

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, 2019
or

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

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

QUIDEL CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

94-2573850

(I.R.S. Employer
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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 Par Value	QDEL	NASDAQ Global Market

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 every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 25, 2019, 41,652,138 shares of the registrant's common stock were outstanding.

INDEX

PART I—FINANCIAL INFORMATION

<u>ITEM 1. Financial Statements (unaudited)</u>	
<u>Consolidated Balance Sheets as of September 30, 2019 and December 31, 2018</u>	<u>3</u>
<u>Consolidated Statements of Income for the three and nine months ended September 30, 2019 and 2018</u>	<u>4</u>
<u>Consolidated Statements of Comprehensive Income for the three and nine months ended September 30, 2019 and 2018</u>	<u>5</u>
<u>Consolidated Statements of Stockholders' Equity for the three and nine months ended September 30, 2019 and 2018</u>	<u>6</u>
<u>Consolidated Statements of Cash Flows for the nine months ended September 30, 2019 and 2018</u>	<u>8</u>
<u>Notes to Consolidated Financial Statements</u>	<u>9</u>
<u>ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>19</u>
<u>ITEM 3. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>26</u>
<u>ITEM 4. Controls and Procedures</u>	<u>27</u>

PART II—OTHER INFORMATION

<u>ITEM 1. Legal Proceedings</u>	<u>27</u>
<u>ITEM 1A. Risk Factors</u>	<u>27</u>
<u>ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>28</u>
<u>ITEM 3. Defaults Upon Senior Securities</u>	<u>28</u>
<u>ITEM 4. Mine Safety Disclosures</u>	<u>28</u>
<u>ITEM 5. Other Information</u>	<u>28</u>
<u>ITEM 6. Exhibits</u>	<u>29</u>
<u>Signatures</u>	<u>30</u>

PART I FINANCIAL INFORMATION

ITEM 1. Financial Statements

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

	September 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 28,914	\$ 43,695
Accounts receivable, net	77,646	58,677
Inventories	61,742	67,379
Prepaid expenses and other current assets	17,112	23,646
Total current assets	185,414	193,397
Property, plant and equipment, net	79,183	73,901
Right-of-use assets	82,075	—
Goodwill	337,016	337,021
Intangible assets, net	154,459	175,029
Deferred tax asset—non-current	22,476	22,192
Other non-current assets	6,893	4,831
Total assets	\$ 867,516	\$ 806,371
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 30,397	\$ 25,171
Accrued payroll and related expenses	12,223	19,210
Operating lease liabilities	5,598	—
Contingent consideration	5,746	3,983
Deferred consideration	42,000	44,000
Revolving Credit Facility	8,188	—
Convertible Senior Notes	12,546	54,379
Other current liabilities	10,474	12,992
Total current liabilities	127,172	159,735
Operating lease liabilities - non-current	80,924	—
Revolving Credit Facility - non-current	—	53,188
Deferred consideration - non-current	107,510	143,158
Contingent consideration - non-current	9,948	15,129
Other non-current liabilities	7,799	9,577
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, \$.001 par value per share; 5,000 shares authorized; none issued or outstanding at September 30, 2019 and December 31, 2018	—	—
Common stock, \$.001 par value per share; 97,500 shares authorized; 41,642 and 39,386 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	42	39
Additional paid-in capital	429,920	363,921
Accumulated other comprehensive income (loss)	143	(139)
Retained earnings	104,058	61,763
Total stockholders' equity	534,163	425,584
Total liabilities and stockholders' equity	\$ 867,516	\$ 806,371

See accompanying notes.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Total revenues	\$ 126,492	\$ 117,399	\$ 382,712	\$ 389,697
Cost of sales	50,633	47,757	156,747	156,116
Gross profit	75,859	69,642	225,965	233,581
Research and development	11,976	13,103	37,629	39,008
Sales and marketing	26,599	26,504	83,114	82,607
General and administrative	12,146	10,620	38,453	32,652
Acquisition and integration costs	4,456	2,521	9,116	10,923
Total operating expenses	55,177	52,748	168,312	165,190
Operating income	20,682	16,894	57,653	68,391
Other expense, net				
Interest expense, net	(3,152)	(4,786)	(12,239)	(19,475)
Loss on extinguishment of debt	—	(1,297)	(748)	(8,262)
Total other expense, net	(3,152)	(6,083)	(12,987)	(27,737)
Income before income taxes	17,530	10,811	44,666	40,654
Provision (benefit) for income taxes	1,349	(11)	2,371	(1,050)
Net income	\$ 16,181	\$ 10,822	\$ 42,295	\$ 41,704
Basic earnings per share	\$ 0.39	\$ 0.28	\$ 1.04	\$ 1.11
Diluted earnings per share	\$ 0.38	\$ 0.27	\$ 1.02	\$ 1.08
Shares used in basic per share calculation	41,642	39,290	40,520	37,490
Shares used in diluted per share calculation	43,206	42,889	43,051	42,467

See accompanying notes.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net income	\$ 16,181	\$ 10,822	\$ 42,295	\$ 41,704
Other comprehensive income (loss)				
Changes in cumulative translation adjustment, net of tax	(544)	(61)	(698)	(55)
Changes in unrealized gains (losses) from cash flow hedges:				
Net unrealized gains on derivative instruments	868	—	1,322	—
Reclassification of net realized gains on derivative instruments included in net income	(230)	—	(342)	—
Total change in unrealized gains (losses) realized from cash flow hedges, net of tax	638	—	980	—
Comprehensive income	\$ 16,275	\$ 10,761	\$ 42,577	\$ 41,649

See accompanying notes.

QUIDEL CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands; unaudited)

	<u>Common Stock</u>		Additional paid-in capital	Accumulated other comprehensive (loss) income	Retained earnings	Total stockholders' equity
	Shares	Par				
Balance at December 31, 2018	39,386	\$ 39	\$ 363,921	\$ (139)	\$ 61,763	\$ 425,584
Issuance of common stock under equity compensation and benefit plans	444	1	8,816	—	—	8,817
Stock-based compensation expense	—	—	2,887	—	—	2,887
Repurchases of common stock	(24)	—	(1,476)	—	—	(1,476)
Other comprehensive gain (loss), net of tax	—	—	—	42	—	42
Net income	—	—	—	—	24,844	24,844
Balance at March 31, 2019	39,806	40	374,148	(97)	86,607	460,698
Issuance of common stock under equity compensation and benefit plans	122	—	1,433	—	—	1,433
Stock-based compensation expense	—	—	3,309	—	—	3,309
Issuance of shares in exchange for Convertible Senior Notes	1,497	1	86,427	—	—	86,428
Tax impact from the conversion of Convertible Senior Notes	—	—	590	—	—	590
Reduction for equity component of Convertible Senior Notes exchanged	—	—	(43,516)	—	—	(43,516)
Repurchases of common stock	(7)	—	(395)	—	—	(395)
Other comprehensive gain (loss), net of tax	—	—	—	146	—	146
Net income	—	—	—	—	1,270	1,270
Balance at June 30, 2019	41,418	41	421,996	49	87,877	509,963
Issuance of common stock under equity compensation and benefit plans	225	1	4,923	—	—	4,924
Stock-based compensation expense	—	—	3,030	—	—	3,030
Repurchases of common stock	(1)	—	(29)	—	—	(29)
Other comprehensive gain (loss), net of tax	—	—	—	94	—	94
Net income	—	—	—	—	16,181	16,181
Balance at September 30, 2019	41,642	\$ 42	\$ 429,920	\$ 143	\$ 104,058	\$ 534,163

QUIDEL CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY--(continued)
(in thousands; unaudited)

	<u>Common Stock</u>						
	<u>Shares</u>	<u>Par</u>	<u>Additional paid-in capital</u>	<u>Accumulated other comprehensive income (loss)</u>	<u>Retained earnings (accumulated deficit)</u>	<u>Total stockholders' equity</u>	
Balance at December 31, 2017	34,540	\$ 35	\$ 239,489	\$ —	\$ (12,420)	\$ 227,104	
Issuance of common stock under equity compensation and benefit plans	516	—	5,652	—	—	5,652	
Stock-based compensation expense	—	—	2,936	—	—	2,936	
Issuance of shares in exchange for Convertible Senior Notes	2,428	2	118,073	—	—	118,075	
Reduction for equity component of Convertible Senior Notes exchanged	—	—	(53,867)	—	—	(53,867)	
Repurchases of common stock	(73)	—	(3,232)	—	—	(3,232)	
Other comprehensive gain (loss), net of tax	—	—	—	20	—	20	
Net income	—	—	—	—	33,958	33,958	
Balance at March 31, 2018	37,411	37	309,051	20	21,538	330,646	
Issuance of common stock under equity compensation and benefit plans	326	—	3,898	—	—	3,898	
Stock-based compensation expense	—	—	2,579	—	—	2,579	
Issuance of shares in exchange for Convertible Senior Notes	1,270	2	82,108	—	—	82,110	
Reduction for equity component of Convertible Senior Notes exchanged	—	—	(46,860)	—	—	(46,860)	
Repurchases of common stock	(6)	—	(375)	—	—	(375)	
Other comprehensive gain (loss), net of tax	—	—	—	(14)	—	(14)	
Net loss	—	—	—	—	(3,076)	(3,076)	
Balance at June 30, 2018	39,001	39	350,401	6	18,462	368,908	
Issuance of common stock under equity compensation and benefit plans	326	—	6,482	—	—	6,482	
Stock-based compensation expense	—	—	2,455	—	—	2,455	
Issuance of shares in exchange for Convertible Senior Notes	1	—	31	—	—	31	
Repurchases of common stock	(2)	—	(183)	—	—	(183)	
Other comprehensive gain (loss), net of tax	—	—	—	(61)	—	(61)	
Net income	—	—	—	—	10,822	10,822	
Balance at September 30, 2018	39,326	\$ 39	\$ 359,186	\$ (55)	\$ 29,284	\$ 388,454	

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

	Nine Months Ended September 30,	
	2019	2018
OPERATING ACTIVITIES:		
Net income	\$ 42,295	\$ 41,704
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation, amortization and other	36,740	34,323
Stock-based compensation expense	10,084	9,190
Impairment loss	1,144	—
Amortization of debt discount and deferred issuance costs	1,367	3,355
Change in fair value of acquisition contingencies	626	745
Accretion of interest on deferred consideration	6,352	7,686
Amortization of inventory step-up to fair value	—	3,650
Loss on extinguishment of debt	748	8,262
Changes in assets and liabilities:		
Accounts receivable	(19,344)	257
Inventories	5,395	155
Prepaid expenses and other current and non-current assets	4,942	(20,328)
Accounts payable	4,429	633
Accrued payroll and related expenses	(5,780)	(24)
Other current and non-current liabilities	(2,237)	3,520
Net cash provided by operating activities:	86,761	93,128
INVESTING ACTIVITIES:		
Acquisitions of property, equipment and intangibles	(18,716)	(22,875)
Proceeds from sale of Summers Ridge Property	—	146,644
Net cash (used for) provided by investing activities:	(18,716)	123,769
FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	13,156	16,031
Payment of debt issuance costs	—	(513)
Payments on Revolving Credit Facility	(45,000)	(10,000)
Payments on finance lease obligation	(262)	(93)
Repurchases of common stock	(1,900)	(3,790)
Payments of acquisition contingent consideration	(4,044)	(6,294)
Payments of deferred consideration	(44,000)	(46,000)
Payments of Term Loan	—	(161,813)
Transaction costs related to debt exchange	(733)	(2,002)
Net cash used for financing activities:	(82,783)	(214,474)
Effect of exchange rates on cash	(43)	185
Net (decrease) increase in cash and cash equivalents	(14,781)	2,608
Cash and cash equivalents, beginning of period	43,695	36,086
Cash and cash equivalents, end of period	\$ 28,914	\$ 38,694
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING TRANSACTIONS:		
Purchase of property, equipment and intangibles by incurring current liabilities	\$ 3,067	\$ 1,650
Reduction of other current liabilities upon issuance of restricted share units	\$ 2,018	\$ —
Extinguishment of Convertible Senior Notes through issuance of common stock	\$ 86,428	\$ 200,217
Principal amount of Term Loan exchanged for Revolving Credit Facility	\$ —	\$ 83,188

See accompanying notes.

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, 2019, and for the three and nine months ended September 30, 2019 and 2018, is unaudited. For further information, refer to the Company’s consolidated financial statements and notes thereto for the year ended December 31, 2018 included in the Company’s 2018 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 2019 and 2018, the Company’s fiscal year will end or has ended on December 29, 2019 and December 30, 2018, respectively. For 2019 and 2018, the Company’s third quarter ended on September 29, 2019 and September 30, 2018, respectively. For ease of reference, the calendar quarter end dates are used herein. The three and nine-month periods ended September 30, 2019 and 2018 each included 13 and 39 weeks, respectively.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Recent Accounting Pronouncements

Accounting Standards Update (“ASU”) 2016-02 and ASU 2018-11 (collectively, “ASC 842”) require a lessee to recognize a lease liability for the obligation to make lease payments and a right-of-use (“ROU”) asset representing the right to use the underlying asset for the lease term on the balance sheet. The Company adopted ASC 842 as of January 1, 2019 using the alternative transition method to apply the guidance. Deferred rent, previously recorded in other current liabilities and other non-current liabilities, was derecognized. The Company elected the package of practical expedients which, among other things, allows the Company to carry forward its historical lease classifications.

The following table presents the effect of the change in accounting principle on the Company’s Consolidated Balance Sheets as of January 1, 2019:

Consolidated Balance Sheet (in thousands)	January 1, 2019	Effect of Change in Accounting Principle	After change in Accounting Principle
ASSETS			
Operating lease right-of-use asset	\$ —	\$ 87,086	\$ 87,086
Total assets	<u>\$ 806,371</u>	<u>\$ 87,086</u>	<u>\$ 893,457</u>
LIABILITIES AND STOCKHOLDERS’ EQUITY			
Current portion of operating lease liability	\$ —	\$ 5,290	\$ 5,290
Other current liabilities	12,992	(448)	12,544
Total current liabilities	159,735	4,842	164,577
Operating lease liability	—	84,866	84,866
Other non-current liabilities	9,577	(2,622)	6,955
Total liabilities and stockholders’ equity	<u>\$ 806,371</u>	<u>\$ 87,086</u>	<u>\$ 893,457</u>

In January 2017, the Financial Accounting Standards Board (“FASB”) issued guidance codified in ASU 2017-04, *Intangibles-Goodwill and Other (Topic 350) Simplifying the Test for Goodwill Impairment*. Under this new guidance, an entity will no longer determine goodwill impairment by calculating the implied fair value of goodwill by assigning the fair value of a reporting unit to all of its assets and liabilities as if that reporting unit had been acquired in a business combination. Instead, an entity will compare the fair value of a reporting unit with its carrying amount and recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit’s fair value. The Company adopted the guidance during the first quarter of 2019 with no impact to the Company’s consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments*, which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables. The standard is effective for the Company beginning in the first quarter of 2020. We are currently evaluating the expected impact of ASU 2016-13 on our consolidated financial statements.

Significant Accounting Policies

During the nine months ended September 30, 2019, there have been no changes to our significant accounting policies as described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018 except as described below and in Note 10. Derivatives and Hedging.

Leases - Lease liabilities represent the obligation to make lease payments and ROU assets represent the right to use the underlying asset during the lease term. Lease liabilities and ROU assets are recognized at the commencement date of the lease based on the present value of lease payments over the lease term at the commencement date. When the implicit rate is unknown, an incremental borrowing rate based on the information available at the commencement date is used in determining the present value of the lease payments. Options to extend or terminate the lease are included in the determination of the lease term when it is reasonably certain that the Company will exercise such options.

For certain classes of assets, the Company accounts for lease and non-lease components as a single lease component. Variable lease payments, including those related to changes in the consumer price index, are recognized in the period in which the obligation for those payments are incurred and are not included in the measurement of the ROU assets or lease liabilities. Short-term leases are excluded from the calculation of the ROU assets and lease liabilities.

Operating leases are included in right-of-use assets, operating lease liabilities and operating lease liabilities - non-current in the Consolidated Balance Sheet. Finance leases are included in property, plant and equipment, net, other current liabilities and other non-current liabilities.

Note 2. Computation of Earnings Per Share

Basic earnings per share (“EPS”) is computed by dividing net income by the weighted-average number of common shares outstanding, including restricted stock units (“RSUs”) vested during the period. Diluted EPS is computed based on the sum of the weighted average number of common shares and potentially dilutive common shares outstanding during the period. Potentially dilutive common shares consist of shares issuable from stock options, unvested RSUs and the 3.25% Convertible Senior Notes due 2020 (“Convertible Senior Notes”). Potentially dilutive common shares from outstanding stock options and unvested RSUs are determined using the average share price for each period under the treasury stock method. Potentially dilutive shares from the Convertible Senior Notes are determined using the if-converted method. Under the provisions of the if-converted method, the Convertible Senior Notes are assumed to be converted and included in the denominator of the EPS calculation and the interest expense, net of tax, recorded in connection with the Convertible Senior Notes is added back to net income.

The Convertible Senior Notes have a dilutive impact when the average market price of the Company’s common stock exceeds the applicable conversion price of the notes. The Senior Convertible Notes became convertible on March 31, 2018 and remained convertible through September 30, 2019.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Numerator:				
Net income used for basic earnings per share	\$ 16,181	\$ 10,822	\$ 42,295	\$ 41,704
Interest expense on Convertible Senior Notes, net of tax	180	791	1,669	4,152
Net income used for diluted earnings per share, if-converted method	<u>\$ 16,361</u>	<u>\$ 11,613</u>	<u>\$ 43,964</u>	<u>\$ 45,856</u>
Basic weighted-average common shares outstanding	41,642	39,290	40,520	37,490
Potentially dilutive shares issuable from Convertible Senior Notes	410	1,825	1,282	3,193
Potentially dilutive shares issuable from stock options and unvested RSUs	1,154	1,774	1,249	1,784
Diluted weighted-average common shares outstanding, if-converted	<u>43,206</u>	<u>42,889</u>	<u>43,051</u>	<u>42,467</u>
Potentially dilutive shares excluded from calculation due to anti-dilutive effect	<u>223</u>	<u>—</u>	<u>198</u>	<u>161</u>

Potentially dilutive shares excluded from the calculation above represent stock options when the combined exercise price and unrecognized stock-based compensation are greater than the average market price for the Company's common stock because their effect is anti-dilutive.

Note 3. Balance Sheet Account Details

Inventories

Inventories are stated at the lower of cost (first-in, first-out) or net realizable value. Inventories consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Raw materials	\$ 23,360	\$ 24,292
Work-in-process (materials, labor and overhead)	20,888	21,280
Finished goods (materials, labor and overhead)	17,494	21,807
Total inventories	<u>\$ 61,742</u>	<u>\$ 67,379</u>

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	September 30, 2019	December 31, 2018
Other receivables	\$ 7,215	\$ 15,507
Prepaid expenses	5,278	4,508
Income taxes receivable	1,887	2,703
Other	2,732	928
Total prepaid expenses and other current assets	<u>\$ 17,112</u>	<u>\$ 23,646</u>

Other Current Liabilities

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

	September 30, 2019	December 31, 2018
Customer incentives	\$ 4,267	\$ 7,516
Income and other taxes payable	775	1,962
Customer deposits	1,884	—
Accrued interest	244	347
Other	3,304	3,167
Total other current liabilities	<u>\$ 10,474</u>	<u>\$ 12,992</u>

Note 4. Income Taxes

The Company calculates its interim income tax provision in accordance with Accounting Standards Codification (“ASC”) 270, *Interim Reporting*, and ASC 740, *Accounting for Income Taxes* (together, “ASC 740”). At the end of each interim period, the Company estimates its annual effective tax rate and applies that rate to its ordinary quarterly earnings to calculate the tax related to ordinary income. The tax effects for other items that are excluded from ordinary income are discretely calculated and recognized in the period in which they occur.

On December 22, 2017, the Tax Cuts and Jobs Act (the “Tax Act”) was enacted into legislation, which includes a broad range of provisions affecting businesses. The Tax Act significantly revised how companies compute their U.S. corporate tax liability by, among other provisions, reducing the corporate tax rate from 35% to 21% for tax years beginning after December 31, 2017, implementing a territorial tax system, and requiring a mandatory one-time tax on U.S.-owned undistributed foreign earnings and profits known as the transition tax.

The Company recognized an income tax provision of \$1.3 million for the three months ended September 30, 2019 and an insignificant amount of income tax benefit for the three months ended September 30, 2018. The Company’s 8% effective tax rate for the three months ended September 30, 2019 differed from the federal statutory rate of 21% primarily due to the discrete impact of excess tax deductions from stock-based compensation and the benefit from research and development (“R&D”) credits. The Company recognized an income tax provision of \$2.4 million and income tax benefit of \$1.1 million for the nine months ended September 30, 2019 and 2018, respectively. The Company’s 5% effective tax rate for the nine months ended September 30, 2019 differed from the federal statutory rate of 21% primarily due to the tax benefit recorded for excess tax benefits from stock-based compensation and the benefit from R&D credits.

The Company is subject to periodic audits by domestic and foreign tax authorities. Due to the carryforward of unutilized credit carryovers, the Company’s federal tax years from 2009 and forward are subject to examination by the U.S. authorities. The Company’s state and foreign tax years for 2001 and forward 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 laws applied to the facts of each matter.

Note 5. Debt

Convertible Senior Notes

In December 2014, the Company issued \$172.5 million aggregate principal amount of its 3.25% Convertible Senior Notes. Debt issuance costs of approximately \$5.1 million were primarily comprised of underwriters fees, legal, accounting and other professional fees, of which \$4.2 million were recorded as a reduction to long-term debt and are being amortized using the effective interest method to interest expense over the six-year term of the Convertible Senior Notes. The remaining \$0.9 million of debt issuance costs were allocated as a component of equity in additional paid-in capital. The implied interest rate of the Convertible Senior Notes was 6.9%, assuming no conversion option. The Convertible Senior Notes mature on December 15, 2020.

The Convertible Senior Notes are 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) 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 5 consecutive business day period following any 5 consecutive trading day period in which the trading price per \$1,000 principal amount of the Convertible Senior Notes 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. 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.

During the third quarter of 2019, the last reported sales price of the Company's common stock was greater than 130% of the Convertible Senior Notes conversion price for 20 or more of the 30 consecutive trading days preceding the quarter-end. Consequently, the Convertible Senior Notes were convertible as of September 30, 2019. If the Convertible Senior Notes were converted as of September 30, 2019, the if-converted amount would exceed the principal by \$0.4 million. The Convertible Senior Notes may be settled at the Company's option in cash or a combination of cash and shares of common stock. Because the settlement could be in cash, the Convertible Senior Notes have been classified as short-term debt as of September 30, 2019.

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. During the nine months ended September 30, 2019, the Company recorded total interest expense of \$2.1 million related to the Convertible Senior Notes, of which \$1.1 million related to the amortization of the debt discount and issuance costs and \$1.0 million related to the coupon due semi-annually. During the nine months ended September 30, 2018, the Company recorded total interest expense of \$5.2 million related to the Convertible Senior Notes of which \$2.7 million related to the amortization of the debt discount and issuance costs and \$2.5 million related to the coupon due semi-annually.

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 price and is a Level 2 measurement.

	September 30, 2019	December 31, 2018
Principal amount outstanding	\$ 13,131	\$ 58,503
Unamortized discount of liability component	(516)	(3,637)
Unamortized debt issuance costs	(69)	(487)
Net carrying amount of liability component	\$ 12,546	\$ 54,379
Carrying value of equity component, net of issuance costs	\$ 2,265	\$ 10,092
Fair value of outstanding Convertible Senior Notes	\$ 25,756	\$ 85,999
Remaining amortization period of discount on the liability component	1.3 years	2.0 years

Credit Agreement

On August 31, 2018, the Company entered into an Amended and Restated Credit Agreement (the "Credit Agreement") which provides the Company with a \$175.0 million Revolving Credit Facility. The balance outstanding under the Revolving Credit Facility as of September 30, 2019 was \$8.2 million. Such balance was repaid in full in October 2019. The Credit Agreement has a term of five years and matures on August 31, 2023.

Loans will bear interest at a rate equal to (i) the London Interbank Offered Rate (“LIBOR”) plus the “applicable rate” or (ii) the “base rate” (defined as the highest of (a) the Bank of America prime rate, (b) the Federal Funds rate plus one-half of one percent and (c) LIBOR plus one percent) plus the “applicable rate.” The initial applicable rate was 1.00% per annum for base rate loans and 2.00% per annum for LIBOR rate loans, and thereafter will be determined in accordance with a pricing grid based on the Company’s Consolidated Leverage Ratio (as defined in the Credit Agreement) ranging from 1.75% to 2.50% per annum for LIBOR rate loans and from 0.75% to 1.50% per annum for base rate loans. In addition, the Company pays a commitment fee on the unused portion of the Credit Agreement based on the Company’s Consolidated Leverage Ratio ranging from 0.15% to 0.30% per annum.

The Credit Agreement is guaranteed by certain material domestic subsidiaries of the Company (the “Guarantors”) and is secured by liens on substantially all of the assets of the Company and the Guarantors, excluding real property and certain other types of excluded assets, and contains affirmative and negative covenants that are customary for credit agreements of this nature. The negative covenants include, among other things, limitations on asset sales, mergers, indebtedness, liens, dividends and other distributions, investments and transactions with affiliates. The Credit Agreement contains two financial covenants: (i) maximum Consolidated Leverage Ratio (as defined in the Credit Agreement) as of the last day of each fiscal quarter of 3.50 to 1.00, which ratio may be increased to 4.50 to 1.00 in case of certain qualifying acquisitions; and (ii) a minimum Consolidated Fixed Charge Coverage Ratio (as defined in the Credit Agreement) of 1.25 to 1.00 as of the end of any fiscal quarter for the most recently completed four fiscal quarters. The Company was in compliance with all financial covenants as of September 30, 2019.

Interest expense recognized under the Credit Agreement including amortization of deferred issuance cost was \$0.3 million and \$1.4 million, respectively, for the three and nine months ended September 30, 2019 and \$1.2 million and \$5.6 million, respectively, for the three and nine months ended September 30, 2018.

Note 6. Stockholders’ Equity

Issuances of Common Stock

A summary of the status of stock option activity for the nine months ended September 30, 2019 is as follows (in thousands, except price data):

	Shares	Weighted-average exercise price per share
Outstanding at December 31, 2018	1,877	\$ 21.53
Granted	169	59.18
Exercised	(628)	17.28
Forfeited	(3)	42.29
Outstanding at September 30, 2019	1,415	\$ 27.89

A summary of the status of restricted stock unit activity for the nine months ended September 30, 2019 is as follows (in thousands, except price data):

	Shares	Weighted-average grant date fair value
Non-vested at December 31, 2018	676	\$ 30.75
Granted	255	59.45
Vested	(120)	25.28
Forfeited	(4)	46.83
Non-vested at September 30, 2019	807	\$ 40.52

During the nine months ended September 30, 2019, the Company issued 42,292 shares of common stock in connection with the Company’s employee stock purchase plan (the “ESPP”).

Stock-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Cost of sales	\$ 265	\$ 255	\$ 807	\$ 751
Research and development	573	539	1,682	1,732
Sales and marketing	827	686	2,850	2,199
General and administrative	1,459	1,295	4,745	4,508
Total stock-based compensation expense	\$ 3,124	\$ 2,775	\$ 10,084	\$ 9,190

As of September 30, 2019, total unrecognized compensation expense was \$26.4 million, which is expected to be recognized over a weighted-average period of approximately 1.95 years.

The estimated fair value of each stock option 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,	
	2019	2018
Risk-free interest rate	2.51%	2.49%
Expected option life (in years)	5.7	6.3
Volatility rate	39%	36%
Dividend rate	0%	0%
Weighted-average grant date fair value	\$ 23.67	\$ 18.76

The fair value of RSUs is determined based on the closing market price of the Company's common stock on the grant date. The weighted-average fair value of RSUs granted during the nine months ended September 30, 2019 and 2018 was \$59.45 and \$49.45, respectively.

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, 2019 or 2018.

Note 7. Industry and Geographic Information

The Company operates in one reportable segment. Sales to customers outside the U.S. represented \$129.0 million (34%) and \$124.3 million (32%) of total revenue for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019 and December 31, 2018, accounts receivable due from foreign customers were \$19.8 million and \$23.4 million, respectively.

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

Customer:	Nine Months Ended September 30,	
	2019	2018
A	17%	17%
B	15%	14%
C	13%	12%
Total:	45%	43%

As of September 30, 2019 and December 31, 2018, accounts receivable from customers with balances due in excess of 10% of total accounts receivable totaled \$51.7 million and \$33.3 million, respectively.

Consolidated total revenues by product category for the three and nine months ended September 30, 2019 and 2018 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Rapid Immunoassay	\$ 42,534	\$ 35,366	\$ 126,800	\$ 132,740
Cardiac Immunoassay	66,820	65,287	200,674	203,581

Specialized Diagnostic Solutions	12,455	12,294	40,595	39,859
Molecular Diagnostic Solutions	4,683	4,452	14,643	13,517
Total revenues	<u>\$ 126,492</u>	<u>\$ 117,399</u>	<u>\$ 382,712</u>	<u>\$ 389,697</u>

Note 8. Commitments and Contingencies

Leases

We lease administrative, research and development, sales and marketing and manufacturing facilities and certain equipment under various non-cancelable lease agreements. Facility leases generally provide for periodic rent increases, and may contain clauses for rent escalation, renewal options or early termination.

The components of lease expense and supplemental cash flow information related to leases were as follows (in thousands):

	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2019
Finance lease ROU asset amortization	\$ 83	\$ 230
Finance lease interest expense	209	629
Total finance lease costs	292	859
Operating lease costs	2,483	7,490
Total lease costs	\$ 2,775	\$ 8,349
Cash paid for amounts included in the measurement of operating lease liabilities:		
Operating cash flows from operating leases	\$ 2,303	\$ 6,887
Operating cash flows from finance leases	\$ 209	\$ 629
Right-of-use assets obtained in exchange for new lease liabilities:		
Operating leases	\$ 62	\$ 390
Finance leases	\$ —	\$ 1,369

Commitments for minimum rentals under non-cancelable leases as of September 30, 2019 are as follows (dollars in thousands):

Years ending December 31,	Operating	Finance
2019	\$ 2,300	\$ 314
2020	9,378	1,264
2021	9,552	1,272
2022	8,544	1,282
2023	8,172	1,293
Thereafter	76,565	3,203
Total lease payments	114,511	8,628
Less: imputed interest	(27,989)	(3,670)
Total	86,522	4,958
Less: current portion	(5,598)	(458)
Non-current portion	\$ 80,924	\$ 4,500
Weighted average remaining lease term	12.3 years	5.8 years
Weighted average discount rate	4%	18%

Summers Ridge Lease — The Company leases two of the four buildings that are located on the Summers Ridge Property in San Diego, California with an initial term of 15 years beginning as of January 2018. Such lease includes options to extend the lease for two additional five-year terms upon satisfaction of certain conditions, which have not been included in the determination of the lease term. The lease is subject to certain must-take provisions related to the remaining two additional buildings. One building is subject to the expiration of the lease with its current tenant for which the expiration date is not yet known. The lease for the remaining building will commence in the fourth quarter of 2019 at which time the Company expects to relocate its headquarters into the facility. The minimum lease payments for this building during the lease term are \$18.3 million. As a result of the relocation, the Company recorded an impairment charge of \$1.1 million during the three and nine months ended September 30, 2019 related to the right-of-use asset and leasehold improvements for the existing headquarters facility. Such impairment loss was measured using discounted cash flows and available market data and recorded within acquisition and integration costs in the accompanying Consolidated Statements of Income.

McKellar Court Lease — In 1999, the Company completed a sale and leaseback transaction of its San Diego facility at McKellar Court to a partnership for which the Company is a 25% limited partner. The partnership is deemed to be a variable interest entity (VIE). The Company is not, however, the primary beneficiary of the VIE as it does not have the power to direct the activities of the partnership and does not have the obligation to absorb losses or receive benefits of the partnership that

could potentially be significant to the partnership. The McKellar Court lease ends in December 2020 and contains options to extend the lease for three additional five-year periods, of which one five-year period is included in the determination of the lease term.

Litigation and Other Legal Proceedings

In *Beckman Coulter Inc. v. Quidel Corporation*, which was filed in the Superior Court for the County of San Diego, California, on November 27, 2017, Beckman Coulter (“Beckman”) alleges that a provision of an agreement between Quidel and Beckman violates state antitrust laws. Our acquisition of the B-type Natriuretic Peptide assay business (“BNP Business”) consisted of assets and liabilities relating to a contractual arrangement with Beckman (the “Beckman Agreement”) for the supply of antibodies and other inputs related to, and distribution of, the Triage® BNP Test for the Beckman Coulter Access Family of Immunoassay Systems. The Beckman Agreement further provides that Beckman, for a specified period, cannot research, develop, manufacture or sell an assay for use in the diagnosis of cardiac diseases that measures or detects the presence or absence of BNP or NT-pro-BNP (a related biomarker) (the “Exclusivity Provision”). In the lawsuit, Beckman asserts that this provision violates certain state antitrust laws and is unenforceable. Beckman contends that it has suffered damages due to this provision and seeks a declaration that this provision is void.

On December 7, 2018, the trial court granted a motion by Beckman for summary adjudication, holding that the Exclusivity Provision is void under California law (the “December 7 Order”). On December 18, 2018, the trial court stayed the effect of the December 7 Order pending a decision on a writ petition Quidel intended to file with the Court of Appeal. Quidel filed its writ petition on January 18, 2019, asking the Court of Appeal to review and reverse the December 7 Order. On February 7, 2019, the trial court stayed all the remaining litigation pending the outcome of the writ petition and vacated all deadlines in the case.

On March 14, 2019, the Court of Appeal issued an order to show cause why the relief sought in Quidel’s petition should not be granted. The Court also stayed the December 7 Order pending a further order from the Court of Appeal. On August 29, 2019, the Court of Appeal issued a written decision ruling in Quidel’s favor and overturning the December 7 Order. Beckman challenged the Court of Appeal’s ruling with a petition for rehearing on September 10, 2019, which was denied on September 13, 2019.

On October 1, 2019, Beckman filed a petition for review of the Court of Appeal’s ruling with the Supreme Court of California (the “Supreme Court”). On October 21, 2019, we filed an answer to Beckman’s petition for review. Beckman has 10 days to file a response to our reply and we expect the Supreme Court to decide whether to grant or deny review of the Court of Appeal ruling by the end of 2019.

Quidel denies that the Exclusivity Provision is unlawful, denies any liability with respect to this matter, and intends to vigorously defend itself. There are multiple factors that prevent us from being able to estimate the amount of loss, if any, that may result from this matter including: (1) we are vigorously defending ourselves and believe that we have a number of meritorious legal defenses; (2) there are unresolved questions of law and fact that could be important to the ultimate resolution of this matter, some of which are subject to potential review by the Supreme Court; and (3) discovery is ongoing. Accordingly, at this time, we are not able to estimate a possible loss or range of loss that may result from this matter or to determine whether such loss, if any, would have a material adverse effect on our financial condition, results of operations or liquidity.

From time to time, the Company is involved in other litigation and proceedings, including matters related to product liability claims, commercial disputes and intellectual property claims, as well as regulatory, employment, and other claims related to our business. The Company accrues for legal claims when, and to the extent that, amounts associated with the claims become probable and are reasonably estimable. The actual costs of resolving legal claims may be substantially higher or lower than the amounts accrued for those claims. For those matters as to which we are not able to estimate a possible loss or range of loss, we are not able to determine whether the loss will have a material adverse effect on our business, financial condition or results of operations or liquidity. No accrual has been recorded as of September 30, 2019 and December 31, 2018 related to such matters as they are not probable and/or reasonably estimable.

Management believes that all such current legal actions, in the aggregate, will not have a material adverse effect on the Company. However, the resolution of, or increase in any accruals for, one or more matters may have a material adverse effect on the Company’s results of operations and cash flows.

The Company also maintains insurance, including coverage for product liability claims, in amounts that management believes are appropriate given the nature of its business.

Note 9. 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, 2019				December 31, 2018			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Derivative assets	\$ —	\$ 1,119	\$ —	\$ 1,119	\$ —	\$ —	\$ —	\$ —
Total assets measured at fair value	\$ —	\$ 1,119	\$ —	\$ 1,119	\$ —	\$ —	\$ —	\$ —
Liabilities:								
Contingent consideration	\$ —	\$ —	\$ 15,694	\$ 15,694	\$ —	\$ —	\$ 19,112	\$ 19,112
Deferred consideration	—	149,510	—	149,510	—	187,158	—	187,158
Total liabilities measured at fair value	\$ —	\$ 149,510	\$ 15,694	\$ 165,204	\$ —	\$ 187,158	\$ 19,112	\$ 206,270

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, 2019 and the year ended December 31, 2018.

Derivative financial instruments are measured based on observable inputs that are corroborated by market data. Observable inputs include broker quotes and daily market foreign currency rates and forward pricing curves.

In connection with the acquisition of the BNP Business, the Company pays annual installments of \$40.0 million each in deferred consideration through April 2023 and up to \$8.0 million each in contingent consideration through April 2022. The fair value of the deferred consideration is calculated based on the net present value of cash payments using an estimated borrowing rate based on a quoted price for a similar liability. The Company recorded \$6.4 million for the accretion of interest on the deferred consideration during the nine months ended September 30, 2019. The fair value of contingent consideration is calculated using a discounted probability weighted valuation model. Significant assumptions used in the measurement include revenue projections and discount rates that are not observed in the market and thus represent Level 3 measurements. Adjustments to fair value are recorded in general and administrative expenses in the Consolidated Statements of Income.

Changes in estimated fair value of contingent consideration liabilities from December 31, 2018 through September 30, 2019 were as follows (in thousands):

	Contingent consideration liabilities (Level 3 measurement)	
Balance at December 31, 2018	\$	19,112
Cash payments		(4,044)
Loss recorded for fair value adjustments		626
Balance at September 30, 2019	\$	15,694

Note 10. Derivatives and Hedging

In the normal course of business, the Company is exposed to gains and losses resulting from fluctuations in foreign currency exchange rates. As part of its strategy to manage the level of exposure to the risk of fluctuations in foreign currency exchange rates, the Company uses designated cash flow hedges in the form of foreign currency forward contracts to mitigate the impact of foreign currency translation on transactions that are denominated primarily in the Euro and the Chinese Yuan. All hedging relationships for all derivative hedges and the underlying hedged items, as well as the risk management objectives and strategies for undertaking the hedge transactions, are formally documented. The Company does not use any derivative financial instruments for trading or other speculative purposes.

Such forward foreign currency contracts are carried at fair value in prepaid expenses and other current assets or other current liabilities depending on the unrealized gain or loss position of the hedged contract as of the balance sheet date. Changes in the value of the derivatives are recorded to other comprehensive income (loss) until the underlying hedged item is recognized in earnings, or the derivative no longer qualifies as a highly effective hedge. The cash flows from derivatives treated as hedges are classified in the Consolidated Statements of Cash Flows in the same category as the item being hedged.

The notional principal amounts for outstanding derivative instruments provide one measure of the transaction volume outstanding and do not represent the amount of our exposure to credit or market loss. Credit risk represents our gross exposure to potential accounting loss on derivative instruments that are outstanding or unsettled if all counterparties failed to perform according to the terms of the contract, based on then-current currency exchange rates at each respective date. We generally enter into master netting arrangements, which reduces credit risk by permitting net settlement of transactions with the same counterparty. We present our derivative assets and derivative liabilities at their net fair values. We did not have any derivative instruments with credit-risk related contingent features that would require us to post collateral.

The following table summarizes the fair value and notional amounts of the foreign currency forward contracts as of September 30, 2019 (in thousands):

	September 30, 2019	
	Notional Amount	Fair Value, Net
Prepaid expenses and other current assets	\$ 27,436	\$ 1,119

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: adverse changes in competitive conditions in domestic and international markets, the reimbursement system currently in place and future changes to that system, changes in economic conditions in our domestic and international markets, lower than anticipated market penetration of our products, our reliance on sales of our influenza diagnostic tests, fluctuations in our operating results resulting from the timing of the onset, length and severity of cold and flu seasons, seasonality, government and media attention focused on influenza and the related potential impact on humans from novel influenza viruses, 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, acquisition and protection of proprietary technology rights; our development of new technologies, products and markets; our reliance on a limited number of key distributors; our exposure to claims and litigation that could result in significant expenses and could ultimately result in an unfavorable outcome for us, including the ongoing litigation between us and Beckman Coulter, Inc.; intellectual property risks, including but not limited to, infringement litigation; our need for additional funds to finance our capital or operating needs; the financial soundness of our customers and suppliers; acceptance of our products among physicians and other healthcare providers; competition with other providers of diagnostic products; failures or delays in receipt of new product reviews or related to currently-marketed products by the U.S. Food and Drug Administration (the “FDA”) or other regulatory authorities or loss of any previously received regulatory approvals or clearances or other adverse actions by regulatory authorities; changes in government policies; costs of and adverse operational impact from failure to comply with government regulations in addition to FDA regulations; compliance with government regulations relating to the handling, storage and disposal of hazardous substances; third-party reimbursement policies and potential cost constraints; our failure to comply with laws and regulations relating to billing and payment for healthcare services; our ability to meet demand for our products; interruptions in our supply of raw materials; product defects; business risks not covered by insurance; costs and disruptions from failures in our information technology and storage systems; our exposure to data corruption, cyber-based attacks, security breaches and privacy violations; competition for and loss of management and key personnel; international risks, including but not limited to, compliance with product registration requirements, compliance with legal requirements, tariffs, exposure to currency exchange fluctuations and foreign currency exchange risk, longer payment cycles, lower selling prices and greater difficulty in collecting accounts receivable, reduced protection of intellectual property rights, social, political and economic instability, increased financial accounting and reporting burdens and complexities, taxes, and diversion of lower priced international products into U.S. markets; changes in tax rates and exposure to additional tax liabilities or assessments; risks relating to our acquisition and integration of the Triage MeterPro Cardiovascular and toxicology business and B-type Natriuretic Peptide assay business (the “Triage and BNP Businesses”); Alere's failure to perform under various transition agreements relating to our acquisition of the Triage and BNP Businesses; that we may incur substantial costs to build our information technology infrastructure to transition the Triage and BNP Businesses; that we may have to write off goodwill relating to our acquisition of the Triage and BNP Businesses; our ability to manage our growth strategy; the level of our indebtedness and deferred payment obligations; our ability to generate sufficient cash to meet our debt service and deferred and contingent payment obligations and our ability to repay, renew or extend, our outstanding debt and its impact on our operations and our ability to obtain financing; that our Revolving Credit Facility is secured by substantially all of our assets; the agreements for our indebtedness place operating and financial restrictions on us and our ability to operate our business; that an event of default could trigger acceleration of our outstanding indebtedness; that we may incur additional indebtedness; increases in interest rate relating to our variable rate debt; 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; our intention of not paying dividends; and our ability to identify and successfully acquire and integrate potential acquisition targets. 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 some forward-looking statements are expressed differently. Forward-looking statements in this Quarterly Report include, among others, statements concerning: our outlook for the remainder of 2019 regarding our strategy, revenue growth, gross margins and earnings, including the sources of expected growth; that we expect to continue to make substantial expenditures for research and development activities; the nature and amount of projected capital expenditures for the remainder of 2019 and our source of funds for such expenditures; the sufficiency of our liquidity and capital resources; our strategy, goals, initiatives and objectives; our strategy, exposure to, and defenses against, claims and litigation, including the pending litigation

with Beckman; the sufficiency of our liquidity and our short-term needs for capital; the sufficiency of our insurance coverage; that we may incur additional debt or issue additional equity; and our intention to continue to evaluate technology, product lines and acquisition opportunities. The risks described under “Risk Factors” in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2018, 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. Except as required by law, we undertake no obligation to publicly release the results of any revision or update of these forward-looking statements, whether as a result of new information, future events or otherwise.

The following should be read in conjunction with the Consolidated Financial Statements and Notes thereto beginning on page 3 of this Quarterly Report.

Overview

We have a leadership position in the development, manufacturing and marketing of rapid diagnostic testing solutions. These diagnostic testing solutions are separated into our four product categories: rapid immunoassay, cardiac immunoassay, specialized diagnostic solutions and molecular diagnostic solutions. We sell our products directly to end users and distributors, in each case, for professional use in physician offices, hospitals, clinical laboratories, reference laboratories, urgent care clinics, leading universities, retail clinics, pharmacies and wellness screening centers. We market our products through a network of distributors and through a direct sales force. The Company operates in one business segment that develops, manufactures and markets our four product categories.

Outlook

We anticipate revenue to grow during the remainder of 2019 with a related positive impact on gross margin and earnings. This growth is expected to be driven primarily by sales of our Cardiac Immunoassays, Sofia Immunoassays and Molecular Diagnostic Solutions. In addition, we expect continued and significant investment in research and development activities as we develop our next generation immunoassay and molecular platforms. We will continue our focus on prudently managing our business and delivering solid financial results, while at the same time striving to continue to introduce new products to the market and maintaining our emphasis on research and development investments for longer term growth. Finally, we will continue to evaluate opportunities to acquire new product lines, technologies and companies.

Three months ended September 30, 2019 compared to the three months ended September 30, 2018

Total Revenues

The following table compares total revenues for the three months ended September 30, 2019 and 2018 (in thousands, except percentages):

	Three Months Ended September 30,		Increase (Decrease)	
	2019	2018	\$	%
Rapid Immunoassay	\$ 42,534	\$ 35,366	\$ 7,168	20%
Cardiac Immunoassay	66,820	65,287	1,533	2%
Specialized Diagnostic Solutions	12,455	12,294	161	1%
Molecular Diagnostic Solutions	4,683	4,452	231	5%
Total revenues	<u>\$ 126,492</u>	<u>\$ 117,399</u>	<u>\$ 9,093</u>	<u>8%</u>

For the three months ended September 30, 2019, total revenue increased to \$126.5 million from \$117.4 million in the prior period. The increase in total revenues was primarily due to higher Rapid Immunoassay sales, particularly respiratory products. In addition, we realized increased Cardiac Immunoassay sales driven primarily by the Asia Pacific region.

Gross Profit

Gross profit increased to \$75.9 million, or 60% of revenue for the three months ended September 30, 2019, compared to \$69.6 million, or 59% of revenue for the three months ended September 30, 2018. The increased gross profit was driven by higher sales volumes as well as improved product mix, partially offset by lower factory overhead absorption. Gross margin increased compared to the same period in the prior year due to improved product mix and lower scrap expense, partially offset by lower factory overhead absorption.

Operating Expenses

The following table compares operating expenses for the three months ended September 30, 2019 and 2018 (in thousands, except percentages):

	Three Months Ended September 30,					
	2019		2018			
	Operating expenses	As a % of total revenues	Operating expenses	As a % of total revenues	Increase (Decrease)	
					\$	%
Research and development	\$ 11,976	9%	\$ 13,103	11%	\$ (1,127)	(9)%
Sales and marketing	\$ 26,599	21%	\$ 26,504	23%	\$ 95	0 %
General and administrative	\$ 12,146	10%	\$ 10,620	9%	\$ 1,526	14 %
Acquisition and integration costs	\$ 4,456	4%	\$ 2,521	2%	\$ 1,935	77 %

Research and Development Expense

Research and development expense for the three months ended September 30, 2019 decreased from \$13.1 million to \$12.0 million due primarily to lower spending on projects related to Cardiovascular and Solana platforms, as they were largely completed in 2018. Such decreases were partially offset by higher spend on projects related to the Sofia and Savanna platforms.

Research and development expenses include direct external costs such as fees paid to third-party contractors and 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.

Sales and Marketing Expense

Sales and marketing expense for the three months ended September 30, 2019 increased slightly from \$26.5 million to \$26.6 million due to higher employee-related costs, mostly offset by lower transition service fees as we complete the globalization of our commercial team.

General and Administrative Expense

General and administrative expense for the three months ended September 30, 2019 increased from \$10.6 million to \$12.1 million compared with the prior year period primarily due to increased facilities costs from the expansion required to integrate the acquired Cardiovascular business and professional service fees incurred in the period, partially offset by lower transition service fees.

Acquisition and Integration Costs

Acquisition and integration costs for the three months ended September 30, 2019 increased from \$2.5 million to \$4.5 million compared with the prior year period primarily due to the impairment loss related to the transition of our headquarter facility and professional service fees.

Other Expense, Net

Interest expense, net primarily relates to accretion of interest on the deferred consideration related to the BNP Business, coupon and accretion interest related to our Convertible Senior Notes and interest and amortization of deferred financing costs associated with the Credit Agreement. The decrease in interest expense of \$1.6 million over the prior year was primarily due to lower debt balances under the Company's Credit Agreement and Convertible Senior Notes and lower deferred consideration liability outstanding. See further discussion in Note 5 of the Notes to the Consolidated Financial Statements in this Quarterly Report.

During the three months ended September 30, 2018, the Company recorded loss on extinguishment of debt of \$1.3 million related to the modification of the Senior Credit Agreement and the resulting write-off of certain previously capitalized costs relating to the previous term loan.

Income Taxes

For the three months ended September 30, 2019, we had an income tax expense of \$1.3 million compared to an insignificant income tax benefit for the three months ended September 30, 2018. The tax benefit for the three months ended September 30, 2018 included the impact the Company's valuation allowance offset by the discrete impact of excess tax benefits from stock-based compensation. For the three months ended September 30, 2019, the Company has no valuation allowance; however the discrete tax benefits for this quarter are lower compared to the same quarter in the prior year.

Nine months ended September 30, 2019 compared to the nine months ended September 30, 2018

Total Revenues

The following table compares total revenues for the nine months ended September 30, 2019 and 2018 (in thousands, except percentages):

	Nine Months Ended September 30,		Increase (Decrease)	
	2019	2018	\$	%
Rapid Immunoassay	\$ 126,800	\$ 132,740	\$ (5,940)	(4)%
Cardiac Immunoassay	200,674	203,581	(2,907)	(1)%
Specialized Diagnostic Solutions	40,595	39,859	736	2 %
Molecular Diagnostic Solutions	14,643	13,517	1,126	8 %
Total revenues	<u>\$ 382,712</u>	<u>\$ 389,697</u>	<u>\$ (6,985)</u>	<u>(2)%</u>

For the nine months ended September 30, 2019, total revenue decreased to \$382.7 million from \$389.7 million in the prior year. The decrease in total revenues was driven primarily by lower Rapid Immunoassay sales as compared with the robust respiratory season in the prior year. Cardiac Immunoassay sales declined from the prior year due to the currency impact of a strengthening U.S. dollar, less favorable geographic mix and lower selling prices as we transition portions of the global business to distribution. The decreases were partially offset by increases in Molecular Diagnostic Solutions and Specialized Diagnostic Solutions.

Gross Profit

Gross profit decreased to \$226.0 million, or 59% of revenue for the nine months ended September 30, 2019, compared to \$233.6 million, or 60% of revenue for the nine months ended September 30, 2018. The decreased gross profit was mainly driven by lower factory overhead absorption, unfavorable currency fluctuation and lower sales volumes. This was partially offset by the inventory step-up amortization during the nine months ended September 30, 2018 that did not recur during the nine months ended September 30, 2019. Gross margin declined compared to the same period in the prior year due to the same factors.

Operating Expenses

The following table compares operating expenses for the nine months ended September 30, 2019 and 2018 (in thousands, except percentages):

	Nine Months Ended September 30,				Increase (Decrease)	
	2019		2018		\$	%
	Operating expenses	As a % of total revenues	Operating expenses	As a % of total revenues		
Research and development	\$ 37,629	10%	\$ 39,008	10%	\$ (1,379)	(4)%
Sales and marketing	\$ 83,114	22%	\$ 82,607	21%	\$ 507	1 %
General and administrative	\$ 38,453	10%	\$ 32,652	8%	\$ 5,801	18 %
Acquisition and integration costs	\$ 9,116	2%	\$ 10,923	3%	\$ (1,807)	(17)%

Research and Development Expense

Research and development expense for the nine months ended September 30, 2019 decreased from \$39.0 million to \$37.6 million due primarily to lower spending on projects related to Cardiovascular and Solana platforms, as they were largely completed in 2018. Such decreases were partially offset by higher spend on projects related to the Sofia and Savanna platforms.

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.

Sales and Marketing Expense

Sales and marketing expense for the nine months ended September 30, 2019 increased \$0.5 million to \$83.1 million compared with the prior year, primarily due to higher employee-related costs, partially offset by lower transition service fees as we complete the globalization of our commercial team.

General and Administrative Expense

General and administrative expense for the nine months ended September 30, 2019 increased from \$32.7 million to \$38.5 million compared with the prior year period, due to increased facilities and compensation costs from international expansion, and professional service fees incurred in the period. The increase was partially offset by lower transition service fees.

Acquisition and Integration Costs

Acquisition and integration costs for the nine months ended September 30, 2019 decreased from \$10.9 million to \$9.1 million as more of the global operations became fully integrated into the business. Such decline was partially offset by an impairment loss related to the transition of our headquarter facility and acquisition-related professional service fees.

Other Expense, net

Interest expense, net was \$12.2 million and \$19.5 million for the nine months ended September 30, 2019 and 2018, respectively. Interest expense, net primarily relates to accretion of interest on the deferred consideration, coupon and accretion of interest related to our Convertible Senior Notes and interest and amortization of deferred financing costs associated with the debt outstanding under our Credit Agreement. The decrease in interest expense of \$7.2 million over the prior year was primarily due to lower debt balances under the Company's Revolving Credit Facility and Convertible Senior Notes and lower deferred consideration liability outstanding. Loss on extinguishment of debt of \$0.7 million for the nine months ended September 30, 2019 relates to the extinguishment of \$45.4 million in aggregate principal of the Convertible Senior Notes in exchange for the Company's common stock during the period.

Loss on extinguishment of debt of \$8.3 million during the nine months ended September 30, 2018 relates to the \$161.8 million early payment on the previous term loan and the extinguishment of \$108.8 million in aggregate principal of the Convertible Senior Notes in exchange for the Company's common stock during the period.

Income Taxes

For the nine months ended September 30, 2019 and 2018, we recognized income tax expense of \$2.4 million and income tax benefit of \$1.1 million, respectively. The primary drivers of the income tax benefit in the nine months ended September 30, 2018 are the excess tax benefits from stock-based compensation and the partial release of the Company's valuation allowance. In the nine months ended September 30, 2019, the company did not have any tax impacts from valuation allowance and the excess tax benefits from stock-based compensation were lower as compared to the same period in the prior year.

Liquidity and Capital Resources

As of September 30, 2019 and December 31, 2018, the principal sources of liquidity consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Cash and cash equivalents	\$ 28,914	\$ 43,695
Amount available to borrow under the Revolving Credit Facility	\$ 166,812	\$ 121,812
Working capital including cash and cash equivalents	\$ 58,242	\$ 33,662
Adjusted working capital (1)	\$ 70,788	\$ 88,041

(1) The Convertible Senior Notes of \$12.5 million and \$54.4 million as of September 30, 2019 and December 31, 2018 respectively are excluded from the adjusted working capital amount as such notes may be settled at the Company's option in cash or a combination of cash and shares of common stock.

As of September 30, 2019, we had \$28.9 million in cash and cash equivalents, a \$14.8 million decrease from December 31, 2018. Our cash requirements fluctuate as a result of numerous factors, such as cash generated from operations, progress in research and development projects, asset acquisitions, technological development spend 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 lines, 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 such transactions.

Our primary source of liquidity, other than our holdings of cash and cash equivalents, has been cash flows from operations, debt financings and proceeds from issuance of common stock. Cash generated from operations provides us with the financial flexibility we need to meet normal operating, investing and financing needs. We anticipate that our current cash and cash equivalents, together with cash provided by operating activities as well as access to funds from our Revolving Credit Facility will be sufficient to fund our near-term capital and operating needs for at least the next 12 months. Normal operating needs include the planned costs to operate our business, including amounts required to fund working capital and capital expenditures. Our primary short-term needs for capital, which are subject to change, include expenditures related to:

- support of commercialization efforts related to our current and future products, including support of our direct sales force and field support resources both in the United States and abroad;
- interest on and repayments of our Convertible Senior Notes, Revolving Credit Facility, deferred consideration, contingent consideration and lease obligations;
- the continued advancement of research and development efforts;
- acquisitions of equipment and other fixed assets for use in our current and future manufacturing and research and development facilities; and
- potential strategic acquisitions and investments.

Our Convertible Senior Notes due in 2020 have a coupon rate of 3.25% and are convertible as of September 30, 2019. The principal balance outstanding as of September 30, 2019 was \$13.1 million. Our Revolving Credit Facility has a principal balance outstanding of \$8.2 million as of September 30, 2019, which was fully repaid in October 2019. See Note 5 of the Notes to Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report for further discussion of the Convertible Senior Notes and the Revolving Credit Facility.

As of September 30, 2019, we have \$165.2 million of deferred and contingent considerations associated with prior acquisitions to be settled in future periods.

We expect our revenue and operating expenses will significantly impact our cash management decisions. Our future capital requirements and the adequacy of our available funds to service our long-term debt and to fund working capital expenditures and business development efforts will depend on many factors, including:

- our ability to realize revenue growth from our new technologies and create innovative products in our markets;
- our ability to leverage our operating expenses to realize operating profits as we grow revenue;
- competing technological and market developments;
- the need to enter into collaborations with other companies or acquire other companies or technologies to enhance or complement our product and service offerings;
- our outstanding debt and covenant restrictions; and

- our ability to successfully integrate acquired businesses.

Cash Flow Summary

	Nine Months Ended September 30,	
	2019	2018
Net cash provided by operating activities:	\$ 86,761	\$ 93,128
Net cash (used for) provided by investing activities:	(18,716)	123,769
Net cash (used for) financing activities:	(82,783)	(214,474)
Effect of exchange rates on cash	(43)	185
Net (decrease) increase in cash and cash equivalents	\$ (14,781)	\$ 2,608

Cash provided by operating activities of \$86.8 million during the nine months ended September 30, 2019 reflects net income of \$42.3 million and non-cash adjustments of \$57.1 million primarily associated with depreciation, amortization, stock-based compensation and accretion of interest on deferred consideration. In addition, we used cash to fund our working capital requirements of \$10.4 million, primarily driven by an increase in accounts receivable. For the nine months ended September 30, 2018, cash provided by operating activities of \$93.1 million reflected net income of \$41.7 million and non-cash adjustments of \$67.2 million associated with depreciation, amortization, stock-based compensation, loss on extinguishment of debt and accretion of interest on deferred consideration. In addition, we used cash to fund our working capital requirements of \$19.3 million, primarily driven by changes in receivables related to our transition services agreements and income tax receivable.

Our investing activities used \$18.7 million during the nine months ended September 30, 2019 primarily related to payments for computer equipment, building improvements, Sofia, Solana and Triage instruments available for lease and manufacturing equipment. Our investing activities provided \$123.8 million during the nine months ended September 30, 2018 primarily from the sale of the Summers Ridge property for approximately \$146.6 million. Additionally, we used \$22.9 million to acquire production equipment, building improvements and Sofia, Solana and Triage instruments available for lease.

We are currently planning approximately \$11.0 million in capital expenditures for the remainder of 2019. The primary purpose for our capital expenditures is to implement facility improvements, to acquire manufacturing and scientific equipment, to purchase or develop information technology and to acquire Sofia, Solana and Triage instruments. We plan to fund these capital expenditures with the cash on our balance sheet.

Cash used by financing activities was \$82.8 million during the nine months ended September 30, 2019 primarily related to the payments of deferred consideration of \$44.0 million, Revolving Credit Facility of \$45.0 million and acquisition contingent consideration of \$4.0 million as well as repurchases of common stock of \$1.9 million, partially offset by proceeds from issuance of stock of \$13.2 million from stock option exercises. Cash used by financing activities of \$214.5 million during the nine months ended September 30, 2018 primarily related to payments on the Company's previous term loan of \$161.8 million, payments on deferred consideration of \$46.0 million, payments on the Revolving Credit Facility of \$10.0 million, payments on acquisition contingent consideration of \$6.3 million, repurchases of common stock of \$3.8 million and \$2.0 million of transaction costs related to the exchange of convertible notes for common stock, partially offset by proceeds from issuance of stock of \$16.0 million from stock option exercises.

Seasonality

Sales of our respiratory 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. Historically, sales of our respiratory products have varied from year to year based, in large part, on the severity, length and timing of the onset of the cold and flu season.

Off-Balance Sheet Arrangements

At September 30, 2019 and December 31, 2018, we did not have any relationships with unconsolidated entities or financial partners, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in such relationships.

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 heading “Recent Accounting Pronouncements” and is incorporated herein by reference.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. On an on-going basis, management evaluates its estimates, including those related to customer programs and incentives, stock-based compensation, goodwill and intangible assets, business combinations, income taxes, and convertible debt. 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 under different assumptions or conditions.

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, 2018. There were no material changes to our critical accounting policies and estimates during the nine months ended September 30, 2019.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

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.

Our Revolving Credit Facility debt is subject to interest rate risk as a portion of the interest rate fluctuates based on the LIBOR. We had \$8.2 million outstanding under our Revolving Credit Facility at September 30, 2019. The weighted average interest rate on these borrowings is 3.87% as of September 30, 2019. A hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would increase our annual interest expense by approximately \$0.1 million. Based on our market risk sensitive instruments outstanding at September 30, 2019, we have determined that there was no material market risk exposure from such instruments to our consolidated financial position, results of operations or cash flows as of such date.

Our current investment policy with respect to our cash and cash equivalents focuses on maintaining acceptable levels of interest rate risk and liquidity. Although we periodically evaluate our placement of investments, as of September 30, 2019, we did not have any cash and cash equivalents placed in funds held in government money market accounts and commercial paper.

Foreign Currency Exchange Risk

We are exposed to foreign currency risks that arise from normal business operations. These risks include the translation of local currency balances of foreign subsidiaries, transaction gains and losses associated with intercompany loans with foreign subsidiaries and transactions denominated in currencies other than a location’s functional currency.

During the nine months ended September 30, 2019, we generated approximately \$85.3 million in revenue denominated in currencies other than the U.S. dollar. The major currencies to which our revenues are exposed are the Euro and the Chinese Yuan. A 100-basis point move in the average exchange rates (assuming a simultaneous and immediate 100 basis point change for the relevant period) would have resulted in an increase or decrease in our reported revenue for the nine months ended September 30, 2019 as follows (in thousands):

<u>Currency</u>	Nine Months Ended September 30, 2019	
Chinese Yuan	\$	445
Euro	\$	294

While our results of operations have been impacted by the effects of currency fluctuations, the revenue and expenses relating to our international operations are generally denominated in local currency, which reduces our economic exposure to foreign exchange risk in those jurisdictions.

Effective fiscal year 2019, the Company has initiated a foreign currency management policy that permits the use of derivative instruments, such as forward contracts, to reduce volatility in our results of operations resulting from foreign exchange rate fluctuations. We do not enter into foreign currency derivative instruments for trading purposes or to engage in speculative activity. See further discussion in Note 10 to the Notes to the Consolidated Financial Statements for additional information related to such forward contracts.

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, 2019 at a reasonable assurance level 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, 2019 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 “Litigation and Other Legal Proceedings” under Note 8 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 year ended December 31, 2018. 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, 2018.

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 30, 2019.

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)
July 1, 2019 - July 28, 2019	472	\$ 59.35	—	\$ 50,000,000
July 29, 2019 - August 25, 2019	—	—	—	50,000,000
August 26, 2019 - September 29, 2019	—	—	—	50,000,000
Total	472	\$ 59.35	—	\$ 50,000,000

(1) We withheld 472 shares of common stock from employees in connection with payment of minimum tax withholding obligations relating to the lapse of restrictions on certain RSUs during the three months ended September 30, 2019.

(2) On December 12, 2018, the Board of Directors authorized a new stock repurchase program, pursuant to which up to \$50.0 million of the Company's shares of common stock may be purchased through December 12, 2020. The Company announced the stock repurchase program on December 18, 2018.

ITEM 3. Defaults Upon Senior Securities

None.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. Other Information

None.

ITEM 6. Exhibits

3.1	<u>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.)</u>
3.2	<u>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.)</u>
3.3	<u>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.)</u>
4.1	<u>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.)</u>
31.1*	<u>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.</u>
31.2*	<u>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.</u>
32.1**	<u>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.</u>
101	The following financial statements from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, formatted in Inline XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Income, (iii) Consolidated Statements of Comprehensive Income, (iv) Consolidated Statements of Cash Flows, and (v) Notes to Consolidated Financial Statements, tagged as blocks of text and including detailed tags.
104	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, formatted in Inline XBRL (included as Exhibit 101).

* Filed herewith.

** Furnished herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: October 30, 2019

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)

Exhibit Index

Exhibit Number

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* Filed herewith.

** Furnished herewith.

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Douglas C. Bryant, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Quidel Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 30, 2019

/s/ DOUGLAS C. BRYANT

Douglas C. Bryant

President and Chief Executive Officer

(Principal Executive Officer)

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Randall J. Steward, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Quidel Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 30, 2019

/s/ RANDALL J. STEWARD

Randall J. Steward

Chief Financial Officer

(Principal Financial Officer)

Certifications by the Principal Executive Officer and Principal Financial Officer of Registrant pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Each of the undersigned hereby certifies, in his capacity as an officer of Quidel Corporation, a Delaware corporation (the “Company”), for purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

- the Company’s Quarterly Report on Form 10-Q for the period ended September 30, 2019 (the “Report”), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: October 30, 2019

/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)