



Quidel Reports Fourth Quarter and Full Year 2015 Financial Results

February 17, 2016

SAN DIEGO, CA -- (Marketwired) -- 02/17/16 -- **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 fourth quarter and year ended December 31, 2015.

Fourth Quarter 2015 Highlights:

- Total revenues were \$52.4 million as compared to \$64.0 million in the fourth quarter of 2014.
- Total influenza revenues decreased 33% from the fourth quarter of 2014 to \$24.3 million.
- Revenues from new products were 34% of total revenue in the fourth quarter.
- Reported GAAP EPS of \$(0.01) per share as compared to \$0.20 per diluted share in the fourth quarter of 2014 and reported non-GAAP EPS of \$0.10 per diluted share as compared to \$0.37 per diluted share in the fourth quarter of 2014.

Full Year 2015 Highlights:

- Total revenues increased by 7% to \$196.1 million, as compared to \$184.2 million in 2014.
- Total influenza revenues increased 8% from 2014 to \$88.4 million.
- Revenues from new products increased 52% over 2014 to \$57.3 million, and were 29% of total revenue.
- Reported GAAP EPS of \$(0.18) per share for the full year 2015 as compared to \$(0.21) per share for the full year 2014 and reported non-GAAP EPS of \$0.32 per diluted share for the full year 2015 as compared to \$0.35 per diluted share for the full year of 2014.
- Received 510(k) clearance from the FDA for the Solana instrumented molecular system and the Solana Group A Strep molecular assay, Quidel's first molecular instrumented system.

Fourth Quarter 2015 Results

Total revenues for the fourth quarter of 2015 were \$52.4 million, versus \$64.0 million in the fourth quarter of 2014. The 18% decrease in revenues was primarily due to lower sales of Infectious Disease products in the fourth quarter of 2015, due to a delayed and weaker flu season than in the fourth quarter of 2014.

Infectious Disease product revenues decreased 23% in the fourth quarter, led by lower sales of influenza and Group A Strep products. Total influenza revenues in the fourth quarter decreased 33% from the fourth quarter of 2014 to \$24.3 million. Of the total influenza revenues, Sofia revenues made up 52%, QuickVue revenues accounted for 34%, and DHI Respiratory revenues were 14%. Over the same period, Women's Health revenues grew 6% to \$9.3 million and Gastrointestinal revenues were flat at \$1.8 million.

"Although we had three consecutive quarters of solid double-digit revenue growth and posted a record year for revenue, the delayed and weaker than expected influenza season, especially in the last few weeks of the year, meaningfully affected our fourth quarter growth," said Douglas Bryant, president and CEO of Quidel Corporation. "Even with quarterly gains in market share with Sofia, a weaker or delayed influenza season can have a significant impact on our fourth quarter results, which underscores the importance of our ongoing efforts to diversify our business. Despite a softer than normal end to the year, we believe that our company remains well-positioned for relatively near-term growth in both the emerging POC and molecular diagnostics categories, and are optimistic about our longer term opportunities."

Cost of Sales in the fourth quarter of 2015 decreased \$3.1 million to \$18.1 million, the result of decreased product revenue. Gross margin for the quarter was 65% as compared to 67% for the same period last year. R&D expense increased by \$0.7 million in the fourth quarter as compared to the same period last year, primarily due to next generation immunoassay instrument development (Sofia 2). Sales and Marketing expense increased by \$0.6 million in the fourth quarter of 2015, as compared to the fourth quarter of 2014 largely due to promotional activities for Virena, our cellular data management system. G&A expense increased by \$0.5 million in the quarter, primarily due to an increase in compensation and professional services.

Net loss for the fourth quarter of 2015 was \$(0.4) million, or \$(0.01) per share, compared to net income of \$7.1 million, or \$0.20 per diluted share, for the fourth quarter of 2014. On a non-GAAP basis, excluding amortization of intangibles, stock compensation expense and certain non-recurring items, net income for the fourth quarter of 2015 was \$3.5 million, or \$0.10 per diluted share, compared to \$13.3 million, or \$0.37 per diluted share, for the same period in 2014.

Full Year 2015 Results

Total revenues for the twelve-month period ended December 31, 2015 were \$196.1 million, as compared to \$184.2 million for 2014. The 7% increase in revenue was primarily driven by stronger sales of Infectious Disease products in the first nine months of 2015, partially offset by weaker sales of Infectious Disease products in the fourth quarter of 2015.

Total influenza revenues for the year increased 8% to \$88.4 million.

Cost of Sales for the full year 2015 decreased by \$2.5 million over 2014 to \$71.7 million due to the expiration of the amortization of the Alere settlement and improved manufacturing efficiencies. R&D expense for 2015 decreased by \$2.4 million over last year due to decreased spend for the Savanna development program partially offset by increased investment in Sofia and Sofia 2 instrument systems and assays. Sales and Marketing expense increased by \$4.8 million in 2015, primarily due to the full-year effect of the expansion and training of a larger sales force in 2015 relative to 2014. G&A increased by \$3.6 million in 2015, primarily due to one-time expenses associated with business development activities that were incurred

in the first quarter.

"In 2015, we launched Solana, our first instrument-based molecular platform, and met several internal milestones that should position us well for several new product introductions in the near- to medium-term," added Mr. Bryant. "In all, we had a solid year of product development and revenue growth, and expect to build on that foundation in 2016."

For the year ended 2015, net loss was \$(6.1) million, or \$(0.18) per share, compared to net loss of \$(7.1) million, or \$(0.21) per share, for the year ended 2014. On a non-GAAP basis, net income for the year ended 2015 was \$11.2 million, or \$0.32 per diluted share, compared to net income of \$12.3 million, or \$0.35 per diluted share, for the year ended 2014.

Non-GAAP Financial Information

The Company is providing non-GAAP financial information to exclude the effect of stock-based compensation, amortization of intangibles and certain non-recurring items on earnings (loss) and net earnings (loss) 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 net earnings (loss) and adjusted net earnings (loss) 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 fourth quarter and full year 2015 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 253-336-7286, and enter the audience pass code 4449-7814.

A live webcast of the call can be accessed at <http://ir.quidel.com>, and the Web site 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 404-537-3406 from the U.S., or 855-859-2056 for international callers, and entering pass code 4449-7814.

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 QuickVue[®], D3[®] Direct Detection and Thyretain[®] leading brand names, as well as under the new Sofia[®], AmpliVue[®], Solana[®] and Lyra[®] 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 research and development engine is also developing a continuum of diagnostic solutions from advanced lateral-flow and direct fluorescent antibody to molecular diagnostic tests to further improve the quality of healthcare in physicians' offices and hospital and reference laboratories. 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, fluctuations in our operating results resulting from seasonality, the timing of the onset, length and severity of cold and flu seasons, government and media attention focused on influenza and the related potential impact on humans from novel influenza viruses, adverse changes in competitive conditions in domestic and international markets, changes in sales levels as it relates to the absorption of our fixed costs, lower than anticipated market penetration of our products, the reimbursement system currently in place and future changes to that system, and changes in economic conditions in our domestic and international markets, the quantity of our product in our distributors' inventory or distribution channels, changes in the buying patterns of our distributors and changes in the healthcare market and consolidation of our customer base; our development and protection of intellectual property; our development of new technologies, products and markets; our reliance on a limited number of key distributors; our reliance on sales of our influenza diagnostics tests; our ability to manage our growth strategy, including our ability to integrate companies or technologies we have acquired or may acquire; intellectual property risks, including but not limited to, infringement litigation; limitations and covenants in our senior credit facility; our need for additional funds to finance our operating needs; volatility and disruption in the global capital and credit markets; acceptance of our products among physicians and other healthcare providers; competition with other providers of diagnostic products; adverse actions or delays in new product reviews or related to currently-marketed products by the U.S. Food and Drug Administration (the "FDA"); changes in government policies; compliance with other government regulations, such as safe working conditions, manufacturing practices, environmental protection, fire hazard and disposal of hazardous substances; third-party reimbursement policies; our ability to meet demand for our products; interruptions in our supply of raw materials; product defects; business risks not covered by insurance and exposure to other litigation claims; interruption to our computer systems; competition for and loss of management and key personnel; international risks, including but not limited to, compliance with product registration requirements, exposure to currency exchange fluctuations and foreign currency exchange risk sharing arrangements, longer payment cycles, lower selling prices and greater difficulty in collecting accounts receivable, reduced protection of intellectual property rights, political and economic instability, taxes, and diversion of lower priced international products into U.S. markets; our significant debt service requirements; the possibility that we may incur additional indebtedness; our ability to settle conversions of our convertible senior notes in cash; the effect on our operating results from the trigger of the conditional conversion feature of our convertible senior notes; dilution resulting from future sales of our equity; volatility in our stock price; provisions in our charter documents, Delaware law and the indenture governing our convertible senior notes that might delay or impede stockholder actions with respect to business combinations or similar transactions; and our intention of not paying dividends. Forward-looking statements typically are identified by the use of terms such as "may," "will," "should," "might," "expect," "anticipate," "estimate," "plan," "intend," "goal," "project," "strategy," "future," and similar words, although 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. We undertake no obligation to publicly release the results of any revision or update of these forward-looking statements, except as required by law.

QUIDEL CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data; unaudited)

	Three months ended December 31,	
	2015	2014
Total revenues	\$ 52,412	\$ 63,953
Cost of sales (excludes amortization of intangible assets from acquired businesses and technology)	18,122	21,263
Research and development	9,939	9,199
Sales and marketing	12,063	11,509
General and administrative	7,408	6,862
Amortization of intangible assets from acquired businesses and technology	2,218	2,205
Total costs and expenses	<u>49,750</u>	<u>51,038</u>
Operating income	2,662	12,915
Interest expense, net	<u>(2,989)</u>	<u>(820)</u>
Income (loss) before provision for taxes	(327)	12,095
Provision for income taxes	50	4,982
Net (loss) income	<u>\$ (377)</u>	<u>\$ 7,113</u>
Basic (loss) earnings per share	\$ (0.01)	\$ 0.21
Diluted (loss) earnings per share	\$ (0.01)	\$ 0.20
Weighted shares used in basic per share calculation	33,522	34,602
Weighted shares used in diluted per share calculation	33,522	35,761
Gross profit as a % of total revenues	65%	67%
Research and development as a % of total revenues	19%	14%
Sales and marketing as a % of total revenues	23%	18%
General and administrative as a % of total revenues	14%	11%

	12/31/2015	12/31/2014
Condensed balance sheet data (in thousands):		
Cash, cash equivalents and restricted cash	\$ 191,534	\$ 204,022
Accounts receivable, net	18,398	34,466
Inventories	26,388	24,763
Total assets	406,505	447,411
Long-term debt	147,329	142,575
Stockholders' equity	218,676	245,011

QUIDEL CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data; unaudited)

	Twelve months ended December 31,	
	2015	2014
Total revenues	\$ 196,129	\$ 184,158
Cost of sales (excludes amortization of intangible assets from acquired businesses and technology)	71,688	74,180
Research and development	35,514	37,913
Sales and marketing	47,886	43,076
General and administrative	29,447	25,811
Amortization of intangible assets from acquired businesses and technology	8,856	8,828
Impairment loss	-	3,558
Total costs and expenses	<u>193,391</u>	<u>193,366</u>
Operating income (loss)	2,738	(9,208)
Interest expense, net	<u>(12,035)</u>	<u>(1,775)</u>
Loss before benefit for income taxes	(9,297)	(10,983)
Benefit for income taxes	(3,218)	(3,909)
Net loss	<u>\$ (6,079)</u>	<u>\$ (7,074)</u>
Basic loss per share	\$ (0.18)	\$ (0.21)
Diluted loss per share	\$ (0.18)	\$ (0.21)
Weighted shares used in basic and diluted per share calculations	34,104	34,451
Gross profit as a % of total revenues	63%	60%
Research and development as a % of total revenues	18%	21%
Sales and marketing as a % of total revenues	24%	23%
General and administrative as a % of total revenues	15%	14%

QUIDEL CORPORATION

Reconciliation of Non-GAAP Financial Information
(In thousands, except per share data; unaudited)

	<i>Three Months Ended</i>		<i>Twelve Months Ended</i>	
	<i>December 31,</i>		<i>December 31,</i>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Net (loss) income - GAAP	\$ (377)	\$ 7,113	\$ (6,079)	\$ (7,074)
Add:				
Non-cash stock compensation expense	1,706	1,952	7,419	6,724
Amortization of intangibles	2,367	4,988	10,091	17,435
Impairment loss	-	-	-	3,558
Amortization of debt discount and issuance costs	1,351	292	5,340	292
One-time business development expenses	-	-	2,390	-
Income tax impact of valuation allowance for deferred tax assets and release of reserve for uncertain tax positions	(34)	1,378	756	1,378
Income tax impact of non-cash stock compensation expense, amortization of intangibles, impairment loss, debt discount and issuance costs and one-time business development expenses	(1,520)	(2,387)	(8,733)	(9,971)
Adjusted net income	<u>\$ 3,493</u>	<u>\$ 13,336</u>	<u>\$ 11,184</u>	<u>\$ 12,342</u>
Basic earnings per share:				
Adjusted net earnings	\$ 0.10	\$ 0.39	\$ 0.33	\$ 0.36
Net (loss) earnings - GAAP	\$ (0.01)	\$ 0.21	\$ (0.18)	\$ (0.21)
Diluted earnings per share:				
Adjusted net earnings	\$ 0.10	\$ 0.37	\$ 0.32	\$ 0.35
Net (loss) earnings - GAAP	\$ (0.01)	\$ 0.20	\$ (0.18)	\$ (0.21)

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