

QUIDEL CORP /DE/
Form 10-Q
October 27, 2008

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended **September 30, 2008**

or

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

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

QUIDEL CORPORATION

(Exact name of Registrant as specified in its charter)

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

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

| | | | |
|---|--|---|---|
| Large accelerated filer <input type="checkbox"/> | Accelerated filer <input checked="" type="checkbox"/> | Non-accelerated filer <input type="checkbox"/> | Smaller reporting company <input type="checkbox"/> |
| (Do not check if a smaller reporting company) | | | |

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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 22, 2008, 32,547,651 shares of common stock were outstanding.

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PART I FINANCIAL INFORMATION

ITEM 1. Financial Statements

QUIDEL CORPORATION

CONSOLIDATED BALANCE SHEETS

(in thousands; unaudited)

| | September 30, 2008 | December 31, 2007 |
|---|-----------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 62,024 | \$ 45,489 |
| Accounts receivable, net | 26,699 | 23,163 |
| Inventories | 11,273 | 11,037 |
| Deferred tax asset - current | 5,955 | 5,955 |
| Prepaid expenses and other current assets | 1,468 | 1,589 |
| Total current assets | 107,419 | 87,233 |
| Property and equipment, net | 18,947 | 19,926 |
| Intangible assets, net | 10,864 | 14,320 |
| Deferred tax asset - non-current | 11,003 | 11,923 |
| Other non-current assets | 661 | 436 |
| Total assets | \$ 148,894 | \$ 133,838 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 3,535 | \$ 5,618 |
| Accrued payroll and related expenses | 3,877 | 4,341 |
| Accrued royalties | 2,661 | 3,289 |
| Current portion of obligations under capital leases | 837 | 764 |
| Other current liabilities | 4,738 | 2,962 |
| Total current liabilities | 15,648 | 16,974 |
| Capital leases, net of current portion | 6,359 | 7,000 |
| Other non-current liabilities | 2,041 | 2,161 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, \$.001 par value per share; 5,000 shares authorized, none issued or outstanding at September 30, 2008 and December 31, 2007 | | |
| Common stock, \$.001 par value per share; 50,000 shares authorized, 32,536 and 32,706 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively | 32 | 33 |
| Additional paid-in capital | 149,806 | 145,440 |
| Accumulated deficit | (24,992) | (37,770) |
| Total stockholders' equity | 124,846 | 107,703 |
| Total liabilities and stockholders' equity | \$ 148,894 | \$ 133,838 |

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, | |
|--|-------------------------------------|----------|------------------------------------|----------|
| | 2008 | 2007 | 2008 | 2007 |
| Total revenues | \$31,868 | \$27,570 | \$94,649 | \$80,084 |
| Costs and expenses | | | | |
| Cost of sales (excludes amortization of intangible assets) | 12,070 | 11,159 | 36,439 | 33,427 |
| Research and development | 2,753 | 3,128 | 8,755 | 9,774 |
| Sales and marketing | 5,141 | 4,667 | 16,052 | 14,051 |
| General and administrative | 3,438 | 3,546 | 10,175 | 10,359 |
| Amortization of intangibles | 1,114 | 1,329 | 3,408 | 4,151 |
| Total costs and expenses | 24,516 | 23,829 | 74,829 | 71,762 |
| Operating income | 7,352 | 3,741 | 19,820 | 8,322 |
| Other income (expense) | | | | |
| Interest income | 364 | 440 | 1,321 | 1,372 |
| Interest expense | (166) | (182) | (510) | (558) |
| Other income (expense) | 160 | | 145 | (4) |
| Total other income | 358 | 258 | 956 | 810 |
| Income before taxes | 7,710 | 3,999 | 20,776 | 9,132 |
| Provision for income taxes | 2,969 | 1,579 | 7,998 | 3,607 |
| Net income | \$ 4,741 | \$ 2,420 | \$ 12,778 | \$ 5,525 |
| Basic earnings per share | \$ 0.15 | \$ 0.08 | \$ 0.40 | \$ 0.17 |
| Diluted earnings per share | \$ 0.15 | \$ 0.07 | \$ 0.39 | \$ 0.17 |
| Shares used in basic per share calculation | 31,915 | 31,784 | 31,891 | 32,031 |
| Shares used in diluted per share calculation | 32,648 | 32,762 | 32,674 | 33,024 |

See accompanying notes.

QUIDEL CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands; unaudited)

| | Nine months ended September 30, | |
|---|------------------------------------|---------------|
| | 2008 | 2007 |
| OPERATING ACTIVITIES: | | |
| Net income | \$ 12,778 | \$ 5,525 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Depreciation and amortization | 6,213 | 7,294 |
| Stock-based compensation expense | 2,963 | 3,416 |
| Deferred tax asset | 920 | 3,521 |
| Excess tax benefit from share-based compensation | (6,192) | |
| Changes in assets and liabilities: | | |
| Accounts receivable | (3,536) | 1,184 |
| Inventories | (236) | (1,983) |
| Prepaid expenses and other current assets | 121 | (276) |
| Accounts payable | (2,335) | (313) |
| Accrued payroll and related expenses | (464) | (80) |
| Accrued royalties | (628) | (1,243) |
| Other current liabilities | 7,968 | 756 |
| Net cash provided by operating activities | 17,572 | 17,801 |
| INVESTING ACTIVITIES: | | |
| Acquisition of property and equipment | (1,855) | (2,449) |
| Acquisition of intangibles | | (850) |
| Other assets | (16) | (85) |
| Net cash used for investing activities | (1,871) | (3,384) |
| FINANCING ACTIVITIES: | | |
| Payments on capital lease obligation | (568) | (501) |
| Purchase of common stock | (6,983) | (17,854) |
| Excess tax benefit from share-based compensation | 6,192 | |
| Proceeds from issuance of common stock, net | 2,193 | 2,581 |
| Net cash provided by (used for) financing activities | 834 | (15,774) |
| Net increase (decrease) in cash and cash equivalents | 16,535 | (1,357) |
| Cash and cash equivalents, beginning of period | 45,489 | 36,625 |
| Cash and cash equivalents, end of period | \$ 62,024 | \$ 35,268 |
| SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION: | | |
| Cash paid during the period for interest | \$ 510 | \$ 558 |
| Cash paid during the period for income taxes | \$ 775 | \$ 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, 2008, and for the three and nine months ended September 30, 2008 and 2007, is unaudited. Operating results for the three and nine months ended September 30, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008. For further information, refer to the consolidated financial statements and footnotes thereto for the year ended December 31, 2007 included in the Company's 2007 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 2008 and 2007, the Company's fiscal year end is December 28 and December 30, respectively. For ease of reference, the calendar quarter end date is used herein. The three and nine month periods ended September 30, 2008 and 2007 both included 13 weeks and 39 weeks, respectively.

Note 2. Comprehensive Income

Net income is equal to comprehensive income for both the three and nine months ended September 30, 2008 and 2007, respectively.

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, 2008, 386,639 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.

Quidel Corporation

Notes to Consolidated Financial Statements (Continued)

(Unaudited)

Note 3. Computation of Earnings Per Share (Continued)

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 | | Nine months ended | |
|--|--------------------|--------|-------------------|--------|
| | September 30, | | September 30, | |
| | 2008 | 2007 | 2008 | 2007 |
| Shares used in basic earnings per share (weighted-average common shares outstanding) | 31,915 | 31,784 | 31,891 | 32,031 |
| Effect of dilutive stock options and restricted stock awards | 733 | 978 | 783 | 993 |
| Shares used in diluted earnings per share calculation | 32,648 | 32,762 | 32,674 | 33,024 |

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, | December 31, |
|-----------------|---------------|--------------|
| | 2008 | 2007 |
| Raw materials | \$ 4,775 | \$ 5,361 |
| Work-in-process | 3,619 | 2,896 |
| Finished goods | 2,879 | 2,780 |
| | \$ 11,273 | \$ 11,037 |

Note 5. Income Taxes

The Company recognizes excess tax benefits associated with the exercise of stock options directly to stockholders' equity only when realized. Accordingly, deferred tax assets are not recognized for net operating loss ("NOL") carryforwards resulting from excess tax benefits. As a result of anticipated utilization of the Company's NOL carryforwards in 2008, a portion of the excess tax benefits associated with share-based compensation were considered realized and increased additional-paid-in-capital in the amount of \$6.2 million as of September 30, 2008.

The Company adopted FIN 48 on January 1, 2007. As of January 1, 2008, the Company had \$6.2 million of unrecognized tax benefits. If recognized, approximately \$5.0 million, net of federal tax benefits, would be recorded as a component of income tax expense.

For the nine months ended September 30, 2008, unrecognized tax benefits increased by approximately \$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 carry forward of unutilized net operating losses and research and development credits.

Quidel Corporation

Notes to Consolidated Financial Statements (Continued)

(Unaudited)

Note 5. Income Taxes (Continued)

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. Stockholders' Equity

During the nine months ended September 30, 2008, 85,000 shares of restricted stock were awarded, 127,788 shares of restricted stock were cancelled, 295,735 shares of common stock were issued due to the exercise of stock options and 18,347 shares of common stock were issued in connection with the Company's employee stock purchase plan (the "ESPP"), resulting in proceeds to the Company of approximately \$2.2 million. Additionally, during the nine months ended September 30, 2008, 486,872 shares of outstanding common stock were repurchased for approximately \$7.0 million, which primarily included shares repurchased under the Company's previously announced share repurchase program, but also included 19,435 shares repurchased in connection with payment of tax withholding obligations relating to the lapse of restrictions on certain restricted stock awards during the nine months ended September 30, 2008.

Note 7. Stock-Based Compensation

The Company's net income for the three months ended September 30, 2008 and 2007 includes \$1.1 million and \$1.0 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, 2008 and 2007. The compensation expense related to the Company's stock-based compensation plans included in the statement of operations for the three months ended September 30, 2008 and 2007 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 \$0.1 million for both periods; and general and administrative of \$0.7 million and \$0.6 million, respectively.

The Company's net income for the nine months ended September 30, 2008 and 2007 includes \$3.0 million and \$3.4 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, 2008 and 2007. The compensation expense related to the Company's stock-based compensation plans included in the statement of operations for the nine months ended September 30, 2008 and 2007 is as follows: cost of sales of \$0.3 million for both periods; research and development of \$0.5 million for both periods; sales and marketing of \$0.1 million and \$0.2 million, respectively; and general and administrative of \$2.1 million and \$2.4 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

Quidel Corporation

Notes to Consolidated Financial Statements (Continued)

(Unaudited)

Note 7. Stock-Based Compensation (Continued)

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, | |
|---------------------------------|---------------------------------------|-------|
| | 2008 | 2007 |
| Expected option life (in years) | 4.27 | 4.61 |
| Volatility rate | 0.50 | 0.68 |
| Risk-free interest rate | 2.43% | 4.72% |
| 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. Prior to fiscal year 2008, the historic volatility rate was determined using the length of the expected option life. As described in Form 10-Q of the first quarter of 2008, the Company changed its look back period in determining volatility to the third quarter of 2005. The Company does not believe this change will have a material impact on its financial statements for fiscal year 2008. 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, 2008, estimated as of the grant date using the Black-Scholes option valuation model, was \$7.03 per option. The total intrinsic value of options exercised was \$3.0 million during the nine months ended September 30, 2008. As of September 30, 2008, total unrecognized compensation cost related to stock options was approximately \$4.2 million and the related weighted-average period over which it is expected to be recognized is approximately 2.77 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. Additionally, compensation expense for the performance-based grants is recorded based on the probability that the performance criteria will be met. 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. The Company has recorded a cumulative expense amount of \$1.3 million between the dates of grant of the Company's performance based awards and September 30, 2008 for performance based grants for which the Company believes that it is probable that the related performance conditions will be met, but for which the performance conditions have not yet been met. The continued assessment of probability may result in additional expense

Quidel Corporation

Notes to Consolidated Financial Statements (Continued)

(Unaudited)

Note 7. Stock-Based Compensation (Continued)

recognition or expense reversal, dependent upon the level of achievement of a performance goal. The measurement date at which the face value of the award is determined for 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, 2008, restricted stock units were granted to certain members of the Board of Directors. The compensation expense associated with restricted stock units was \$0.2 million for both the nine months ended September 30, 2008 and 2007, respectively.

The total amount of unrecognized compensation cost related to restricted stock and restricted stock units as of September 30, 2008 was approximately \$3.1 million, which is expected to be recognized over a weighted-average period of approximately 1.5 years.

Note 8. Industry and Geographic Information

The Company operates in one reportable segment. Sales to customers outside the U.S. represented \$12.3 million (13%) and \$10.3 million (13%) of total revenue for the nine months ended September 30, 2008 and 2007, respectively. As of September 30, 2008 and December 31, 2007, balances due from foreign customers were \$2.9 million and \$4.0 million, respectively.

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

| | Nine months ended September 30, | |
|-----------|---------------------------------------|------|
| | 2008 | 2007 |
| Customer: | | |
| A | 20% | 19% |
| B | 18% | 16% |
| C | 11% | 10% |
| | 49% | 45% |

As of September 30, 2008, accounts receivable from customers with balances due in excess of 10% of total accounts receivable totaled \$19.2 million while, at December 31, 2007, accounts receivable from customers with balances due in excess of 10% of total accounts receivable totaled \$12.0 million.

Note 9. Fair Value Measurement

Effective January 1, 2008, the Company adopted the provisions of SFAS No. 157, Fair Value Measurements. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in accordance with GAAP, and expands disclosures about fair value measurements, but does not require any new fair value measurements. SFAS No. 157's valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect market assumptions. Pursuant to SFAS No. 157, the fair value of our cash

Quidel Corporation

Notes to Consolidated Financial Statements (Continued)

(Unaudited)

Note 9. Fair Value Measurement (Continued)

equivalents is determined based on Level 1 inputs, which consist of quoted prices in active markets for identical assets.

Note 10. Subsequent Events

As of September 30, 2008, the Company had a \$30.0 million unsecured credit facility. As of that same date, the Company had \$30.0 million of availability under the credit facility, and no amounts were outstanding. In addition, the Company was in material compliance with all covenants.

On October 8, 2008, the Company entered into a new \$120.0 million senior secured syndicated credit facility (the "Senior Credit Facility"), which matures on October 8, 2013. The new credit facility replaces the Company's \$30 million credit facility dated as of January 31, 2005 with Bank of America. The Senior Credit Facility bears interest at a rate ranging from 0.50% to 1.75% plus the lender's prime rate or, at the Company's option, a rate ranging from 1.50% to 2.75% plus the London InterBank Offering Rate. The agreement governing the Senior Credit Facility is subject to certain customary limitations, including among others: limitation on liens; limitation on mergers, consolidations and sales of assets; limitation on debt; limitation on dividends, stock redemptions and the redemption and/or prepayment of other debt; limitation on investments (including loans and advances) and acquisitions; limitation on transactions with affiliates; and limitation on annual capital expenditures. The Company is also subject to financial covenants which include a funded debt to earnings before interest, taxes, depreciation and amortization (EBITDA) ratio, and an interest coverage ratio. The Senior Credit Facility is secured by substantially all present and future assets and properties of the Company.

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, success in executing on our strategic initiatives, 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 and the level of success in our recent distributor incentive programs, 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 this Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2007, 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 specifically developed for the physician office lab and acute care markets globally. We sell our products to professionals for use in physician offices, hospitals, clinical laboratories, retail clinics 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 \$94.6 million for the nine months ended September 30, 2008 from \$80.1 million for the nine months ended September 30, 2007. This growth was largely driven by increased domestic 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.

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We derive a significant portion of our total revenue from a relatively small number of distributors. Approximately 49% and 45% of our total revenue for the nine months ended September 30, 2008 and 2007, respectively, were derived from sales through our three largest distributors.

Outlook

For the remainder of fiscal year 2008, we anticipate year-over-year revenue growth. We expect gross margins will be positively affected by a more favorable product mix as well as increased unit volumes, partially offset by lower average selling prices. 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 QuickVue® RSV test for the qualitative detection of respiratory syncytial virus ("RSV") to be a well-received companion test to our QuickVue® tests for influenza this season so that physicians are well prepared to diagnose and appropriately manage patients with influenza and/or RSV. We received Clinical Laboratory Improvement Amendments of 1988 ("CLIA") waiver on our RSV test in February 2008. Internationally, we expect our previously announced global alliance with bioMérieux to increase the reach of our products to markets around the world. Consistent with recent historical periods, the Company has grown operating expenses at a rate less than our revenue growth rate, and we expect this to continue for the remainder of fiscal 2008.

Results of Operations

Three months ended September 30, 2008 compared to the three months ended September 30, 2007

Total Revenues

The following table compares total revenues for the three months ended September 30, 2008 and 2007 (in thousands, except percentages):

| | For the three months ended September 30, | | Increase (Decrease) | |
|---|--|-----------------|---------------------|------------|
| | 2008 | 2007 | \$ | % |
| Infectious disease net product sales | \$24,620 | \$18,551 | \$ 6,069 | 33% |
| Reproductive and women's health net product sales | 4,013 | 5,936 | (1,923) | (32)% |
| Other net product sales | 2,892 | 2,747 | 145 | 5% |
| Royalty income and license fees | 343 | 336 | 7 | 2% |
| Total revenues | \$31,868 | \$27,570 | \$ 4,298 | 16% |

The increase in total revenues was primarily driven by increased sales of our infectious disease products, partially offset by a decrease in our reproductive and women's health products. We believe the increase in our infectious disease products is related to our previously disclosed strategic sales initiative that commenced during the second quarter of 2008, which is in support of the upcoming cold and flu season. Our recent multi-quarter strategic sales initiative covers both seasonal and non-seasonal products. We believe the decrease associated with our reproductive and women's health products is largely driven by ordering patterns associated with our strategic sales initiative. Based on information from the third quarter of 2008, there have been increases in end user market share related to this strategic sales initiative and we continue to expect this will translate into end user market share gain in future periods, and this may result in more normalized inventory levels.

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 \$12.1 million, or 38% of total revenues for the three months ended September 30, 2008, compared to \$11.2 million, or 40% of total revenues for the three months ended September 30, 2007. The absolute dollar increase is primarily related to the variable nature of direct costs (material and labor) associated with the 16% increase in total revenues. The percentage decrease in cost of sales to revenue was largely due to a more favorable product mix of our infectious disease products, partially offset by lower average selling prices on our infectious disease and reproductive and women's health products.

Operating Expenses

The following table compares operating expenses for the three months ended September 30, 2008 and 2007 (in thousands, except percentages):

| | 2008 | | 2007 | | Increase (Decrease) | |
|-----------------------------|--------------------|--------------------------|--------------------|--------------------------|---------------------|-------|
| | Operating expenses | As a % of total revenues | Operating expenses | As a % of total revenues | \$ | % |
| Research and development | \$ 2,753 | 9% | \$ 3,128 | 11% | \$(375) | (12)% |
| Sales and marketing | 5,141 | 16% | 4,667 | 17% | 474 | 10% |
| General and administrative | 3,438 | 11% | 3,546 | 13% | (108) | (3)% |
| Amortization of intangibles | 1,114 | 3% | 1,329 | 5% | (215) | (16)% |

Research and Development Expense

The decrease in research and development expense is due primarily to the discontinuation of our layered thin film immunoassay program in the fourth quarter of 2007 as well as lower costs during the quarter associated with the timing of clinical studies, partially offset by increased investment in other strategic research and development efforts. 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 substantial costs related to clinical trials as well as our overall efforts under our QVB programs.

Sales and Marketing Expense

The increase in sales and marketing expense is primarily related to increased investment in our sales force to further support our leadership position and seek to take advantage of further opportunities in POC diagnostics as well as increased expenses associated with distributor events and trade shows. Other key components of this expense relate to continued investment in assessing future product extensions and enhancements and product shipment costs.

General and Administrative Expense

The slight decrease in general and administrative for the three months ended September 30, 2008 was primarily due to lower stock compensation expense, partially offset by increased headcount, which were added during late 2007.

Amortization of Intangibles

The amortization of intangible assets decreased primarily due to the full amortization of certain purchased technology in fiscal year 2007.

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We completed our annual evaluation for impairment of goodwill in December 2007 and subsequently determined that there were no impairment indicators as of September 30, 2008. A significant decline in our projected revenue, 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 and trademarks.

Other Income (Expense)

The decrease in interest income is related to the decrease in interest rates, partially offset by an increase in our average cash balance during the three months ended September 30, 2008 as compared to the three months ended September 30, 2007. Interest expense relates to interest paid on obligations under capital leases, which are primarily associated with our San Diego facility.

Income Taxes

The effective tax rate for the three months ended September 30, 2008 and 2007 was 38.5% and 39.5%, respectively. We recognized a tax expense of \$3.0 million and \$1.6 million for the three months ended September 30, 2008 and 2007, respectively. The reduction in effective tax rate is primarily due to a decrease in permanent book-tax differences including stock compensation.

Nine months ended September 30, 2008 compared to the nine months ended September 30, 2007

Total Revenues

The following table compares total revenues for the nine months ended September 30, 2008 and 2007 (in thousands, except percentages):

| | For the nine months ended September 30, | | Increase (Decrease) | |
|---|---|-----------------|------------------------|------------|
| | 2008 | 2007 | \$ | % |
| Infectious disease net product sales | \$66,250 | \$50,600 | \$15,650 | 31% |
| Reproductive and women's health net product sales | 18,495 | 19,087 | (592) | (3)% |
| Other net product sales | 9,038 | 9,510 | (472) | (5)% |
| Royalty income and license fees | 866 | 887 | (21) | (2)% |
| Total revenues | \$94,649 | \$80,084 | \$14,565 | 18% |

The increase in total revenues was driven by increased sales of our infectious disease products. Our revenues were favorably impacted due to the timing of the 2007/2008 flu season during the first quarter of 2008 as well as our recent strategic sales initiative implemented in the second quarter of 2008.

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 9% to \$36.4 million, or 38% of total revenues for the nine months ended September 30, 2008, compared to \$33.4 million, or 42% of total revenues for the nine months ended September 30, 2007. The absolute dollar increase is primarily related to the variable nature of direct

costs (material and labor) associated with the 18% increase in total revenues. The percentage decrease in cost of sales as a percentage of revenue was largely due to a more favorable product mix of our infectious disease products and the leverage of our manufacturing costs associated with higher sales volume, partially offset by lower average selling prices on our infectious disease and reproductive and women's health products.

Operating Expenses

The following table compares operating expenses for the nine months ended September 30, 2008 and 2007 (in thousands, except percentages):

| | For the nine months ended September 30, | | | | | |
|-----------------------------|--|-----------------------------------|-----------------------|-----------------------------------|------------------------|-------|
| | 2008 | | 2007 | | Increase (Decrease) | |
| | Operating expenses | As a % of total revenues | Operating expenses | As a % of total revenues | \$ | % |
| Research and development | \$ 8,755 | 9% | \$ 9,774 | 12% | \$(1,019) | (10)% |
| Sales and marketing | 16,052 | 17% | 14,051 | 18% | 2,001 | 14% |
| General and administrative | 10,175 | 11% | 10,359 | 13% | (184) | (2)% |
| Amortization of intangibles | 3,408 | 4% | 4,151 | 5% | (743) | (18)% |

Research and Development Expense

The decrease in research and development expense is due primarily to the discontinuation of our layered thin film immunoassay program in the fourth quarter of 2007, partially offset by increased investment in other strategic research and development efforts. 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 substantial costs related to clinical trials as well as our overall efforts under our QVB programs.

Sales and Marketing Expense

The increase in sales and marketing expense is primarily related to increased investment in our sales force to further support our leadership position and seek to take advantage of further opportunities in POC diagnostics as well as increased expenses associated with distributor events and tradeshows. Other key components of this expense relate to continued investment in assessing future product extensions and enhancements, programs aimed at distribution partners and product shipment costs.

General and Administrative Expense

General and administrative expense decreased slightly for the nine months ended September 30, 2008 as compared to the nine months ended September 30, 2007. There was an overall decrease in stock-based compensation expense due to the departure of an executive in early 2008, as well as higher costs during 2007 associated with the departure of our former Chief Financial Officer, both of which were partially offset by increased headcount, which were added during late 2007.

Amortization of Intangibles

The amortization of intangible assets decreased primarily due to the full amortization of certain purchased technology in fiscal year 2007.

Other Income (Expense)

The decrease in interest income is related to the decrease in interest rates, partially offset by an increase in our average cash balance during the nine months ended September 30, 2008 as compared to the nine months ended September 30, 2007. Interest expense relates to interest paid on obligations under capital leases, which are primarily associated with our San Diego facility.

Income Taxes

The effective tax rate for the nine months ended September 30, 2008 and 2007 was 38.5% and 39.5%, respectively. We recognized a tax expense of \$8.0 million and \$3.6 million for the nine months ended September 30, 2008 and 2007, respectively. The reduction in effective tax rate is primarily due to a decrease in permanent book-tax differences including stock compensation.

Liquidity and Capital Resources

As of September 30, 2008, our principal sources of liquidity consisted of \$62.0 million in cash and cash equivalents, as well as the \$30.0 million available to us under our unsecured credit facility (the "Senior Credit Facility"). Our working capital as of September 30, 2008 was \$91.8 million.

Our cash provided by operating activities was \$17.6 million for the nine months ended September 30, 2008. We had net income of \$12.8 million, including \$6.2 million of depreciation and amortization of intangible assets. Other changes in operating assets and liabilities included an increase in accounts receivable due to the timing of sales during the quarter and inventory of \$3.5 million and \$0.2 million, respectively, and a decrease in accounts payable, accrued payroll and related expenses and accrued royalties of \$2.3 million, \$0.5 million and \$0.6 million, respectively. The decreases in accounts payable and accrued royalties were largely due to seasonal demand fluctuations of our influenza product, while the decrease in payroll and related expenses was largely related to payments made during the period under our 2007 employee compensation programs.

Our investing activities used \$1.9 million during the nine months ended September 30, 2008 primarily for the acquisition of production and scientific equipment and building improvements.

We are planning approximately \$3.1 million in capital expenditures for the remainder of 2008. 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.

Financing activities provided \$0.8 million of cash during the nine months ended September 30, 2008. This was primarily related to the benefit of \$6.2 million from excess taxes from share-based compensation and proceeds of \$2.2 million from the issuance of common stock under our equity incentive plans, largely offset by the repurchase of approximately 0.5 million shares of our common stock in the open market at a cost of approximately \$7.0 million and payments on obligation under our capital leases related to our building in San Diego of \$0.6 million.

As of September 30, 2008, we had a \$30.0 million unsecured credit facility. As of that same date, we had \$30.0 million of availability under the credit facility, and no amounts were outstanding. In addition, we were in material compliance with all covenants.

On October 8, 2008, we entered into a new \$120.0 million senior secured syndicated credit facility (the "Senior Credit Facility"), which matures on October 8, 2013. The new credit facility replaces the Company's \$30 million credit facility dated as of January 31, 2005 with Bank of America. The Senior Credit Facility bears interest at a rate ranging from 0.50% to 1.75% plus the lender's prime rate or, at the Company's option, a rate ranging from 1.50% to 2.75% plus the London InterBank Offering Rate.

The agreement governing the Senior Credit Facility is subject to certain customary limitations, including among others: limitation on liens; limitation on mergers, consolidations and sales of assets; limitation on debt; limitation on dividends, stock redemptions and the redemption and/or prepayment of other debt; limitation on investments (including loans and advances) and acquisitions; limitation on transactions with affiliates; and limitation on annual capital expenditures. We are also subject to financial covenants which include a funded debt to earnings before interest, taxes, depreciation and amortization (EBITDA) ratio, and an interest coverage ratio. The Senior Credit Facility is secured by substantially all present and future assets and properties of the Company.

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, 2008, 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, stock-based compensation, 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.

There have been no other significant changes in critical accounting policies or management estimates since the year ended December 31, 2007. 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, 2007.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

The fair market value of any outstanding balances drawn under our floating interest rate line of credit 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, 2008. Based on our market risk sensitive instruments outstanding at September 30, 2008 and 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, 2008, 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 or less 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. Continued change in the values of the Euro, the Japanese Yen 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 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, 2008 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, 2008 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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

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, 2007, except for the risk factor set forth below. 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, 2007.

As described previously and herein under Part I, Item 2 "Management's Discussion and Analysis of Financial Condition and Results of Operations", as part of our recent strategic sales initiative with several of our key distributors, we received initial stocking orders and committed purchases to drive our goal of increased market share both for seasonal and non-seasonal products. If we are unsuccessful under this strategic initiative and are unable to drive market share conversion, or if we experience a late or mild influenza season, this could result in increased inventory in the domestic market and may significantly and adversely impact our sales for the remainder of fiscal 2008 and the first quarter of 2009.

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, 2008.

| | 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, 2008 | 1,478 | \$ 19.52 | | \$ 14,742,000 |
| August 1 August 31, 2008 | | | | 14,742,000 |
| September 1 September 30, 2008 | | | | 14,742,000 |
| Total | 1,478 | \$ 19.52 | | \$ 14,742,000 |

(1) 1,478 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, 2008.

(2) In June 2005, we announced that our Board of Directors authorized us to repurchase up to \$25.0 million in shares of our common stock under a stock repurchase program. In March 2007, we announced that our Board of Directors authorized us to purchase up to an additional \$25.0 million in shares of our common stock under our stock 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 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, Swing Line Lender and L/C Issuer, dated as of October 8, 2008. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on October 10, 2008.)
- 10.2 Security Agreement by and among Registrant, as Borrower, direct and indirect domestic subsidiaries of Borrower, each additional grantor that may become a party thereto and Bank of America, N.A., as Agent, dated as of October 8, 2008. (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on October 10, 2008.)
- 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 24, 2008

QUIDEL CORPORATION

/s/ CAREN L. MASON

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

/s/ JOHN M. RADAK

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

Exhibit Index

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*

Filed herewith.

QuickLinks

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