QUIDEL CORP /DE/
Form 10-Q
October 29, 2010

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2010

or

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

For the transition period from to

Commission File Number: 0-10961

QUIDEL CORPORATION

(Exact name of Registrant as specified in its charter)

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

10165 McKellar Court, San Diego, California 92121
(Address of principal executive offices, 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 þ 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 o 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	Accelerated filer þ	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 þ

As of October 27, 2010, 28,506,263 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, except par value; unaudited)

	September 30, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,229	$ 89,003
Marketable securities		3,999
Accounts receivable, net	12,862	9,717
Inventories	19,263	15,038
Deferred tax asset current	7,308	6,018
Income tax receivable	5,456	
Prepaid expenses and other current assets	3,499	2,448
Total current assets	55,617	126,223
Property and equipment, net	30,942	21,251
Goodwill	70,411	6,470
Intangible assets, net	54,705	1,943
Deferred tax asset non-current		9,065
Other non-current assets	1,788	1,393
Total assets	$ 213,463	$ 166,345
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 4,824	$ 5,212
Accrued payroll and related expenses	3,977	5,187
Accrued royalties	1,900	5,513
Current portion of lease obligation	260	234
Income taxes payable	758	6,151
Other current liabilities	5,440	7,227
Total current liabilities	17,159	29,524
Long term debt	73,551	
Lease obligation, net of current portion	6,637	6,527
Deferred tax liability non-current	458	
Income taxes payable	2,360	2,360
Other non-current liabilities	2,104	1,484
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $.001 par value per share; 5,000 shares authorized; none issued or outstanding at September 30, 2010 and December 31, 2009		
Common stock, $.001 par value per share; 50,000 shares authorized; 28,508 and 29,026 shares issued and outstanding at September 30, 2010 and	29	29

December 31, 2009, respectively				
Additional paid-in capital		108,050		112,426
Accumulated other comprehensive income				34
Retained earnings		3,115		13,961
Total stockholders equity		111,194		126,450
Total liabilities and stockholders equity	$	213,463	$	166,345

See accompanying notes.

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

	Three months ended September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
Total revenues	$ 28,225	$ 56,152	$ 81,630	$ 97,685
Costs and expenses				
Cost of sales (excludes amortization of intangible assets of $1.7 million, $0.3 million, $4.1 million and $0.9 million, respectively)	12,807	17,670	37,678	36,169
Amortization of inventory fair value adjustment from acquisition			1,118	
Total cost of sales (excludes amortization of intangible assets of $1.7 million, $0.3 million, $4.1 million and $0.9 million, respectively)	12,807	17,670	38,796	36,169
Research and development	6,148	3,157	18,772	9,003
Sales and marketing	5,797	6,400	18,068	16,538
General and administrative	4,759	4,325	13,792	12,125
Amortization of intangible assets from acquired businesses	1,624		3,743	
Amortization of intangible assets from licensed technology	324	345	972	1,040
Business acquisition and integration costs, and restructuring charges	115		2,181	2,038
Total costs and expenses	31,574	31,897	96,324	76,913
Operating (loss) income	(3,349)	24,255	(14,694)	20,772
Other (expense) income				
Interest income	15	53	195	299
Interest expense	(645)	(148)	(1,655)	(459)
Other expense		(5)		(5)
Total other expense	(630)	(100)	(1,460)	(165)
(Loss) income before provision for taxes	(3,979)	24,155	(16,154)	20,607
(Benefit) provision for income taxes	1,882	9,215	(5,309)	7,831
Net (loss) income	$ (5,861)	$ 14,940	$ (10,845)	$ 12,776
Basic and diluted (loss) earnings per share	$ (0.21)	$ 0.50	$ (0.38)	$ 0.42
Shares used in basic per share calculation	28,183	29,713	28,362	30,151
Shares used in diluted per share calculation	28,183	30,149	28,362	30,547

See accompanying notes.

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

	Nine months ended September 30,	
	2010	**2009**
OPERATING ACTIVITIES:		
Net (loss) income	$ (10,845)	$ 12,776
Adjustments to reconcile net (loss) income to net cash (used for) provided by operating activities:		
Depreciation, amortization and other	8,779	4,478
Stock-based compensation expense	3,881	2,502
Gain on sale of assets	2	
Deferred tax asset	(947)	2,200
Excess tax benefit from share-based compensation		(1,400)
Changes in assets and liabilities:		
Accounts receivable	3,694	(108)
Inventories	864	(1,181)
Income tax receivable	(1,306)	
Prepaid expenses and other current assets	(243)	(920)
Accounts payable	(2,454)	871
Accrued payroll and related expenses	(1,689)	1,996
Accrued royalties	(3,877)	1,993
Accrued income taxes payable	(5,393)	
Other current and non-current liabilities	(3,856)	4,547
Net cash (used for) provided by operating activities	(13,390)	27,754
INVESTING ACTIVITIES:		
Acquisitions of property and equipment	(5,305)	(3,180)
Payment for licensed technology	(2,000)	
Purchase of business, net of cash acquired of $3.1 million	(128,162)	
Purchases of marketable securities		(4,984)
Proceeds from sale of marketable securities	3,999	
Other assets	65	(107)
Net cash used for investing activities	(131,403)	(8,271)
FINANCING ACTIVITIES:		
Payments on lease obligation	(153)	(640)
Purchases of common stock	(9,181)	(19,542)
Borrowing from line of credit	75,000	
Payments on borrowing from line of credit	(3,000)	
Excess tax benefit from share-based compensation		1,400
Proceeds from issuance of common stock, net of cancellations	1,056	1,739
Other	(703)	

Net cash provided by (used for) financing activities	63,019	(17,043)
Net (decrease) increase in cash and cash equivalents	(81,774)	2,440
Cash and cash equivalents, beginning of period	89,003	57,908
Cash and cash equivalents, end of period	$ 7,229	$ 60,348
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid during the period for interest	$ 1,655	$ 459
Cash paid during the period for income taxes	$ 6,952	$ 200
NON-CASH INVESTING ACTIVITIES:		
Purchase of capital equipment by incurring current liabilities	$ 369	$ 869

See accompanying notes.

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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. Certain reclassifications have been made to prior year amounts to conform to the current year presentation. 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, 2010, and for the three and nine months ended September 30, 2010 and 2009, is unaudited. Operating results for the three and nine months ended September 30, 2010 are not necessarily indicative of the results that may be expected for the year ending December 31, 2010. For further information, refer to the Company s consolidated financial statements and footnotes thereto for the year ended December 31, 2009 included in the Company s 2009 Annual Report on Form 10-K. Subsequent events have been evaluated up to and including the date these financial statements were issued.

For 2010 and 2009, the Company s fiscal year will or has ended on January 2, 2011 and January 3, 2010, respectively. For 2010 and 2009, the Company s third quarter ended on October 3, 2010 and September 27, 2009, respectively. For ease of reference, the calendar quarter end dates are used herein. The three and nine month periods ended September 30, 2010 and 2009 both included 13 weeks and 39 weeks, respectively.

Note 2. Acquisition

On February 19, 2010, the Company acquired Diagnostic Hybrids, Inc. (DHI) a privately-held, *in vitro* diagnostics (IVD) company, based in Athens, Ohio, that is a market leader in the manufacturing and commercialization of FDA-cleared direct and culture-based fluorescent IVD assays used in hospital and reference laboratories for a variety of diseases, including viral respiratory infections, herpes, Chlamydia and other viral infections, and thyroid diseases. DHI s direct sales force serves over 700 North American customers, and its products are sold via distributors outside the United States. DHI s products are offered under various brand names including, among others, ELVIS®, R-Mix , Mixed Fresh Cells , FreshCells , ReadyCells and Thyretain . The Company paid approximately $131.2 million in cash to acquire DHI. The Company paid for the acquisition of DHI using cash and cash equivalents on hand and borrowing $75.0 million under the Senior Credit Facility (as defined below). Included in the consolidated statements of operations for the nine months ended September 30, 2010 is revenue and net loss of $24.3 million and $0.4 million, respectively, related to the operations of DHI since acquisition. Net loss of $0.4 million includes the amortization of acquired intangibles and interest expense on the borrowing under the Company s Senior Credit Facility.

The purchase price of DHI is allocated to the underlying net assets acquired and liabilities assumed based on their respective fair values as of February 19, 2010 with any excess purchase price allocated to goodwill. The Company s preliminary allocation of the purchase price to the net tangible and intangible assets acquired and liabilities assumed as of September 30, 2010 is as follows:

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Quidel Corporation
Notes to Consolidated Financial Statements (Continued)
(Unaudited)

Note 2. Acquisition (Continued)

(in thousands)	
Total cash consideration	$ 131,212
Allocated to:	
Current assets	27,219
Property, plant and equipment	7,799
Other non-current assets	82
In-process research and development	2,110
Intangible assets	53,410
Current liabilities (excluding current portion of note payable)	(4,172)
Note payable to state agency	(1,882)
Other non-current liabilities	(17,295)
Goodwill	63,941
Net assets acquired	$ 131,212

The Company expects to complete the allocation of the purchase price by the end of the first quarter of 2011. The allocation of the purchase price is preliminary pending completion of the final valuation of the deferred tax assets and liabilities resulting from the acquisition. Included in the goodwill amount is $16.5 million related to deferred tax liabilities recorded as a result of the inability to deduct intangible amortization expense associated with the acquisition of DHI. The Company s cost basis in the intangible assets is zero requiring an adjustment to the deferred tax liability to properly capture the Company s ongoing tax rate. The remainder of the goodwill balance reflects the complementary strategic fit that the acquisition of DHI brought to the Company.

The following table presents the amounts assigned to the identifiable intangible assets acquired. Intangible assets (except for in-process research and development) are amortized on a straight-line basis over the weighted-average amortization periods noted below for each type. In-process research and development is not amortized, but assessed at least annually for impairment, or more frequently when events or changes in circumstances indicate that the asset might be impaired.

(in thousands)	**Fair value**	**Weighted-average amortization period (years)**
Customer relationships	$ 5,450	8.0
Purchased technology	46,570	8.0
Patents and trademarks	1,390	15.0
In-process research and development	2,110	N/A
Total	$ 55,520	

The following unaudited pro forma financial information shows the combined results of operations of the Company, including DHI, as if the acquisition had occurred as of the beginning of the periods presented. The unaudited pro forma financial information is not intended to represent or be indicative of the Company s consolidated financial results of operations that would have been reported had the acquisition been completed as of the beginning of the periods presented and should not be taken as indicative of the Company s future consolidated results of operations.

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Quidel Corporation
Notes to Consolidated Financial Statements (Continued)
(Unaudited)

Note 2. Acquisition (Continued)

(in thousands, except per share data)	Three months ended September 30, 2010	Three months ended September 30, 2009	Nine months ended September 30, 2010	Nine months ended September 30, 2009
Pro forma total revenues	$ 28,225	$ 68,207	$ 87,335	$ 132,412
Pro forma net (loss) income	$ (5,861)	$ 15,178	$ (13,563)	$ 14,062
Pro forma basic net (loss) earnings per share(1)	$ (0.21)	$ 0.51	$ (0.48)	$ 0.47
Pro forma diluted net (loss) earnings per share(1)	$ (0.21)	$ 0.50	$ (0.48)	$ 0.46

(1) Included in the pro forma $0.48 net loss per share for the nine months ended September 30, 2010 is $5.3 million of transaction expenses relating to the acquisition of DHI, which contributed $0.11 to the pro forma net loss per share.

Note 3. Comprehensive (Loss) Income

Net (loss) income is equal to comprehensive (loss) income for both the three and nine months ended September 30, 2010 and 2009, respectively.

Note 4. Computation of (Loss) Earnings Per Share

Basic (loss) earnings per share was computed by dividing net (loss) 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 only performance conditions 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 would be anti-dilutive. For the three and nine months ended September 30, 2009, 1.4 million and 1.6 million shares were excluded from the calculation of diluted earnings per share as their effect was anti-dilutive, respectively.

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

	Three months ended September 30,		Nine months ended September 30,	
	2010	**2009**	**2010**	**2009**
Shares used in basic (loss) earnings per share (weighted-average common shares outstanding)	28,183	29,713	28,362	30,151
Effect of dilutive stock options and restricted stock awards		436		396
Shares used in diluted (loss) earnings per share calculation	28,183	30,149	28,362	30,547

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Quidel Corporation
Notes to Consolidated Financial Statements (Continued)
(Unaudited)

Note 5. Inventories

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

	September 30, 2010	December 31, 2009
Raw materials	$ 8,234	$ 5,307
Work-in-process (materials, labor and overhead)	4,991	3,711
Finished goods (materials, labor and overhead)	6,038	6,020
	$ 19,263	$ 15,038

Note 6. Other Current Liabilities

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

	September 30, 2010	December 31, 2009
Customer incentives	$ 827	$ 4,824
Stock repurchases not settled as of December 31, 2009		1,234
Accrued liability for technology licenses	2,750	
Accrued professional fees	257	345
Current portion of note payable to state agency	210	
Accrued interest on line of credit	29	
Other	1,367	824
	$ 5,440	$ 7,227

Note 7. Income Taxes

The Company s effective tax rate for the nine months ended September 30, 2010 and 2009 was 32.9% and 38.0%, respectively. The Company recognized a tax benefit of $5.3 million and tax expense of $7.8 million for the nine months ended September 30, 2010 and 2009, respectively. For the nine months ended September 30, 2010, the income tax benefit includes a charge related to the re-valuation of the Company s deferred tax assets due to a change in the statutory state tax rate. For the year ended December 31, 2010, the annual effective tax rate is impacted by the deferred tax asset re-valuation discussed above, certain acquisition related non-deductible transaction costs, the exclusion of the federal research and development tax credit and reversing a portion of a tax benefit recognized in 2009 relating to the Company s production deduction.

The Company is subject to periodic audits by domestic and foreign tax authorities. The Company s federal tax years for 1995 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 its assessment of many factors, including past experience and interpretations of tax law applied to the facts of each matter.

Note 8. 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 for base rate loans at a rate equal to (i) the higher of (a) the lender s prime rate and (b) the Federal funds rate plus one-half of one percent, plus (ii) the applicable rate or for Eurodollar rate loans the interest rate is equal to (i) the Eurodollar rate, plus (ii) the applicable rate. The applicable rate is generally determined in accordance with a performance pricing grid based on the Company s leverage ratio and ranges from 0.50% to 1.75% for base rate loans and from 1.50% to 2.75% for Eurodollar rate loans. The current applicable rate is subject to adjustment, as described below. The agreement governing the Senior Credit Facility is

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Quidel Corporation
Notes to Consolidated Financial Statements (Continued)
(Unaudited)

Note 8. Line of Credit (Continued)

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 EBITDA ratio (as defined in the Senior Credit Facility, with adjusted EBITDA generally calculated as earnings before, among other adjustments, interest, taxes, depreciation and amortization) not to exceed 3:00 to 1:00 as of the end of each fiscal quarter, and an interest coverage ratio of not less than 3:50 to 1:00 as of the end of each fiscal quarter. The Senior Credit Facility is secured by substantially all present and future assets and properties of the Company. As of September 30, 2010, the Company had $48.0 million available under the Senior Credit Facility. The Company s ability to borrow under the Senior Credit Facility fluctuates from time to time due to, among other factors, the Company s borrowings under the facility and its funded debt to adjusted EBITDA ratio. At September 30, 2010, the Company had $72.0 million outstanding under the Senior Credit Facility which was borrowed in connection with the acquisition of DHI. At September 30, 2010, the Company was in compliance with all covenants.

During the first quarter of 2010, the Senior Credit Facility was amended for various matters, including amending the credit and security agreement to (i) permit the acquisition of all capital stock of DHI, (ii) allow certain indebtedness and liens related to the DHI acquisition to remain outstanding after the close of the acquisition and (iii) to amend the Senior Credit Facility to increase the aggregate amount of permitted stock repurchases thereunder. In addition, during the third quarter of 2010, the Senior Credit Facility was amended to exclude the application of the funded debt to adjusted EBITDA ratio and interest coverage ratio for the measurement date occurring on December 31, 2010. The amendment also increased the applicable interest rate under the credit agreement by 50 basis points commencing on the date of the amendment and remaining effective until the Company delivers its compliance certificate for the first quarter of 2011 showing compliance with both financial covenants. If such compliance is demonstrated, the applicable rate will decrease by 50 basis points.

Note 9. Stockholders Equity

During the nine months ended September 30, 2010, 161,903 shares of restricted stock were awarded, 79,559 shares of restricted stock were cancelled, 114,330 shares of common stock were issued due to the exercise of stock options and 25,030 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 $1.1 million. Additionally, during the nine months ended September 30, 2010, 740,177 shares of outstanding common stock were repurchased for approximately $9.2 million, which primarily included shares repurchased under the Company s previously announced share repurchase program, but also included 27,677 shares repurchased in connection with 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, 2010.

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Quidel Corporation
Notes to Consolidated Financial Statements (Continued)
(Unaudited)

Note 10. Stock-Based Compensation

The compensation expense related to the Company s stock-based compensation plans included in the accompanying Consolidated Statements of Operations for the three and nine months ended September 30, 2010 and 2009 was as follows (in millions):

	Three months ended September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
Cost of sales	$ 0.1	$ 0.1	$ 0.5	$ 0.3
Research and development	0.2	0.1	0.4	0.2
Sales and marketing	0.1	0.1	0.3	0.2
General and administrative	0.9	0.5	2.7	2.0
Restructuring charges				(0.2)
	$ 1.3	$ 0.8	$ 3.9	$ 2.5

Total compensation expense recognized for the three months ended September 30, 2010 and 2009 includes $1.0 million and $0.7 million related to stock options and $0.3 million and $0.1 million related to restricted stock, respectively. Total compensation expense recognized for the nine months ended September 30, 2010 and 2009 includes $3.0 million and $1.9 million related to stock options and $0.9 million and $0.6 million related to restricted stock, respectively. As of September 30, 2010, total unrecognized compensation expense related to nonvested stock options was $5.8 million, which is expected to be recognized over a weighted-average period of approximately 2.5 years. As of September 30, 2010, total unrecognized compensation expense related to nonvested restricted stock was $2.1 million, which is expected to be recognized over a weighted-average period of approximately 2.6 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, 2010 and 2009.

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.

	Nine months ended September 30,	
	2010	2009
Expected option life (in years)	4.89	4.65
Volatility rate	0.52	0.52
Risk-free interest rate	2.40%	1.87%
Forfeiture rate	15.5%	15.5%
Dividend rate	0%	0%

The weighted-average grant date fair value of stock options granted during the nine months ended September 30, 2010 and 2009 was $6.86 and $4.80, 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 11. Industry and Geographic Information

The Company operates in one reportable segment. Sales to customers outside the U.S. represented $13.9 million (17%) and $21.7 million (22%) of total revenue for the nine months ended September 30, 2010 and 2009, respectively. As of September 30, 2010 and December 31, 2009, balances due from foreign customers were

$2.0 million and $7.2 million, respectively.

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Quidel Corporation
Notes to Consolidated Financial Statements (Continued)
(Unaudited)

Note 11. Industry and Geographic Information (Continued)

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

	Nine months ended September 30,	
	2010	**2009**
Customer:		
A	11%	16%
B	6%	14%
C	3%	13%
D	6%	11%
	26%	54%

As of September 30, 2010, accounts receivable from customers with balances due in excess of 10% of total accounts receivable totaled $4.0 million while, at December 31, 2009, accounts receivable from customers with balances due in excess of 10% of total accounts receivable totaled $6.8 million.

Note 12. Lease Obligation

During 1999, the Company completed a sale and leaseback transaction of its approximately 78,000 square-foot executive, administrative, manufacturing and research and development facility in San Diego. The facility was sold for $15.0 million, of which $3.8 million was capital contributed by the Company. The sale was an all cash transaction, netting the Company approximately $7.0 million. The Company is a 25% limited partner in the partnership that acquired the facility. The transaction was deemed a financing transaction under the guidance in ASC Topic 840-40, Accounting for Sales of Real Estate. The assets sold remain on the books of the Company and will continue to be depreciated over the estimated useful life. The Company s lease was initially for 15 years, with options to extend the lease for up to two additional five-year periods.

In December 2009, the Company amended the terms of its lease agreement which had no significant impact on the Company s financial statements. The amended terms include a new ten-year lease term through December 2019, with options to extend the lease for up to three additional five-year periods. The Company will amortize the lease obligation over this new term. The amount of the monthly rental payments remain the same under the amendment. In addition, the Company has the option to purchase the general partner s interest in the partnership in January 2015 for a fixed price. The Company has determined that the partnership is a variable interest entity (VIE). The Company is not, however, the primary beneficiary of the VIE as it does not absorb the majority of the partnership s expected losses or receive a majority of the partnership s residual returns. The Company made lease payments to the partnership in connection with the San Diego facility of approximately $0.8 million and $1.1 million for the nine months ended September 30, 2010 and 2009, respectively.

Note 13. 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 s estimates, assumptions and specific knowledge of the assets/liabilities and related market assumptions. The fair value of our cash equivalents are determined based on Level 1 inputs, which consist of quoted prices in active markets for identical assets.

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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, our ability to develop new products and technology, 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 medical reimbursement system currently in place and future changes to that system, manufacturing and production delays or difficulties, adverse regulatory actions or delays in product reviews by the U.S. Food and Drug Administration (the FDA), compliance with FDA and environmental regulations, our ability to meet unexpected increases in demand for our products, our ability to execute our growth strategy, including the integration of new companies or technologies, disruptions in the global capital and credit markets, our ability to hire key personnel, 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 acceptance, 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 fiscal year, including projections about our revenue, gross margins, expenses, effective tax rate and the effect the DHI acquisition will have on the seasonality of our business; projected capital expenditures for the fiscal year and our source of funds for such expenditures; the sufficiency of our liquidity and capital resources; the future impact of deferred tax assets or liabilities; the expected vesting periods of unrecognized compensation expense; and our intention to continue to evaluate technology and Company acquisition 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, 2009, 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 testing solutions. These diagnostic testing solutions primarily include applications in infectious diseases, women s health and gastrointestinal diseases. We sell our products directly to end users and distributors, in each case, for professional use in physician offices, hospitals, clinical laboratories, reference laboratories, leading universities, retail clinics and wellness screening centers. We market our products in the U.S. through a network of national and regional distributors, and a direct sales force. Internationally, we sell and market primarily in Japan and Europe through distributor arrangements.

Outlook

The influenza pandemic of 2009 has not recurred in the first three quarters of 2010 and we do not expect it to recur in the fourth quarter of 2010. Accordingly, we have experienced a significant decrease in our influenza test sales, related earnings and cash flows during the first three quarters of 2010. Additionally, we anticipate gross margins will trend lower year over year as a result of the product mix shift from 2009 s high level of influenza sales. Also, we

expect a normal 2010/2011 cold and flu season, however, we do not expect U.S. distributors to significantly build inventories ahead of the

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season as they have in prior years, and as a result we expect to see more of a shift in our influenza test sales from Q4 2010 to Q1 2011. Nonetheless, the acquisition of DHI builds upon and diversifies our revenue base and we expect the acquisition to lessen the effect of seasonality on our business quarter to quarter. We will continue our focus on prudently managing our business and delivering solid financial results, while at the same time striving to continue to introduce new products to the market and maintaining our emphasis on research and development investments for longer term growth. Finally, we will continue to evaluate opportunities to acquire new product lines and technologies, as well as, company acquisitions.

Results of Operations

Three months ended September 30, 2010 compared to the three months ended September 30, 2009

Total Revenues

During the first quarter of 2010, in connection with the acquisition of DHI, we changed our disease state classifications within our one reportable segment to better reflect current business activities and taking into account the products sold by DHI. The information for all prior periods presented has been restated to conform to the current presentation. The following table compares total revenues for the three months ended September 30, 2010 and 2009 (in thousands, except percentages):

	For the three months ended September 30,		Increase (Decrease)	
	2010	2009	$	%
Infectious disease net product sales	$ 16,188	$ 47,023	$ (30,835)	(66)%
Women s health net product sales	8,717	6,473	2,244	35%
Gastrointestinal disease net product sales	1,661	619	1,042	168%
Other net product sales	946	1,720	(774)	(45)%
Royalty, license fees and grant revenue	713	317	396	125%
Total revenues	$ 28,225	$ 56,152	$ (27,927)	(50)%

The decrease in total revenues was primarily due to a decrease in sales of our influenza products as a result of the influenza pandemic which occurred in 2009. Partially offsetting the decrease in total revenues was an increase in sales as a result of the acquisition of DHI which contributed $9.4 million; including $7.0 million in infectious disease, $1.5 million in women s health, $0.7 million in gastrointestinal disease and $0.2 million in grant revenue.

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

Cost of Sales

Cost of sales decreased 28% to $12.8 million, or 45% of total revenues for the three months ended September 30, 2010, compared to $17.7 million, or 31% of total revenues for the three months ended September 30, 2009. The absolute dollar decrease in cost of sales is primarily related to the variable nature of direct costs (material and labor) associated with the 50% decrease in total revenues. The increase in cost of sales as a percentage of total revenue was primarily related to an unfavorable product mix.

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Operating Expenses

The following table compares operating expenses for the three months ended September 30, 2010 and 2009 (in thousands, except percentages):

	For the three months ended September 30,					
	2010		2009		Increase (Decrease)	
	Operating expenses	As a % of total revenues	Operating expenses	As a % of total revenues	$	%
Research and development	$ 6,148	22%	$ 3,157	6%	$ 2,991	95%
Sales and marketing	5,797	21%	6,400	11%	(603)	(9)%
General and administrative	4,759	17%	4,325	8%	434	10%
Amortization of intangible assets from acquired businesses	1,624	6%			1,624	N/A
Amortization of intangible assets from licensed technology	324	1%	345	1%	(21)	(6)%
Business acquisition and integration costs	115	1%			115	N/A

Research and Development Expense

Research and development expense increased $2.5 million as a result of the acquisition of DHI. In addition, there was an increase in costs associated with the development of potential new technologies and with products under development.

Sales and Marketing Expense

Sales and marketing expense decreased primarily related to a decrease in sales commissions and product shipment costs and product promotions associated with a lower sales volume for 2010 excluding DHI compared to 2009. Partially offsetting the decrease was an increase of $0.6 million as a result of the acquisition of DHI. 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 overall increase in general and administrative expense reflects an increase of $0.9 million from the acquisition of DHI, partially offset by a decrease in employee incentives associated with a lower sales volume for 2010 excluding DHI compared to 2009.

Amortization of Intangible Assets from Acquired Businesses

Amortization of intangible assets from acquired businesses consists of customer relationships, purchased technology and patents and trademarks acquired in connection with the acquisition of DHI.

Amortization of Intangible Assets from Licensed Technology

Amortization of intangible assets from licensed technology consists primarily of expense associated with purchased technology.

Business Acquisition and Integration Costs

We incurred $0.1 million in expenses in the third quarter of 2010 primarily related to professional fees for acquisition and integration activities.

Other Income (Expense)

The decrease in interest income is related to the decrease in the average interest rate and a decrease in our average cash balance during the three months ended September 30, 2010 as compared to the three months ended

September 30, 2009. Interest expense primarily relates to interest paid on borrowings under the Senior Credit Facility and interest paid on our lease obligation associated with our San Diego facility.

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Income Taxes

During the three months ended September 30, 2010, we decreased our expected annual effective tax rate. Therefore, we reversed a portion of the tax benefit previously recorded for the six months ended June 30, 2010. The adjustment resulted in recognizing tax expense on a pre-tax loss, as opposed to a tax benefit, for the three months ended September 30, 2010. For the year ended December 31, 2010, the annual effective tax rate is impacted by a deferred tax asset re-valuation due to a change in the statutory state tax rate, certain acquisition related non-deductible transaction costs, the exclusion of the federal research and development tax credit, and reversing a portion of a tax benefit recognized in 2009 relating to our production deduction.

Nine months ended September 30, 2010 compared to the nine months ended September 30, 2009

Total Revenues

During the first quarter of 2010, in connection with the acquisition of DHI, we changed our disease state classifications within our one reportable segment to better reflect current business activities and taking into account the products sold by DHI. The information for all prior periods presented has been restated to conform to the current presentation. The following table compares total revenues for the nine months ended September 30, 2010 and 2009 (in thousands, except percentages):

	For the nine months ended September 30,		Increase (Decrease)	
	2010	2009	$	%
Infectious disease net product sales	$ 47,478	$ 70,918	$ (23,440)	(33)%
Women s health net product sales	24,714	18,333	6,381	35%
Gastrointestinal disease net product sales	4,283	2,449	1,834	75%
Other net product sales	3,400	5,011	(1,611)	(32)%
Royalty, license fees and grant revenue	1,755	974	781	80%
Total revenues	$ 81,630	$ 97,685	$ (16,055)	(16)%

The decrease in total revenues was primarily due to a decrease in sales of our influenza products as a result of the influenza pandemic which occurred in 2009. Partially offsetting the decrease in total revenues was an increase in sales as a result of the acquisition of DHI which contributed $24.3 million; including $18.6 million in infectious disease, $3.5 million in women s health, $1.6 million in gastrointestinal disease and $0.6 million in grant revenue. In addition, total revenues relating to our core non-seasonal products increased as a result of inventory levels normalizing at our distributors during late 2009. During the first nine months of 2010, sales of our core non-seasonal products more closely matched distributor sales to our end-use customers.

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

Cost of Sales

Cost of sales increased 7% to $38.8 million, or 48% of total revenues for the nine months ended September 30, 2010, compared to $36.2 million, or 37% of total revenues for the nine months ended September 30, 2009. The absolute dollar increase in cost of sales is primarily related to the acquisition of DHI largely offset by decreased costs associated with lower influenza sales year-over-year. The increase in cost of sales as a percentage of total revenue was primarily related to an unfavorable product mix and the amortization of an inventory fair value adjustment associated with the acquisition of DHI.

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Operating Expenses

The following table compares operating expenses for the nine months ended September 30, 2010 and 2009 (in thousands, except percentages):

	For the nine months ended September 30,					
	2010		2009			
	Operating expenses	As a % of total revenues	Operating expenses	As a % of Total revenues	Increase (Decrease) $	Increase (Decrease) %
Research and development	$ 18,772	23%	$ 9,003	9%	$ 9,769	109%
Sales and marketing	18,068	22%	16,538	17%	1,530	9%
General and administrative	13,792	17%	12,125	12%	1,667	14%
Amortization of intangible assets from acquired businesses	3,743	5%			3,743	N/A
Amortization of intangible assets from licensed technology	972	1%	1,040	1%	(68)	(7)%
Business acquisition and integration costs, and restructuring charges	2,181	3%	2,038	2%	143	7%

Research and Development Expense

Research and development expense increased $7.0 million as a result of the acquisition of DHI. In addition, there was an increase in costs associated with the development of potential new technologies and with products under development.

Sales and Marketing Expense

Sales and marketing expense increased $2.3 million as a result of the acquisition of DHI. The overall increase was partially offset by a decrease in sales commissions and product promotions associated with a lower sales volume for 2010 excluding DHI compared to 2009. Other key components of this expense relate to continued investment in assessing future product extensions and enhancements and market research.

General and Administrative Expense

General and administrative expense increased $2.0 million as a result of the acquisition of DHI. The overall increase was partially offset by a decrease in employee incentives associated with a lower sales volume for 2010 excluding DHI compared to 2009 and a decrease in transition costs from those incurred in the first quarter of 2009 relating to the hiring of our new Chief Executive Officer.

Amortization of Intangible Assets from Acquired Businesses

Amortization of intangible assets from acquired businesses consists of customer relationships, purchased technology and patents and trademarks acquired in connection with the acquisition of DHI.

Amortization of Intangible Assets from Licensed Technology

Amortization of intangible assets from licensed technology consists primarily of expense associated with purchased technology.

Business Acquisition and Integration Costs, and Restructuring Charges

We incurred $2.2 million in expenses during the nine months ended September 30, 2010 primarily related to professional fees for acquisition and integration activities. 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 the average interest rate and a decrease in our average cash balance during the nine months ended September 30, 2010 as compared to the nine months ended September 30, 2009.

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Interest expense primarily relates to interest paid on borrowings under the Senior Credit Facility and interest paid on our lease obligation associated with our San Diego facility.

Income Taxes

The effective tax rate for the nine months ended September 30, 2010 and 2009 was 32.9% and 38.0%, respectively. We recognized a tax benefit of $5.3 million and tax expense of $7.8 million for the nine months ended September 30, 2010 and 2009, respectively. For the nine months ended September 30, 2010, the income tax benefit includes a charge related to the re-valuation of our deferred tax assets due to a change in the statutory state tax rate. For the year ended December 31, 2010, the annual effective tax rate is impacted by the deferred tax asset re-valuation discussed above, certain acquisition related non-deductible transaction costs, the exclusion of the federal research and development tax credit, and reversing a portion of a tax benefit recognized in 2009 relating to our production deduction.

Liquidity and Capital Resources

As of September 30, 2010, our principal sources of liquidity consisted of $7.2 million in cash and cash equivalents, as well as $48.0 million available to us under our Senior Credit Facility. Our working capital as of September 30, 2010 was $38.5 million.

Cash used for our operating activities was $13.4 million during the nine months ended September 30, 2010. We had a net loss of $10.8 million, including non-cash charges of $8.8 million of depreciation and amortization of intangible assets and property and equipment. Other changes in operating assets and liabilities included a decrease in income taxes payable of $5.4 million primarily as a result of tax payments made during the first nine months of 2010 as a result of higher taxable earnings in 2009. Accrued royalties decreased by $3.9 million reflecting the lower revenue base in which we pay royalties. The decrease in other current and non-current liabilities of $3.9 million reflects lower customer incentives related to the decrease in revenues that are eligible for volume discounts for the first nine months of 2010 compared to 2009.

Our investing activities used $131.4 million during the nine months ended September 30, 2010 primarily related to the purchase of DHI. In addition, we used approximately $5.3 million for the acquisition of production and scientific equipment and building improvements. These uses of cash were partially offset by proceeds of $4.0 million as a result of the sale of our marketable securities during the first nine months of 2010.

We are planning approximately $2.0 million in capital expenditures for the remainder of 2010. The primary purpose for our capital expenditures is to acquire manufacturing equipment, implement facility improvements, and for the purchase or development of information technology. We plan to fund these capital expenditures with cash flow from operations and other available sources of liquidity. We have $1.0 million in firm purchase commitments with respect to such planned capital expenditures as of the date of filing this report.

Our financing activities generated approximately $63.0 million of cash during the nine months ended September 30, 2010. This was primarily related to our borrowing of $75.0 million under the Senior Credit Facility in connection with the acquisition of DHI, which was partially offset by our repurchase of 740,177 shares of our common stock at a cost of approximately $9.2 million and re-payments on our borrowing from the Senior Credit Facility of $3.0 million.

Our $120.0 million Senior Credit Facility matures on October 8, 2013. The Senior Credit Facility bears interest for base rate loans at a rate equal to (i) the higher of (a) the lender s prime rate and (b) the Federal funds rate plus one-half of one percent, plus (ii) the applicable rate or for Eurodollar rate loans the interest rate is equal to (i) the Eurodollar rate, plus (ii) the applicable rate. The applicable rate is generally determined in accordance with a performance pricing grid based on our leverage ratio and ranges from 0.50% to 1.75% for base rate loans and from 1.50% to 2.75% for Eurodollar rate loans. The current applicable rate is subject to adjustment, as described below. 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 EBITDA ratio (as defined in the Senior Credit Facility, with adjusted EBITDA generally calculated as earnings before, among other adjustments, interest, taxes, depreciation and amortization) not to exceed 3:00 to 1:00 as

of the end of each fiscal quarter, and an interest coverage ratio of not less than 3:50 to 1:00 as of the end of each fiscal quarter. The Senior Credit Facility is secured by substantially all present and future

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assets and properties of the Company. As of September 30, 2010, we had $48.0 million available under the Senior Credit Facility. Our ability to borrow under the Senior Credit Facility fluctuates from time to time due to, among other factors, our borrowings under the facility and our funded debt to adjusted EBITDA ratio. At September 30, 2010, we had $72.0 million outstanding under the Senior Credit Facility which was borrowed in connection with the acquisition of DHI. At September 30, 2010, we were in compliance with all covenants.

During the first quarter of 2010, the Senior Credit Facility was amended for various matters, including amending the credit and security agreement to (i) permit the acquisition of all capital stock of DHI, (ii) allow certain indebtedness and liens related to the DHI acquisition to remain outstanding after the close of the acquisition and (iii) to amend the Senior Credit Facility to increase the aggregate amount of permitted stock repurchases thereunder. In addition, during the third quarter of 2010, the Senior Credit Facility was amended to exclude the application of the funded debt to adjusted EBITDA ratio and interest coverage ratio for the measurement date occurring on December 31, 2010. While we expect a normal 2010/2011 cold and flu season, we do not expect U.S. distributors to significantly build inventories ahead of the season as they have in prior years, and as a result we expect to see more of a shift in our influenza test sales from Q4 2010 to Q1 2011. Accordingly, we determined it was prudent to amend the existing terms of the Senior Credit Facility to provide us more flexibility. The amendment also increased the applicable interest rate under the credit agreement by 50 basis points commencing on the date of the amendment and remaining effective until we deliver our compliance certificate for the first quarter of 2011 showing compliance with both financial covenants. If such compliance is demonstrated, the applicable rate will decrease by 50 basis points.

Our 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. In addition, we intend to continue to evaluate candidates for acquisitions or technology licensing. If we determine to proceed with any such transactions, we may need to incur additional debt, or issue additional equity, to successfully complete the transactions. Based on our current cash position and our current assessment of future operating results, we believe that our existing sources of liquidity will be adequate to meet our operating needs during the next 12 months.

Off-Balance Sheet Arrangements

At September 30, 2010, we did not have any relationships or other arrangements 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 we believe are 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.

There have been no significant changes in critical accounting policies or management estimates since the year ended December 31, 2009. 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, 2009.

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ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

The fair market value of our floating interest rate debt is subject to interest rate risk. Generally, the fair market value of floating interest rate debt will vary as interest rates increase or decrease. We had $72.0 million outstanding under our Senior Credit Facility at September 30, 2010. The weighted average interest rate on these borrowings is currently 2.51%. A hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would increase our annual interest expense by approximately $0.7 million. Based on our market risk sensitive instruments outstanding at September 30, 2010 and 2009, we have determined that there was no material market risk exposure from such instruments 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, 2010, our cash and cash equivalents were placed in money market or overnight funds that we believe are highly liquid and not subject to material market fluctuation risk.

Foreign Currency Exchange Risk

The majority 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, 2010 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, 2010 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

The following risk factors replace in their entirety those risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2009.

Risks Related to Our Business

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

Fluctuations in our operating results, for any reason, could cause our growth or operating results to fall below the expectations of investors and securities analysts. For the nine months ended September 30, 2010, total revenue decreased 16% to $81.6 million from $97.7 million for the nine months ended September 30, 2009. This was largely driven by a decrease in sales of our influenza products as a result of the influenza pandemic which occurred in 2009 which was partially offset by the acquisition of DHI in early 2010 and an increase in our core non-seasonal products as a result of inventory levels normalizing at our distributors during late 2009.

We base the scope of our operations and related expenses on our estimates of future sales. A significant portion of our operating expenses are fixed, and we may not be able to rapidly adjust our expenses if our sales fall short of our expectations. Our sales estimates for future periods are based, among other factors, on estimated end-user demand for our products. Furthermore, if end-user consumption is less than estimated, sales to our distribution partners would be expected to fall short of expectations.

Factors that are beyond our control and that could affect our sales and other operating results in the future include:

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

- timing of the onset, length and severity of the cold and flu seasons;

- government and media attention focused on influenza and the related potential impact on humans from novel influenza viruses, such as H1N1 and avian flu;

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

- changes in the reimbursement systems or reimbursement amounts that end-users rely upon in choosing to use our products;

- changes in economic conditions in our domestic and international markets, such as economic downturns, decreased healthcare spending, reduced consumer demand, inflation and currency fluctuations;

- changes in sales levels because a significant portion of our costs are fixed costs, relatively higher sales would be expected to increase profitability, while relatively lower sales would not reduce costs by the same proportion, and could cause operating losses;

- lower than anticipated market penetration of our new or more recently introduced products;

- significant quantities of our product or that of our competitors in our distributors inventories or distribution channels; and

- changes in distributor buying patterns.

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Our senior credit facility imposes restrictions on our operations and activities, limits the amount we can borrow, and requires us to comply with various financial covenants.

We currently have a $120.0 million senior secured syndicated credit facility, which matures on October 8, 2013. Our senior credit facility bears interest for base rate loans at a rate equal to (i) the higher of (a) the lender s prime rate and (b) the Federal funds rate plus one-half of one percent, plus (ii) the applicable rate or for Eurodollar rate loans the interest rate is equal to (i) the Eurodollar rate, plus (ii) the applicable rate. The applicable rate is generally determined in accordance with a performance pricing grid based on our leverage ratio and ranges from 0.50% to 1.75% for base rate loans and from 1.50% to 2.75% for Eurodollar rate loans. The current applicable rate is subject to adjustment, as described in footnote 8 in the Notes to Consolidated Financial Statements . The agreement governing our senior credit facility includes certain customary limitations on our operations and activities, 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 EBITDA ratio (as defined in our senior credit facility, with adjusted EBITDA generally calculated as earnings before, among other adjustments, interest, taxes, depreciation and amortization) not to exceed 3:00 to 1:00 as of the end of each fiscal quarter, and an interest coverage ratio of not less than 3:50 to 1:00 as of the end of each fiscal quarter. If we fail to comply with these restrictions or covenants, our senior credit facility could become due and payable prior to maturity. As of September 30, 2010 we were in compliance with all financial covenants.

We may incur significant additional indebtedness. Our indebtedness could be costly or have adverse consequences.

We may incur significant additional indebtedness, subject to the restrictions in our senior credit facility (for which we may obtain waivers). As of September 30, 2010, we had $48.0 million available under our senior credit facility. Our borrowing capacity can fluctuate from time to time due to, among other factors, our funded debt to adjusted EBITDA ratio as and when measured under the senior credit facility.

Our indebtedness could be costly or have adverse consequences, such as:

- requiring us to dedicate a substantial portion of our cash flows from operations to payments on our debt;
- limiting our ability to obtain future financing for working capital, capital expenditures, acquisitions, debt obligations and other general corporate requirements;
- making us more vulnerable to adverse conditions in the general economy or our industry and to fluctuations in our operating results, including affecting our ability to comply with and maintain any financial tests and ratios required under our indebtedness;
- limiting our flexibility to engage in certain transactions or to plan for, or react to, changes in our business and the diagnostics industry;
- putting us at a disadvantage compared to competitors that have less relative and/or less restrictive debt; and
- subjecting us to additional restrictive financial and other covenants.

We may need to raise additional funds to finance our future capital or operating needs, which could have adverse consequences on our operations and the interests of our stockholders.

Seasonal fluctuations in our operating results could limit the cash we have available for research and development and other operating needs or cause us to fail to comply with the financial covenants in the documents governing our indebtedness. As a result, we may need to seek to raise funds through public or private debt or sale of equity to achieve our business strategy or to avoid non-compliance with our financial covenants. In addition, we may need funds to complete acquisitions, or may issue equity in connection with acquisitions. If we raise funds or acquire other technologies or businesses through issuance of equity, this could dilute the interests of our stockholders. Moreover, the availability of additional capital, whether debt or equity from private capital sources (including banks) or the

public capital markets, fluctuates as our financial condition and industry or market conditions in general change. There may be times when the private capital markets and the public debt or equity markets lack sufficient liquidity or when our securities cannot be sold at attractive prices, in which case we would not

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be able to access capital from these sources on favorable terms, if at all. We can give no assurance as to the terms or availability of additional capital.

On September 1, 2010, we filed a shelf registration statement with the SEC providing for the sale of up to an aggregate of $150.0 million of equity and debt securities from time to time in one or more transactions. This registration statement was declared effective by the SEC on September 9, 2010. However, we cannot provide assurances that we will be able to raise capital on favorable terms under the registration statement, if at all.

To remain competitive, we must continue to develop, obtain and protect our proprietary technology rights; otherwise, we may lose market share or need to reduce prices as a result of competitors selling technologically superior products that compete with our products.

Our ability to compete successfully in the diagnostic market depends on continued development and introduction of new proprietary technology and the improvement of existing technology. If we cannot continue to develop, obtain and protect proprietary technology, our total revenue and gross profits could be adversely affected. Moreover, our current and future licenses may not be adequate for the operation of our business.

Our competitive position is heavily dependent on obtaining and protecting our own proprietary technology or obtaining licenses from others. Our ability to obtain patents and licenses, and their benefits, is uncertain. We have issued patents both in the U.S. and internationally, with expiration dates ranging from the present through approximately 2027. Additionally, we have patent applications pending in various foreign jurisdictions. These pending patent applications may not result in the issuance of any patents, or if issued, may not have priority over others applications or may not offer meaningful protection against competitors with similar technology or may not otherwise provide commercial value. Moreover, any patents issued to us may be challenged, invalidated, found unenforceable or circumvented in the future. In addition to our patents in the U.S., we have patents issued in various other countries including, Australia, Canada, Japan and various European countries, including France, Germany, Italy, Spain and the United Kingdom. Third parties can make, use and sell products covered by our patents in any country in which we do not have patent protection. We also license the right to use our products to our customers under label licenses that are for research purposes only. These licenses could be contested and, because we cannot monitor all potential unauthorized uses of our products around the world, we might not be aware of an unauthorized use or might not be able to enforce the license restrictions in a cost-effective manner. Also, we may not be able to obtain licenses for technology patented by others and required to produce our products on commercially reasonable terms.

To protect or enforce our patent rights, it may be necessary for us to initiate patent litigation proceedings against third parties, such as infringement suits or interference proceedings. These lawsuits would be expensive, take significant time and would divert management s attention from other business concerns. In the event that we seek to enforce any of our patents against an infringing party, it is likely that the party defending the claim will seek to invalidate the patents we assert, which could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly, and our patent applications at risk of not being issued. Further, these lawsuits may provoke the defendants to assert claims against us. If we pursue any such claim, we cannot assure you that we will prevail in any of such suits or proceedings or that the damages or other remedies awarded to us, if any, will be commercially valuable.

In addition to our patents, we rely on confidentiality agreements and other similar arrangements with our employees and other persons who have access to our proprietary and confidential information, together with trade secrets and other common law rights, to protect our proprietary and confidential technology. These agreements and laws may not provide meaningful protection for our proprietary technology in the event of unauthorized use or disclosure of such information or in the event that our competitors independently develop technologies that are substantially equivalent or superior to ours. Moreover, the laws of some foreign jurisdictions may not protect intellectual property rights to the same extent as those in the United States. In the event of unauthorized use or disclosure of such information, if we encounter difficulties or are otherwise unable to effectively protect our intellectual property rights domestically or in foreign jurisdictions, our business, operating results and financial condition could be materially and adversely affected.

In order to remain competitive and profitable, we must expend considerable resources to research new technologies and products and develop new markets, and there is no assurance our efforts to develop new technologies, products or markets will be successful or such technologies, products or markets will be

commercially viable.

We devote a significant amount of financial resources to researching and developing new technologies, new products and new markets. The development, manufacture and sale of diagnostic products require a significant investment of resources. Moreover, no assurances can be given that our efforts to develop new technologies or products will be successful or that such technologies and products will be commercially viable.

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The development of new markets also requires a substantial investment of resources, such as new employees, offices and manufacturing facilities. Accordingly, we are likely to incur increased operating expenses as a result of our increased investment in sales and marketing activities, manufacturing scale-up and new product development associated with our efforts to accomplish our growth strategies.

No assurance can be given that we will be successful in implementing our operational, growth and other strategic efforts. In addition, the funds for our strategic development projects have in the past come primarily from our business operations and a working capital line of credit. If our business slows and we become less profitable, and as a result have less money available to fund research and development, we will have to decide at that time which programs to reduce, and by how much. Similarly, if adequate financial, personnel, equipment or other resources are not available, we may be required to delay or scale back our strategic efforts. Our operations will be adversely affected if our total revenue and gross profits do not correspondingly increase or if our technology, product and market development efforts are unsuccessful or delayed. Furthermore, our failure to successfully introduce new technologies or products and develop new markets could have a material adverse effect on our business and prospects.

We rely on a limited number of key distributors which account for a substantial majority of our total revenue. The loss of any key distributor or an unsuccessful effort by us to directly distribute our products could lead to reduced sales.

Although we have many distributor relationships in the U.S., the market is dominated by a small number of these distributors. Four of our distributors, which are considered to be among the market leaders, collectively accounted for approximately 52%, 57% and 56% of our total revenue for the years ended December 31, 2009, 2008 and 2007, respectively. We had sales to four separate distributors for whom sales to each exceeded 10% of total revenue for the year ended December 31, 2009. These distributors were Cardinal Healthcare Corporation, Physician Sales and Services Corporation, McKesson Corporation and Fisher Scientific Corporation (Fisher). In addition, we rely on a few key distributors for a majority of our international sales, and expect to continue to do so for the foreseeable future. The loss or termination of our relationship with any of these key distributors could significantly disrupt our business unless suitable alternatives were timely found or lost sales to one distributor are absorbed by another distributor. Finding a suitable alternative to a lost or terminated distributor may pose challenges in our industry s competitive environment, and another suitable distributor may not be found on satisfactory terms, if at all. For instance, some distributors already have exclusive arrangements with our competitors, and others do not have the same level of penetration into our target markets as our existing distributors. If total revenue to these or any of our other significant distributors were to decrease in any material amount in the future or we are not successful in timely transitioning business to new distributors, our business, operating results and financial condition could be materially and adversely affected.

Our operating results are heavily dependent on sales of our influenza diagnostic tests.

Although we continue to diversify our products, a significant percentage of our total revenues still continue to come from a limited number of our product families. In particular, revenues from the sale of our influenza tests represent a significant portion of our total revenues and are expected to remain so in at least the near future. In addition, the gross margins derived from sales of our influenza tests are significantly higher than the gross margins from our other core products. As a result, if sales or revenues of our influenza tests decline for any reason whether as a result of market share loss or price pressure, obsolescence, a mild flu season, regulatory matters or any other reason our operating results would be materially and adversely affected on a disproportionate basis.

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

Our business strategy contemplates further growth, which is likely to result in expanding the scope of operating and financial systems and the geographical area of our operations, including further expansion outside the U.S., as new products and technologies are developed and commercialized or new geographical markets are entered. We acquired DHI in February 2010. We may experience difficulties integrating the operations of DHI and other companies or technologies that we may acquire with our own operations, and as a result we may not realize our anticipated benefits and cost savings within our expected time frame, or at all. Because we have a relatively small executive staff, future growth may also divert management s attention from other aspects of our business, and will place a strain on existing management and our operational, financial and management information systems. Furthermore, we may expand into

markets in which we have less experience or incur higher costs. We expect to need to execute a number of tasks in a timely, efficient and successful manner in order to realize the benefits and cost savings of acquisitions, including retaining and assimilating key personnel, managing the regulatory and reimbursement approval processes, intellectual property protection strategies and

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commercialization activities, creating uniform standards, controls, procedures, policies and information systems, including with respect to disclosure controls and procedures and internal control over financial reporting, and meeting the challenges inherent in efficiently managing an increased number of employees in different geographic locations, including the need to implement appropriate systems, policies, benefits and compliance programs. Acquisitions may subject us to other risks, including unanticipated costs and expenditures, potential changes in relationships with strategic partners, potential contractual or intellectual property issues, fluctuations in quarterly results and financial condition as a result of timing of acquisitions and potential accounting charges and write-downs, and potential unknown liabilities associated with the strategic combination and the combined operations. Should we encounter difficulties in managing these tasks and risks, our growth strategy may suffer and our total revenue and gross profits could be adversely affected.

Intellectual property risks and third-party claims of infringement, misappropriation of proprietary rights or other claims against us could adversely affect our ability to market our products, require us to redesign our products or attempt to seek licenses from third parties, and materially adversely affect our operating results. In addition, the defense of such claims could result in significant costs and divert the attention of our management and other key employees.

Companies in or related to our industry often aggressively protect and pursue their intellectual property rights. There are often intellectual property risks associated with developing and producing new products and entering new markets, and we may not be able to obtain, at reasonable cost or upon commercially reasonable terms, if at all, licenses to intellectual property of others that is alleged to be part of such new or existing products. From time to time, we have received, and may continue to receive, notices that claim we have infringed upon, misappropriated or misused other parties proprietary rights.

We have hired and will continue to hire individuals or contractors who have experience in medical diagnostics and these individuals or contractors may have confidential trade secret or proprietary information of third parties. We cannot assure you that these individuals or contractors will not use this third-party information in connection with performing services for us or otherwise reveal this third-party information to us. Thus, we could be sued for misappropriation of proprietary information and trade secrets. Such claims are expensive to defend and could divert our attention and result in substantial damage awards and injunctions that could have a material adverse effect on our business, financial condition or results of operations.

Moreover, in the past we have been engaged in litigation with parties that claim, among other matters, that we infringed their patents. The defense and prosecution of patent and trade secret claims are both costly and time consuming. We or our customers may be sued by other parties that claim that our products have infringed their patents or misappropriated their proprietary rights or that may seek to invalidate one or more of our patents. An adverse determination in any of these types of disputes could prevent us from manufacturing or selling some of our products, limit or restrict the type of work that employees involved with such products may perform for us, increase our costs of revenue and expose us to significant liability.

As a general matter, our involvement in litigation or in any claims to determine proprietary rights, as may arise from time to time, could materially and adversely affect our business, financial condition and results of operations for reasons such as:

- pending litigation may of itself cause our distributors or end-users to reduce purchases of our products;
- it may consume a substantial portion of our managerial and financial resources;
- its outcome would be uncertain and a court may find any third-party patent claims valid and infringed by our products (issuing a preliminary or permanent injunction) that would require us to withdraw or recall such products from the market, redesign such products offered for sale or under development or restrict employees from performing work in their areas of expertise;
- governmental agencies may commence investigations or criminal proceedings against our employees, former employees and us relating to claims of misappropriation or misuse of another party s proprietary rights;

- an adverse outcome could subject us to significant liability in the form of past royalty payments, penalties, special and punitive damages, the opposing party s attorney fees, and future royalty payments significantly affecting our future earnings; and

- failure to obtain a necessary license (upon commercially reasonable terms, if at all) upon an adverse outcome could prevent us from selling our current products or other products we may develop.

Even if licenses to intellectual property rights are available, they can be costly. We have entered into various licensing agreements, which require royalty payments based on specified product sales. Royalty expenses under these licensing agreements collectively totaled $13.5 million, $10.5 million and $9.4 million for the years ended December 31, 2009, 2008 and 2007, respectively. We believe we will continue to incur substantial royalty expenses relating to future sales of our products.

In addition to the foregoing, we may also be required to indemnify some customers, distributors and strategic partners under our agreements with such parties if a third party alleges or if a court finds that our products or activities have infringed upon,

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misappropriated or misused another person s proprietary rights. Further, our products may contain technology provided to us by other parties such as contractors, suppliers or customers. We may have little or no ability to determine in advance whether such technology infringes the intellectual property rights of a third party. Our contractors, suppliers and licensors may not be required or financially able to indemnify us in the event that a claim of infringement is asserted against us, or they may be required to indemnify us only up to a maximum amount, above which we would be responsible for any further costs or damages.

Volatility and disruption to the global capital and credit markets may adversely affect our results of operations and financial condition, as well as our ability to access credit and the financial soundness of our customers and suppliers.

Since 2008, the global capital and credit markets have experienced a period of unprecedented turmoil and upheaval, characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States federal government. These conditions could adversely affect the demand for our products and services and, therefore, reduce purchases by our customers, which would negatively affect our revenue growth and cause a decrease in our profitability. In addition, interest rate fluctuations, financial market volatility or credit market disruptions may limit our access to capital, and may also negatively affect our customers and our suppliers ability to obtain credit to finance their businesses. As a result, our customers needs and ability to purchase our products or services may decrease, and our suppliers may increase their prices, reduce their output or change their terms of sale. If our customers or suppliers operating and financial performance deteriorates, or if they are unable to make scheduled payments or obtain credit, our customers may not be able to pay, or may delay payment of, accounts receivable owed to us, and our suppliers may restrict credit or impose different payment terms or reduce or terminate production of products they supply to us. Any inability of customers to pay us for our products and services, or any demands by suppliers for different payment terms, may adversely affect our earnings and cash flow. Additionally, both state and federal government sponsored and private payers, as a result of budget deficits or reductions, may seek to reduce their health care expenditures by renegotiating their contracts with us. Any reduction in payments by such government sponsored or private payers may adversely affect our earnings and cash flow. Declining economic conditions may also increase our costs. If economic conditions remain volatile, our results of operations or financial condition could be adversely affected.

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

A large part of our business is based on the sale of rapid point-of-care (POC) diagnostic tests that physicians and other healthcare providers can administer in their own facilities without sending samples to central laboratories. Clinical reference laboratories and hospital-based laboratories are significant competitors of ours in connection with these rapid POC diagnostic tests and provide a majority of the diagnostic tests used by physicians and other healthcare providers. Our future sales depend on, among other matters, capture of sales from these laboratories by achieving market acceptance of POC testing from physicians and other healthcare providers. If we do not capture sales at the levels in our budget, our total revenue will not grow as much as we expect and the costs we incur or have incurred will be disproportionate to our sales levels. We expect that clinical reference and hospital-based laboratories will continue to compete vigorously against our POC diagnostic products in order to maintain and expand their existing dominance of the overall diagnostic testing market. Moreover, even if we can demonstrate that our products are more cost-effective, save time, or have better performance, physicians and other healthcare providers may resist changing to POC tests. Our failure to achieve market acceptance from physicians and healthcare providers with respect to the use of our POC diagnostic products would have a negative effect on our future sales growth.

The industry and market segment in which we operate are highly competitive, and intense competition with other providers of POC diagnostic products may reduce our sales and margins.

In addition to competition from laboratories, our POC diagnostic tests compete with similar products made by our competitors. There are a large number of multinational and regional competitors making investments in competing technologies and products, including several large pharmaceutical and diversified healthcare companies. We also face competition from our distributors as some have created, and others may decide to create, their own products to compete with ours. A number of our competitors have a potential competitive advantage because they have

substantially greater financial, technical, research and other resources, and larger, more established marketing, sales, distribution and service organizations than we have. These competitors include, among others, Alere Inc. (formerly, Inverness Medical Innovations, Inc.), Beckman Coulter Primary Care Diagnostics, Fisher, Genzyme Diagnostics Corporation, and Becton Dickinson and Company. Moreover, some competitors offer broader product lines and have greater name recognition than we have. If our competitors products are more effective than ours or take market share from our products through more effective marketing or competitive pricing, our total revenue and profits could be materially and adversely affected.

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

The testing, manufacture and sale of our products are subject to regulation by numerous governmental authorities in the U.S., principally the FDA and corresponding state and foreign regulatory agencies. The FDA regulates most of our products, which are currently all Class I or II devices. The U.S. Department of Agriculture regulates our veterinary products. Our future performance depends on, among other matters, when and at what cost we will receive regulatory approval for new products. In addition, certain of our foreign product registrations are owned or controlled by our international distribution partners, such that any change in our arrangement with such partners could result in the loss of or delay in transfer of any such product registrations, thereby interrupting our ability to sell our products in those markets. Regulatory review can be a lengthy, expensive and uncertain process, making the timing and costs of clearances and approvals difficult to predict. Our total revenue would be negatively affected by failures or delays in the receipt of approvals or clearances, the loss of previously received approvals or clearances or the placement of limits on the marketing and use of our products.

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

Changes in government policy could adversely affect our business and profitability.

Changes in government policy could have a significant impact on our business by increasing the cost of doing business, affecting our ability to sell our products and negatively impacting our profitability. Such changes could include modifications to existing legislation, such as U.S. tax policy, or entirely new legislation, such as the recently adopted healthcare reform bill signed into law in the U.S. Although we cannot fully predict the many ways that health care reform might affect our business, the law imposes a 2.3% excise tax on certain transactions, including many U.S. sales of medical devices, which we expect will include U.S. sales of our test kits. This tax is scheduled to take effect in 2013. It is unclear whether and to what extent, if at all, other anticipated developments resulting from health care reform, such as an increase in the number of people with health insurance, may provide us additional revenue to offset this increased tax. If additional revenue does not materialize, or if our efforts to offset the excise tax through spending cuts or other actions are unsuccessful, the increased tax burden would adversely affect our financial performance.

We are subject to numerous government regulations in addition to FDA regulation, and compliance with laws, including changed or new laws, could increase our costs and adversely affect our operations.

In addition to FDA and other regulations referred to above, numerous laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances impact our business operations. If these laws or their interpretation change or new laws regulating any of our businesses are adopted, the costs of compliance with these laws could substantially increase our overall costs. Failure to comply with any laws, including laws regulating the manufacture and marketing of our products, could result in substantial costs and loss of sales or customers. Because of the number and extent of the laws and regulations affecting our industry, and the number of governmental agencies whose actions could affect our operations, it is impossible to reliably predict the full nature and impact of future legislation or regulatory developments relating to our industry and our products. To the extent the costs and procedures associated with meeting new or changing requirements are substantial, our business and results of operations could be adversely affected.

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

Our research and development and manufacturing activities involve the controlled use of hazardous materials. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. These regulations include federal statutes commonly known as CERCLA, RCRA and the Clean Water Act.

Compliance with these laws and regulations is already expensive. If any governmental authorities were to impose new environmental regulations requiring compliance in addition to that required by existing regulations, or alter their interpretation of the requirements of such regulations, such environmental regulations could impair our research, development or production efforts by imposing additional, and possibly substantial, costs or restrictions on our business. In addition, because of the nature of the penalties provided for in some of these environmental regulations, we could be required to pay sizeable fines, penalties or damages in the event of noncompliance with environmental laws. Any environmental violation or remediation requirement could also

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partially or completely shut down our research and manufacturing facilities and operations, which would have a material adverse effect on our business. The risk of accidental contamination or injury from these hazardous materials cannot be completely eliminated and exposure of individuals to these materials could result in substantial fines, penalties or damages that are not covered by insurance.

Our total revenue could be affected by third-party reimbursement policies and potential cost constraints.

The end-users of our products are primarily physicians and other healthcare providers. In the U.S., healthcare providers such as hospitals and physicians who purchase diagnostic products generally rely on third-party payers, principally private health insurance plans, federal Medicare and state Medicaid, to reimburse all or part of the cost of the procedure. Use of our products would be adversely impacted if physicians and other health care providers do not receive adequate reimbursement for the cost of our products by their patients third-party payers. Our total revenue could also be adversely affected by changes or trends in reimbursement policies of these governmental or private healthcare payers. We believe that the overall escalating cost of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry, both foreign and domestic, to reduce the cost of products and services. Given the efforts to control and reduce healthcare costs in the U.S. in recent years, currently available levels of reimbursement may not continue to be available in the future for our existing products or products under development. Third-party reimbursement and coverage may not be available or adequate in either the U.S. or foreign markets, current reimbursement amounts may be decreased in the future and future legislation, regulation or reimbursement policies of third-party payers may reduce the demand for our products or adversely impact our ability to sell our products on a profitable basis.

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

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

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

Unexpected increases in demand for our products could also require us to obtain additional raw materials in order to manufacture products to meet the demand. Some raw materials require significant ordering lead time and we may not be able to timely access sufficient raw materials in the event of an unexpected increase in demand, particularly those obtained from a sole supplier or a limited group of suppliers.

Interruptions in the supply of raw materials and components could adversely affect our operations and financial results.

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

If one or more of our products is claimed to be defective, we could be subject to claims of liability and harm to our reputation that could adversely affect our business.

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

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We are exposed to business risk which, if not covered by insurance, could have an adverse effect on our results of operations.

We face a number of business risks, including exposure to product liability claims. Although we maintain insurance for a number of these risks, we may face claims for types of damages, or for amounts of damages, that are not covered by our insurance. For example, although we currently carry product liability insurance for liability losses, there is a risk that product liability or other claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of our policy. Also, our existing insurance may not be renewed at the same cost and level of coverage as currently in effect, or may not be renewed at all. Further, we do not currently have insurance against many environmental risks we confront in our business. If we are held liable for a claim against which we are not insured or for damages exceeding the limits of our insurance coverage, whether arising out of product liability matters or from some other matter, that claim could have a material adverse effect on our results of operations.

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

Our future success depends in part on our ability to retain our key technical, sales, marketing and executive personnel and our ability to identify and hire additional qualified personnel. Competition for these personnel is intense, both in the industry in which we operate and where our operations are located. Further, we expect to grow our operations, and our needs for additional management and other key personnel are expected to increase. If we are not able to retain existing key personnel, or timely identify and hire replacement or additional qualified personnel to meet expected growth, our business could be adversely impacted.

We face risks relating to our international sales, including inherent economic, political and regulatory risks, which could impact our financial performance, cause interruptions in our current business operations and impede our growth.

Our products are sold internationally, with the majority of our international sales to our customers in Japan and Europe. We currently sell and market our products through distributor organizations and sales agents. Sales to foreign customers accounted for 21%, 15%, and 14% of our total revenue for the years ended December 31, 2009, 2008 and 2007, respectively. Our international sales are subject to inherent economic, political and regulatory risks, which could impact our financial performance, cause interruptions in our current business operations and impede our international growth. These foreign risks include, among others:

- compliance with multiple different registration requirements and new and changing registration requirements, our inability to benefit from registration for our products inasmuch as registrations may be controlled by a distributor, and the difficulty in transitioning our product registrations,
- tariffs or other barriers as we continue to expand into new countries and geographic regions;
- exposure to currency exchange fluctuations against the U.S. dollar;
- longer payment cycles, generally lower average selling prices and greater difficulty in accounts receivable collection;
- reduced protection for, and enforcement of, intellectual property rights;
- political and economic instability in some of the regions where we currently sell our products or that we may expand into in the future;
- potentially adverse tax consequences; and
- diversion to the U.S. of our products sold into international markets at lower prices.

Currently, the majority 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. In order to maintain a competitive price for our products internationally, we may have to continue to provide discounts or otherwise effectively reduce our prices, resulting in a lower margin on products sold internationally. 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.

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Investor confidence and our share price may be adversely impacted if we or our independent registered public accounting firm conclude that our internal controls over financial reporting are not effective.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring us, as a public company, to include a report of management on our internal controls over financial reporting in our Annual Reports on Form 10-K that contains an assessment by management of the effectiveness of our internal controls over financial reporting. In addition, our independent registered public accounting firm must attest to the effectiveness of our internal controls over financial reporting. How companies are implementing these requirements, including internal control reforms, if any, to comply with Section 404 s requirements, and how independent registered public accounting firms are applying these requirements and testing companies internal controls, remain subject to uncertainty. The requirements of Section 404 of the Sarbanes-Oxley Act of 2002 are ongoing. We expect that our internal controls will continue to evolve as our business activities change. Although we seek to diligently and vigorously review our internal controls over financial reporting in an effort to ensure compliance with the Section 404 requirements, any control system, regardless of how well designed, operated and evaluated, can provide only reasonable, not absolute, assurance that its objectives will be met. In addition, the integration of the business and operations of any future acquisitions could heighten the risk of deficiencies in our internal controls, particularly in the case of acquisitions of private companies, which may not have internal controls over financial reporting adequate for public company reporting. If, during any year, our independent registered public accounting firm is not satisfied with our internal controls over financial reporting or the level at which these controls are documented, designed, operated, tested or assessed, or if the independent registered public accounting firm interprets the requirements, rules or regulations differently than we do, then it may issue a report that is qualified. This could result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements and effectiveness of our internal controls, which ultimately could negatively impact the market price of our shares.

Risks Related to Our Common Shares

Our stock price has been highly volatile, and an investment in our stock could suffer a significant decline in value.

The market price of our common shares has been highly volatile and has fluctuated substantially in the past. For example, between December 31, 2007 and September 30, 2010, the closing price of our common shares, as reported by the Nasdaq Global Market, has ranged from a low of $7.92 to a high of $20.81. We expect our common shares to continue to be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including the risk factors discussed herein.

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

Future sales or other dilution of our equity could depress the market price of our common shares.

Sales of our common shares in the public market, or the perception that such sales could occur, could negatively impact the market price of our common shares. As of September 30, 2010:

- approximately 28.5 million of our common shares were issued of which approximately 28.1 million are generally tradable in the public markets without restrictions; and

- approximately 3.2 million of our common shares were issuable upon exercise of outstanding stock options under our various equity incentive plans at a weighted average exercise price of $12.24.

We also have a number of institutional stockholders that own significant blocks of our common shares. If one or more of these stockholders were to sell large portions of their holdings in a relatively short time, for liquidity or other reasons, the prevailing market price of our common shares could be negatively affected.

In addition, the issuance of additional common shares, or issuances of securities convertible into or exercisable for our common shares or other equity linked securities, including preferred stock or warrants, will dilute the ownership

interest of our common stockholders and could depress the market price of our common shares and impair our ability to raise capital through the sale of additional equity securities.

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We may need to seek additional capital. If this additional financing is obtained through the issuance of equity securities, debt convertible into equity or options or warrants to acquire equity securities, our existing stockholders could experience significant dilution upon the issuance, conversion or exercise of such securities.

Our governing documents and rights plan may delay stockholder actions with respect to business combinations or the election of directors, or delay or prevent a sale of the company or changes in management.

Our governing documents and our stockholder rights plan may have the effect of delaying stockholder actions with respect to business combinations or the election of directors, or delaying or preventing a sale of the company or a change in our management, including the following:

Our bylaws require stockholders to give written notice of any proposal or director nomination to us within a specified period of time prior to any stockholder meeting and do not permit stockholders to call a special meeting of the stockholders, unless such stockholders hold at least 50% of our stock entitled to vote at the meeting.

Under our stockholder rights plan, the acquisition of 15% or more of our outstanding common shares by any person or group, unless approved by our Board of Directors, will trigger the right of our stockholders (other than the acquiror of 15% or more of our common shares) to acquire additional common shares, and, in certain cases, the stock of the potential acquiror, at a 50% discount to market price, thus increasing the acquisition cost to a potential acquiror.

Our Board of Directors may approve the issuance, without further action by the stockholders, of our preferred shares, and to fix the rights and preferences thereof. An issuance of preferred shares with dividend and liquidation rights senior to our common shares or convertible into a large number of our common shares could prevent a potential acquiror from gaining effective economic or voting control.

We do not pay dividends and this may negatively affect the price of our common shares.

We have not paid dividends on our common shares and do not anticipate paying dividends on our common shares in the foreseeable future. The future price of our common shares may be adversely impacted because we have not paid and do not anticipate paying dividends.

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, 2010:

Period	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly announced plans or programs	Approximate dollar value of shares that may yet be purchased under the plans or programs(1)
July 1 July 31, 2010		$		$ 10,300,000
August 1 August 31, 2010				10,300,000
September 1 September 30, 2010				10,300,000
Total		$		$ 10,300,000

(1) From June 2005 to December 2009 our Board of Directors authorized us to repurchase up to $100.0 million in shares of our common stock under a stock repurchase program under four separate authorizations of $25.0 million each. 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 2, 2011 unless extended by our Board of Directors.

ITEM 5. OTHER INFORMATION

None.

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ITEM 6. Exhibits

Exhibit Number	
3.1*	Restated Certificate of Incorporation of Quidel Corporation.
3.2	Amended and Restated Bylaws of Quidel Corporation. (Incorporated by reference to Exhibit 3.2 to the Registrant s Current Report on Form 8-K filed on November 8, 2000.)
4.1*	Certificate of Designations of Series C Junior Participating Preferred Stock.
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.)
10.1(1)	Q4 2010 Employee Deferred Compensation Program for Quidel Corporation. (Incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed on September 8, 2010.)
10.2	Second Amendment to Credit Agreement, dated as of September 27, 2010, by and among Quidel Corporation, the financial institutions listed on the signature pages thereof and Bank of America, N.A., as agent for the lenders, and each of the guarantors listed on the signature pages thereof. (Incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed on September 29, 2010.)
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.

Date: October 29, 2010

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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