



Quidel Reports Fourth Quarter and Full Year 2014 Financial Results

February 11, 2015

SAN DIEGO, CA -- (Marketwired) -- 02/11/15 -- **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, 2014.

Fourth Quarter 2014 Highlights:

- Total revenues were \$63.6 million as compared to \$50.2 million in the fourth quarter of 2013.
- Revenues from new products increased 101% from the fourth quarter of 2013.
- Reported GAAP EPS of \$0.20 per diluted share as compared to \$0.03 per diluted share in the fourth quarter of 2013 and reported non-GAAP EPS of \$0.37 per diluted share as compared to \$0.20 per diluted share in the fourth quarter of 2013.
- Received the United States Food and Drug Administration's (FDA's) first simultaneous 510(k) clearance and CLIA waiver designation ever granted, for Sofia Strep A+ Fluorescent Immunoassay.
- Received 510(k) clearance from the FDA for AmpliVue® Bordetella Pertussis hand-held molecular assay.
- Received 510(k) clearance from the FDA for Lyra® Human Parainfluenza Viruses 1, 2, 3 molecular PCR assay.
- Received 510(k) clearance from the FDA for Lyra Adenovirus molecular PCR assay.
- Raised \$172.5 million in a convertible senior notes offering.

Full Year 2014 Highlights:

- Total revenues increased by 4% to \$182.6 million, as compared to \$175.4 million in 2013.
- Revenues from new products increased 95% over 2013.
- Received a total of eight 510(k) clearances from the FDA, seven of which were for molecular products.
- Received two CLIA waiver designations from the FDA for Sofia products (RSV, Strep A+).
- Received an award for up to \$12.6 million in additional funding from the Bill and Melinda Gates Foundation as part of an amendment to the initial agreement for the development of our Savanna system.

Fourth Quarter 2014 Results

Total revenues for the fourth quarter of 2014 rose 27% to \$63.6 million, versus the fourth quarter of 2013. The increase in revenues was due to greater sales of Infectious Disease products in the fourth quarter of 2014.

Infectious Disease product revenues grew 29% in the fourth quarter, led by increased sales of influenza, Group A Strep and RSV products. Total influenza revenues in the fourth quarter increased 45% to \$36.3 million, from the fourth quarter of 2013, led by a 97% increase in Sofia influenza orders, as well as a 25% increase in QuickVue® influenza sales. Over the same period, Women's Health revenues grew 7% to \$8.8 million and Gastrointestinal revenues increased 2% to \$1.9 million.

"We continue to be pleased with the progress we are making as a company. We rebounded from a slow start to the year and realized a very strong fourth quarter, due in part to market share gains with our Sofia Influenza A+B product, and the largest number of Sofias placed in any quarter since launch," said Douglas Bryant, president and CEO of Quidel Corporation. "Additionally, we received CLIA waiver of Sofia Strep A+ in December, which provides another key opportunity to grow the total number of Sofia installations well beyond our initial goal of 10,000 units running our initial menu of assays."

In the quarter, total costs and expenses were \$50.7 million as compared to \$49.9 million in the fourth quarter of 2013. Cost of Sales increased \$2.6 million, the result of increased product revenue. Gross margin for the quarter was 67% as compared to 63% for the same period last year. R&D expense decreased by \$2.1 million in the fourth quarter as compared to the same period last year, due primarily to lower clinical trials and labor costs. Sales and Marketing expense increased by \$1.5 million in the fourth quarter, driven primarily by added personnel costs as part of our sales organization expansion, as compared to the fourth quarter of 2013.

Net income for the fourth quarter of 2014 was \$7.1 million, or \$0.20 per diluted share, compared to net income of \$1.1 million, or \$0.03 per diluted share, for the fourth quarter of 2013. On a non-GAAP basis, excluding amortization of intangibles, stock compensation expense and certain non-recurring items, net income for the fourth quarter of 2014 was \$13.3 million, or \$0.37 per diluted share, compared to \$7.0 million, or \$0.20 per diluted share, for the same period in 2013.

Full Year 2014 Results

Total revenues for the twelve-month period ended December 31, 2014 were \$182.6 million, as compared to \$175.4 million for the same period in 2013. The 4% increase in revenue was primarily driven by stronger sales of Infectious Disease products in the fourth quarter of 2014.

For the full year ended December 31, 2014, total costs and expenses were \$191.8 million as compared to \$170.6 million over the same period in 2013. Cost of Sales for the full year increased by \$7.2 million over 2013 due to higher revenue and increased Sofia instrumentation costs. R&D expense for 2014 increased by \$3.7 million over last year due to added investment in our Savanna system and molecular platforms. Sales and Marketing expense increased by \$7.7 million, due to the full-year effect of the expansion and training of a larger sales force in 2014 relative to 2013.

"We achieved a number of product development milestones in 2014. Among the accomplishments for the year: we received the FDA's first

simultaneous 510(k) clearance and CLIA waiver designation granted from a dual submission for Sofia Strep A+; our AmpliVue Pertussis assay was 510(k) cleared with a very short review time and sooner than we had expected; we received *de novo* clearances for both Lyra HSV 1+2/VZV and Lyra Strep A + C/G assays; we officially introduced both of our newest instrument systems in development, Solana and Savanna, in the summer; and placed the first Savanna alpha unit in South Africa before year-end," added Mr. Bryant. "In all, we met most of the milestones we set for ourselves, and are confident in our ability to execute toward our goals for 2015."

For the year ended 2014, net loss was \$(7.1) million, or \$(0.21) per share, compared to net income of \$7.4 million, or \$0.21 per diluted share, for the year ended 2013. On a non-GAAP basis, net income for the year ended 2014 was \$12.3 million, or \$0.35 per diluted share, compared to net income of \$21.3 million, or \$0.61 per diluted share, for the year ended 2013.

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 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 800-798-2864, or from outside the U.S. dial 617-614-6206, and enter the pass code 909-745-88.

A live webcast of the call can be accessed at <http://www.quidel.com>, and 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 888-286-8010 from the U.S., or 617-801-6888 for international callers, and entering pass code 270-507-37.

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® 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; the reimbursement system currently in place and future changes to that system; changes in economic conditions in our 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 quantity of our product in our distributors' inventory or distribution channels, changes in the buying patterns of our distributors and changes in the health care 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 US markets; our significant debt service requirements; the possibility that we may incur additional indebtedness; our inability 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 chart documents, Delaware law and our convertible senior notes that might delay or impede stockholder actions with respect to our 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,

	2014	2013
Total revenues	\$ 63,597	\$ 50,170
Cost of sales (excludes amortization of intangible assets from acquired businesses and technology)	21,263	18,679
Research and development	9,199	11,262
Sales and marketing	11,153	9,695
General and administrative	6,862	6,752
Amortization of intangible assets from acquired businesses and technology	2,205	2,214
Impairment loss	--	--
Facility restructuring charges	--	1,332
Total costs and expenses	50,682	49,934
Operating income	12,915	236
Interest expense, net	(820)	(325)
Income (loss) before provision (benefit) for taxes	12,095	(89)
Provision (benefit) for income taxes	4,982	(1,228)
Net income	\$ 7,113	\$ 1,139
Basic earnings per share	\$ 0.21	\$ 0.03
Diluted earnings per share	\$ 0.20	\$ 0.03
Weighted shares used in basic per share calculation	34,602	34,024
Weighted shares used in diluted per share calculation	35,761	35,126
Gross profit as a % of total revenues	67 %	63 %
Research and development as a % of total revenues	14 %	22 %
Sales and marketing as a % of total revenues	18 %	19 %
General and administrative as a % of total revenues	11 %	14 %
Condensed balance sheet data (in thousands):	12/31/2014	12/31/2013
Cash, cash equivalents and restricted cash	\$ 204,022	\$ 9,357
Accounts receivable, net	34,466	29,928
Inventories	24,763	27,639
Total assets	451,550	271,485
Long term debt	146,714	5,126
Stockholders' equity	245,011	223,779

QUIDEL CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data; unaudited)

Twelve months ended December 31,

	2014	2013
Total revenues	\$ 182,615	\$ 175,410
Cost of sales (excludes amortization of intangible assets from acquired businesses and technology)	74,180	66,976
Research and development	37,913	34,186
Sales and marketing	41,533	33,829
General and administrative	25,811	25,581
Amortization of intangible assets from acquired businesses and technology	8,828	8,171
Impairment loss	3,558	--
Facility restructuring charges	--	1,825
Total costs and expenses	191,823	170,568

Operating (loss) income	(9,208)	4,842
Interest expense, net	<u>(1,775)</u>	<u>(1,408)</u>
(Loss) income before benefit for income taxes	(10,983)	3,434
Benefit for income taxes	<u>(3,909)</u>	<u>(3,956)</u>
Net (loss) income	<u>\$ (7,074)</u>	<u>\$ 7,390</u>
Basic (loss) earnings per share	\$ (0.21)	\$ 0.22
Diluted (loss) earnings per share	\$ (0.21)	\$ 0.21
Weighted shares used in basic per share calculation	34,451	33,836
Weighted shares used in diluted per share calculation	34,451	34,947
Gross profit as a % of total revenues	59 %	62 %
Research and development as a % of total revenues	21 %	19 %
Sales and marketing as a % of total revenues	23 %	19 %
General and administrative as a % of total revenues	14 %	15 %

QUIDEL CORPORATION

Non-GAAP Financial Information

(In thousands, except per share data; unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2014	2013	2014	2013
	(unaudited)		(unaudited)	
Net income (loss) - GAAP	\$ 7,113	\$ 1,139	\$ (7,074)	\$ 7,390
Add:				
Non-cash stock compensation expense	1,952	3,324	6,724	8,771
Amortization of intangibles	4,988	4,169	17,435	16,564
Impairment loss	--	--	3,558	--
Facility restructuring charge	--	1,332	--	1,825
Amortization of debt discount and issuance costs	292	--	292	--
Income tax impact of 2012 research and development tax credit	--	--	--	(510)
Income tax impact of valuation allowance for deferred tax assets and release of reserve for uncertain tax positions	1,378	--	1,378	(3,458)
Income tax impact of non-cash stock compensation expense, amortization of intangibles and impairment loss	<u>(2,387)</u>	<u>(3,001)</u>	<u>(9,971)</u>	<u>(9,234)</u>
Adjusted net income	<u>\$ 13,336</u>	<u>\$ 6,963</u>	<u>\$ 12,342</u>	<u>\$ 21,348</u>
Basic earnings per share:				
Adjusted net earnings	\$ 0.39	\$ 0.20	\$ 0.36	\$ 0.63
Net earnings (loss) - GAAP	\$ 0.21	\$ 0.03	\$ (0.21)	\$ 0.22
Diluted earnings per share:				
Adjusted net earnings	\$ 0.37	\$ 0.20	\$ 0.35	\$ 0.61
Net earnings (loss) - GAAP	\$ 0.20	\$ 0.03	\$ (0.21)	\$ 0.21

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