Quidel Reports Third Quarter 2018 Financial Results

November 6, 2018

SAN DIEGO--(BUSINESS WIRE)--Nov. 6, 2018-- **Quidel Corporation (NASDAQ: QDEL),** a provider of rapid diagnostic testing solutions, cellular-based virology assays and molecular diagnostic systems, announced today financial results for the third quarter ended September 30, 2018.

Third Quarter 2018 Highlights

- Total revenue was $117.4 million as compared to $50.9 million in the third quarter of 2017.
- Cardiac Immunoassay revenue was $65.3 million.
- Influenza revenue was $21.6 million as compared to $23.1 million in the third quarter of 2017.
- Reported GAAP EPS of $0.27 per diluted share in the third quarter of 2018, as compared to $(0.16) per share in the third quarter of 2017. Excluding the one-time costs associated with the loss on extinguishment of debt, diluted EPS was $0.30 for the third quarter of 2018. Reported non-GAAP EPS of $0.59 per diluted share in the third quarter of 2018, as compared to $0.17 per diluted share in the third quarter of 2017.
- Received FDA clearance and CLIA waiver for Sofia® 2 Lyme FIA from finger-stick whole blood specimens.
- Received FDA clearance for Solana® Bordetella Complete® molecular diagnostic assay for pertussis (whooping cough), parapertussis infections.

Third Quarter 2018 Results

Total revenue for the third quarter of 2018 was $117.4 million, versus $50.9 million for the third quarter of 2017. The 131% increase in sales from the third quarter of 2018 was driven by incremental revenue from the acquired Cardiac Immunoassay business and 60% revenue growth from our Molecular Diagnostic Solutions. This was slightly offset by a 3% decline in the Rapid Immunoassay business, due to the timing of Influenza orders in the third quarter of 2018 as compared to the third quarter of 2017.

Cardiac Immunoassay revenue, which includes revenue from the Triage, Triage Toxicology and Beckman BNP products acquired in October 2017, totaled $65.3 million in the third quarter of 2018, growing 4% from the third quarter of 2017. Rapid Immunoassay product revenue (which includes QuickVue, Sofia and Eye Health products) decreased 3% in the third quarter of 2018 to $35.4 million, primarily due to a $1.5 million decrease in Influenza revenue from the third quarter of 2017. Molecular Diagnostic Solutions revenue increased 60% to $4.5 million, led by 88% revenue growth from Solana, our instrumented molecular diagnostic system. Specialized Diagnostic Solutions revenue, which includes revenue from Virology/DHI, Specialty and Other, increased 5% from the third quarter of 2017 to $12.3 million.

“We delivered another strong quarter, with continued commercial traction in the Cardiac Immunoassay product segment. In addition, integration of the acquired businesses is going well, and the programs to deliver operational synergies remain on track," said Douglas Bryant, president and CEO of Quidel Corporation. "We saw growth in Sofia and Molecular, and a 19% increase year-over-year in influenza outsales from distributors to our customers. As a result, inventories at distribution are low, which positions us nicely for Q4 influenza revenue in advance of the season. Importantly, we also launched our CLIA-waived Sofia 2 Lyme whole blood diagnostic assay. Although approval was received late in the Lyme season, the early indications from the market are positive, and we expect to build on that momentum going into the 2019 Lyme season. As we move into the fourth quarter, we are well positioned and remain focused on delivering long-term growth.”

Gross Profit in the third quarter of 2018 increased to $69.6 million, driven by the addition of the Cardiac Immunoassay products from the acquisition of the Triage and BNP Businesses in October 2017. Overall, gross margin for the quarter was 59% as compared to 58% for the same period last year, due to lower amortization of intangibles on our legacy Quidel business. R&D expense increased by $5.6 million in the third quarter as compared to the same period last year, primarily due to incremental expense for the Triage business, as well as increased investment in the Savanna molecular diagnostic platform. Sales and Marketing expense increased by $12.9 million in the third quarter of 2018, as compared to the third quarter of 2017, largely due to expenses associated with the global infrastructure for the Triage business. G&A expense increased by $4.0 million in the quarter, primarily due to additional costs associated with the Triage business. As a percentage of revenue, operating expenses before integration costs were 43% in the third quarter of 2018 as compared to 54% in the third quarter of 2017. Acquisition and Integration Costs in the quarter decreased by $2.1 million to $2.5 million, as more of the global operations become fully integrated into the business. The loss on extinguishment of debt represents one-time costs of $1.3 million related to the partial write off of unamortized debt issuance costs related to the Senior Credit Facility.

Net income for the third quarter of 2018 was $10.8 million, or $0.27 per diluted share, as compared to a net loss of $5.5 million, or $(0.16) per share, for the third quarter of 2017. Excluding the one-time costs associated with the loss on extinguishment of debt, diluted EPS was $0.30 for the third quarter of 2018. On a non-GAAP basis, net income for the third quarter of 2018 was $25.5 million, or $0.59 per diluted share, as compared to net income of $5.9 million, or $0.17 per diluted share, for the same period in 2017.

Results for the Nine Months Ended September 30, 2018

Total revenue for the nine-month period ended September 30, 2018 was $389.7 million, versus $162.9 million for the same period in 2017. The 139% increase in sales was driven by incremental revenue from the acquired Cardiac Immunoassay business, 14% revenue growth from the Rapid Immunoassay business and 48% revenue growth from our Molecular Diagnostic Solutions.

Cardiac Immunoassay revenue, which includes revenues from the Triage, Triage Toxicology and Beckman BNP products acquired in October 2017, totaled $203.6 million in the nine-month period ended September 30, 2018. Rapid Immunoassay product revenue increased 14% in the nine-month

period ended September 30, 2018 to $132.7 million, led by a 60% rise in Sofia revenue, while QuickVue sales declined 28% from the same period of 2017. Molecular Diagnostic Solutions revenue increased 48% to $13.5 million for the nine-month period ended September 30, 2018, led by 120% revenue growth from Solana, our instrumented molecular diagnostic system. Specialized Diagnostic Solutions revenue increased 6% from the nine-month period ended September 30, 2018 to $39.9 million.

Influenza revenue for the nine months ended September 30, 2018 increased 24% to $91.7 million as compared to $74.0 million in the first nine months of 2017.

Gross Profit in the nine-month period ended September 30, 2018 increased to $233.6 million, the result of increased sales revenue from the acquired Triage and BNP Businesses and improved product mix, with a higher mix of Influenza products in the current year. Gross margin for the nine-month period ended September 30, 2018 was flat to prior year, at 60%. Included in the 2018 gross margin is the one-time impact of the Triage/BNP inventory step-up of fair value which reduced the consolidated gross margin by one percentage point. R&D expense increased by $16.0 million in the nine-month period ended 2018 as compared to the same period last year, primarily due to additional expenses associated with the acquired Triage business, and additional investments in the Savanna molecular diagnostic platform. Sales and Marketing expense increased by $41.7 million in the nine-month period ended 2018, as compared to the same period in 2017, largely due to incremental costs associated with the Triage business, as well as higher compensation costs associated with improved company performance. G&A expense increased by $12.2 million, primarily due to costs associated with Triage and BNP Businesses, as well as higher professional fees and compensation expenses. As a percentage of revenue, operating expenses before integration costs were 40% in the nine months ended September 30, 2018 as compared to 52% for the comparable nine-month period in the prior year. Acquisition and Integration Costs were $10.9 million in the period. The loss on extinguishment of debt includes one-time costs of $6.0 million related to the partial write-off of unamortized debt issuance costs related to the Senior Credit Facility, and $2.3 million loss associated with the Convertible Senior Note exchange agreements.

Net income for the nine-month period ended September 30, 2018 was $41.7 million, or $1.08 per diluted share, as compared to net loss of $3.1 million, or $(0.09) per share, for the same period in 2017. Excluding the one-time costs associated with the loss on extinguishment of debt, diluted EPS was $1.24 for the nine-month period ended September 30, 2018. On a non-GAAP basis, net income for the nine months ended September 30, 2018 was $95.2 million, or $2.24 per diluted share, as compared to net income of $17.2 million, or $0.50 per diluted share, for the same period in 2017.

Non-GAAP Financial Information

The Company is providing non-GAAP financial information to exclude the effect of stock-based compensation, amortization of intangibles, non-cash interest expense, impact of the valuation allowance for deferred tax assets and certain non-recurring items on income and net earnings per share as a supplement to its consolidated financial statements, which are presented in accordance with generally accepted accounting principles in the U.S., or GAAP.

Management is providing the adjusted gross profit, adjusted operating income, adjusted net income and adjusted net earnings per share information for the periods presented because it believes this enhances the comparison of the Company's financial performance from period-to-period, and to that of its competitors. This press release is not meant to be considered in isolation, or as a substitute for results prepared in accordance with GAAP. A reconciliation of the non-GAAP financial measures to the comparable GAAP measures is included in this press release as part of the attached financial tables.

Conference Call Information

Quidel management will host a conference call to discuss the third quarter 2018 results as well as other business matters today beginning at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). During the conference call, management may answer questions concerning business and financial developments and trends. Quidel's responses to these questions, as well as other matters discussed during the conference call, may contain or constitute material information that has not been previously disclosed.

To participate in the live call by telephone from the U.S., dial 877-930-5791, or from outside the U.S. dial 253-336-7286, and enter the audience pass code 802-9037.

A live webcast of the call can be accessed on the Investor Relations section of the Quidel website (http://ir.quidel.com). The website replay will be available for 14 days. The telephone replay will be available for 48 hours beginning at 8:00 p.m. Eastern Time (5:00 p.m. Pacific Time) today by dialing 855-859-2056 from the U.S., or by dialing 404-537-3406 for international callers, and entering pass code 802-9037.

About Quidel Corporation

Quidel Corporation serves to enhance the health and well-being of people around the globe through the development of diagnostic solutions that can lead to improved patient outcomes and provide economic benefits to the healthcare system. Marketed under the Sofia®, QuickVue®, D3® Direct Detection, Thyretain®, Triage® and InflammaDry® leading brand names, as well as under the new Solana®, AmpliVue® and Lyra® molecular diagnostic brands, Quidel's products aid in the detection and diagnosis of many critical diseases and conditions, including, among others, influenza, respiratory syncytial virus, Strep A, herpes, pregnancy, thyroid disease and fecal occult blood. Quidel's recently acquired Triage® system of tests comprises a comprehensive test menu that provides rapid, cost-effective treatment decisions at the point-of-care (POC), offering a diverse immunoassay menu in a variety of tests to provide diagnostic answers for quantitative BNP, CK-MB, d-dimer, myoglobin, troponin I and qualitative TOX Drug Screen. Quidel's research and development engine is also developing a continuum of diagnostic solutions from advanced immunoassay to molecular diagnostic tests to further improve the quality of healthcare in physicians' offices, hospital and reference laboratories, and other alternate sites, like urgent care centers and retail clinics, where healthcare is provided. For more information about Quidel's comprehensive product portfolio, visit quidel.com.

This press release 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; 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, 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, the quantity of our product in our distributors' inventory or distribution channels, changes in the buying patterns of our distributors, and changes in the healthcare market and consolidation of our customer base; our development and protection of proprietary technology rights; our development of new technologies, products and markets; our reliance on a limited number of key distributors; 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; adverse actions or delays in 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; changes in government policies; our exposure to claims and litigation, including litigation currently pending against us; costs of or our 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; 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; our exposure to cyber-based attacks and security breaches; competition for and loss of management and key personnel; international risks, including but not limited to, compliance with product registration requirements, exposure to currency exchange fluctuations and foreign currency exchange risk sharing arrangements, longer payment cycles, lower selling prices and greater difficulty in collecting accounts receivable, reduced protection of intellectual property rights, political and economic instability, taxes, and diversion of lower priced international products into U.S. markets; changes in tax rates and exposure to additional tax liabilities or assessments; risks relating to the acquisition and integration of 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; the amount of, and our ability to repay, renew or extend, our outstanding debt and its impact on our operations and our ability to obtain financing; that substantially the Senior Credit Facility is secured by substantially all of our assets; our prepayment requirements under the Senior Credit Facility; the agreements for our indebtedness place operating and financial restrictions on the Company; that an event of default could trigger acceleration of our outstanding indebtedness; the effect on our operating results from the trigger of the conditional conversion feature of our Convertible Senior Notes; 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; and our intention of not paying dividends. Forward-looking statements typically are identified by the use of terms such as "may," "will," "should," "might," "expect," "anticipate," "estimate," "plan," "intend," "goal," "project," "strategy," "future," and similar words, although some forward-looking statements are expressed differently. The risks described 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 press release. 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.

QUIDEL CORPORATION

(In thousands, except per share data; unaudited)

	Three Months Ended September 30,	
Consolidated Statements of Operations:	**2018**	**2017**
Total revenues	$ 117,399	$ 50,894
Cost of sales	47,757	21,204
Gross profit	69,642	29,690
Research and development	13,103	7,468
Sales and marketing	26,504	13,588
General and administrative	10,620	6,580
Acquisition and integration costs	2,521	4,591
Total costs and expenses	52,748	32,227
Operating income (loss)	16,894	(2,537)
Other expense, net:		
Interest expense, net	(4,786)	(2,784)
Loss on extinguishment of debt	(1,297)	—
Total other expense, net	(6,083)	(2,784)
Income (loss) before income taxes	10,811	(5,321)
(Benefit) provision for income taxes	(11)	204
Net income (loss)	$ 10,822	$ (5,525)
Basic earnings (loss) per share	$ 0.28	$ (0.16)
Diluted earnings (loss) per share	$ 0.27	$ (0.16)
Shares used in basic per share calculation	39,290	33,913
Shares used in diluted per share calculation	42,889	33,913
Gross profit as a % of total revenues	59 %	58 %

Research and development as a % of total revenues	11	%	15	%
Sales and marketing as a % of total revenues	23	%	27	%
General and administrative as a % of total revenues	9	%	13	%

Consolidated net revenues by product category are as follows:

Rapid Immunoassay	$ 35,366	$ 36,458
Cardiac Immunoassay	65,287	—
Specialized Diagnostic Solutions	12,294	11,655
Molecular Diagnostic Solutions	4,452	2,781
Total revenues	$ 117,399	$ 50,894

Condensed balance sheet data:	**9/30/2018**	**12/31/2017**
Cash and cash equivalents	$ 38,694	$ 36,086
Accounts receivable, net	66,845	67,046
Inventories	63,309	67,078
Total assets	793,884	935,251
Short-term debt	54,046	20,184
Long-term debt	86,912	381,110
Stockholders' equity	388,454	227,104

	Nine Months Ended September 30,	
Consolidated Statements of Operations:	**2018**	**2017**
Total revenues	$ 389,697	$ 162,853
Cost of sales	156,116	65,838
Gross profit	233,581	97,015
Research and development	39,008	22,970
Sales and marketing	82,607	40,875
General and administrative	32,652	20,483
Acquisition and integration costs	10,923	7,022
Total costs and expenses	165,190	91,350
Operating income	68,391	5,665
Other expense, net:		
Interest expense, net	(19,475)	(8,387)
Loss on extinguishment of debt	(8,262)	—
Total other expense, net	(27,737)	(8,387)
Income before income taxes	40,654	(2,722)
(Benefit) provision for income taxes	(1,050)	355
Net income	$ 41,704	$ (3,077)
Basic earnings (loss) per share	$ 1.11	$ (0.09)
Diluted earnings (loss) per share	$ 1.08	$ (0.09)
Shares used in basic per share calculation	37,490	33,538
Shares used in diluted per share calculation	42,467	33,538

Gross profit as a % of total revenues	60	%	60	%
Research and development as a % of total revenues	10	%	14	%
Sales and marketing as a % of total revenues	21	%	25	%
General and administrative as a % of total revenues	8	%	13	%

Consolidated net revenues by product category are as follows:

Rapid Immunoassay	$ 132,740	$ 115,974
Cardiac Immunoassay	203,581	—
Specialized Diagnostic Solutions	39,859	37,731
Molecular Diagnostic Solutions	13,517	9,148
Total revenues	$ 389,697	$ 162,853

QUIDEL CORPORATION

Reconciliation of Non-GAAP Financial Information

(In thousands, except per share data; unaudited)

	Three months ended September 30,							
	Gross Profit		Operating Income		Net Income		Diluted EPS	
	2018	2017	2018	2017	2018	2017	2018	2017
GAAP Financial Results	$ 69,642	$ 29,690	$ 16,894	$ (2,537)	$ 10,822	$ (5,525)		
Interest expense on Convertible Senior Notes, net of tax (a)					791	—		
Net income (loss) used for diluted earnings per share, if-converted method					11,613	(5,525)	$ 0.27	$ (0.16)
Adjustments:								
Interest expense on Convertible Senior Notes (a)					—	1,388		
Non-cash stock compensation expense	255	117	2,775	1,879	2,775	1,879		
Amortization of intangibles	1,998	2,030	7,031	2,720	7,031	2,720		
Amortization of debt discount and issuance costs on credit facility					145	—		
Non-cash interest expense for deferred consideration					2,285	—		
Loss on extinguishment of Senior Credit Facility					1,297	—		
Acquisition and integration costs			2,521	4,591	2,521	4,591		
Income tax impact of adjustments (a)(b)					(3,050)	(3,700)		
Income tax impact of valuation allowance for deferred tax assets					836	4,590		
Adjusted (c)	$ 71,895	$ 31,837	$ 29,221	$ 6,653	$ 25,453	$ 5,943	$ 0.59	$ 0.17

(a) The if-converted method was not applicable during 2017 as the Convertible Senior Notes were not convertible.

(b) Income tax impact of adjustments represents the tax impact related to the non-GAAP adjustments listed above and reflects an effective tax rate of 19% for 2018 and 35% for 2017.

(c) Adjusted net earnings per share for the three months ended September 30, 2018 was calculated using an adjusted diluted weighted average shares outstanding of 42.9 million shares. Adjustments from GAAP diluted weighted average shares outstanding consisted of 1.8 million potentially dilutive shares issuable from Convertible Senior Notes and 1.8 million potentially dilutive shares issuable from stock options and unvested RSUs.

QUIDEL CORPORATION

Reconciliation of Non-GAAP Financial Information

(In thousands, except per share data; unaudited)

	Nine months ended September 30,							
	Gross Profit		Operating Income		Net Income		Diluted EPS	
	2018	2017	2018	2017	2018	2017	2018	2017
GAAP Financial Results	$ 233,581	$ 97,015	$ 68,391	$ 5,665	$ 41,704	$ (3,077)		
Interest expense on Convertible Senior Notes, net of tax (a)					4,152	—		
Net income (loss) used for diluted earnings per share, if-converted method					45,856	(3,077)	$ 1.08	$ (0.09)
Adjustments:								
Interest expense on Convertible Senior Notes (a)					—	4,129		
Non-cash stock compensation expense	751	354	9,190	5,938	9,190	5,938		
Amortization of intangibles	6,739	5,543	21,890	7,605	21,890	7,605		
Amortization of debt discount and issuance costs on credit facility					760	—		
Non-cash interest expense for deferred consideration					7,686	—		
Loss on extinguishment of Convertible Senior Notes					2,304	—		
Loss on extinguishment of Senior Credit Facility					5,958	—		
Amortization of inventory step-up of fair value	3,650	—	3,650	—	3,650	—		
Change in fair value of acquisition contingencies			745	—	745	—		
Acquisition and integration costs			10,923	7,022	10,923	7,022		
Income tax impact of adjustments (a)(b)					(11,990)	(8,640)		
Income tax impact of valuation allowance for deferred tax assets					(1,786)	4,264		
Adjusted (c)	$ 244,721	$ 102,912	$ 114,789	$ 26,230	$ 95,186	$ 17,241	$ 2.24	$ 0.50

(a) The if-converted method was not applicable during 2017 as the Convertible Senior Notes were not convertible.

(b) Income tax impact of adjustments represents the tax impact related to the non-GAAP adjustments listed above and reflects an effective tax rate of 19% for 2018 and 35% for 2017.

(c) Adjusted net earnings per share for the nine months ended September 30, 2018 was calculated using an adjusted diluted weighted average shares outstanding of 42.5 million shares. Adjustments from GAAP diluted weighted average shares outstanding consisted of 3.2 million potentially dilutive shares issuable from Convertible Senior Notes and 1.8 million potentially dilutive shares issuable from stock options and unvested RSUs.

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