

QUIDEL CORP /DE/
Form 10-Q
October 29, 2015
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

or

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

For the transition period from _____ to _____

Commission File Number: 0-10961

QUIDEL CORPORATION

(Exact name of registrant as specified in its charter)

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

12544 High Bluff Drive, Suite 200, San Diego, California 92130

(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 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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer 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

As of October 28, 2015, 33,254,841 shares of the registrant's 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, 2015 | December 31, 2014 |
|---|-----------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 182,560 | \$ 200,895 |
| Accounts receivable, net | 31,020 | 34,466 |
| Inventories | 24,568 | 24,763 |
| Deferred tax asset—current | 7,754 | 8,316 |
| Restricted cash | 1,810 | 3,127 |
| Prepaid expenses and other current assets | 3,371 | 2,914 |
| Total current assets | 251,083 | 274,481 |
| Property, plant and equipment, net | 52,267 | 49,226 |
| Goodwill | 80,733 | 80,748 |
| Intangible assets, net | 34,138 | 41,890 |
| Other non-current assets | 821 | 1,066 |
| Total assets | \$ 419,042 | \$ 447,411 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 11,003 | \$ 12,421 |
| Accrued payroll and related expenses | 9,264 | 8,349 |
| Current portion of lease obligation | 710 | 509 |
| Current portion of contingent consideration (see Note 9) | 598 | 733 |
| Deferred grant revenue | 5,517 | 6,330 |
| Other current liabilities | 9,238 | 8,043 |
| Total current liabilities | 36,330 | 36,385 |
| Long-term debt | 141,946 | 137,958 |
| Lease obligation, net of current portion | 4,041 | 4,617 |
| Contingent consideration—non-current (see Note 9) | 5,009 | 5,023 |
| Deferred tax liability—non-current | 7,956 | 14,890 |
| Income taxes payable | 1,746 | 806 |
| Deferred rent | 2,335 | 2,228 |
| Other non-current liabilities | 265 | 493 |
| Commitments and contingencies (see Note 9) | | |
| Stockholders' equity: | | |
| Preferred stock, \$.001 par value per share; 5,000 shares authorized; none issued or outstanding at September 30, 2015 and December 31, 2014 | — | — |
| Common stock, \$.001 par value per share; 97,500 shares authorized; 33,419 and 34,433 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively | 33 | 34 |
| Additional paid-in capital | 209,474 | 229,374 |
| Accumulated other comprehensive loss | (23 |) (29 |
| Retained earnings | 9,930 | 15,632 |
| Total stockholders' equity | 219,414 | 245,011 |

| | | |
|--|-----------|-----------|
| Total liabilities and stockholders' equity | \$419,042 | \$447,411 |
| See accompanying notes. | | |

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

| | Three months ended | | Nine months ended | |
|--|--------------------|-----------|-------------------|------------|
| | September 30, | | September 30, | |
| | 2015 | 2014 | 2015 | 2014 |
| Total revenues | \$46,812 | \$41,193 | \$143,717 | \$120,205 |
| Costs and expenses | | | | |
| Cost of sales (excludes amortization of intangible assets of \$1,590, \$1,571, \$4,751, and \$4,713, respectively) | 16,961 | 16,768 | 53,566 | 52,917 |
| Research and development | 8,419 | 11,506 | 25,575 | 28,714 |
| Sales and marketing | 12,112 | 11,396 | 35,823 | 31,567 |
| General and administrative | 5,889 | 5,879 | 22,039 | 18,949 |
| Amortization of intangible assets from acquired businesses and technology | 2,219 | 2,207 | 6,638 | 6,623 |
| Impairment loss | — | 3,558 | — | 3,558 |
| Total costs and expenses | 45,600 | 51,314 | 143,641 | 142,328 |
| Operating income (loss) | 1,212 | (10,121) | 76 | (22,123) |
| Interest expense, net | (3,090) | (224) | (9,046) | (955) |
| Loss before benefit for income taxes | (1,878) | (10,345) | (8,970) | (23,078) |
| Benefit for income taxes | (1,116) | (4,578) | (3,268) | (8,891) |
| Net loss | \$(762) | \$(5,767) | \$(5,702) | \$(14,187) |
| Basic and diluted loss per share | \$(0.02) | \$(0.17) | \$(0.17) | \$(0.41) |
| Weighted shares used in basic and diluted per share calculation | 33,683 | 34,480 | 34,313 | 34,340 |
| See accompanying notes. | | | | |

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QUIDEL CORPORATION
 CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
 (in thousands; unaudited)

| | Three months ended | | Nine months ended | |
|---|--------------------|-------------|-------------------|--------------|
| | September 30, | | September 30, | |
| | 2015 | 2014 | 2015 | 2014 |
| Net loss | \$ (762) | \$ (5,767) | \$ (5,702) | \$ (14,187) |
| Other comprehensive income (loss), net of tax | | | | |
| Changes in cumulative translation adjustment | (8) | (20) | 6 | (35) |
| Comprehensive loss | \$ (770) | \$ (5,787) | \$ (5,696) | \$ (14,222) |
| See accompanying notes. | | | | |

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

| | Nine months ended September 30, | |
|---|------------------------------------|-------------|
| | 2015 | 2014 |
| OPERATING ACTIVITIES: | | |
| Net loss | \$(5,702 |) \$(14,187 |
| Adjustments to reconcile net loss to net cash provided by operating activities: | | |
| Depreciation, amortization and other | 17,537 | 20,578 |
| Impairment loss | — | 3,558 |
| Stock-based compensation expense | 5,713 | 4,772 |
| Amortization of debt discount and deferred issuance costs | 4,232 | 244 |
| Change in deferred tax assets and liabilities | (6,368 |) (9,241 |
| Change in fair value of acquisition contingencies | — | 42 |
| Changes in assets and liabilities: | | |
| Accounts receivable | 3,441 | 5,464 |
| Inventories | 186 | 4,115 |
| Income taxes receivable | 234 | 153 |
| Prepaid expenses and other current and non-current assets | (305 |) (609 |
| Restricted cash | 1,317 | (5,078 |
| Accounts payable | (1,947 |) (780 |
| Accrued payroll and related expenses | 772 | 406 |
| Income taxes payable | 729 | 119 |
| Deferred grant revenue | (813 |) 5,884 |
| Other current and non-current liabilities | 1,226 | 2,038 |
| Net cash provided by operating activities | 20,252 | 17,478 |
| INVESTING ACTIVITIES: | | |
| Acquisitions of property and equipment | (12,003 |) (8,492 |
| Acquisition of intangibles | — | (92 |
| Net cash used for investing activities | (12,003 |) (8,584 |
| FINANCING ACTIVITIES: | | |
| Payments on lease obligation | (375 |) (326 |
| Repurchases of common stock | (27,617 |) (1,956 |
| Proceeds from issuance of common stock | 2,152 | 4,503 |
| Payments of debt issuance costs | (365 |) — |
| Payments on acquisition contingencies | (129 |) (2,112 |
| Payment for acquisition holdback | (229 |) — |
| Net cash (used for) provided by financing activities | (26,563 |) 109 |
| Effect of exchange rates on cash | (21 |) (26 |
| Net (decrease) increase in cash and cash equivalents | (18,335 |) 8,977 |
| Cash and cash equivalents, beginning of period | 200,895 | 8,388 |
| Cash and cash equivalents, end of period | \$182,560 | \$17,365 |
| SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION: | | |
| Cash paid for interest | \$3,744 | \$725 |
| Cash paid for income taxes | \$1,920 | \$467 |
| NON-CASH INVESTING ACTIVITIES: | | |
| Purchase of capital equipment by incurring current liabilities | \$1,433 | \$269 |
| NON-CASH FINANCING ACTIVITIES: | | |

| | | |
|--|-------|-------|
| Reduction of other current liabilities upon issuance of restricted stock units | \$408 | \$663 |
| See accompanying notes. | | |

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Quidel Corporation

Notes to Consolidated Financial Statements

(Unaudited)

Note 1. Summary of Significant Accounting Policies

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 United States ("GAAP") 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 GAAP for complete financial statements. In the opinion of management, all adjustments considered necessary for a fair presentation (consisting of normal recurring accruals) have been included.

The information at September 30, 2015, and for the three and nine months ended September 30, 2015 and 2014, is unaudited. For further information, refer to the Company's consolidated financial statements and notes thereto for the year ended December 31, 2014 included in the Company's 2014 Annual Report on Form 10-K. Operating results for any quarter are historically seasonal in nature and are not necessarily indicative of the results expected for the full year.

For 2015 and 2014, the Company's fiscal year will end or has ended on January 3, 2016 and December 28, 2014, respectively. For 2015 and 2014, the Company's third quarter ended on September 27, 2015 and September 28, 2014, respectively. For ease of reference, the calendar quarter end dates are used herein. The three and nine month periods ended September 30, 2015 and 2014 each included 13 and 39 weeks, respectively.

Change in Accounting Principle

The Company historically presented deferred debt issuance costs, or fees related to directly issuing debt, as assets on the Consolidated Balance Sheets. During the first quarter of 2015, the Company adopted guidance codified in ASU 2015-03, Interest - Imputation of Interest (Subtopic 835-30), Simplifying the Presentation of Debt Issuance Costs. The guidance simplifies the presentation of debt issuance costs by requiring debt issuance costs to be presented as a deduction from the corresponding liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs is not affected. Therefore, these costs will continue to be amortized as interest expense using the effective interest method pursuant to ASC 835-30-35-2 through 35-3. The Company elected to early adopt the requirements of ASU 2015-03 effective the first quarter ended March 31, 2015 and applied this guidance retrospectively to all prior periods presented in the Company's financial statements.

The reclassification does not impact net income (loss) as previously reported or any prior amounts reported on the Consolidated Statements of Comprehensive Income (Loss) or the Consolidated Statements of Cash Flows. The following table presents the effect of the retrospective application of this change in accounting principle on the Company's Consolidated Balance Sheets as of December 31, 2014:

| Consolidated Balance Sheets (in thousands) | As Reported December 31, 2014 | Effect of Change in Accounting Principle | After change in Accounting Principle |
|---|-------------------------------------|---|--|
| ASSETS | | | |
| Current assets: | | | |
| Prepaid expenses and other current assets | \$3,554 | \$(640) |) \$2,914 |
| Total current assets | 275,121 | (640) |) 274,481 |
| Other non-current assets | 4,565 | (3,499) |) 1,066 |
| Total assets | \$451,550 | \$(4,139) |) \$447,411 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | | |
| Long-term debt | 142,097 | (4,139) |) 137,958 |
| Total liabilities and stockholders' equity | \$451,550 | \$(4,139) |) \$447,411 |

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Comprehensive Loss

Comprehensive loss includes foreign currency translation adjustments excluded from the Company's Consolidated Statements of Operations.

Use of Estimates

The preparation of financial statements requires the Company 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, management evaluates its estimates, including those related to revenue recognition, customer programs and incentives, bad debts, inventories, intangible assets, software development costs, stock-based compensation, restructuring, contingencies and litigation, contingent consideration, the fair value of the debt component of convertible debt instruments, and income taxes. Management bases its estimates on historical experience and on various other assumptions that it believes 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.

Revenue Recognition

The Company records revenues primarily from product sales. These revenues are recorded net of rebates and other discounts that are estimated at the time of sale, and are largely driven by various customer program offerings, including special pricing agreements, promotions and other volume-based incentives. Revenue from product sales are recorded upon passage of title and risk of loss to the customer. Passage of title to the product and recognition of revenue occurs upon delivery to the customer when sales terms are free on board ("FOB") destination and at the time of shipment when the sales terms are FOB shipping point and there is no right of return.

A portion of product sales includes revenues for diagnostic kits, which are utilized on leased instrument systems under the Company's "reagent rental" program. The reagent rental program provides customers the right to use the instruments at no separate cost to the customer in consideration for a multi-year agreement to purchase annual minimum amounts of consumables ("reagents" or "diagnostic kits"). When an instrument is placed with a customer under a reagent rental agreement, the Company retains title to the equipment and it remains capitalized on the Company's Consolidated Balance Sheets as property and equipment. The instrument is depreciated on a straight-line basis over the shorter of the lease term or the life of the instrument. Depreciation expense is recorded in cost of sales included in the Consolidated Statements of Operations. The reagent rental agreements represent one unit of accounting as the instrument and consumables (reagents) are interdependent in producing a diagnostic result and neither has a stand-alone value with respect to these agreements. No revenue is recognized at the time of instrument placement. All revenue is recognized when the title and risk of loss for the diagnostic kits have passed to the customer.

Royalty income from the grant of license rights is recognized during the period in which the revenue is earned and the amount is determinable from the licensee. The Company also earns income from the licensing of technology.

The Company earns income from grants for research and commercialization activities. On November 6, 2012, the Company was awarded a milestone-based grant totaling up to \$8.3 million from the Bill and Melinda Gates Foundation to develop, manufacture and validate a quantitative, low-cost, nucleic acid assay for HIV drug treatment monitoring on the integrated Savanna MDx platform for use in limited resource settings. Upon execution of the grant agreement, the Company received \$2.6 million to fund subsequent research and development activities and received milestone payments totaling \$2.5 million in 2013. On September 10, 2014, the Company entered into an amended grant agreement with the Bill and Melinda Gates Foundation for additional funding of up to \$12.6 million with the intent to accelerate the development of the Savanna MDx platform in the developing world. Upon execution of the amended grant agreement, the Company received \$10.6 million in cash. The Company received a payment of \$2.4 million in April 2015 and expects to receive the remaining milestone payment of up to \$2.8 million in 2016. Under the original and amended grant agreements, the Company recognizes grant revenue on the basis of the lesser of the amount recognized on a proportional performance basis or the amount of cash payments that are non-refundable as of the end of each reporting period. The Company recognized \$0.8 million and \$3.4 million for the three months ended September 30, 2015 and 2014, respectively, and recognized \$3.2 million and \$4.7 million for the nine months ended September 30, 2015 and 2014, respectively, as grant revenue associated with this grant. Cash payments received are restricted as to use until expenditures contemplated in the grant are incurred or committed. Therefore, the Company

classified \$1.8 million and \$3.1 million of funds received from the Bill and Melinda Gates Foundation as restricted cash as of September 30, 2015 and December 31, 2014, respectively. In addition, the Company has classified \$5.5 million and \$6.3 million as deferred grant revenue as of September 30, 2015 and December 31, 2014, respectively.

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Fair Value Measurements

The Company uses the fair value hierarchy established in ASC Topic 820, Fair Value Measurements and Disclosures, which 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 that 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).

The carrying amounts of the Company's financial instruments, including cash, receivables, accounts payable, and accrued liabilities approximate their fair values due to their short-term nature. Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of trade accounts receivable. The Company establishes reserves for estimated uncollectible accounts and believes its reserves are adequate.

Changes to the recording of prior period freight billed to customers from sales and marketing expenses to revenues. The Company corrected immaterial errors in the classification of freight billed to customers of \$0.3 million and \$1.2 million for the three and nine months ended September 30, 2014, from sales and marketing expense as previously reported in the Consolidated Statements of Operations to revenues. The adjustments did not impact net income (loss) as previously reported or any prior amounts reported on the Consolidated Balance Sheets, Statements of Cash Flows, Statements of Comprehensive (Loss) Income or Statements of Stockholders' Equity. Management evaluated the materiality both qualitatively and quantitatively and determined it was not material to the previously reported consolidated financial statements.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued guidance codified in Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers, which amends the guidance in former ASC 605, Revenue Recognition. This guidance is intended to improve and converge with international standards relating to the financial reporting requirements for revenue from contracts with customers. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under current authoritative guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. The original guidance was effective for annual reporting periods beginning after December 15, 2016. However, in July 2015, the FASB deferred by one year the effective dates of the new revenue recognition standard for entities reporting under GAAP. As a result, the standard will be effective for public entities for annual reporting periods beginning after December 15, 2017, including interim periods therein. The Company is currently evaluating the impact of this guidance and expects to adopt the standard in the first quarter of 2018.

In August 2014, the FASB issued guidance codified in ASU 2014-15 (Subtopic 205-40), Presentation of Financial Statements - Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. The guidance requires management to evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued (or available to be issued when applicable). Management will be required to make this evaluation for both annual and interim reporting periods and will make certain disclosures if it concludes that substantial doubt exists or when its plans alleviate substantial doubt about the entity's ability to continue as a going concern. Substantial doubt exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or available to be issued). The term probable is used consistently with its use in ASC Topic 450, Contingencies. The guidance is effective for annual periods ending after December 15, 2016 and for interim reporting periods starting in the first

quarter 2017, with early adoption permitted. The Company expects to adopt ASU 2014-15 for the annual reporting period ended December 31, 2016, which is not expected to have a significant impact on the Company's consolidated financial statements.

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In February 2015, the FASB issued guidance codified in ASU 2015-02 (Topic 810), Consolidation - Amendments to the Consolidation Analysis. The guidance affects reporting entities that are required to evaluate whether they should consolidate certain legal entities. Specifically, the guidance amends (i) the identification of variable interests (fees paid to a decision maker or service provider), (ii) the Variable Interest Entity (VIE) characteristics for a limited partnership or similar entity and (iii) the primary beneficiary determination. The guidance is effective for annual periods ending after December 15, 2015 and for interim reporting periods starting in the first quarter 2016, with early adoption permitted. ASU 2015-02 is not expected to have a significant impact on the Company's consolidated financial statements.

In July 2015, the FASB issued guidance codified in ASU 2015-11 (Topic 330), Simplifying the Measurement of Inventory. The guidance applies to inventory that is measured using first-in, first-out ("FIFO") or average cost. Under the guidance, an entity should measure inventory that is within scope at the lower of cost and net realizable value, which is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The guidance is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, with early adoption permitted as of the beginning of an interim or annual reporting period. The Company expects to early adopt ASU 2015-11 in the first quarter of 2016, which is not expected to have a significant impact on the Company's consolidated financial statements.

Note 2. Computation of Loss Per Share

For the three and nine months ended September 30, 2015 and 2014, basic loss per share was computed by dividing net loss by the weighted-average number of common shares outstanding, including restricted stock units vested during the period. Diluted earnings per share ("EPS") reflects the potential dilution that could occur if the earnings were divided by the weighted-average number of common shares and potentially dilutive common shares from outstanding stock options as well as unvested restricted stock units. Potential 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 restricted stock units.

For the three and nine months ended September 30, 2015 and 2014, there were no differences between the number of common shares used for the basic and diluted EPS computation because the Company incurred a net loss and the effect would be anti-dilutive. Stock options and shares of restricted stock that would have been included in the diluted EPS calculation if the Company had earnings amounted to 0.9 million and 1.0 million for the three months ended September 30, 2015 and 2014, respectively, and 1.0 million and 1.1 million for the nine months ended September 30, 2015 and 2014, respectively.

Additionally, stock options are excluded from the calculation of diluted EPS when the combined exercise price, unrecognized stock-based compensation and expected tax benefits upon exercise are greater than the average market price for the Company's common stock because their effect is anti-dilutive. Stock options totaling 2.2 million and 1.8 million for the three and nine months ended September 30, 2015, respectively, and 1.2 million and 1.1 million for the three and nine months ended September 30, 2014, respectively, were not included in the computation of diluted EPS because the exercise of such options would be anti-dilutive.

As discussed in Note 6, the Company issued Convertible Senior Notes ("Convertible Senior Notes") in December 2014. It is the Company's intent and policy to settle conversions through combination settlement, which essentially involves repayment of an amount of cash equal to the "principal portion" and delivery of the "share amount" in excess of the conversion value over the principal portion in cash or shares of common stock ("conversion premium"). No conversion premium existed as of September 30, 2015, therefore, there was no dilutive impact from the Convertible Senior Notes to diluted EPS.

Note 3. Inventories

Inventories are recorded at the lower of cost (first-in, first-out) or market. Inventories consisted of the following, net of reserves of \$0.4 million and \$2.2 million at September 30, 2015 and December 31, 2014, respectively (in thousands):

| | September 30, 2015 | December 31, 2014 |
|---------------|-----------------------|----------------------|
| Raw materials | \$10,969 | \$10,472 |

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| | | |
|---|----------|----------|
| Work-in-process (materials, labor and overhead) | 8,343 | 6,834 |
| Finished goods (materials, labor and overhead) | 5,256 | 7,457 |
| Total inventories | \$24,568 | \$24,763 |

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Note 4. Other Current Liabilities

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

| | September 30, 2015 | December 31, 2014 |
|--|-----------------------|----------------------|
| Customer incentives and rebates | \$5,571 | \$4,729 |
| Accrued research and development costs | 183 | 990 |
| Accrued interest | 1,604 | 311 |
| Other | 1,880 | 2,013 |
| Total other current liabilities | \$9,238 | \$8,043 |

Note 5. Income Taxes

The Company recognized income tax benefit of \$1.1 million and \$4.6 million for the three months ended September 30, 2015 and 2014, respectively, which represents an effective tax rate of 59% and 44%, respectively. For the nine months ended September 30, 2015 and 2014, the Company recognized an income tax benefit of \$3.3 million and \$8.9 million, respectively, which represents an effective tax rate of 36% and 39%, respectively. For the nine months ended September 30, 2015, the effective tax rate was lower compared to the same periods of 2014 due primarily to the valuation allowance recorded for state deferred tax assets, partially offset by the federal manufacturing deduction.

The Company is subject to periodic audits by domestic and foreign tax authorities. The Company's federal tax years for 2011 and forward are subject to examination by the U.S. authorities. With few exceptions, the Company's state and foreign tax years beginning with 2001 and 2003, respectively, are subject to examination by applicable tax authorities. The Company believes that it has appropriate support for the income tax positions taken on its tax returns and that its accruals for tax liabilities are adequate for all open years based on an assessment of many factors, including past experience and interpretations of tax law applied to the facts of each matter.

Note 6. Debt

3.25% Convertible Senior Notes due 2020

In December 2014, the Company issued Convertible Senior Notes in the aggregate principal amount of \$172.5 million. The Convertible Senior Notes have a coupon rate of 3.25% and are due 2020. Debt issuance costs of approximately \$5.1 million were incurred, of which \$4.2 million consisted of underwriters fees, legal, accounting and other professional fees, and are recorded as a reduction to long-term debt and are being amortized to interest expense using the effective interest method over the six-year term of the Convertible Senior Notes. The remaining \$0.9 million of debt issuance costs are allocated as a component of equity in additional paid-in capital. Deferred issuance costs related to the Convertible Senior Notes were \$3.7 million and \$4.1 million as of September 30, 2015 and December 31, 2014, respectively.

The Convertible Senior Notes will be convertible into cash, shares of common stock, or a combination of cash and shares of common stock based on an initial conversion rate, subject to adjustment, of 31.1891 shares per \$1,000 principal amount of the Convertible Senior Notes (which represents an initial conversion price of approximately \$32.06 per share) on the business day immediately preceding September 15, 2020. The conversion will occur in the following circumstances and to the following extent: (1) during any calendar quarter commencing after the calendar quarter ending on March 31, 2015, if the last reported sales price of the Company's common stock, for at least 20 trading days (whether or not consecutive) in the period of 30 consecutive trading days ending on the last trading day of the calendar quarter immediately preceding the calendar quarter in which the conversion occurs, is more than 130% of the conversion price of the notes in effect on each applicable trading day; (2) during the five consecutive business day period following any five consecutive trading day period in which the trading price per \$1,000 principal amount of the Convertible Senior Note for each such trading day was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such day; or (3) upon the occurrence of specified events described in the indenture for the Convertible Senior Notes. On or after September 15, 2020 until the close of business on the second scheduled trading day immediately preceding the stated maturity date, holders may surrender their notes for conversion at any time, regardless of the foregoing circumstances.

It is the Company's intent and policy to settle conversions through combination settlement, which essentially involves repayment in cash equal to the "principal portion" and delivery of the "share amount" in excess of the principal portion in

shares of common stock or cash. In general, for each \$1,000 in principal, the “principal portion” of cash upon settlement is defined as the lesser of \$1,000, or the conversion value during the 25-day observation period as described in the indenture for

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the Convertible Senior Notes. The conversion value is the sum of the daily conversion value which is the product of the effective conversion rate divided by 25 days and the daily volume weighted average price (“VWAP”) of the Company’s common stock. The “share amount” is the cumulative “daily share amount” during the observation period, which is calculated by dividing the daily VWAP into the difference between the daily conversion value (i.e., conversion rate x daily VWAP) and \$1,000.

The Company pays 3.25% interest per annum on the principal amount of the Convertible Senior Notes semi-annually in arrears in cash on June 15 and December 15 of each year. The Convertible Senior Notes mature on December 15, 2020. During the nine months ended September 30, 2015, the Company recorded total interest expense of \$8.2 million related to the Convertible Senior Notes of which \$4.0 million related to the amortization of the debt discount and issuance costs and \$4.2 million related to the coupon due semi-annually.

If a fundamental change, as defined in the indenture for the Convertible Senior Notes, such as an acquisition, merger, or liquidation of the Company, occurs prior to the maturity date, subject to certain limitations, holders of the Convertible Senior Notes may require the Company to repurchase all or a portion of their Convertible Senior Notes for cash at a repurchase price equal to 100% of the principal amount of the Convertible Senior Notes to be repurchased, plus any accrued and unpaid interest to, but excluding, the repurchase date.

The Company accounts separately for the liability and equity components of the Convertible Senior Notes in accordance with authoritative guidance for convertible debt instruments that may be settled in cash upon conversion. The guidance requires the carrying amount of the liability component to be estimated by measuring the fair value of a similar liability that does not have an associated conversion feature. Because the Company has no outstanding non-convertible public debt, the Company determined that senior, unsecured corporate bonds traded on the market represent a similar liability to the Convertible Senior Notes without the conversion option. Based on market data available for publicly traded, senior, unsecured corporate bonds issued by companies in the same industry and with similar maturity, the Company estimated the implied interest rate of its Convertible Senior Notes to be 6.9%, assuming no conversion option. Assumptions used in the estimate represent what market participants would use in pricing the liability component, which were defined as Level 2 observable inputs. The estimated implied interest rate was applied to the Convertible Senior Notes, which resulted in a fair value of the liability component of \$141.9 million upon issuance, calculated as the present value of implied future payments based on the \$172.5 million aggregate principal amount. The \$30.7 million difference between the cash proceeds of \$172.5 million and the estimated fair value of the liability component was recorded in additional paid-in capital, net of tax and issuance costs, as the Convertible Senior Notes were not considered redeemable.

As a policy election under applicable guidance related to the calculation of diluted net EPS, the Company elected the combination settlement method as its stated settlement policy and applied the treasury stock method in the calculation of dilutive impact of the Convertible Senior Notes. The Convertible Senior Notes were not convertible as of September 30, 2015. If the Convertible Senior Notes were converted as of September 30, 2015, the if-converted value would not exceed the principal amount.

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The following table summarizes information about the equity and liability components of the Convertible Senior Notes (dollars in thousands). The fair values of the respective notes outstanding were measured based on quoted market prices.

| | September 30, 2015 | December 31, 2014 |
|--|-----------------------|----------------------|
| Principal amount of Convertible Senior Notes outstanding | \$172,500 | \$172,500 |
| Unamortized discount of liability component | (26,893 |) (30,403 |
| Unamortized debt issuance costs (1) | (3,661 |) (4,139 |
| Net carrying amount of liability component | 141,946 | 137,958 |
| Less: current portion | — | — |
| Long-term debt | \$141,946 | \$137,958 |
| Carrying value of equity component, net of issuance costs | \$29,758 | \$29,758 |
| Fair value of outstanding Convertible Senior Notes (2) | \$166,023 | \$190,613 |
| Remaining amortization period of discount on the liability component | 5.3 years | 6.0 years |

(1) Includes reclassification of \$0.6 million from prepaid expenses and other current assets and \$3.5 million from other non-current assets as of December 31, 2014.

(2) Subsequent to the issuance of the financial statements for the year ended December 31, 2014, the Company discovered an error in its disclosure of the fair value of outstanding convertible senior notes. The fair value of the Convertible Senior Notes at December 31, 2014 was \$190.6 million instead of the amount originally disclosed in the Company's Annual Report on Form 10-K, which inappropriately reflected only the book value of the long-term debt component of the Convertible Senior Notes, which was \$142.1 million. The revision in the disclosure of fair value for the Convertible Senior Notes did not impact net loss as previously reported or any prior amounts reported on the Consolidated Balance Sheets, Statements of Operations, Statements of Comprehensive (Loss) Income, Statements of Cash Flows or Statements of Stockholders' Equity as of and for the year ended December 31, 2014.

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") that matures on August 10, 2017. As part of this amendment, the Company incurred an additional \$1.0 million in deferred financing costs related to the Senior Credit Facility. The Company had previously recorded \$0.6 million related to the prior credit facility. Deferred financing costs are amortized on a straight-line basis over the term of the Senior Credit Facility. The Company presents debt issuance costs as an asset when there is no associated liability. As of September 30, 2015, the Company had deferred financing costs related to the Senior Credit Facility of \$0.3 million included as a portion of other non-current assets and \$0.3 million included as a portion of prepaid expenses and other current assets. As of December 31, 2014, the Company had deferred financing costs related to the Senior Credit Facility of \$0.5 million included as a portion of other non-current assets and \$0.3 million included as a portion of prepaid expenses and other current assets. The Senior Credit Facility bears interest at either the London Interbank Offered Rate ("LIBOR") or the base rate, plus, in each case, an applicable margin. The base rate is equal to the highest 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 margin is generally determined in accordance with a performance pricing grid based on the Company's 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. The agreement governing the Senior Credit Facility includes certain customary limitations, including among others: limitation on liens; limitation on mergers, consolidations and dispositions 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; and limitation on transactions with affiliates. The Company is 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. Funded debt is defined as outstanding borrowings on the Senior Credit Facility plus Convertible Senior Notes, less the Company's domestic cash and cash equivalents in excess of \$15.0 million. The Senior Credit Facility is secured by

substantially all present and future assets and properties of the Company and is senior to the Convertible Senior Notes. As of September 30, 2015 and December 31, 2014, the Company had no borrowings outstanding. The Company had \$95.9 million available under the Senior Credit Facility as of September 30, 2015. 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, 2015, the Company was in compliance with all financial covenants.

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Note 7. Stockholders' Equity

Issuances and Repurchases of Common Stock

During the nine months ended September 30, 2015, 69,828 shares of common stock were issued in conjunction with the vesting and release of restricted stock units, 92,164 shares of common stock were issued due to the exercise of stock options and 52,677 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 \$2.2 million. During the nine months ended September 30, 2015, 1,211,769 shares of outstanding common stock were repurchased under the Company's previously announced share repurchase program for approximately \$27.2 million. Additionally, 17,181 shares of outstanding common stock were repurchased in connection with payment of minimum tax withholding obligations for certain employees relating to the lapse of restrictions on certain restricted stock units for approximately \$0.4 million. As of September 30, 2015, there was \$22.9 million available under the Company's share repurchase program.

Stock-Based Compensation

The compensation expense related to the Company's stock-based compensation plans included in the accompanying Consolidated Statements of Operations was as follows (in thousands):

| | Three months ended September 30, | | Nine months ended September 30, | |
|--|----------------------------------|----------|---------------------------------|----------|
| | 2015 | 2014 | 2015 | 2014 |
| Cost of sales | \$ 113 | \$ 103 | \$ 454 | \$ 431 |
| Research and development | 268 | 221 | 562 | 786 |
| Sales and marketing | 351 | 222 | 1,228 | 702 |
| General and administrative | 987 | 747 | 3,469 | 2,853 |
| Total stock-based compensation expense | \$ 1,719 | \$ 1,293 | \$ 5,713 | \$ 4,772 |

Total compensation expense recognized for the three months and nine months ended September 30, 2015 includes \$1.1 million and \$3.5 million related to stock options and \$0.6 million and \$2.2 million related to restricted stock units, respectively. Total compensation expense recognized for the three and nine months ended September 30, 2014 includes \$0.9 million and \$3.3 million related to stock options and \$0.4 million and \$1.5 million related to restricted stock units, respectively. As of September 30, 2015, total unrecognized compensation expense related to non-vested stock options was \$7.5 million, which is expected to be recognized over a weighted-average period of approximately 2.4 years. As of September 30, 2015, total unrecognized compensation expense related to non-vested restricted stock units was \$3.0 million, which is expected to be recognized over a weighted-average period of approximately 2.7 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, 2015 and 2014.

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, | | |
|---------------------------------|---------------------------------|--------|---|
| | 2015 | 2014 | |
| Risk-free interest rate | 1.48 | % 1.59 | % |
| Expected option life (in years) | 6.23 | 5.77 | |
| Volatility rate | 40 | % 42 | % |
| Dividend rate | — | % — | % |

The weighted-average fair value of stock options granted during the nine months ended September 30, 2015 and 2014 was \$9.60 and \$10.95, respectively. The Company granted 616,994 and 542,020 stock options during the nine months ended September 30, 2015 and 2014, respectively. The weighted-average fair value of restricted stock units granted during the nine months ended September 30, 2015 and 2014 was \$23.47 and \$25.34, respectively. The Company granted 146,164 and 116,319 shares of restricted stock units during the nine months ended September 30, 2015 and 2014, respectively. The fair value of restricted stock units is determined based on the closing market price of the Company's common stock on the grant date.

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Note 8. Industry and Geographic Information

The Company operates in one reportable segment. Sales to customers outside the U.S. represented \$18.8 million (13%) and \$16.7 million (14%) of total revenue for the nine months ended September 30, 2015 and 2014, respectively. As of September 30, 2015 and December 31, 2014, balances due from foreign customers were \$4.3 million and \$5.5 million, respectively.

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

| Customer: | Nine months ended September 30, | | |
|-----------|---------------------------------|------|---|
| | 2015 | 2014 | |
| A | 23 | % 16 | % |
| B | 16 | % 16 | % |
| C | 11 | % 10 | % |
| | 50 | % 42 | % |

As of September 30, 2015 and December 31, 2014, accounts receivable from customers with balances due in excess of 10% of total accounts receivable totaled \$23.5 million and \$23.7 million, respectively.

Note 9. Commitments and Contingencies

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 that management believes are appropriate given the nature of its business. At September 30, 2015 and December 31, 2014, the Company had \$0.3 million accrued as a liability for various legal matters where the Company deemed the liability probable and estimable.

Licensing Arrangements

The Company has entered into various licensing and royalty agreements, which largely require payments based on specified product sales as well as the achievement of specified milestones. The Company had royalty and license expenses relating to those agreements of approximately \$0.1 million for both of the three months ended September 30, 2015 and 2014. The Company had royalty and license expenses relating to those agreements of approximately \$0.5 million and \$0.6 million for the nine months ended September 30, 2015 and 2014, respectively.

Research and Development Agreements

The Company has entered into various research and development agreements that 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 or resource expenditures. These milestones generally include achievement of prototype assays, validation lots and clinical trials. At September 30, 2015 and December 31, 2014, total future commitments under the terms of these agreements are estimated at \$3.8 million and \$4.3 million, respectively. The commitments will fluctuate as we agree to new phases of development under the existing arrangements.

Contingent Consideration

In conjunction with the acquisition of BioHelix Corporation (“BioHelix”) in May 2013, the Company agreed to contingent consideration ranging from \$5.0 million to \$13.0 million upon achievement of certain research and development milestones and revenue targets through 2018. At December 31, 2014, all research and development milestones had been achieved and all payments related to research and development milestones had been disbursed. No payments related to the royalty revenue earn-out were disbursed during the three months ended September 30, 2015 and 2014. Payments of \$0.1 million and \$49,000 related to the revenue royalty earn-out were disbursed during the nine months ended September 30, 2015 and 2014, respectively. As of September 30, 2015, the current portion of the contingent consideration is \$0.6 million and the

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non-current portion of the contingent consideration is \$4.9 million. The fair value of the remaining contingent consideration related to the revenue royalty earn-out to be settled in cash is estimated based on the Monte Carlo Simulation Model.

In August 2013, the Company completed a business combination accomplished by acquiring the assets of AnDiaTec GmbH & Co. KG (“AnDiaTec”), a privately-held, diagnostics company, based in Germany. The Company agreed to contingent consideration of up to €0.5 million (\$0.6 million based on the September 30, 2015 currency conversion rate) upon achievement of certain revenue targets through 2018. As of September 30, 2015, the current portion of the contingent consideration is \$25,000 and the non-current portion of the contingent consideration is \$0.1 million, based on the Monte Carlo Simulation Model. In addition, the Company agreed to pay the founder of AnDiaTec contingent payments of up to €3.0 million (\$3.4 million based on the September 30, 2015 currency conversion rate) upon achievement of certain research and development milestones, subject to continued employment. The Company paid \$0.3 million for the achievement of agreed upon research and development milestones during the three months ended September 30, 2015 and \$0.6 million during the three months ended September 30, 2014. The Company paid \$1.2 million and \$0.9 million for the achievement of agreed upon research and development milestones during the nine months ended September 30, 2015 and 2014, respectively. In October 2015, the Company paid \$0.5 million for the achievement of agreed upon research and development milestones that were accrued for as of September 30, 2015. These costs are recorded as compensation expense included in research and development expense in the Consolidated Statements of Operations.

Note 10. Lease Obligation

In the fourth quarter of 2013, the Company entered into a lease for approximately 30,000 square feet of office space and moved the executive and administrative functions into this facility in the second quarter of 2014. The lease expires in 2022 with options to extend the lease for two additional five-year periods. This operating lease included a lease incentive for tenant improvements of \$1.7 million, which has been included as a leasehold improvement in property, plant and equipment and as deferred rent. At September 30, 2015, the total deferred rent was \$2.6 million, of which \$0.3 million was included in other current liabilities.

During 1999, the Company completed a sale and leaseback transaction of its San Diego McKellar 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. 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 is amortizing the lease obligation over the new lease term. The amount of the monthly rental payments remains the same under the amendment. In August 2015, the lease agreement was amended to extend the timing to January 1, 2016 to exercise an option in the lease to purchase the general partner’s interest in the partnership 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 \$0.3 million for each of the three months ended September 30, 2015 and 2014 and \$0.9 million and \$0.8 million for the nine months ended September 30, 2015 and 2014, respectively.

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Note 11. Fair Value Measurements

The following table presents the Company's hierarchy for its assets and liabilities measured at fair value on a recurring basis as of the following periods (in thousands):

| | September 30, 2015 | | | | December 31, 2014 | | | |
|--|--------------------|---------|----------|------------|-------------------|---------|----------|----------|
| | Level 1 | Level 2 | Level 3 | Total | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | | | | | |
| Cash equivalents | \$ 168,123 | \$— | \$— | \$ 168,123 | \$ 3,057 | \$— | \$— | \$ 3,057 |
| Total assets measured at fair value | \$ 168,123 | \$— | \$— | \$ 168,123 | \$ 3,057 | \$— | \$— | \$ 3,057 |
| Liabilities: | | | | | | | | |
| Contingent consideration | — | — | 5,607 | 5,607 | — | — | 5,756 | 5,756 |
| Total liabilities measured at fair value | \$— | \$— | \$ 5,607 | \$ 5,607 | \$— | \$— | \$ 5,756 | \$ 5,756 |

There were no transfers of assets or liabilities between Level 1, Level 2 and Level 3 categories of the fair value hierarchy during the three and nine month periods ended September 30, 2015 and the year ended December 31, 2014. The Company used Level 1 inputs to determine the fair value of a portion of its cash equivalents, which primarily consist of funds held in a money market account, and as such, the carrying value of such cash equivalents approximates fair value. As of September 30, 2015 and December 31, 2014, the carrying value of these cash equivalents was \$168.1 million and \$3.1 million, respectively.

The Company assesses the fair value of contingent consideration to be settled in cash related to acquisitions using the Monte Carlo Simulation Model for the royalty earn-out portion of the contingent liability. This is a Level 3 measurement. Significant assumptions used in the measurement include future royalty payments and the discount rate associated with the potential volatility of the acquired business. The Company recorded no changes to the fair value of the contingent consideration for the three months ended September 30, 2014. Due to changes in the estimated future royalty payments and a shorter discounting period, the fair value of the contingent consideration liabilities changed, resulting in a \$42,000 loss recorded to cost of sales in the Consolidated Statements of Operations during the nine months ended September 30, 2014. The Company recorded no changes to the fair value of the contingent consideration liabilities during the three and nine month periods ended September 30, 2015.

Changes in estimated fair value of contingent consideration liabilities from December 31, 2014 through September 30, 2015 are as follows (in thousands):

| | Contingent consideration liabilities (Level 3 measurement) |
|---|---|
| Balance at December 31, 2014 | \$5,756 |
| Cash payments | (129) |
| Unrealized gain on foreign currency translation | (20) |
| Balance at September 30, 2015 | \$5,607 |

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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, fluctuations in our operating results resulting from seasonality, the timing of the onset, length and severity of cold and flu seasons, government and media attention focused on influenza and the related potential impact on humans from novel influenza viruses, adverse changes in competitive conditions in domestic and international markets, changes in sales levels as it relates to the absorption of our fixed costs, lower than anticipated market penetration of our products, the reimbursement system currently in place and future changes to that system, and changes in economic conditions in our domestic and international markets, the quantity of our product in our distributors' inventory or distribution channels, changes in the buying patterns of our distributors and changes in the healthcare market and consolidation of our customer base; our development and protection of intellectual property; our development of new technologies, products and markets; our reliance on a limited number of key distributors; our reliance on sales of our influenza diagnostics tests; our ability to manage our growth strategy, including our ability to integrate companies or technologies we have acquired or may acquire; intellectual property risks, including but not limited to, infringement litigation; limitations and covenants in our Senior Credit Facility; our need for additional funds to finance our operating needs; volatility and disruption in the global capital and credit markets; acceptance of our products among physicians and other healthcare providers; competition with other providers of diagnostic products; adverse actions or delays in new product reviews or related to currently-marketed products by the U.S. Food and Drug Administration (the "FDA"); changes in government policies; compliance with other government regulations, such as safe working conditions, manufacturing practices, environmental protection, fire hazard and disposal of hazardous substances; third-party reimbursement policies; our ability to meet demand for our products; interruptions in our supply of raw materials; product defects; business risks not covered by insurance and exposure to other litigation claims; interruption to our computer systems; competition for and loss of management and key personnel; international risks, including but not limited to, compliance with product registration requirements, exposure to currency exchange fluctuations and foreign currency exchange risk sharing arrangements, longer payment cycles, lower selling prices and greater difficulty in collecting accounts receivable, reduced protection of intellectual property rights, political and economic instability, taxes, and diversion of lower priced international products into U.S. markets; the possibility that we may incur additional indebtedness; our ability to settle conversions of our Convertible Senior Notes in cash; the effect on our operating results from the trigger of the conditional conversion feature of our Convertible Senior Notes; dilution resulting from future sales of our equity; volatility in our stock price; provisions in our charter documents, Delaware law and the indenture governing our Convertible Senior Notes that might delay or impede stockholder actions with respect to business combinations or similar transactions; and our intention of not paying dividends. Forward-looking statements typically are identified by the use of terms such as "may," "will," "should," "might," "expect," "anticipate," "estimate," "plan," "intend," "goal," "project," "strategy," "future," and similar words, although forward-looking statements are expressed differently. Forward-looking statements in this Quarterly Report include, among others, statements concerning: our outlook and strategy for the remainder of the 2015 fiscal year; projected capital expenditures for the remainder of the 2015 fiscal year, including the components thereof, and our source of funds for such expenditures; the sufficiency of our liquidity and capital resources; our strategy, goals and objectives; including, among others, continuing to make substantial investment in research and development and sales and marketing; that we may enter into additional foreign currency exchange risk sharing arrangements; our exposure to claims and litigation; expectations regarding grant revenues and expenditures in the remainder of 2015; that we will continue to incur substantial research and development expenses; the exposure of our money market assets to market fluctuation risk; the impact and timing of our adoption of new accounting pronouncements; and our intention to

continue to evaluate product, technology and company acquisition opportunities and our financing needs related thereto. The risks described under “Risk Factors” in Item 1A of this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2014, 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.

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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, public health 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 our products primarily through distributor arrangements.

Outlook

We continue to realize momentum in sales of our Sofia and molecular assays. For the remainder of 2015, we will continue to focus on prudently managing our business and delivering long-term sustainable growth through the creation of a broader-based diagnostic company serving our existing customers as well as targeting larger and faster growing markets. We anticipate significant investment in research and development, focused primarily on our Sofia and molecular programs. In addition, we continue to invest in our U.S. sales organization and related marketing programs, in support of recent product launches. We will also continue to evaluate opportunities to acquire new product lines, technologies and companies that would enable us to expand more quickly.

Three months ended September 30, 2015 compared to the three months ended September 30, 2014

Total Revenues

The following table compares total revenues for the three months ended September 30, 2015 and 2014 (in thousands, except percentages):

| | For the three months ended | | Increase (Decrease) | | |
|--|----------------------------|----------|---------------------|------|----|
| | September 30, 2015 | 2014 | \$ | % | |
| Infectious disease net product sales | \$33,393 | \$26,301 | \$7,092 | 27 | % |
| Women's health net product sales | 9,478 | 8,760 | 718 | 8 | % |
| Gastrointestinal disease net product sales | 1,803 | 1,995 | (192) | (10) |)% |
| Other net product sales | 1,091 | 410 | 681 | 166 | % |
| Royalty, license fees and grant revenue | 1,047 | 3,727 | (2,680) | (72) |)% |
| Total revenues | \$46,812 | \$41,193 | \$5,619 | 14 | % |

For the three months ended September 30, 2015, total revenue increased to \$46.8 million from \$41.2 million in the prior period. The Company realized growth in infectious disease, women's health and other revenues. The increase in the infectious disease category was primarily due to stronger Influenza and Strep A sales driven by continued share gains on the Sofia platform. The increase in the women's health category was driven by growth in our hCG and Thyretain product lines. The increase in the other revenues category was driven by timing of sales for our veterinary products. For the three months ended September 30, 2015, royalty, license fees and grant revenue decreased \$2.7 million due to timing of grant revenues associated with the amended Bill and Melinda Gates grant.

Cost of Sales

Cost of sales was \$17.0 million, or 36% of total revenues for the three months ended September 30, 2015 compared to \$16.8 million, or 41% of total revenues for the three months ended September 30, 2014. The decrease in cost of sales as a percentage of total revenues is primarily driven by favorable product mix, the expiration of the amortization of the Alere settlement and improved manufacturing efficiencies. This is partially offset by lower grant revenue and higher depreciation expense related to the increased number of Sofia instrument placements.

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Operating Expenses

The following table compares operating expenses for the three months ended September 30, 2015 and 2014 (in thousands, except percentages):

| | For the three months ended September 30, | | | | Increase (Decrease) | | | |
|---|--|----------------|--------------------|----------------|---------------------|------|--|---|
| | 2015 | As a % of | 2014 | As a % of | \$ | % | | |
| | Operating expenses | total revenues | Operating expenses | total revenues | | | | |
| Research and development | \$8,419 | 18 % | \$11,506 | 28 % | \$(3,087) | (27) | | % |
| Sales and marketing | \$12,112 | 26 % | \$11,396 | 28 % | \$716 | 6 | | % |
| General and administrative | \$5,889 | 13 % | \$5,879 | 14 % | \$10 | — | | % |
| Amortization of intangible assets from acquired businesses and technology | \$2,219 | 5 % | \$2,207 | 5 % | \$12 | 1 | | % |
| Impairment loss | \$— | — % | \$3,558 | 9 % | \$(3,558) | N/A | | |

Research and Development Expense

Research and development expense for the three months ended September 30, 2015 decreased from \$11.5 million to \$8.4 million due primarily to a decrease in development spend for the Savanna MDx platform partially offset by increased spend for our next generation Sofia instrument.

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. We expect our research and development costs to be significant as we move other product candidates into preclinical and clinical trials and advance our existing development programs and product candidates into later stages of development.

Sales and Marketing Expense

Sales and marketing expense for the three months ended September 30, 2015 increased from \$11.4 million to \$12.1 million compared with the prior year period, due to additional investment in our sales organization through expansion and increased compensation.

General and Administrative Expense

General and administrative expense was for \$5.9 million for the three months ended September 30, 2015 and 2014. General and administrative expense includes primarily personnel costs, information technology, facilities, and professional service fees.

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 more recent acquisitions of Diagnostic Hybrids, Inc., BioHelix, and AnDiaTec.

Impairment Loss

During the three months ended September 30, 2014, we determined we would not be able to recover the carrying value of certain capitalized software, purchased in-process research and development and manufacturing line assets related to the Project Stella (Bobcat) assets and related technology. As a result, we recorded an impairment loss totaling \$3.6 million. No such loss was recorded during the three months ended September 30, 2015.

Interest Expense, net

Interest expense consists of fees paid to maintain our ability to borrow under the Senior Credit Facility, interest paid on our lease obligation for our San Diego McKellar facility, and interest expense associated with our \$172.5 million aggregate

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principal amount of 3.25% Convertible Senior Notes due 2020 (“Convertible Senior Notes”) issued in December 2014, as applicable. The increase in interest expense of \$2.9 million for the three months ended September 30, 2015 was primarily due to the coupon interest and amortization of the debt discount and issuance costs related to the Convertible Senior Notes. There were no borrowings under the Senior Credit Facility during the three months ended September 30, 2015 or September 30, 2014.

Income Taxes

Our effective tax rate for the three months ended September 30, 2015 and 2014 was 59% and 44%, respectively. We recognized income tax benefit of \$1.1 million and \$4.6 million for the three months ended September 30, 2015 and 2014, respectively. For the three months ended September 30, 2015, the effective tax rate was higher compared to the third quarter of 2014 due primarily to the federal manufacturing deduction and other discrete items calculated over a small pre-tax loss.

Nine months ended September 30, 2015 compared to the nine months ended September 30, 2014

Total Revenues

The following table compares total revenues for the nine months ended September 30, 2015 and 2014 (in thousands, except percentages):

| | For the nine months ended | | Increase (Decrease) | | |
|--|---------------------------|--------------------|---------------------|------|----|
| | September 30, 2015 | September 30, 2014 | \$ | % | |
| Infectious disease net product sales | \$ 103,123 | \$ 80,400 | \$ 22,723 | 28 | % |
| Women’s health net product sales | 27,876 | 25,581 | 2,295 | 9 | % |
| Gastrointestinal disease net product sales | 5,393 | 5,558 | (165) | (3) |)% |
| Other net product sales | 3,250 | 2,946 | 304 | 10 | % |
| Royalty, license fees and grant revenue | 4,075 | 5,720 | (1,645) | (29) |)% |
| Total revenues | \$ 143,717 | \$ 120,205 | \$ 23,512 | 20 | % |

For the nine months ended September 30, 2015, total revenue increased to \$143.7 million from \$120.2 million in the prior year. The Company realized growth in infectious disease, women's health and other revenues. The increase in the infectious disease category was primarily due to stronger Influenza and Strep A product sales. The increase in the women's health category was driven by growth for our Thyretain, hCG, Bone Health and Autoimmune/Complement product lines. Royalty, license fees and grant revenue decreased year over year due to decreased grant revenues associated with the amended Bill and Melinda Gates Foundation grant.

Cost of Sales

Cost of sales was \$53.6 million, or 37% of total revenues for the nine months ended September 30, 2015 compared to \$52.9 million, or 44% of total revenues for the nine months ended September 30, 2014. The decrease in cost of sales as a percentage of total revenues is primarily driven by the expiration of the amortization of the Alere settlement and improved manufacturing efficiencies. This is partially offset by lower grant revenues and higher depreciation expense related to the Sofia instruments.

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Operating Expenses

The following table compares operating expenses for the nine months ended September 30, 2015 and 2014 (in thousands, except percentages):

| | For the nine months ended September 30, | | | | Increase (Decrease) | |
|---|---|----------------|--------------------|----------------|---------------------|--------|
| | 2015 | As a % of | 2014 | As a % of | \$ | % |
| | Operating expenses | total revenues | Operating expenses | total revenues | | |
| Research and development | 25,575 | 18 % | 28,714 | 24 % | \$(3,139) | (11) % |
| Sales and marketing | 35,823 | 25 % | 31,567 | 26 % | \$4,256 | 13 % |
| General and administrative | 22,039 | 15 % | 18,949 | 16 % | \$3,090 | 16 % |
| Amortization of intangible assets from acquired businesses and technology | 6,638 | 5 % | 6,623 | 6 % | \$15 | — % |
| Impairment loss | — | — % | 3,558 | 3 % | \$(3,558) | N/A |

Research and Development Expense

Research and development expense for the nine months ended September 30, 2015 decreased from \$28.7 million to \$25.6 million due primarily to a decrease in development spend for the Savanna MDx platform partially offset by an increase in development spend for our next generation Sofia instrument.

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. We expect our research and development costs to be significant as we move other product candidates into preclinical and clinical trials and advance our existing development programs and product candidates into later stages of development.

Sales and Marketing Expense

Sales and marketing expense for the nine months ended September 30, 2015 increased from \$31.6 million to \$35.8 million compared with the prior year period, due primarily to increased compensation costs associated with higher revenues and additional investment in our sales organization through expansion and training of a larger sales force.

General and Administrative Expense

General and administrative expense for the nine months ended September 30, 2015 increased from \$18.9 million to \$22.0 million compared with the prior year period, due primarily to an increase of \$2.4 million in one-time fees for professional services and internal costs related to business development activities incurred in the first quarter of 2015 and have concluded. Additional increases over prior year include higher stock-based compensation and medical device excise tax.

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 more recent acquisitions of Diagnostic Hybrids, Inc., BioHelix, and AnDiaTec.

Impairment Loss

During the nine months ended September 30, 2014, we determined we would not be able to recover the carrying value of certain capitalized software, purchased in-process research and development and manufacturing line assets related to the Project Stella (Bobcat) assets and related technology. As a result, we recorded an impairment loss totaling \$3.6 million. No such loss was recorded during the nine months ended September 30, 2015.

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principal amount of 3.25% Convertible Senior Notes issued in December 2014, as applicable. The increase in interest expense of \$8.1 million for the nine months ended September 30, 2015 was primarily due to the coupon interest and amortization of the debt discount and issuance costs related to the Convertible Senior Notes. There were no borrowings under the Senior Credit Facility during the nine months ended September 30, 2015 or September 30, 2014.

Income Taxes

For the nine months ended September 30, 2015 and 2014, we recognized an income tax benefit of \$3.3 million and \$8.9 million, respectively. Our effective tax rates for the nine months ended September 30, 2015 and 2014 was 36% and 39%, respectively. For the nine months ended September 30, 2015, the effective tax rate was lower primarily due to the change in valuation allowance related to certain state deferred tax assets, partially offset by an increase in the federal manufacturing deduction.

Liquidity and Capital Resources

As of September 30, 2015 and December 31, 2014, the principal sources of liquidity consisted of the following (in thousands):

| | September 30, 2015 | December 31, 2014 |
|---|--------------------|-------------------|
| Cash and cash equivalents | \$182,560 | \$200,895 |
| Restricted cash | 1,810 | 3,127 |
| Cash, cash equivalents, and restricted cash | \$184,370 | \$204,022 |
| Working capital including cash, cash equivalents, and restricted cash | \$214,753 | \$238,096 |
| Amount available to borrow under the Senior Credit Facility | \$95,900 | \$95,700 |

As of September 30, 2015, we had \$182.6 million in cash and cash equivalents, in large part due to the issuance of \$172.5 million aggregate principal amount of 3.25% Convertible Senior Notes in December 2014 and cash generated from operations for the nine months ended September 30, 2015. During the year ended December 31, 2014, we received \$10.6 million and during the nine months ended September 30, 2015 we received \$2.4 million, pursuant to the Bill and Melinda Gates Foundation grant agreement, which was restricted as to use until expenditures contemplated in the grant were incurred or committed. We recorded this restricted cash as a current asset as we anticipate making expenditures under the grant within one year. As of September 30, 2015, restricted cash was \$1.8 million.

Cash provided by operating activities was \$20.3 million during the nine months ended September 30, 2015. We had a net loss of \$5.7 million, including non-cash charges of \$17.5 million of depreciation and amortization of intangible assets and property and equipment, stock-based compensation of \$5.7 million, and amortization of debt discount and deferred issuance costs of \$4.2 million. We also had a decrease in accounts receivable of \$3.4 million due to the seasonal nature of our business. Cash provided by operating activities was \$17.5 million during the nine months ended September 30, 2014. We had a net loss of \$14.2 million, including non-cash charges of \$20.6 million of depreciation and amortization of intangible assets and property and equipment, and stock-based compensation of \$4.8 million. We also had a decrease in accounts receivable of \$5.5 million due to the seasonal nature of our business.

Our investing activities used \$12.0 million during the nine months ended September 30, 2015 and \$8.6 million during the nine months ended September 30, 2014 primarily related to the acquisition of production equipment, Sofia instruments available for lease and building improvements.

We are planning approximately \$6.0 million in capital expenditures for the remainder of 2015. The primary purpose for our capital expenditures is to acquire manufacturing and scientific equipment, to purchase or develop information technology, and to implement facility improvements. We plan to fund these capital expenditures with cash flow from operations and other available sources of liquidity.

Cash used by financing activities was \$26.6 million during the nine months ended September 30, 2015 and was primarily related to repurchases of common stock under our share repurchase program at a cost of approximately \$27.2 million. Additionally, we made payments of debt issuance costs of \$0.4 million and payments on the lease obligation of \$0.4 million. These amounts were partially offset by proceeds from issuance of common stock of \$2.2 million. Cash provided by financing activities was \$0.1 million during the nine months ended September 30, 2014 and primarily related to proceeds from issuance

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of common stock of \$4.5 million offset by repurchases of common stock of \$2.0 million and payments on acquisition contingencies of \$2.1 million.

In December 2014, we issued Convertible Senior Notes in the aggregate principle amount of \$172.5 million. The Convertible Senior Notes have a coupon rate of 3.25% and are due 2020. The Convertible Senior Notes were not convertible as of September 30, 2015. For detailed information of the terms of the Convertible Senior Notes, see Note 6 of the Notes to Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report under the heading “3.25% Convertible Senior Notes due 2020,” which is incorporated by reference herein.

On August 10, 2012, we entered into an amended and restated \$140.0 million Senior Credit Facility that matures on August 10, 2017. As of September 30, 2015 and December 31, 2014, we had no borrowings outstanding under the Senior Credit Facility. As of September 30, 2015, we were in compliance with all financial covenants. For detailed information of the terms of the Senior Credit Facility see Note 6 of the Notes to Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report under the heading “Line of Credit,” which is incorporated by reference herein. 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 new product line, company or technology acquisitions or technology licensing. If we decide 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.

Seasonality

Sales of our infectious disease products are subject to, and significantly affected by, the seasonal demands of the cold and flu seasons, prevalent during the fall and winter. As a result of these seasonal demands, we typically experience lower sales volume in the second and third quarters of the calendar year, and typically have higher sales in the first and fourth quarters of the calendar year.

Off-Balance Sheet Arrangements

At September 30, 2015, 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.

Recent Accounting Pronouncements

Information about recently adopted and proposed accounting pronouncements is included in Note 1 of the Notes to Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report under the headings “Change in Accounting Principle” and “Recent Accounting Pronouncements” and is incorporated by reference herein.

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 GAAP. 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 revenue recognition, customer programs and incentives, stock-based compensation, bad debts, inventories, intangible assets, software development costs, restructuring, contingencies and litigation, contingent consideration, the fair value of the debt component of convertible debt instruments, and income taxes. 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, 2014.

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ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

We had no borrowings outstanding under our Senior Credit Facility at September 30, 2015. If we had borrowings under the credit facility, the interest rate would have been 1.45% as of September 30, 2015. A hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would not increase our annual interest expense as there are no borrowings.

We are not subject to interest rate risk on our Convertible Senior Notes as the notes have a fixed interest rate of 3.25%. For fixed rate debt, changes in interest rates will generally affect the fair value of the debt instrument, but not our earnings or cash flows. Under our current policies, we do not use interest rate derivative instruments to manage our exposure to changes in interest rates.

The Company's current investment policy with respect to cash and cash equivalents focuses on maintaining acceptable levels of interest rate risk and liquidity. Although the Company continually evaluates the placement of investments, as of September 30, 2015, 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 against the U.S. Dollar could have an impact on our business, financial condition and results of operations. We do not currently hedge against exchange rate fluctuations, which means that we are fully exposed to exchange rate changes. In addition, we have agreements with a number of foreign vendors 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, 2015 to ensure 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, 2015 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1. Legal Proceedings

The information set forth in the section entitled "Legal" under Note 9 of the Notes to the Consolidated Financial Statements, included in Part I, Item I of this Quarterly Report, is incorporated herein by reference.

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, 2014. 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, 2014.

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

Issuer Purchases of Equity Securities

The table below sets forth information regarding repurchases of our common stock by us during the three months ended September 27, 2015:

| Period | Total number of shares purchased (1) | 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 (2) |
|--------------------------------------|--------------------------------------|------------------------------|--|--|
| June 29, 2015 - July 26, 2015 | 367,850 | \$22.82 | 367,850 | \$27,215,670 |
| July 27, 2015 - August 23, 2015 | 109,735 | 20.66 | 108,456 | 24,974,539 |
| August 24, 2015 - September 27, 2015 | 103,404 | 20.45 | 103,313 | 22,861,536 |
| Total | 580,989 | \$21.99 | 579,619 | \$22,861,536 |

(1) In addition to our share repurchase program, we repurchased 1,370 shares of common stock from employees in connection with payment of minimum tax withholding obligations relating to the lapse of restrictions on certain restricted stock units during the three months ended September 30, 2015.

(2) On February 24, 2015, our Board of Directors authorized an amendment to extend our previously announced stock repurchase program. The Board of Directors has authorized us to repurchase up to an aggregate of \$50.0 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. The repurchase program will expire on February 24, 2017 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.

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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 Form 10-Q for the quarter ended September 30, 2010.) |
| 3.2 | Certificate of Amendment to the Restated Certificate of Incorporation of Quidel Corporation. (Incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on May 6, 2015.) |
| 3.3 | Amended and Restated Bylaws of Quidel Corporation. (Incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on February 27, 2015.) |
| 4.1 | Certificate of Designations of Series C Junior Participating Preferred Stock. (Incorporated by reference to Exhibit 4.1 to the Registrant's Form 10-Q for the quarter ended September 30, 2010.) |
| 10.1 | Amendment No. 4 to Credit Agreement, dated as of August 6, 2015, by and among Quidel Corporation, as Borrower, Diagnostic Hybrids, Inc., as Guarantor, each lender party thereto, Bank of America, N.A., as Administrative Agent, L/C Issuer and Swing Line Lender. (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8 K filed on August 12, 2015.) |
| 10.2(1)* | Employment Offer Letter, dated October 4, 2015, between the Registrant and Edward K. Russell. |
| 10.3(1)* | Agreement Re: Change in Control, entered into on October 12, 2015, between the Registrant and Edward K. Russell. |
| 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 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 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.INS* | XBRL Instance Document |
| 101.SCH* | XBRL Taxonomy Extension Schema Document |
| 101.CAL* | XBRL Taxonomy Calculation Linkbase Document |
| 101.DEF* | XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB* | XBRL Taxonomy Label Linkbase Document |
| 101.PRE* | XBRL Taxonomy Presentation Linkbase Document |

* Filed herewith.

(1) Indicates a management plan or compensatory 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, 2015

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)

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Exhibit Index

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