QUIDEL CORP /DE/ Form 10-Q October 29, 2012 Table of Contents

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2012

or

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

For the transition period from to

Commission File Number: 0-10961

# **QUIDEL CORPORATION**

(Exact name of Registrant as specified in its charter)

**Delaware** (State or other jurisdiction of

94-2573850 (I.R.S. Employer

incorporation or organization)

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 x No "

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 x No "

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

Large accelerated filer " Accelerated filer

Non-accelerated filer " (Do not check if a smaller reporting company) Smaller reporting company " Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes " No x

As of October 24, 2012, 33,350,305 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)

	Sep	otember 30, 2012	Dec	cember 31, 2011
ASSETS				
Current assets:				
Cash and cash equivalents	\$	17,842	\$	61,332
Accounts receivable, net		17,132		14,646
Inventories		16,909		14,654
Deferred tax asset current		10,681		10,681
Income tax receivable		136		167
Prepaid expenses and other current assets		6,380		3,246
Total current assets		69,080		104,726
Property and equipment, net		30,535		28,086
Goodwill		71,013		71,013
Intangible assets, net		64,179		73,830
Other non-current assets		1,970		1,239
Total assets	\$	236,777	\$	278,894
LIABILITIES AND STOCKHOLDERS EQUITY				
Current liabilities:				
Accounts payable	\$	4,679	\$	5,001
Accrued payroll and related expenses		5,394		5,377
Accrued royalties		229		15,093
Current portion of lease obligation		367		329
Other current liabilities		4,760		7,126
Total current liabilities		15,429		32,926
Long term debt		19,000		42,000
Lease obligation, net of current portion		5,667		5,947
Deferred tax liability non-current		4,648		7,040
Income taxes payable		4,413		4,667
Other non-current liabilities		952		928
Commitments and contingencies				
Stockholders equity:				
Preferred stock, \$.001 par value per share; 5,000 shares authorized; none issued or outstanding at September 30, 2012 and December 31, 2011				
Common stock, \$.001 par value per share; 50,000 shares authorized; 33,297 and 33,276 shares issued				
and outstanding at September 30, 2012 and December 31, 2011, respectively		33		33
Additional paid-in capital		180,059		175,030
Retained earnings		6,576		10.323
retained earnings		0,370		10,323
Total stockholders equity		186,668		185,386

Total liabilities and stockholders equity

\$ 236,777

\$ 278,894

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, 2012 2011		September 30, Septem	
Total revenues	\$ 32,998	\$ 33,108	\$ 101,816	\$ 120,212
Costs and expenses				
Cost of sales (excludes amortization of intangible assets of \$1,438, \$1,670, \$4,315 and				
\$5,009, respectively)	14,872	14,996	43,688	47,579
Research and development	5,085	5,884	20,433	19,559
Sales and marketing	7,776	6,487	21,989	18,996
General and administrative	4,759	5,194	15,812	17,135
Amortization of intangible assets from acquired businesses and technology	1,728	1,791	5,165	5,342
Total costs and expenses	34,220	34,352	107,087	108,611
Operating (loss) income	(1,222)	(1,244)	(5,271)	11,601
Other (expense) income				
Interest income	8	42	35	151
Interest expense	(286)	(485)	(985)	(1,639)
Other expense	(27)		(27)	
Total other expense	(305)	(443)	(977)	(1,488)
(Loss) income before taxes	(1,527)	(1,687)	(6,248)	10,113
(Benefit) provision for income taxes	(851)	(574)	(2,501)	3,438
Net (loss) income	\$ (676)	\$ (1,113)	\$ (3,747)	\$ 6,675
Basic and diluted (loss) earnings per share	\$ (0.02)	\$ (0.03)	\$ (0.11)	\$ 0.20
Shares used in basic per share calculation	33,004	33,019	33,036	32,833
Shares used in diluted per share calculation	33,004	33,019	33,036	33,189
C				

See accompanying notes.

# QUIDEL CORPORATION

# CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands; unaudited)

	Nine mon Septem 2012	
OPERATING ACTIVITIES:		
Net (loss) income	\$ (3,747)	\$ 6,675
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Depreciation, amortization and other	16,485	12,063
Loss on disposal of assets	27	
Stock-based compensation expense	5,001	5,798
Change in deferred tax assets and liabilities	(2,392)	2,527
Changes in assets and liabilities:		
Accounts receivable	(2,486)	(3,828)
Inventories	(2,140)	2,856
Income tax receivable	31	8,267
Prepaid expenses and other current assets	(2,611)	(594)
Accounts payable	(877)	(289)
Accrued payroll and related expenses	(160)	2,155
Accrued royalties	(148)	(1,858)
Accrued income taxes payable	(254)	
Other current and non-current liabilities	(844)	521
Net cash provided by operating activities	5,885	34,293
INVESTING ACTIVITIES:		
Acquisitions of property and equipment	(6,903)	(3,254)
Acquisitions of intangibles	(15,359)	(14,264)
Purchase of business	(1,000)	
Proceeds from sale of fixed assets	115	
Net cash used for investing activities	(23,147)	(17,518)
FINANCING ACTIVITIES:		
Payments on lease obligation	(242)	(207)
Purchases of common stock	(3,407)	(625)
Payments on line of credit	(23,000)	(30,000)
Payments on note payable to state agency	(1,498)	
Issuance of common stock, net of cancellations	2,960	59,221
Other	(1,041)	(907)
Net cash (used for) provided by financing activities	(26,228)	27,482
Net (decrease) increase in cash and cash equivalents	(43,490)	44,257
Cash and cash equivalents, beginning of period	61,332	6,788
Cash and cash equivalents, end of period	\$ 17,842	\$ 51,045
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid during the period for interest	\$ 985	\$ 1,639

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Cash paid during the period for income taxes	\$	\$ 200
NON-CASH INVESTING ACTIVITIES:		
Purchase of capital equipment by incurring current liabilities	\$ 555	\$ 157
Purchase of licensed technology by incurring current liabilities	\$	\$ 16,563
NON-CASH FINANCING ACTIVITIES:		
Reduction of other non-current assets upon issuance of common stock	\$	\$ 478
Increase of other non-current assets upon issuance of common stock	\$ 652	\$

# **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. The Company reclassified patent and trademark expenses of \$0.3 million and \$0.8 million from research and development expense to general and administrative expense on the Consolidated Statements of Operations for the three and nine months ended September 30, 2011, respectively. The Company reclassified stock-based compensation expense of \$0.6 million from accrued payroll and related expenses to stock-based compensation expense on the Consolidated Statements of Cash Flows for the nine months ended September 30, 2011. For the nine months ended September 30, 2011, the Company reclassified a reduction of other non-current assets of \$0.5 million from cash provided by financing activities and from cash provided by operating activities to non-cash financing activities on the Consolidated Statements of Cash flows.

The information at September 30, 2012, and for the three and nine months ended September 30, 2012 and 2011, is unaudited. Operating results for the three and nine months ended September 30, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012. For further information, refer to the Company s consolidated financial statements and footnotes thereto for the year ended December 31, 2011 included in the Company s 2011 Annual Report on Form 10-K. Subsequent events have been evaluated up to and including the date these financial statements were issued. In the opinion of management, all adjustments considered necessary for a fair presentation (consisting of normal recurring accruals) have been included. Operating results for any quarter are historically seasonal in nature and are not necessarily indicative of the results expected for the full year.

For 2012 and 2011, the Company s fiscal year will or has ended on December 30, 2012 and January 1, 2012, respectively. For 2012 and 2011, the Company s third quarter ended on September 30, 2012 and October 2, 2011, respectively. For ease of reference, the calendar quarter end dates are used herein. The three and nine month periods ended September 30, 2012 and 2011 both included 13 and 39 weeks, respectively.

# Note 2. Comprehensive (loss) income

Net (loss) income is equal to comprehensive (loss) income for the three and nine months ended September 30, 2012 and 2011. During the first quarter ended March 31, 2012, the Company adopted Accounting Standards Update No. 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income.

# Note 3. Computation of Earnings Per Share

Diluted net income per share is reported based on the more dilutive of the treasury stock or the two-class method. Under the two-class method, net income is allocated to common stock and participating securities. The Company sunvested restricted stock awards and certain unvested restricted stock units meet the definition of participating securities. Basic net income per share under the two-class method is computed by dividing net income adjusted for earnings allocated to unvested stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted net income per share under the two-class method is computed by dividing net income adjusted for earnings allocated to unvested stockholders for the period by the weighted average number of common and common equivalent shares outstanding during the period. The Company excludes stock options from the calculation of diluted net income per share when the combined exercise price, unrecognized stock-based compensation and assumed tax benefits upon exercise are greater than the average market price for the Company s common stock because their effect is anti-dilutive. For the nine months ended September 30, 2011, 1.9 million shares were excluded from the calculation of diluted earnings per share (EPS) as their effect was anti-dilutive.

# **Quidel Corporation**

# **Notes to Consolidated Financial Statements**

# (Unaudited)

# **Note 3. Computation of Earnings Per Share (Continued)**

For the three and nine months ended September 30, 2012 and the three months ended September 30, 2011 there were no differences between the number of common shares used for the basic and diluted EPS computations as they were periods in which the Company incurred a net loss. Due to the fact that the holders of participating securities are not contractually required to share in the Company s losses, in applying the two-class method to compute basic net loss per common share, no allocation to participating securities was made for periods in which the Company incurred a net loss.

The following table sets forth the computation of basic and diluted EPS for the nine months ended September 30, 2011 (in thousands, except per share amounts):

	2011
Basic net income per share:	
Net income	\$ 6,675
Less: income allocated to participating securities	(61)
Net income allocated to common stockholders	\$ 6,614
Weighted average common shares outstanding basic	32,833
Net income per share basic	\$ 0.20
Diluted net income per share:	
Net income	\$ 6,675
Less: income allocated to participating securities	(60)
Net income allocated to common stockholders	\$ 6,615
Weighted average common shares outstanding basic	32,833
Dilutive securities	356
Weighted average common shares outstanding diluted	33,189
Net income per share diluted	\$ 0.20

# **Note 4. Inventories**

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

	September 30, 2012		December 31, 2011	
Raw materials	\$	5,554	\$	5,239

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Work-in-process (materials, labor and overhead)	4,708	3,632
Finished goods (materials, labor and overhead)	6,647	5,783
	\$ 16,909	\$ 14,654

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# **Quidel Corporation**

#### Notes to Consolidated Financial Statements

#### (Unaudited)

# **Note 5. Other Current Liabilities**

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

	September 30, 2012		-		ember 31, 2011
Accrued liability for technology licenses	\$	530	\$ 863		
Customer incentives		1,400	2,352		
Accrued interest income taxes		607	491		
Customer prepayments		48	202		
Current portion of note payable to state agency			1,498		
Unearned research and development collaboration funds received		1,222			
Other		953	1,720		
	\$	4,760	\$ 7,126		

# Note 6. Income Taxes

The Company s effective tax rate for the nine months ended September 30, 2012 and 2011 was 40.0% and 34.0%, respectively. The Company recognized an income tax benefit of \$2.5 million and an income tax expense of \$3.4 million for the nine months ended September 30, 2012 and 2011, respectively. The primary difference between the September 30, 2012 and September 30, 2011 effective tax rate is due to the exclusion of the federal research and development tax credit due to the expiration of the statute. In addition, the Company reduced the reserve for uncertain tax positions resulting from a federal statutory audit. During the quarter ended September 30, 2012, the Company was notified by the Internal Revenue Service that it is examining the Company s federal tax returns for the years ended 2007 through 2010.

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 an assessment of many factors, including past experience and interpretations of tax law applied to the facts of each matter.

# Note 7. Line of Credit

On August 10, 2012, the Company entered into an amended and restated \$140.0 million senior secured syndicated credit facility (the Senior Credit Facility), which matures on August 10, 2017. The Senior Credit Facility amends and restates the Company is \$120.0 million senior secured credit facility dated October 8, 2008. As part of this amendment, the Company incurred \$1.0 million in deferred financing costs related to the Senior Credit Facility in addition to the \$0.6 million it had previously recorded related to the original credit facility. As of September 30, 2012, the Company had \$1.6 million included as a portion of other non-current assets. The Senior Credit Facility bears interest at either LIBOR or the base rate plus in each case the applicable margin. The base rate is equal to the higher of (i) the lender is prime rate, (ii) the federal funds rate plus one-half of one percent and (iii) LIBOR plus one percent. The applicable rate is generally determined in accordance with a performance pricing grid based on the Company is leverage ratio and ranges from 1.25% to 2.50% for LIBOR rate loans and from 0.25% to 1.50% for base rate loans (weighted average interest rate of 1.72% at September 30, 2012). 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 disposition of assets. The Company is also subject to

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financial covenants which include a funded debt to adjusted EBITDA ratio (as defined in the Senior Credit Facility, with adjusted EBITDA generally calculated as earnings before, among other adjustments, interest, taxes, depreciation, amortization, and stock-based compensation) not to exceed 3:1 as of the end of each fiscal quarter, and an interest coverage ratio of not less than 3:1 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.

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# **Quidel Corporation**

#### **Notes to Consolidated Financial Statements**

#### (Unaudited)

# Note 7. Line of Credit (continued)

As of September 30, 2012, the Company had \$60.0 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. As of September 30, 2012, the Company had \$19.0 million outstanding under the Senior Credit Facility. As of September 30, 2012, the Company was in compliance with all financial covenants.

# Note 8. Stockholders Equity

During the nine months ended September 30, 2012, 135,295 shares of restricted stock were awarded, 17,165 shares of restricted stock were cancelled, 197,109 shares of common stock were issued due to the exercise of stock options and 44,290 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 \$3.0 million (excludes \$0.6 million included in prepaid expenses and other current assets as of September 30, 2012). Additionally, during the nine months ended September 30, 2012, 231,704 shares of outstanding common stock were repurchased for approximately \$3.4 million, which primarily included shares repurchased under the Company s previously announced share repurchase program, but also included 31,304 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, 2012. There was approximately \$22.1 million remaining under the Company s share repurchase program as of September 30, 2012.

# **Note 9. 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, 2012 and 2011 was as follows (in millions):

	en	Three months ended September 30,		nonths ded iber 30,
	2012	2011	2012	2011
Cost of sales	\$ 0.2	\$ 0.1	\$ 0.4	\$ 0.5
Research and development	0.2	0.3	0.8	0.8
Sales and marketing	0.2	0.2	0.4	0.3
General and administrative	0.8	1.0	3.4	4.2
	\$ 1.4	\$ 1.6	\$ 5.0	\$ 5.8

Total compensation expense recognized for the three months ended September 30, 2012 and 2011 includes \$0.9 million and \$1.0 million related to stock options and \$0.5 million and \$0.6 million related to restricted stock, respectively. Total compensation expense recognized for the nine months ended September 30, 2012 and 2011 includes \$3.0 million and \$3.6 million related to stock options and \$2.0 million and \$2.2 million related to restricted stock, respectively. As of September 30, 2012, total unrecognized compensation expense related to non-vested stock options was \$5.0 million, which is expected to be recognized over a weighted-average period of approximately 2.2 years. As of September 30, 2012, total unrecognized compensation expense related to non-vested restricted stock was \$2.0 million, which is expected to be recognized over a weighted-average period of approximately 1.0 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, 2012 and 2011.

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.

# **Quidel Corporation**

#### **Notes to Consolidated Financial Statements**

(Unaudited)

# Note 9. Stock-Based Compensation (Continued)

	Nine mo	ed
	Septemb	er 30,
	2012	2011
Expected option life (in years)	5.52	5.22
Volatility rate	0.46	0.47
Risk-free interest rate	0.83%	2.05%
Dividend rate	0%	0%

The weighted-average grant date fair value of stock options granted during the nine months ended September 30, 2012 and 2011 was \$6.51 and \$5.73, respectively. The Company granted 621,705 and 519,337 stock options during the nine months ended September 30, 2012 and 2011, respectively. The weighted-average grant date fair value of restricted stock granted during the nine months ended September 30, 2012 and 2011 was \$15.49 and \$12.86, respectively. The Company granted 135,295 and 207,532 shares of restricted stock during the nine months ended September 30, 2012 and 2011, respectively. The grant date fair value of restricted stock is determined based on the closing market price of the Company s common stock on the grant date.

# Note 10. Industry and Geographic Information

The Company operates in one reportable segment. Sales to customers outside the U.S. represented \$15.9 million (16%) and \$13.8 million (11%) of total revenue for the nine months ended September 30, 2012 and 2011, respectively. As of September 30, 2012 and December 31, 2011, balances due from foreign customers were \$1.7 million and \$4.8 million, respectively.

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

	,	e months ended ember 30,
	2012	2011
Customer:		
A	16%	15%
В	6%	12%
	22%	27%

As of September 30, 2012, accounts receivable from customers with balances due in excess of 10% of total accounts receivable totaled \$8.1 million while, at December 31, 2011, accounts receivable from customers with balances due in excess of 10% of total accounts receivable totaled \$5.5 million.

# Note 11. Commitments and Contingencies

# **Licensing Arrangements**

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On September 27, 2011, the Company entered into the Second Amendment (the Amendment ) to Quidel/Inverness Settlement Agreement dated April 27, 2005 (the Agreement ), as amended by an addendum dated June 19, 2006, with Alere Inc. (formerly known as Inverness Medical Innovations, Inc.) ( Alere ).

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# **Quidel Corporation**

#### **Notes to Consolidated Financial Statements**

(Unaudited)

# **Note 11. Commitments and Contingencies (Continued)**

The Amendment, which was effective as of April 1, 2011, amended certain royalty and other provisions in the Agreement and enabled the Company to buy-down and buy-out its future royalty obligation under the Agreement for payments totaling \$29.5 million. Under the Amendment, the Company made an initial cash payment of \$13.8 million to Alere in September 2011 in connection with a buy-down of the Company s royalty obligations for the period beginning July 1, 2011. In addition, the Company exercised its buy-out right for any remaining future royalty obligation by exercising the Royalty Termination Option (as defined in the Amendment) in January 2012, thereby terminating the Company s obligation to pay future royalties under the Agreement in exchange for a fixed cash payment in the amount of \$15.7 million less \$1.0 million of specified third quarter 2011 royalties. This amount was paid in February 2012.

In conjunction with Financial Accountings Standards Board Accounting Standard Update No. 2009-05, *Fair Value Measurements and Disclosures (Topic 820)*, the Company assigned \$28.8 million to the licensed technology and \$0.7 million as a one-time charge to cost of sales. In determining the fair value allocation between the intangible asset licensed technology and the one-time charge to cost of sales, the Company assessed the past and estimated future revenue streams related to present and future products that use the patents that are subject to the Amendment. The effective life and related amortization of the licensed technology will be based on the higher of the percentage of usage or the straight-line method. This percentage of usage will be determined using the revenues generated from products covered by the patents that are subject to the Amendment. The terms of the Amendment provide for an estimated useful life of 3.5 years for this asset. The Company recorded \$1.9 million and \$5.7 million of amortization expense included as a portion of cost of sales for the three and nine months ended September 30, 2012, respectively.

In addition to the royalty agreement noted above, the Company has entered into various other licensing agreements, which largely require royalty payments based on specified product sales as well as the achievement of specified milestones. The Company had royalty expenses relating to those agreements of approximately \$0.2 million and \$0.4 million for the three months ended September 30, 2012 and 2011, respectively, and \$0.6 million and \$1.5 million for the nine months ended September 30, 2012 and 2011, respectively.

# Legal

The Company is involved in various claims and litigation matters from time to time in the ordinary course of business. Management believes that all such current legal actions, in the aggregate, will not have a material adverse effect on the Company. The Company also maintains insurance, including coverage for product liability claims, in amounts which management believes are appropriate given the nature of its business. At September 30, 2012 and December 31, 2011, the Company had \$0.8 million accrued as a liability for various legal matters where the Company deemed the liability probable and estimable.

#### **Research and Development Collaboration Agreements**

The Company has entered into various collaboration agreements which provide it with rights to develop, manufacture and market products using the intellectual property and technology of its collaborative partners. Under the terms of certain of these agreements, the Company is required to make periodic payments based on achievement of certain milestones. These milestones generally include achievement of prototype assays, validation lots and clinical trials. At September 30, 2012, total future milestone payments which may become due under the terms of these agreements are estimated at \$3.9 million in the aggregate. These costs may fluctuate based on estimated development costs and activities and are expected to be paid at various dates through December 2013.

# **Quidel Corporation**

#### **Notes to Consolidated Financial Statements**

(Unaudited)

# **Note 11. Commitments and Contingencies (Continued)**

During the three months ended September 30, 2012, the Company entered into a master collaboration agreement with a third party for the development of molecular diagnostic assays over a five year term. In connection with mutually agreed upon project plans and timelines for each molecular assay, the third party is expected to reimburse the Company a portion of total product development costs. As of September 30, 2012, the Company and the third party have executed project plans for several assays under the master agreement. Reimbursements of development costs are recorded as a reduction to research and development expense and recognized at the lower of cumulative cash received, or to be received, or a proportion of actual costs incurred as a percentage of total costs expected to be incurred for all projects in the agreement. Accordingly, the Company recorded a receivable from the development partner for the first payment in the amount of \$2.5 million as a component of prepaid expenses and other current assets as of September 30, 2012, the earned portion of \$1.3 million as a reduction to research and development expense for the three months ended September 30, 2012, and the unearned portion of \$1.2 million as a component of other current liabilities as of September 30, 2012.

#### Note 12. Lease Obligation

During 1999, the Company completed a sale and leaseback transaction of its San Diego facility. 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. 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 remains the same under the amendment. The combined carrying value of the land and building subject to this lease, net of accumulated depreciation, was \$2.3 million and \$2.4 million as of September 30, 2012 and December 31, 2011, respectively. 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 of approximately \$0.8 million for each of the nine months ended September 30, 2012 and 2011.

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# **Quidel Corporation**

#### **Notes to Consolidated Financial Statements**

# (Unaudited)

# Note 13. Fair Value Measurement

ASC Topic 820, Fair Value Measurements and Disclosures requires the valuation of assets and liabilities subject to fair value measurements using a three tiered approach and fair value measurement be classified and disclosed by the Company in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability;

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e. supported by little or no market activity).

As of September 30, 2012 and December 31, 2011, the carrying amount of the Company s Senior Credit Facility approximates fair value because it has a variable interest rate that reflects market changes to interest rates and changes in the Company s leverage ratio. As of September 30, 2012 and December 31, 2011, the Company used Level 2 inputs to determine the fair value of its Senior Credit Facility. As of September 30, 2012 and December 31, 2011, the carrying amount of the Company s cash equivalents approximates fair value. Cash equivalents primarily consisted of funds held in a money market account. As of September 30, 2012 and December 31, 2011, the carrying value of cash equivalents was \$10.9 million and \$46.9 million, respectively, and was determined based on Level 1 inputs.

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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 Quarterly 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 s forward-looking statements are expressed differently. Forward-looking statements in this Quarterly Report include, among others, statements concerning: our outlook for the remainder of 2012, including projections about our revenue, gross profit, expenses, and net earnings; projected capital expenditures for the remainder of 2012 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 maintain our emphasis on research and development, to introduce new products, and to continue to evaluate technology and Company acquisition opportunities and the source of funds for such investments. 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, 2011, 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 audited 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 through distributor arrangements.

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#### Outlook

We anticipate revenue growth over the next three months as compared to the same three month period in the prior year and a related positive impact on gross profit and net earnings. 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 and commercialization 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, 2012 compared to the three months ended September 30, 2011

# **Total Revenues**

The following table compares total revenues for the three months ended September 30, 2012 and 2011 (in thousands, except percentages):

		ree months tember 30,	Increa (Decrea	
	2012	2011	\$	%
Infectious disease net product sales	\$ 21,622	\$ 21,996	\$ (374)	(2)%
Women s health net product sales	8,741	8,145	596	7%
Gastrointestinal disease net product sales	1,584	1,719	(135)	(8)%
Other net product sales	540	689	(149)	(22)%
Royalty, license fees and grant revenue	511	559	(48)	(9)%
Total revenues	\$ 32,998	\$ 33,108	\$ (110)	0%

The increase in women shealth net product sales was driven primarily by an increase in sales from our pregnancy products of \$0.4 million. This increase was offset by a decrease in infectious disease product sales driven primarily by a decrease in sales from our flu products of \$0.5 million. The revenue from our royalty, license fees and grant revenue category for all periods primarily relates to royalty payments earned on our patented technologies utilized by third parties.

#### Cost of Sales

Cost of sales was \$14.9 million, or 45% of total revenues for the three months ended September 30, 2012, compared to \$15.0 million, or 45% of total revenues for the three months ended September 30, 2011. The absolute dollar value of cost of sales was relatively constant for direct and indirect costs for both periods.

# **Operating Expenses**

The following table compares operating expenses for the three months ended September 30, 2012 and 2011 (in thousands, except percentages):

		For the thr ended Sep	ree months tember 30,			
	20	12	20	11	Increase (De	ecrease)
		As a %				
		of		As a % of		
	Operating	total	Operating	total		
	expenses	revenues	expenses	revenues	\$	%
Research and development	\$ 5,085	15%	\$ 5,884	18%	\$ (799)	(14)%
Sales and marketing	7,776	24%	6,487	20%	1,289	20%

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General and administrative	4,759	14%	5,194	16%	(435)	(8)%
Amortization of intangible assets from acquired businesses and						(4)
technology	1,728	5%	1,791	5%	(63)	%

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# **Research and Development Expense**

Research and development expense for the three months ended September 30, 2012 decreased from \$5.9 million to \$5.1 million primarily due to a research and development reimbursement of \$1.3 million associated with the collaboration agreement described in Note 11 to the consolidated financial statements. Excluding this reimbursement, research and development increased by \$0.5 million for costs associated with the development of potential new technologies and with products under development.

Research and development expenses include direct external costs such as fees paid to consultants, and internal direct and indirect costs such as compensation and other expenses for research and development personnel, supplies and materials, clinical trials and studies, facility costs and depreciation.

Due to the risks inherent in the product development process and given the early-stage of development of certain projects, we are unable to estimate with meaningful certainty the costs we will incur in the continued development of our product candidates for commercialization. In addition, we have not historically tracked research and development costs by individual project. However, we expect our research and development costs to be substantial as we move other product candidates into preclinical and clinical trials and advance our existing product candidates into later stages of development.

# Sales and Marketing Expense

Sales and marketing expense for the three months ended September 30, 2012 increased from \$6.5 million to \$7.8 million due to additional investments of \$1.3 million in our sales organization including an increase in personnel, travel, training costs, and incentives related to Sofia instrument placements. 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 for the three months ended September 30, 2012 decreased from \$5.2 million to \$4.8 million primarily due to a decrease in the incentive compensation accrual of \$0.2 million for the three months ended September 30, 2012 because of a weak 2011/2012 cold and flu season.

# Amortization of Intangible Assets from Acquired Businesses and Technology

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

# Other Income (Expense)

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. The reduction in the outstanding principle balance under the line of credit from \$42.0 million as of September 30, 2011 to \$19.0 million as of September 30, 2012 resulted in a reduction to interest expense of \$0.2 million.

#### **Income Taxes**

As of the three months ended September 30, 2012 and September 30, 2011, our expected annual effective tax rate was 55.7% and 34.0%, respectively. We recognized a tax benefit of \$0.9 million and \$0.6 million for the three months ended September 30, 2012 and 2011, respectively. The primary difference between the September 30, 2012 and September 30, 2011 effective tax rate is due to the exclusion of the federal research and development tax credit due to the expiration of the statute. In addition, we reduced our reserve for uncertain tax positions resulting from a federal statutory audit.

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Nine months ended September 30, 2012 compared to the nine months ended September 30, 2011

#### **Total Revenues**

The following table compares total revenues for the nine months ended September 30, 2012 and 2011 (in thousands, except percentages):

		ine months otember 30,	Increase (Decrease)	
	2012	2011	\$	%
Infectious disease net product sales	\$ 66,735	\$ 84,894	\$ (18,159)	(21)%
Women s health net product sales	25,638	24,556	1,082	4%
Gastrointestinal disease net product sales	4,790	5,254	(464)	(9)%
Other net product sales	3,266	3,708	(442)	(12)%
Royalty, license fees and grant revenue	1,387	1,800	(413)	(23)%
Total revenues	\$ 101,816	\$ 120,212	\$ (18,396)	(15)%

The decrease in total revenues was largely related to a weak 2011/2012 cold and flu season. This had an adverse impact on our infectious disease products, including influenza, Group A Strep, RSV and DFA respiratory. This was partially offset by stronger sales in our women s health product line driven by increased sales of our thyroid products of \$0.5 million and increased sales from our pregnancy products of \$0.4 million. Revenues in other product categories remained relatively constant period over period.

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 8% to \$43.7 million, or 43% of total revenues for the nine months ended September 30, 2012, compared to \$47.6 million, or 40% of total revenues for the nine months ended September 30, 2011. The absolute dollar decrease in cost of sales is primarily related to the variable nature of direct costs (material and labor) associated with the 15% decrease in total revenues. The increase in cost of sales as a percent of total revenue is primarily due to a shift in product mix as flu volume was lower in the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 because of a weak 2011/2012 cold and flu season.

# **Operating Expenses**

The following table compares operating expenses for the nine months ended September 30, 2012 and 2011 (in thousands, except percentages):

		For the nii	ne months			
		ended Sep	tember 30,			
	2012 2011		11	Increase (Decrease)		
		As a %				
	Operating expenses	of total revenues	Operating expenses	As a % of total revenues	\$	%
Research and development	\$ 20,433	20%	\$ 19,559	16%	\$ 874	4%
Sales and marketing	21,989	22%	18,996	16%	2,993	16%
General and administrative	15,812	16%	17,135	14%	(1,323)	(8)%
Amortization of intangible assets from acquired businesses and						
technology	5,165	5%	5,342	4%	(177)	(3)%
Research and Development Expense						

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Research and development expense increased from \$19.6 million to \$20.4 million for the nine months ended September 30, 2012 primarily due to an overall increase of \$2.3 million for costs associated with the development of potential new technologies and with products under development. The increase was partially offset by the research and development reimbursement of \$1.3 million associated with the collaboration agreement described in Note 11 to the consolidated financial statements.

Research and development expenses include direct external costs such as fees paid to consultants, and internal direct and indirect costs such as compensation and other expenses for research and development personnel, supplies and materials, clinical trials and studies, facility costs and depreciation.

Due to the risks inherent in the product development process and given the early-stage of development of certain projects, we are unable to estimate with meaningful certainty the costs we will incur in the continued development of our

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product candidates for commercialization. In addition, we do not currently track research and development costs by individual project. However, we expect our research and development costs to be substantial as we move other product candidates into preclinical and clinical trials and advance our existing product candidates into later stages of development.

# Sales and Marketing Expense

Sales and marketing expense increased from \$19.0 million to \$22.0 million for the nine months ended September 30, 2012 due to increased costs of \$3.0 million for additional investments in our sales organization, including an increase in personnel and corresponding travel and training costs. 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 costs decreased from \$17.1 million to \$15.8 million for the nine months ended September 30, 2012 primarily due to a decrease in the incentive compensation accrual of \$0.9 million because of a weak 2011/2012 cold and flu season.

# Amortization of Intangible Assets from Acquired Businesses and Technology

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 acquired technology consists primarily of expense associated with purchased technology.

# Other Income (Expense)

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. The reduction in the outstanding principle balance under the line of credit from \$42.0 million as of September 30, 2011 to \$19.0 million as of September 30, 2012 resulted in a reduction to interest expense of \$0.7 million.

# **Income Taxes**

The effective tax rate for the nine months ended September 30, 2012 and 2011 was 40.0% and 34.0%, respectively. We recognized a tax benefit of \$2.5 million and a tax expense of \$3.4 million for the nine months ended September 30, 2012 and 2011, respectively. The primary difference between the September 30, 2012 and September 30, 2011 effective tax rate is due to the exclusion of the federal research and development tax credit due to the expiration of the statute. In addition, we reduced our reserve for uncertain tax positions resulting from a federal statutory audit.

# **Liquidity and Capital Resources**

As of September 30, 2012, our principal sources of liquidity consisted of \$17.8 million in cash and cash equivalents, and \$60.0 million available to us under our Senior Credit Facility, which can fluctuate from time to time due to, among other factors, our funded debt to adjusted earnings before interest, taxes, depreciation, amortization and stock compensation (adjusted EBITDA) ratio. Our working capital as of September 30, 2012 was \$53.7 million.

Cash provided by operating activities was \$5.9 million during the nine months ended September 30, 2012. We had a net loss of \$3.7 million, including non-cash charges of \$21.5 million of depreciation and amortization of intangible assets and property and equipment, and stock-based compensation. Other significant changes in operating assets and liabilities include an increase in deferred tax assets net of liabilities of \$2.4 million, accounts receivable of \$2.5 million, and inventory of \$2.1 million all of which are related to the seasonal nature of our business. Prepaid expenses and other current assets increased by \$2.6 million primarily due to a \$2.5 million receivable as described in Note 11 to the consolidated financial statements. Cash provided by operating activities was \$34.3 million during the nine months ended September 30, 2011. We had net earnings of \$6.7 million, including non-cash charges of \$17.9 million of depreciation and amortization of intangible assets and property and equipment, and stock-based compensation. The most significant changes in operating assets and liabilities included an increase in accounts receivable of \$3.8 million and decreases in inventories and income tax receivable of \$2.9 million and \$8.3 million, respectively. The increase in accounts receivable and the decrease in inventory are related to the seasonal nature of our business, while the decrease in income tax receivable is due to a tax refund received during the nine months ended September 30, 2011.

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Our investing activities used \$23.1 million during the nine months ended September 30, 2012 primarily related to the acquisition of intangibles associated with our exercise of a buyout clause under the Alere Amendment. During the nine months ended September 30, 2012, we exercised the buy-out right under the Alere Amendment, which allowed us to buy-out any remaining future royalty obligation for a fixed cash payment in the amount of \$15.7 million less \$1.0 million of specified third quarter 2011 royalties. In addition, we used cash for investing activities associated with the acquisition of production and scientific equipment, and building improvements during the nine months ended September 30, 2012. Our investing activities used \$17.5 million during the nine months ended September 30, 2011 primarily related to the acquisition of licensed technology associated with the Alere Amendment as discussed in Note 11 to the Consolidated Financial Statements. In addition, we acquired production and scientific equipment, and building improvements during the nine months ended September 30, 2011.

We are planning approximately \$5.5 million in capital expenditures for the remainder of 2012. The primary purpose for our capital expenditures is to acquire manufacturing and scientific equipment, implement facility improvements, the purchase or development of information technology and leased instruments under customer rental agreements. We plan to fund these capital expenditures with cash flow from operations and other available sources of liquidity. We have \$4.1 million in firm purchase commitments with respect to such planned capital expenditures as of the date of filing this report.

Cash used for financing activities of \$26.2 million during the nine months ended September 30, 2012 was primarily related to repayments under our Senior Credit Facility of \$23.0 million, and repurchases of 200,400 shares of our common stock under our share repurchase program at a cost of approximately \$2.9 million. Our financing activities generated \$27.5 million of cash during the nine months ended September 30, 2011. This was primarily related to proceeds from the sale of our common stock, partly offset by repayments made under the line of credit, both of which occurred during the first quarter of 2011.

On August 10, 2012, we entered into an amended and restated \$140.0 million senior secured syndicated credit facility (the Senior Credit Facility ), which matures on August 10, 2017. The Senior Credit Facility amends and restates our \$120.0 million senior secured credit facility dated October 8, 2008. As part of this amendment, we incurred \$1.0 million in deferred financing costs related to the Senior Credit Facility in addition to the \$0.6 million we had previously recorded related to the original credit facility. As of September 30, 2012, we had \$1.6 million included as a portion of other non-current assets. The Senior Credit Facility bears interest at either LIBOR or the base rate plus in each case the applicable margin. The base rate is equal to the higher of (i) the lender s prime rate, (ii) the federal funds rate plus one-half of one percent and (iii) LIBOR plus one percent. The applicable rate is generally determined in accordance with a performance pricing grid based on our leverage ratio and ranges from 1.25% to 2.50% for LIBOR rate loans and from 0.25% to 1.50% for base rate loans (weighted average interest rate of 1.72% at September 30, 2012). 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 disposition of assets. We are also subject to financial covenants which include a funded debt to adjusted EBITDA ratio (as defined in the Senior Credit Facility, with adjusted EBITDA generally calculated as earnings before, among other adjustments, interest, taxes, depreciation, amortization, and stock-based compensation) not to exceed 3:1 as of the end of each fiscal quarter, and an interest coverage ratio of not less than 3:1 as of the end of each fiscal quarter. The Senior Credit Facility is secured by substantially all of our present and future assets and properties. As of September 30, 2012, we had \$60.0 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 its funded debt to adjusted EBITDA ratio. As of September 30, 2012, we had \$19.0 million outstanding under the Senior Credit Facility. As of September 30, 2012, we were in compliance with all financial covenants.

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.

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# **Off-Balance Sheet Arrangements**

At September 30, 2012, 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.

# **New Accounting Standards**

In September 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2011-08, *Intangibles Goodwill and Other (Topic 350): Testing Goodwill for Impairment*, ( ASU 2011-08 ), to allow entities to use a qualitative approach to test goodwill for impairment. ASU 2011-08 permits an entity to first perform a qualitative assessment to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying value. If it is concluded that this is the case, it is necessary to perform the currently prescribed two-step goodwill impairment test. Otherwise, the two-step goodwill impairment test is not required. The provisions of this ASU were effective for us for fiscal years and interim periods beginning after December 31, 2011, and the adoption did not have an impact on our consolidated financial statements.

In July 2012, the FASB issued Accounting Standards Update No. 2012-02, *Intangibles Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment*, ( ASU 2012-02 ), to simplify the testing for a drop in value of intangible assets such as trademarks, patents, and distribution rights. The amended standard reduces the cost of accounting for indefinite-lived intangible assets, especially in cases where the likelihood of impairment is low. The changes permit businesses and other organizations to first use subjective criteria to determine if an intangible asset has lost value. The amendments to U.S. GAAP will be effective for fiscal years starting after September 15, 2012. Early adoption is permitted. We are currently evaluating the impact of our pending adoption of ASU 2012-02 on our consolidated financial statements.

# **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.

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, 2011.

During the quarter ended September 30, 2012, we entered into a collaborative arrangement with a third party. ASC topic 808, Collaborative Arrangements, defines a collaborative arrangement as an arrangement where the parties are active participants and have exposure to significant risks. We are accounting for the joint development and commercialization activities with the third party as a joint risk sharing collaboration in accordance with ASC topic 808, Collaborative Arrangements. Payments from the third party are recorded as a reduction to research and development expense in the accompanying consolidated financial statements due to the nature of the activities.

Determining the fair values and useful lives of the intangible assets acquired in connection with the Alere Amendment described in Note 11 requires the exercise of judgment. While there are a number of different generally accepted valuation methods to estimate the value of intangible assets, we used the discounted cash flow method in determining the value of licensed technology associated with the Alere Amendment. This method required significant management judgment to forecast the future operating results used in the analysis. In addition, other significant estimates were required such as residual growth rates and discount factors. The estimates we used to value and amortize intangible assets were consistent with the plans and estimates that we use to manage our business and were based on available historical information and industry estimates and averages. These judgments can significantly affect our net operating results.

# 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 \$19.0 million outstanding under our Senior Credit Facility at September 30, 2012. The weighted average interest rate on these borrowings is currently 1.72%. 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 \$0.2 million. Based on our market risk sensitive instruments outstanding at September 30, 2012, 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 date.

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, 2012, 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. In addition, we have a supply agreement with a foreign vendor whereby we evenly share the foreign currency exchange fluctuation risk. We may, in the future, enter into similar such arrangements.

# 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, 2012 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 quarter ended September 30, 2012 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

We are involved in various claims and litigation matters from time to time in the ordinary course of business. We believe that all such current legal actions, in the aggregate, will not have a material adverse effect on the company. We also maintain insurance, including coverage for product liability claims, in amounts which we believe are appropriate given the nature of the business.

# ITEM 1A. Risk Factors

There has been no material change in our risk factors as previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011. For a detailed description of our risk factors, refer to Item 1A, Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2011.

# 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, 2012:

Deviced	Total number of shares	Average price paid	Total number of shares purchased as part of publicly announced plans	valu	oroximate dollar ne of shares that may yet be purchased nder the plans or
Period	purchased(1)	per share	or programs		programs
July		\$		\$	22,081,000
August					22,081,000
September					22,081,000
Total		\$		\$	22,081,000

(1) On November 28, 2011, we announced that our Board of Directors authorized us to repurchase up to an aggregate of \$25.0 million in shares of our common stock under our stock repurchase program. Any shares of common stock repurchased under this program will no longer be deemed outstanding upon repurchase and will be returned to the pool of authorized shares. This repurchase program will expire on November 8, 2013 unless extended by our Board of Directors.

# ITEM 3. Defaults Upon Senior Securities

None.

# ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. Other Information

None.

#### ITEM 6. Exhibits

#### Exhibit Number

- 3.1 Restated Certificate of Incorporation of Quidel Corporation. (Incorporated by reference to Exhibit 3.1 to the Registrant s Quarterly Report on Form 10-Q filed on October 29, 2010.)
- 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. (Incorporated by reference to Exhibit 4.1 to the Registrant s Quarterly Report on Form 10-Q filed on October 29, 2010.)
- 10.1 Amended and Restated Credit Agreement. (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed August 15, 2012)
- Amended and Restated Security Agreement. (Incorporated by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed August 15, 2012)
- 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.
- 101\*\* XBRL Instance Document
- 101\*\* XBRL Taxonomy Extension Schema Document
- 101\*\* XBRL Taxonomy Calculation Linkbase Document
- 101\*\* XBRL Taxonomy Label Linkbase Document
- 101\*\* XBRL Taxonomy Presentation Linkbase Document
- \* Filed herewith.
- \*\* Pursuant to applicable securities laws and regulations, we are deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and are not subject to liability under any anti-fraud provisions of the federal securities laws as long as we have made a good faith attempt to comply with the submission requirements and promptly amend the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. Users of this data are advised that, pursuant to Rule 406T, these interactive data files are deemed not filed and otherwise are not subject to liability.

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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 26, 2012

# QUIDEL CORPORATION

/s/ DOUGLAS C. BRYANT Douglas C. Bryant President and Chief Executive Officer

(Principal Executive Officer)

/s/ RANDALL J. STEWARD Randall J. Steward Chief Financial Officer

(Principal Financial Officer and Accounting Officer)

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#### **Exhibit Index**

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