QUIDEL CORP /DE/
Form 10-Q
October 21, 2009

# UNITED STATES <br> SECURITIES AND EXCHANGE COMMISSION <br> Washington, D.C. 20549 

FORM 10-Q
(Mark One)

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

For the quarterly period ended September 30, 2009
or

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

For the transition period from to
Commission File Number: 0-10961
QUIDEL CORPORATION
(Exact name of Registrant as specified in its charter)

## Delaware

(State or other jurisdiction of incorporation or organization)

94-2573850
(I.R.S. Employer

Identification No.)

10165 McKellar Court, San Diego, California 92121
(Address of principal executive offices, including zip code)
(858) 552-1100
(Registrant s telephone number, including area code)
Not Applicable
(Former name, former address and former fiscal year, if changed since last report)
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 p No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes - No o

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 o

Non-accelerated filer o (Do not check if a smaller reporting company)

Smaller reporting
company o

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

As of October 16, 2009, 30,146,350 shares of common stock were outstanding.

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PART I FINANCIAL INFORMATION ITEM 1. Financial Statements

QUIDEL CORPORATION<br>CONSOLIDATED BALANCE SHEETS<br>(in thousands, except par value; unaudited)

|  | $\begin{gathered} \text { September } \\ 30, \\ 2009 \end{gathered}$ |  | $\begin{gathered} \text { December } \\ 31, \\ 2008 \end{gathered}$ |  |
| :---: | :---: | :---: | :---: | :---: |
| ASSETS |  |  |  |  |
| Current assets: |  |  |  |  |
| Cash and cash equivalents | \$ | 60,348 | \$ | 57,908 |
| Marketable securities |  | 4,984 |  |  |
| Accounts receivable, net |  | 25,428 |  | 25,320 |
| Inventories |  | 12,883 |  | 11,702 |
| Deferred tax asset current |  | 5,043 |  | 5,043 |
| Prepaid expenses and other current assets |  | 1,973 |  | 1,053 |
| Total current assets |  | 110,659 |  | 101,026 |
| Property and equipment, net |  | 19,829 |  | 19,081 |
| Intangible assets, net |  | 8,753 |  | 9,833 |
| Deferred tax asset non-current |  | 9,040 |  | 11,240 |
| Other non-current assets |  | 1,518 |  | 1,628 |
| Total assets | \$ | 149,799 | \$ | 142,808 |
| LIABILITIES AND STOCKHOLDERS EQUITY |  |  |  |  |
| Current liabilities: |  |  |  |  |
| Accounts payable | \$ | 6,057 | \$ | 4,317 |
| Accrued payroll and related expenses |  | 4,715 |  | 2,719 |
| Accrued royalties |  | 4,652 |  | 2,659 |
| Current portion of obligations under capital leases |  | 941 |  | 862 |
| Other current liabilities |  | 7,270 |  | 4,877 |
| Total current liabilities |  | 23,635 |  | 15,434 |
| Capital leases, net of current portion |  | 5,418 |  | 6,137 |
| Deferred rent |  | 828 |  | 948 |
| Other non-current liabilities |  | 1,807 |  | 1,053 |
| Commitments and contingencies |  |  |  |  |
| Stockholders equity: |  |  |  |  |
| Preferred stock, $\$ .001$ par value per share; 5,000 shares authorized; none issued or outstanding at September 30, 2009 and December 31, 2008 |  |  |  |  |
| Common stock, $\$ .001$ par value per share; 50,000 shares authorized; 30,141 and 31,894 shares issued and outstanding at September 30, 2009 and |  |  |  |  |
| December 31, 2008, respectively |  | 30 |  | 32 |
| Additional paid-in capital |  | 124,227 |  | 138,126 |
| Accumulated deficit |  | $(6,146)$ |  | $(18,922)$ |
| Total stockholders equity |  | 118,111 |  | 119,236 |

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Total liabilities and stockholders equity
\$ 149,799 \$ 142,808
See accompanying notes.
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| QUIDEL CORPORATION <br> CONSOLIDATED STATEMENTS OF INCOME <br> (in thousands, except per share data; unaudited) |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: |
|  | Three months ended September 30, 2009 2008 |  | Nine months ended September 30, |  |
| Total revenues | \$ 56,152 | \$ 31,868 | \$97,685 | \$ 94,649 |
| Costs and expenses |  |  |  |  |
| Cost of sales (excludes amortization of intangible assets) | 17,670 | 12,070 | 36,169 | 36,439 |
| Research and development | 3,157 | 2,753 | 9,003 | 8,755 |
| Sales and marketing | 6,400 | 5,141 | 16,538 | 16,052 |
| General and administrative | 4,325 | 3,438 | 12,125 | 10,175 |
| Amortization of intangibles | 345 | 1,114 | 1,040 | 3,408 |
| Restructuring charges |  |  | 2,038 |  |
| Total costs and expenses | 31,897 | 24,516 | 76,913 | 74,829 |
| Operating income | 24,255 | 7,352 | 20,772 | 19,820 |
| Other (expense) income |  |  |  |  |
| Interest income | 53 | 364 | 299 | 1,321 |
| Interest expense | (148) | (166) | (459) | (510) |
| Other (expense) income | (5) | 160 | (5) | 145 |
| Total other (expense) income | (100) | 358 | (165) | 956 |
| Income before taxes | 24,155 | 7,710 | 20,607 | 20,776 |
| Provision for income taxes | 9,215 | 2,969 | 7,831 | 7,998 |
| Net income | \$ 14,940 | \$ 4,741 | \$ 12,776 | \$ 12,778 |
| Basic earnings per share | \$ 0.50 | \$ 0.15 | \$ 0.42 | \$ 0.40 |
| Diluted earnings per share | \$ 0.50 | \$ 0.15 | \$ 0.42 | \$ 0.39 |
| Shares used in basic per share calculation | 29,713 | 31,915 | 30,151 | 31,891 |
| Shares used in diluted per share calculation | 30,149 | 32,648 | 30,547 | 32,674 |

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| QUIDEL CORPORATION <br> CONSOLIDATED STATEMENTS OF CASH FLOWS (in thousands; unaudited) |  |  |
| :---: | :---: | :---: |
|  | Nine months ended September 30, |  |
| OPERATING ACTIVITIES: |  |  |
| Net income | \$ 12,776 | \$ 12,778 |
| Adjustments to reconcile net income to net cash provided by operating activities: |  |  |
| Depreciation, amortization and other | 4,478 | 6,213 |
| Stock-based compensation expense | 2,502 | 2,963 |
| Deferred tax asset | 2,200 | 920 |
| Excess tax benefit from share-based compensation | $(1,400)$ | $(6,192)$ |
| Changes in assets and liabilities: |  |  |
| Accounts receivable | (108) | $(3,536)$ |
| Inventories | $(1,181)$ | (236) |
| Prepaid expenses and other current assets | (920) | 121 |
| Accounts payable | 871 | $(2,335)$ |
| Accrued payroll and related expenses | 1,996 | (464) |
| Accrued royalties | 1,993 | (628) |
| Other current and non-current liabilities | 4,547 | 7,968 |
| Net cash provided by operating activities | 27,754 | 17,572 |
| INVESTING ACTIVITIES: |  |  |
| Acquisition of property and equipment | $(3,180)$ | $(1,855)$ |
| Purchases of marketable securities | $(4,984)$ |  |
| Other assets | (107) | (16) |
| Net cash used for investing activities | $(8,271)$ | $(1,871)$ |
| FINANCING ACTIVITIES: |  |  |
| Payments on capital lease obligation | (640) | (568) |
| Purchase of common stock | $(19,542)$ | $(6,983)$ |
| Excess tax benefit from share-based compensation | 1,400 | 6,192 |
| Proceeds from issuance of common stock, net | 1,739 | 2,193 |
| Net cash (used for) provided by financing activities | $(17,043)$ | 834 |
| Net increase in cash and cash equivalents | 2,440 | 16,535 |
| Cash and cash equivalents, beginning of period | 57,908 | 45,489 |
| Cash and cash equivalents, end of period | \$ 60,348 | \$ 62,024 |

## SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:

| Cash paid during the period for interest | $\$$ | 459 | $\$$ | 510 |
| :--- | :--- | :--- | :--- | :--- |
| Cash paid during the period for income taxes | $\$$ | 200 | $\$$ | 775 |

See accompanying notes.

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## Quidel Corporation <br> 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, 2009, and for the three and nine months ended September 30, 2009 and 2008, is unaudited. Operating results for the three and nine months ended September 30, 2009 are not necessarily indicative of the results that may be expected for the year ending December 31, 2009. For further information, refer to the consolidated financial statements and footnotes thereto for the year ended December 31, 2008 included in the Company s 2008 Annual Report on Form 10-K. Subsequent events have been evaluated up to and including October 20, 2009 which is the date these financial statements were issued.

Each of the Company s fiscal quarters end on the Sunday closest to the end of the calendar quarter. For 2009 and 2008, the Company s fiscal year end is January 3, 2010 and December 28, 2008, respectively. For ease of reference, the calendar quarter end dates are used herein. The three and nine month periods ended September 30, 2009 and 2008 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, 2009 and 2008, 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 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 share as their effect is anti-dilutive. For the three months ended September 30, 2009 and 2008, 1.4 million shares and 0.8 million shares were excluded from the calculation of diluted earnings per share as their effect was anti-dilutive. For the nine months ended September 30, 2009 and 2008, 1.6 million shares and 0.6 million shares were excluded from the calculation of diluted earnings per share as their effect was 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 <br> September 30, |  |
| :---: | :---: | :---: | :---: | :---: |
|  | 2009 | 2008 | 2009 | 2008 |
| Shares used in basic earnings per share (weighted-average common shares outstanding) | 29,713 | 31,915 | 30,151 | 31,891 |

Effect of dilutive stock options and restricted stock awards

436
733
396
Shares used in diluted earnings per share calculation

$$
30,149
$$

$$
32,648
$$

$$
30,547
$$32,674

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## Quidel Corporation <br> Notes to Consolidated Financial Statements (Continued) (Unaudited)

## Note 4. Inventories

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

|  | $\begin{gathered} \text { September } \\ \text { 30, } \\ 2009 \end{gathered}$ |  | $\begin{gathered} \text { December } \\ 31, \\ 2008 \end{gathered}$ |  |
| :---: | :---: | :---: | :---: | :---: |
| Raw materials | \$ | 4,732 | \$ | 4,956 |
| Work-in-process (materials, labor and overhead) |  | 3,599 |  | 3,108 |
| Finished goods (materials, labor and overhead) |  | 4,552 |  | 3,638 |
|  | \$ | 12,883 | \$ | 11,702 |

## Note 5. Other Current Liabilities

Other current liabilities consisted of the following (in thousands):

|  | September | December |
| :--- | :---: | ---: | ---: | ---: |
| 30, |  |  |

## Note 6. Income Taxes

The Company recognizes excess tax benefits associated with the exercise of stock options directly to stockholders equity only when realized. As of September 30, 2009 and 2008, $\$ 1.4$ million and $\$ 6.2$ million, respectively, was considered realized and was recorded as a reduction to our income taxes payable and increased additional paid-in capital in the accompanying Consolidated Balance Sheets.

The Company is subject to periodic audits by domestic and foreign tax authorities. The Company s federal 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.

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 7. Line of Credit

The Company currently has a $\$ 120.0$ million senior secured syndicated credit facility (the Senior Credit Facility ), which matures on October 8, 2013. 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, as defined in the Senior Credit Facility) ratio, and an interest coverage ratio. The Senior Credit Facility is secured by substantially all present and future assets and properties of the Company. As of September 30, 2009, the Company had approximately $\$ 118.0$ million available under the Senior Credit Facility, which can fluctuate from time to time due to, among other factors, the Company s funded debt to EBITDA ratio. At September 30, 2009, the Company had no amounts outstanding under the Senior Credit Facility and was in compliance with all financial covenants.

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# Quidel Corporation <br> Notes to Consolidated Financial Statements (Continued) (Unaudited) 

## Note 8. Stockholders Equity

During the nine months ended September 30, 2009, 172,289 shares of restricted stock were awarded, 168,418 shares of restricted stock were cancelled, 328,899 shares of common stock were issued due to the exercise of stock options and 22,384 shares of common stock were issued in connection with the Company s employee stock purchase plan (the ESPP ), resulting in net proceeds to the Company of approximately $\$ 1.7$ million. Additionally, during the nine months ended September 30, 2009, 2,114,884 shares of outstanding common stock were repurchased for approximately $\$ 19.5$ million, which primarily included shares repurchased under the Company s previously announced share repurchase program, but also included 58,952 shares repurchased in connection with the Company s payment of minimum tax withholding obligations for certain employees relating to the lapse of restrictions on certain restricted stock awards during the nine months ended September 30, 2009.

## Note 9. Stock-Based Compensation

The compensation expense related to the Company s stock-based compensation plans included in the accompanying Statements of Income for the three and nine months ended September 30, 2009 and 2008 was as follows (in millions):

|  | Three months ended September 30, |  |  |  | Nine months ended <br> September 30, |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Cost of sales | \$ |  | \$ | 0.1 | \$ | \$ | 0.3 |
| Research and development |  | 0.1 |  | 0.2 |  |  | 0.5 |
| Sales and marketing |  | 0.1 |  | 0.1 |  |  | 0.1 |
| General and administrative |  | 0.5 |  | 0.7 |  |  | 2.1 |
| Restructuring charges |  |  |  |  |  |  |  |
|  | \$ |  | \$ |  |  |  | 3.0 |

Total compensation expense recognized for the three months ended September 30, 2009 and 2008 includes $\$ 0.7$ million and $\$ 0.5$ million related to stock options and $\$ 0.1$ million and $\$ 0.6$ million related to restricted stock, respectively. Total compensation expense recognized for the nine months ended September 30, 2009 and 2008 includes $\$ 1.9$ million and $\$ 1.7$ million related to stock options and $\$ 0.6$ million and $\$ 1.3$ million related to restricted stock, respectively. Total compensation expense for the nine months ended September 30, 2009 is net of a $\$ 0.2$ million compensation expense reversal for certain terminated employees in connection with the Company s restructuring plan. As of September 30, 2009, total unrecognized compensation expense related to nonvested stock options was $\$ 6.5$ million, which is expected to be recognized over a weighted-average period of approximately 3.1 years. As of September 30, 2009, total unrecognized compensation expense related to nonvested restricted stock was $\$ 1.4$ million, which is expected to be recognized over a weighted-average period of approximately 3.2 years. Compensation expense capitalized to inventory and compensation expense related to the Company s ESPP were not material for the three and nine months ended September 30, 2009 and 2008.

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## Quidel Corporation <br> Notes to Consolidated Financial Statements (Continued) (Unaudited)

Note 9. Stock-Based Compensation (Continued)
The estimated fair value of each stock 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.

|  | $\begin{array}{c}\text { Nine months } \\ \text { ended }\end{array}$ |  |
| :--- | :---: | :---: |
| September 30, |  |  |$]$

The weighted-average grant date fair value of stock options granted during the nine months ended September 30, 2009 and 2008 was $\$ 4.80$ and $\$ 7.03$, respectively. The grant date fair value of restricted stock is determined based on the closing market price of the Company s common stock on the grant date.

## Note 10. Industry and Geographic Information

The Company operates in one reportable segment. Sales to customers outside the U.S. represented $\$ 21.7$ million ( $22 \%$ ) and $\$ 12.3$ million ( $13 \%$ ) of total revenue for the nine months ended September 30, 2009 and 2008, respectively. As of September 30, 2009 and December 31, 2008, balances due from foreign customers were $\$ 8.5$ million and $\$ 4.7$ million, respectively.

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

|  | Nine months <br> ended |  |
| :--- | :---: | :---: |
| September 30, |  |  |
| Customer: | $\mathbf{2 0 0 9}$ |  |, $\mathbf{2 0 0 8}$

As of September 30, 2009, accounts receivable from customers with balances due in excess of $10 \%$ of total accounts receivable totaled $\$ 21.7$ million while, at December 31, 2008, accounts receivable from customers with balances due in excess of $10 \%$ of total accounts receivable totaled $\$ 17.9$ million.

## Note 11. Fair Value Measurement

The Company s valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs are generally developed internally, utilizing management sestimates, assumptions and specific knowledge of the assets/liabilities and related market assumptions. The fair value of our cash equivalents and marketable securities are determined based on Level 1 inputs, which consist of quoted prices in active markets for identical assets. The Company s marketable securities consist of commercial paper with maturities no greater than 180 days. Unrealized gains were immaterial in the period.

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## Quidel Corporation <br> Notes to Consolidated Financial Statements (Continued) (Unaudited)

## Note 12. Restructuring Charges

In March 2009, the Company announced and implemented a restructuring plan (the Restructuring Plan ). The Restructuring Plan primarily consisted of a workforce reduction (approximately $10 \%$ of the Company s total workforce) as well as consolidation of facility space at its Santa Clara, California location. The expected completion or cash payout date for the workforce reduction is the end of fiscal 2009, at which time the COBRA benefits will expire for terminated employees. The expected completion date relating to the Santa Clara lease liability is November 2014, the end of the current lease term. The Company recorded a charge of $\$ 2.0$ million during the nine months ended September 30, 2009, which is net of a $\$ 0.2$ million stock-based compensation expense reversal for certain terminated employees. During the three months ended September 30, 2009, the Company reduced the restructuring liability by $\$ 0.1$ million for cash payments made during the period. As of September 30, 2009, the remaining accrual is classified as accrued payroll and related expenses of $\$ 0.1$ million, other current liabilities of $\$ 0.2$ million and other non-current liabilities of $\$ 0.8$ million in the accompanying Consolidated Balance Sheets. As part of the Restructuring Plan, the Company recorded an impairment charge related to a fixed asset no longer in use. Additionally, the Company vacated the unutilized portion of its Santa Clara facility in April 2009 and recorded a restructuring charge of approximately $\$ 1.1$ million in the second quarter of 2009.

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## 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 that may be described or implied in the forward-looking statements. 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 timing of onset, length and severity of cold and flu seasons, the level of success in executing on our strategic initiatives, our reliance on sales of our influenza diagnostic tests, uncertainty surrounding the detection of novel influenza viruses involving human specimens, adverse changes in the competitive and economic conditions in domestic and international markets, our reliance on and 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, potential 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. Forward-looking statements in this Quarterly Report include, among others, statements concerning: our outlook for the remainder of 2009 , including projections about our revenue, gross margins and expenses, projected capital expenditures during the remainder of 2009 and our source of funds for such expenditures; the sufficiency of our liquidity and capital resources; and our intention to continue to evaluate acquisition licensing opportunities. 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, 2008, 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, except as required by law.

## Overview

We have a leadership position in the development, manufacturing and marketing of rapid diagnostic solutions for decentralized applications including point-of-care ( POC ) in infectious diseases and reproductive and women shealth. 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, Europe and the Middle East through exclusive distributor arrangements.

## Outlook

For the remainder of fiscal year 2009, we anticipate year-over-year revenue growth primarily driven by our infectious disease product lines. We expect gross margins will be positively affected by a more favorable product mix and improved average selling prices through a significant reduction and re-alignment of incentive programs throughout our distribution channel. Internationally, we expect continued growth for fiscal year 2009 as we increase the reach of our products to markets around the world. While we successfully executed our restructuring in the first quarter of 2009, we expect costs and expenses to be higher year-over-year, largely as a result of significant investments in new product development, evaluating new technologies, marketing programs aimed at driving increased awareness for influenza testing and increases in our telesales and managed care sales groups.

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## Results of Operations

Three months ended September 30, 2009 compared to the three months ended September 30, 2008
Total Revenues
The following table compares total revenues for the three months ended September 30, 2009 and 2008 (in thousands, except percentages):

|  | For the three months ended September 30, |  | Increase (Decrease) |  |
| :---: | :---: | :---: | :---: | :---: |
|  | 2009 | 2008 | \$ | \% |
| Infectious disease net product sales | \$ 47,023 | \$ 24,620 | \$ 22,403 | 91\% |
| Reproductive and women s health net product sales | 5,524 | 4,013 | 1,511 | 38\% |
| Other net product sales | 3,288 | 2,892 | 396 | 14\% |
| Royalty income and license fees | 317 | 343 | (26) | (8)\% |
| Total revenues | \$ 56,152 | \$ 31,868 | \$ 24,284 | 76\% |

The increase in total revenues was primarily due to increased sales globally of our influenza products during the quarter. We believe this increase reflects a combination of factors, including a significantly higher than normal incidence of influenza during the summer with the emergence of the 2009 H1N1 virus and an increase in the number of new physicians using flu tests to aid in the diagnosis of influenza.

The revenue from royalty income and license fees for all periods primarily relate to royalty payments earned on our patented technologies utilized by third parties.

## Cost of Sales

Cost of sales increased $46 \%$ to $\$ 17.7$ million, or $31 \%$ of total revenues for the three months ended September 30, 2009, compared to $\$ 12.1$ million, or $38 \%$ of total revenues for the three months ended September 30, 2008. The percentage decrease in cost of sales as a percentage of total revenue was largely due to a more favorable product mix of increased sales of our infectious disease products.

## Operating Expenses

The following table compares operating expenses for the three months ended September 30, 2009 and 2008 (in thousands, except percentages):

|  | For the ended Se |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  | 2008 |  | Increase (Decrease) |  |
|  |  | As a \% <br> of |  | $\begin{gathered} \text { As a \% \% } \\ \text { of } \end{gathered}$ |  |  |
|  | expenses | revenues | expenses | revenues | \$ | \% |
| Research and development | \$3,157 | 6\% | \$2,753 | 9\% | \$ 404 | 15\% |
| Sales and marketing | 6,400 | 11\% | 5,141 | 16\% | 1,259 | 25\% |
| General and administrative | 4,325 | 8\% | 3,438 | 11\% | 887 | 26\% |
| Amortization of intangibles | 345 | 1\% | 1,114 | 3\% | (769) | (69)\% |

## Research and Development Expense

Research and development expense increased due primarily to development of potential new technologies and products under development, clinical studies related to our influenza products and an employee bonus accrual.

## Sales and Marketing Expense

Sales and marketing expense increased largely as a result of product promotions related to influenza, increased investment in our sales force to further support our leadership position and higher sales commissions corresponding to increased sales of our infectious disease products. Other key components of this expense relate to continued
investment in assessing future product extensions and enhancements and market research.

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## General and Administrative Expense

The increase in general and administrative expense is primarily related to an employee bonus accrual and increased costs in connection with our new credit facility.

## Amortization of Intangibles

The amortization of intangible assets decreased primarily due to the full amortization of a license agreement in December 2008.

## Other Income (Expense)

The decrease in interest income is related to the decrease in interest rates and a decrease in our average cash balance during the three months ended September 30, 2009 as compared to the three months ended September 30, 2008. 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, 2009 and 2008 was $38.1 \%$ and $38.5 \%$, respectively. We recognized tax expense of $\$ 9.2$ million and $\$ 3.0$ million for the three months ended September 30, 2009 and 2008, respectively.
Nine months ended September 30, 2009 compared to the nine months ended September 30, 2008 Total Revenues
The following table compares total revenues for the nine months ended September 30, 2009 and 2008 (in thousands, except percentages):

|  | For the nine months ended September 30, |  | Increase (Decrease) |  |
| :---: | :---: | :---: | :---: | :---: |
|  | 2009 | 2008 | \$ | \% |
| Infectious disease net product sales | \$ 70,918 | \$ 66,250 | \$ 4,668 | 7\% |
| Reproductive and women s health net product sales | 15,686 | 18,495 | $(2,809)$ | (15)\% |
| Other net product sales | 10,107 | 9,038 | 1,069 | 12\% |
| Royalty income and license fees | 974 | 866 | 108 | 12\% |
| Total revenues | \$97,685 | \$ 94,649 | \$ 3,036 | 3\% |

The increase in total revenues was largely due to a net increase in global sales of our influenza products, partially offset by a decrease in sales of our women s and reproductive health products. The decrease in sales of our women s and reproductive health products was primarily related to our 2008 strategic sales initiative that affected distributor ordering patterns and had a resulting increase in their inventories at the beginning of fiscal year 2009. The increase in other net product sales was largely attributable to higher sales of our veterinary products.

We derive a significant portion of our total revenue from a relatively small number of distributors. Approximately $63 \%$ and $61 \%$ of our total revenue for the nine months ended September 30, 2009 and 2008, respectively, were derived from sales through our five largest distributors.

The revenue from royalty income and license fees for all periods primarily relate to royalty payments earned on our patented technologies utilized by third parties.

## Cost of Sales

Cost of sales decreased $1 \%$ to $\$ 36.2$ million, or $37 \%$ of total revenues for the nine months ended September 30, 2009 , compared to $\$ 36.4$ million, or $38 \%$ of total revenues for the nine months ended September 30, 2008. The percentage decrease in cost of sales as a percentage of total revenue was largely due to a more favorable product mix of increased sales of our infectious disease products.

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## Operating Expenses

The following table compares operating expenses for the nine months ended September 30, 2009 and 2008 (in thousands, except percentages):


## Research and Development Expense

Research and development expense increased due primarily to development of potential new technologies and products under development, clinical studies related to our influenza products and an employee bonus accrual.

## Sales and Marketing Expense

Sales and marketing expense increased in 2009 primarily due to product promotions related to influenza and an increased investment in our sales force to further support our leadership position. Other key components of this expense relate to continued investment in assessing future product extensions and enhancements and market research.

## General and Administrative Expense

The increase in general and administrative expense is primarily related to the hiring of new executives, an employee bonus accrual and costs incurred in connection with our new credit facility.

## Amortization of Intangibles

The amortization of intangible assets decreased primarily due to the full amortization of a license agreement in December 2008.

## Restructuring Charges

We recorded a restructuring charge of $\$ 2.0$ million, comprised of severance costs and costs associated with vacating the unutilized portion of our Santa Clara facility, during the nine months ended September 30, 2009, which is net of a $\$ 0.2$ million stock-based compensation expense reversal for certain terminated employees.

## Other Income (Expense)

The decrease in interest income is related to the decrease in interest rates and a decrease in our average cash balance during the nine months ended September 30, 2009 as compared to the nine months ended September 30, 2008. 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, 2009 and 2008 was $38.0 \%$ and $38.5 \%$, respectively. We recognized tax expense of $\$ 7.8$ million and $\$ 8.0$ million for the nine months ended September 30, 2009 and 2008, respectively.

## Liquidity and Capital Resources

As of September 30, 2009, our principal sources of liquidity consisted of $\$ 60.3$ million in cash and cash equivalents, $\$ 5.0$ million in marketable securities, as well as the $\$ 118.0$ million available to us under our senior secured syndicated credit facility (the Senior Credit Facility ), which can fluctuate from time to time due to, among other factors, our funded debt to EBITDA ratio. Our working capital as of September 30, 2009 was $\$ 87.0$ million.

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Changes in operating assets and liabilities are primarily driven by the increase and timing of revenue during the nine months ended September 30, 2009.

Our investing activities used $\$ 8.3$ million during the nine months ended September 30, 2009 primarily for the acquisition of production and scientific equipment, building improvements and the purchase of marketable securities.

We are planning approximately $\$ 4.0$ million in capital expenditures for the remainder of 2009. 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 have $\$ 4.0$ million in firm purchase commitments with respect to such planned capital expenditures as of the date of filing this report.

Our financing activities used $\$ 17.0$ million of cash during the nine months ended September 30, 2009. This was primarily related to the repurchase of approximately 2.1 million shares of our common stock at a cost of approximately $\$ 19.5$ million. Our proceeds from the issuance of common stock, associated with the exercising of stock options, was $\$ 1.7$ million during the nine months ended September 30, 2009. Additionally, a benefit was realized in the amount of $\$ 1.4$ million from excess taxes from share-based compensation.

Our $\$ 120.0$ million Senior Credit Facility matures on October 8, 2013. The Senior Credit Facility bears interest at a rate ranging from $0.50 \%$ to $1.75 \%$ plus the lender s prime rate or, at our 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 terms of the Senior Credit Facility require us to comply with certain financial covenants which include a funded debt to earnings before interest, taxes, depreciation and amortization (EBITDA, as defined in the Senior Credit Facility) ratio, and an interest coverage ratio. The Senior Credit Facility is secured by substantially all present and future assets and properties of the Company. As of September 30, 2009, we had approximately $\$ 118.0$ million available under the Senior Credit Facility. At September 30, 2009, we had no amounts outstanding under the Senior Credit Facility and we were in compliance with all financial covenants.

We also intend to continue evaluation of acquisition and technology licensing candidates. As such, we may need to incur additional debt, or issue 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, 2009, 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.

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There have been no significant changes in critical accounting policies or management estimates since the year ended December 31, 2008. 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, 2008.

## ITEM 3. Quantitative and Qualitative Disclosures About Market Risk <br> 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, 2009. Based on our market risk sensitive instruments outstanding at September 30, 2009 and 2008, 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 and marketable securities focuses on maintaining acceptable levels of interest rate risk and liquidity. Although we continually evaluate our placement of investments, as of September 30, 2009, our cash and cash equivalents and marketable securities were placed in certificates of deposit, commercial paper, money market 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 negatively impact international sales of our products, 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 are 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, 2009 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, 2009 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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## 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, 2008. 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, 2008.

## 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, 2009:

| Period | Total number of shares <br> purchased | Average price paid per share | Total number of shares purchased as part of publicly announced plan or program |  | Approximate dollar value of shares that may yet be purchased nder the plan or program |
| :---: | :---: | :---: | :---: | :---: | :---: |
| July 1 July 31, 2009 |  | \$ |  | \$ | 8,066,000 |
| August 1 August 31, 2009 |  |  |  |  | 8,066,000 |
| September 1 September 30, 2009 |  |  |  |  | 8,066,000 |
| Total |  | \$ |  | \$ | 8,066,000 |

(1) 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 repurchase up to an additional
$\$ 25.0$ million in shares of our common stock under our stock repurchase program. In December 2008, we announced that our Board of Directors authorized us to repurchase 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 on December 1, 2010 unless extended by our Board of Directors.

## ITEM 5. OTHER INFORMATION

None.

## ITEM 6. Exhibits

## Exhibit <br> 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 Registrant 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.)

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## Exhibit

Number
10.1*(1) Employment Offer Letter, dated June 22, 2009, between Quidel Corporation and Timothy T. Stenzel.
10.2*(1) Agreement Re: Change in Control, entered into on September 1, 2009, between Quidel Corporation and Timothy T. Stenzel.
31.1* Certification by Principal 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 Principal Financial and Accounting 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 Principal Executive Officer and Principal Financial and Accounting 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.
(1) Indicates a management plan or compensatory plan or arrangement.


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## 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.

## QUIDEL CORPORATION

/s/ DOUGLAS C. BRYANT
Douglas C. Bryant
President and Chief Executive Officer
(Principal Executive Officer)
/s/ JOHN M. RADAK
John M. Radak
Chief Financial Officer
(Principal Financial Officer and Accounting
Officer)

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## Exhibit Index

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

