expected option life is based on a weighted-average calculation combining the average life of options that have already been exercised and post-vest cancellations with the estimated life of the remaining vested and unexercised options. The expected volatility rate is based on the historic volatility of the Company's stock. The risk-free interest rate is based on the U.S. Treasury yield curve over the expected term of the option. The Company's estimated forfeiture rate is based on its historic experience. The Company has never paid cash dividends on its common stock and does not anticipate paying cash dividends in the foreseeable future. Consequently, the Company uses an expected dividend yield of zero in the Black-Scholes option valuation model.

The Company's determination of fair value is affected by the Company's stock price as well as a number of assumptions that require judgment. The weighted-average fair value of each option granted during the nine months ended September 30, 2007, estimated as of the grant date using the Black-Scholes option valuation model, was \$8.73 per option. The total intrinsic value of options exercised was \$5.0 million during the nine months ended September 30, 2007. As of September 30, 2007, total unrecognized compensation cost related to stock options was approximately \$3.2 million and the related weighted-average period over which it is expected to be recognized is approximately 2.0 years.

Restricted Stock Awards The fair value of stock awards is determined based on the closing market price of the Company's common stock on the grant date, or as described below in the case of performance-based stock grants. Compensation expense for stock awards is measured at the grant date and recognized ratably over the vesting period. Stock awards granted during 2007 include time-based and performance-based awards. The performance-based awards are tied to the achievement of three-year performance goals and restrictions lapse at the end of the three-year period depending upon the Company's achievement of predetermined revenue and EBITDA goals. The recognition of compensation expense associated with performance-based grants requires judgment in assessing the probability of meeting the performance goals, as well as defined criteria for assessing achievement of the performance-related goals. This may result in significant expense recognition in the period in which the performance goals are met or when achievement of the goals is deemed probable. The measurement date of the performance-based stock grants takes place when the grant is authorized and the specific achievement goals are communicated. The communication date of the performance goals can impact the valuation and associated expense of the stock grant.

Restricted Stock Units During the nine months ended September 30, 2007, restricted stock units were granted to certain members of the Board of Directors. The compensation expense associated with this grant was \$0.1 million for both the three and nine months ended September 30, 2007.

The total amount of unrecognized compensation cost related to restricted stock and restricted stock units as of September 30, 2007 was approximately \$5.1 million, which is expected to be recognized over a weighted-average period of approximately 2.16 years.

Note 9. Industry and Geographic Information

The Company operates in one reportable segment. Sales to customers outside the U.S. represented \$10.3 million (13%) and \$12.6 million (19%) of total revenue for the nine months ended September 30, 2007 and 2006, respectively. As of September 30, 2007 and December 31, 2006, balances due from foreign customers were \$1.5 million and \$5.5 million, respectively.

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

	Nine months ended September 30,	
	2007	2006
Customer:		
A	19%	18%
B	16%	16%
C	10%	10%
D	6%	14%
E	4%	11%
	55%	69%

As of September 30, 2007, accounts receivable from customers with balances due in excess of 10% of total accounts receivable totaled \$12.2 million while, at December 31, 2006, accounts receivable from customers with balances due in excess of 10% of total accounts receivable totaled \$11.3 million.

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 and Forward-Looking Statements

This Report on Form 10-Q contains forward-looking statements within the meaning of the federal securities laws that involve material risks, assumptions 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 from those currently expected. As such, no forward-looking statement can be guaranteed. Differences in actual results and performance may arise as a result of a number of factors including, without limitation, seasonality, the length and severity of cold and flu seasons, uncertainty surrounding the detection of novel influenza viruses involving human specimens, adverse changes in the competitive and economic conditions in domestic and international markets, actions of our major distributors, technological changes and uncertainty with research and technology development, including any future molecular-based technology, the reimbursement system currently in place and future changes to that system, manufacturing and production delays or difficulties, adverse actions or delays in product reviews by the U.S. Food and Drug Administration (the "FDA"), intellectual property, product liability, environmental or other litigation, required patent license fee payments not currently reflected in our costs, potential inadequacy of booked reserves and possible impairment of goodwill, and lower than anticipated sales or market penetration of our new products. Forward-looking statements typically are identified by the use of terms such as "may," "will," "should," "might," "expect," "anticipate," "estimate" and similar words, although some forward-looking statements are expressed differently. The risks described under "Risk Factors" in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2006, and elsewhere herein and in reports and registration statements that we file with the Securities and Exchange Commission (the "SEC") from time to time, should be carefully considered. You are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Quarterly Report. The following should be read in conjunction with the Consolidated Financial Statements and notes thereto beginning on page 3 of this Quarterly Report. We undertake no obligation to publicly release the results of any revision or update of these forward-looking statements.

Overview

We have a leadership position in the development, manufacturing and marketing of rapid diagnostic solutions at the point-of-care ("POC") in infectious diseases and reproductive and women's health. We focus on POC testing solutions developed for the physician office lab, acute care and alternate markets globally. We primarily earn revenue from sales of products for use in physician offices, hospitals, clinical laboratories and wellness screening centers. We market our products in the U.S. through a network of national and regional distributors, supported by a direct sales force. Internationally, we sell and market primarily in Japan and Europe by channeling products through distributor organizations and sales agents.

Our total revenues increased to \$80.1 million for the nine months ended September 30, 2007 from \$67.2 million for the nine months ended September 30, 2006. This growth was largely driven by increased sales of our infectious disease products. We continued to focus our efforts to strengthen market and brand leadership in infectious disease and reproductive and women's health by delivering economic and clinical proof through our Quidel Value Build ("QVB") program.

We derive a significant portion of our total revenue from two product categories. For the nine months ended September 30, 2007 and 2006, we derived approximately 87% of our total revenue from sales of our infectious disease and reproductive and women's health products. Additionally, we derive a significant portion of our total revenue from a relatively small number of distributors. Approximately 55% and 69% of our total revenue for the nine months ended September 30, 2007 and 2006, respectively, were derived from sales through our five largest distributors.

Outlook

For the next twelve months, we anticipate period-over-period revenue growth in our core products and from recent product launches. We believe gross margins will continue to be positively affected by increased unit volumes, increased average selling prices, and a more favorable product and geographical mix. We continue to expect a gradual conversion of the fecal occult blood test market from the current guaiac-based test to an immunochemical-based test. Successful conversion of this market requires changing physician behavior through education, focused in part on clinical and economic validation. Additionally, we expect our respiratory syncytial virus ("RSV") product to be a well-received companion test to our QuickVue® Influenza A+B test so that physicians are well prepared to diagnose and appropriately manage patients with influenza and/or RSV. While we are currently selling our RSV test in the acute care market, we have not been granted a waiver under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), and are currently not able to sell our RSV product to the majority of physician office labs. In Japan, the influenza market continues to experience downward pricing pressure and, for a second consecutive year, there was mild incidence of influenza. This will lead to continued softness in our fourth quarter of 2007 and our first quarter of 2008 influenza sales into the Japanese market. Nonetheless, we believe we are well positioned domestically and continue to anticipate significant growth with respect to our aggregate influenza sales.

Over the next twelve months, we also expect an incremental increase in spending in our sales force and sales and marketing programs, as well as clinical trials in support of our core products and recent product launches as we further validate the clinical efficacy and economic efficiency of our existing products. We also expect these investments will further our leadership position in POC diagnostics. We continue to conduct internal and external validations of our tests as compared to several domestic and international competitive tests. We anticipate having results of these studies presented and published in several venues in 2007 and 2008. We also expect to increase our investment in research and development activities over the next twelve months, in line with our revenue growth, as we continue our focus on expanding our capabilities to accelerate innovation and development of new technologies. This increase also reflects a reallocation of research and development spend away from our Layered Thin Film immunoassay program, which we recently decided to discontinue, in light of other more promising technology and product opportunities. While we anticipate increased investment spending in our research and development efforts, we expect more moderate growth in other areas of operating expenses compared to revenue growth.

Results of Operations**Three months ended September 30, 2007 compared to the three months ended September 30, 2006****Total Revenues**

The following table compares total revenues for the three months ended September 30, 2007 and 2006 (in thousands, except percentages):

	For the three months ended September 30,		Increase	
	2007	2006	\$	%
Net product sales	\$ 27,234	\$ 23,436	\$ 3,798	16%
Royalty income and license fees	336	284	52	18%
Total revenues	\$ 27,570	\$ 23,720	\$ 3,850	16%

The increase in total revenues for the quarter was largely driven by an overall increase in sales of our infectious disease products. We believe revenue from these products has continued to increase due to successes related to our QVB programs, which have resulted in strengthened customer relationships and preferred partnership programs. We believe our average selling prices in the U.S. have continued to increase largely as a result of our clinical proof claims and product quality, while we have experienced downward pressure in the Japanese market as a result of reimbursement changes and increased competition. Sales of our infectious disease and reproductive and women's health products accounted for 89% of our total revenue for three months ended September 30, 2007, compared to 87% for the three months ended September 30, 2006.

Royalty income and license fees primarily relates to payments earned on our patented technologies utilized by third parties.

Cost of Sales

Cost of sales increased 8% to \$11.2 million, or 40% of total revenues for the three months ended September 30, 2007, compared to \$10.3 million, or 44% of total revenues for the three months ended September 30, 2006. The absolute dollar increase is primarily related to the increase in direct costs (material and labor) associated with product mix and the 16% increase in total revenues. The percentage decrease in cost of sales to revenue was largely due to a more favorable product and geographic mix, as well as increased average selling prices.

Operating Expenses

The following table compares operating expenses for the three months ended September 30, 2007 and 2006 (in thousands, except percentages):

	For the three months ended September 30,				Increase	
	2007		2006		\$	%
	Operating expenses	As a % of total revenues	Operating expenses	As a % of total revenues		
Research and development	\$ 3,128	11%	\$ 3,126	13%	\$ 2	0%
Sales and marketing	4,667	17%	4,080	17%	587	14%
General and administrative	3,546	13%	3,322	14%	224	7%
Amortization of intangibles	1,329	5%	849	4%	480	57%

Research and Development Expense

Our research and development expenses were relatively constant. However, we did recognize a reduction in personnel-related costs due to the completion of certain phases of development projects, which was largely offset by increased clinical activity. While we may experience some fluctuation in our research and development activities related to the timing of certain projects, the primary components of research and development expense are personnel and material costs associated with development of potential new technologies and processes and with products under development. In addition, we continue to incur costs related to intellectual property, clinical activity as well as our overall efforts under our QVB programs.

Sales and Marketing Expense

The increase in sales and marketing expense was primarily related to an overall increase in sales personnel and related programs and expenses, which support our leadership position and strategies to capitalize further on opportunities in POC diagnostics. Other key components of this expense relate to continued investment in assessing future product extensions and enhancements, market research, programs aimed at distribution partners and end-user customers and reimbursement-related activities and product shipment costs.

General and Administrative Expense

The increase in general and administrative expenses was largely as a result of a net increase in compensation expense, which was primarily comprised of stock-based compensation.

Amortization of Intangibles

The increase in amortization of intangibles was primarily due to the amortization of intellectual property related to a license agreement entered into during late 2006.

We completed our annual evaluation for impairment of goodwill in December 2006 and subsequently determined that there was no material impairment of assets as of September 30, 2007. 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 other intangible assets, which are being amortized over a period of two to twelve years, include purchased technology, license agreements, patents, trademarks and a favorable lease.

Other Income (Expense)

The increase in other income was largely related to interest income and was driven by an increase in our average cash balance as well as more favorable interest rates during the three months ended September 30, 2007 as compared to the three months ended September 30, 2006. Interest expense relates to interest paid on obligations under capital leases, primarily associated with our San Diego facility.

Income Taxes

The effective tax rate for the three months ended September 30, 2007 was 39.5%. We did not recognize a tax expense in the third quarter of 2006 as the income tax provision for the three months ended September 30, 2006 was offset by the reversal of deferred tax asset valuation allowances.

Nine months ended September 30, 2007 compared to the nine months ended September 30, 2006**Total Revenues**

The following table compares total revenues for the nine months ended September 30, 2007 and 2006 (in thousands, except percentages):

	For the nine months ended September 30,		Increase (decrease)	
	2007	2006	\$	%
Net product sales	\$ 79,197	\$ 66,310	\$ 12,887	19 %
Royalty income and license fees	887	931	(44)	(5)%
Total revenues	\$ 80,084	\$ 67,241	\$ 12,843	19 %

The increase in total revenues for the nine months ended September 30, 2007 as compared to the same period last year was largely driven by an incremental increase in sales of our infectious disease product family. We believe revenue from these products has continued to increase due to successes related to our QVB programs, which have resulted in strengthened customer relationships and preferred partnership programs. We believe that sales of our influenza products continue to increase as a result of increased market awareness and the demonstrated quality of our tests. We believe our average selling prices in the U.S. have continued to increase largely as a result of our clinical proof claims and product quality, while we have experienced downward pressure in the Japanese market as a result of reimbursement changes and increased competition. Sales of our infectious disease and reproductive and women's health products accounted for 87% of our total revenue for the nine months ended September 30, 2007, compared to 88% for the nine months ended September 30, 2006.

Royalty income and license fees primarily relates to payments earned on patented technologies of ours utilized by third parties.

Cost of Sales

Cost of sales increased 13% to \$33.4 million, or 42% of total revenue for the nine months ended September 30, 2007, compared to \$29.5 million, or 44% of total revenues for the nine months ended September 30, 2006. The absolute dollar increase was primarily related to the increase in direct costs (material and labor) associated with product mix and the 19% increase in total revenues. The percentage decrease in cost of sales to revenue was primarily due to a more favorable product and geographic mix, higher unit volume and increased average selling prices.

Operating Expenses

The following table compares operating expenses for the nine months ended September 30, 2007 and 2006 (in thousands, except percentages):

	For the nine months ended September 30,				Increase (decrease)	
	2007		2006		\$	%
	Operating expenses	As a % of total revenues	Operating expenses	As a % of total revenues		
Research and development	\$ 9,774	12%	\$ 9,903	15%	\$ (129)	(1)%
Sales and marketing	14,051	18%	12,312	18%	1,739	14 %
General and administrative	10,359	13%	9,547	14%	812	9 %
Amortization of intangibles	4,151	5%	2,979	4%	1,172	39 %

Research and Development Expense

The decrease in our research and development expenses was driven primarily by a reduction in personnel-related costs due to the completion of certain phases of development projects, partially offset by investments in the development of new technology platforms. While we may experience some fluctuation in our research and development activities associated with the timing of certain projects, the primary components of research and development expense are personnel and material costs associated with development of potential new technologies and processes and with products under development. In addition, we continue to incur costs related to intellectual property, clinical activity as well as our overall efforts under our QVB programs.

Sales and Marketing Expense

The increase in sales and marketing expense was primarily related to an overall increase in sales personnel and related programs and expenses, which support our leadership position and strategies to capitalize further on opportunities in POC diagnostics. Other key components of this expense relate to continued investment in assessing future product extensions and enhancements, market research (including voice of customer surveys), programs aimed at distribution partners and end-user customers and reimbursement-related activities and product shipment costs.

General and Administrative Expense

The increase in general and administrative expenses was primarily driven by increased stock-based compensation expense and costs related to the departure of our former Chief Financial Officer and hiring a new Chief Financial Officer.

Amortization of Intangibles

The increase in amortization of intangibles was primarily due to the amortization of intellectual property related to a license agreement entered into during late 2006.

Other Income (Expense)

The increase in interest income is largely related to the increase in our average cash balance as well as more favorable interest rates for the nine months ended September 30, 2007 as compared to the nine months ended September 30, 2006. Interest expense relates to interest paid on obligations under capital leases, primarily associated with our San Diego facility.

Income Taxes

The effective tax rate for the nine months ended September 30, 2007 was 39.5%. We did not recognize tax expense for the nine months ended September 30, 2006 as the income tax provision was offset by the reversal of deferred tax asset valuation allowances.

Liquidity and Capital Resources

As of September 30, 2007, our principal sources of liquidity consisted of \$35.3 million in cash and cash equivalents, as well as \$30.0 million available to us under our Senior Credit Facility, as described below. Our working capital as of September 30, 2007 was \$53.6 million.

Our operating activities provided \$17.8 million of cash. In addition to the impact on cash from net income, we had decreases in accounts receivable and accrued royalties related to higher sales during the fourth quarter of 2006. Inventory was higher as a result of increased production activities for the upcoming cold and flu season.

Our investing activities used \$3.4 million during the nine months ended September 30, 2007. This included \$2.4 million for the acquisition of production and scientific equipment and building improvements.

We are currently planning approximately \$5.0 million in capital expenditures over the next twelve months. The primary purpose for our capital expenditures is to acquire manufacturing equipment, implement facility improvements, and for information technology. We plan to fund these capital expenditures with cash flow from operations. We do not have any firm purchase commitments with respect to such planned capital expenditures as of the date of filing this report.

Our financing activities used \$15.8 million of cash during the nine months ended September 30, 2007. This was primarily related to the repurchase of approximately 1.6 million shares of stock in the open market at a cost of \$17.9 million and payments on obligations under our capital leases related to our building in San Diego of \$0.5 million, partially offset by proceeds of \$2.6 million received from the issuance of common stock under our equity incentive plans and our employee stock purchase plan.

We currently have a \$30.0 million credit facility (the "Senior Credit Facility"), which matures on June 30, 2009. The Senior Credit Facility bears interest at a rate ranging from 0% to 0.75% plus the lender's prime rate or, at our option, a rate ranging from 0.75% to 1.75% plus the London InterBank Offering Rate. The agreement governing our Senior Credit Facility also contains certain customary covenants restricting our ability to, among other matters, incur additional indebtedness, create liens or other encumbrances, pay dividends or make other restricted payments, make investments, loans and guarantees or sell or otherwise dispose of a substantial portion of assets to, or merge or consolidate with, another entity. The terms of the Senior Credit Facility require us to comply with certain financial covenants, including: a minimum net worth, a maximum ratio of debt drawn under the Senior Credit Facility to earnings before interest, taxes, depreciation and amortization ("EBITDA") and a fixed charge coverage ratio. As of September 30, 2007, we had \$30.0 million of availability under the Senior Credit Facility and we were in material compliance with all covenants.

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 transactions. 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 our 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 and the foreseeable future.

Off-Balance Sheet Arrangements

At September 30, 2007, we did not have any 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.

Effective January 1, 2007, we adopted the provisions of Financial Accounting Standards Board ("FASB") Interpretation No. 48, "*Accounting for Uncertainty in Income Taxes*" ("FIN 48"). FIN 48 provides guidance for the recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. In accordance with FIN 48, we recognized a cumulative-effect adjustment of \$0.7 million, increasing the January 1, 2007 balance of retained earnings. See Note 5 for more information on income taxes.

Except for the adoption of FIN 48, there have been no significant changes in critical accounting policies or management estimates since the year ended December 31, 2006. A comprehensive discussion of our critical accounting policies and management estimates is included in Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2006.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

The fair market value of our 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 September 30, 2007. Based on our market risk sensitive instruments outstanding at September 30, 2007, 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.

Our current investment policy with respect to our cash and cash equivalents focuses on maintaining acceptable levels of interest rate risk and liquidity. Although we continually evaluate our placement of investments, as of September 30, 2007, our cash and cash equivalents were placed in money market and/or overnight funds that are highly liquid and which we believe are not subject to material market fluctuation risk.

Foreign Currency Exchange Risk

All of our international sales are negotiated for and paid in U.S. dollars. Nonetheless, these sales are 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 impact international sales of our products and our anticipated foreign operations, as could changes in the general economic conditions in those markets. Continued change in the values of the Euro, the Japanese Yen and other foreign currencies could have an 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 changes.

ITEM 4. Controls and Procedures

Evaluation of disclosure controls and procedures. We have performed an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), of the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act"). Based on that evaluation, our CEO and CFO concluded that our disclosure controls and procedures were effective as of September 30, 2007 to provide reasonable assurance that information required to be disclosed by us in the reports filed or submitted by us under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Changes in internal control over financial reporting. There was no change in our internal control over financial reporting during the three months ended September 30, 2007 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION**ITEM 1. Legal Proceedings**

None.

ITEM 1A. Risk Factors

There has been no material change in our risk factors as previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2006. For a detailed description of our risk factors, refer to Item 1A, "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2006.

ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds

The table below sets forth information regarding repurchases of our common stock by us during the three months ended September 30, 2007.

	Total number of shares purchased (1)	Average price paid per share	Total number of shares purchased as part of publicly announced program	Approximate dollar value of shares that may yet be purchased under the program (2)
July 1 - July 31, 2007		\$		\$ 21,480,000
August 1 - August 31, 2007	5,951	13.60	5,759	21,445,000
September 1 - September 30, 2007				21,445,000
Total	5,951	\$ 13.35	5,759	\$ 21,445,000

(1)

In addition to our stock repurchase program, 192 shares of common stock were repurchased by us in connection with payment of minimum tax withholding obligations relating to the lapse of restrictions on certain restricted stock awards during the three months ended September 30, 2007.

(2)

Our Board of Directors has authorized us to repurchase up to \$50.0 million in shares of our common stock under the repurchase program. Any shares of common stock repurchased under this program will no longer be deemed outstanding upon repurchase and will be returned to the pool of authorized shares. This repurchase program will expire no later than March 9, 2009 unless extended by our Board of Directors.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. 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 December 29, 2006 between Quidel Corporation and American Stock Transfer and Trust Company, as Rights Agent. (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on January 5, 2007.)
 - 10.1 Credit Agreement, by and among the Registrant, as Borrower, each lender from time to time party thereto (collectively, "Lenders" and individually, a "Lender") and Bank of America, N.A., as Agent and L/C Issuer, dated as of January 31, 2005 and as amended through September 27, 2007. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on October 1, 2007.)
 - 10.2 Fourth Amendment to Credit Agreement, dated as of September 27, 2007, by and among the Registrant, as Borrower, certain subsidiaries of the Registrant, each lender from time to time a party thereto and Bank of America, N.A., as Agent and L/C Issuer. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on October 1, 2007.)
 - 31.1* Certification by Chief Executive Officer of Registrant pursuant to Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
 - 31.2* Certification by Chief Financial Officer of Registrant pursuant to Rules 13a-14 and 15d-14, as adopted 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 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
-

*
Filed herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: October 26, 2007

QUIDEL CORPORATION

/s/ CAREN L. MASON

Caren L. Mason
President and Chief Executive Officer
(Principal Executive Officer) and Director

/s/ JOHN M. RADAK

John M. Radak
Chief Financial Officer
(Principal Financial Officer and Accounting Officer)

22

Exhibit Index

**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 December 29, 2006 between Quidel Corporation and American Stock Transfer and Trust Company, as Rights Agent. (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on January 5, 2007.)
- 10.1 Credit Agreement, by and among the Registrant, as Borrower, each lender from time to time party thereto (collectively, "Lenders" and individually, a "Lender") and Bank of America, N.A., as Agent and L/C Issuer, dated as of January 31, 2005 and as amended through September 27, 2007. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on October 1, 2007.)
- 10.2 Fourth Amendment to Credit Agreement, dated as of September 27, 2007, by and among the Registrant, as Borrower, certain subsidiaries of the Registrant, each lender from time to time a party thereto and Bank of America, N.A., as Agent and L/C Issuer. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on October 1, 2007.)
- 31.1* Certification by Chief Executive Officer of Registrant pursuant to Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2* Certification by Chief Financial Officer of Registrant pursuant to Rules 13a-14 and 15d-14, as adopted 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 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

*

Filed herewith.

QuickLinks

INDEX

PART I FINANCIAL INFORMATION

ITEM 1. Financial Statements

QUIDEL CORPORATION CONSOLIDATED BALANCE SHEETS (in thousands; unaudited)

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

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

Quidel Corporation Notes to Consolidated Financial Statements (Unaudited)

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

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

ITEM 4. Controls and Procedures

PART II OTHER INFORMATION

ITEM 1. Legal Proceedings

ITEM 1A. Risk Factors

ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds

ITEM 5. OTHER INFORMATION

ITEM 6. Exhibits

SIGNATURES

Exhibit Index