Quidel Receives CLIA Waiver for Its Sofia(R) Diagnostic Test for Respiratory Syncytial Virus (RSV)

June 2, 2014

SAN DIEGO, CA -- (Marketwired) -- 06/02/14 -- ***Quidel Corporation*** (NASDAQ: QDEL), a provider of rapid diagnostic testing solutions, cellular-based virology assays and molecular diagnostic systems, announced today that Quidel has received Clinical Laboratory Improvement Amendments (CLIA) waiver from the U.S. Food and Drug Administration (FDA) for its Sofia RSV Fluorescent Immunoassay (FIA) for the rapid detection of respiratory syncytial virus (RSV).

RSV is responsible for respiratory tract infections, principally among pediatric and elderly populations. In the pediatric setting, almost all children become infected by RSV by their second birthday. The Centers for Disease Control and Prevention (CDC) estimate that in the United States, RSV is responsible for 75,000 to 125,000 hospitalizations annually for bronchiolitis and pneumonia among children younger than one year.[1]

Symptoms of RSV infection are often similar to other respiratory infections, and include coughing, sneezing, a runny nose, fever and sometimes a decrease in appetite. Unless diagnostic testing is performed to aid in the diagnosis, RSV infection can be confused with influenza virus infection in young patients.

The simple-to-use Sofia Analyzer and Sofia RSV FIA employ unique software and immunofluorescence-based chemistry to yield an automated, objective and highly reliable result for aiding in the diagnosis of RSV infections within minutes of obtaining the nasopharyngeal swab or nasopharyngeal aspirate specimen from the patient. In addition to the several thousand hospitals, medical centers and smaller clinics in the United States, the receipt of CLIA waiver expands the available point-of-care market for the Sofia test system.

"We are very pleased to receive CLIA waiver for our Sofia RSV assay, and thus gain ready access to the CLIA-waived segment of the market, which includes physician office labs, emergency departments and other CLIA-waived facilities," said Douglas Bryant, president and chief executive officer of Quidel Corporation. "Our Sofia system was engineered to be easy-to-use while increasing accuracy and minimizing interpretation and testing errors that are often encountered with other rapid tests. We believe this test will allow healthcare workers in nearly any medical setting to test confidently for RSV and to receive an accurate test result within minutes of the patient's arrival."

The Sofia test system is CE-marked, 510(k)-cleared, and commercially available in Europe, the United States and the rest of the world. Quidel also sells other FDA-cleared assays in the Sofia format; these include Influenza A+B (also CLIA-waived), Group A Strep, and human Chorionic Gonadotropin (hCG) for pregnancy. Other assays, using this novel Sofia platform, are in development. Quidel also offers a molecular diagnostic test for RSV and hMPV in its Lyra PCR format; this *in vitro* diagnostic test was cleared by the FDA in March 2013.

1. http://www.cdc.gov/rsv/about/faq.html

About Quidel Corporation

Quidel Corporation serves to enhance the health and wellbeing 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™ brandsQuidel'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; that we may incur significant additional indebtedness; 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 product reviews 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 of 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; volatility in our stock price; dilution resulting from future sales of our equity; and

provisions in our charter documents and Delaware law that might delay stockholder actions with respect to business combinations or the election of directors. 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.

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