Quidel Receives FDA Clearance for Its Sofia(R) hCG Fluorescent Immunoassay (FIA)

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SAN DIEGO, CA -- (Marketwired) -- 08/05/13 -- ***Quidel Corporation*** (NASDAQ: QDEL), a provider of rapid diagnostic testing solutions, cell-based virology assays and molecular diagnostic systems, announced today that it has received 510(k) clearance from the United States Food and Drug Administration (FDA) for its Sofia® hCG fluorescent immunoassay for use on the Sofia Analyzer for the rapid, objective detection of elevated levels of human chorionic gonadotropin (hCG), an early indicator of pregnancy.

Sofia is the brand name for Quidel's next-generation, immunoassay system. The Sofia Analyzer and Sofia hCG FIA with proprietary Kinetic Check™ Technology combine unique immunofluorescence chemistry, advanced lateral flow technology, and failure alert and fail-safe systems designed to ensure a reliable, objective, highly accurate, diagnostic result within three (3) minutes of application of the patient's specimen.

"Historically, Quidel has been an infectious disease and women's health company with considerable technical expertise in both segments, and so, to us, the development of women's health assays like the Sofia hCG FIA, is a natural expansion opportunity," said Douglas Bryant, president and chief executive officer of Quidel Corporation. "We are pleased to receive clearance for this assay because we believe Sofia's accuracy and speed can play a vital role in medical settings, such as obstetrics and gynecology, where important patient decisions are made every day."

The 510(k) clearance allows Quidel to market and sell its new Sofia hCG FIA in the United States. The Sofia Analyzer was 510(k) cleared in October of 2011, and its first test, the Sofia Influenza A+B FIA, received Clinical Laboratory Improvement Amendments (CLIA) waiver by the FDA in April of 2012. Quidel also sells the Sofia Strep A FIA, which received FDA clearance in June 2013.

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® and AmpliVue® 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 www.quidel.com and Diagnostic Hybrids at www.dhiusa.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 and changes in the buying patterns of our distributors; our development of new technologies, products and markets; our development and protection of intellectual property; 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 POC diagnostic products; changes in government policies; adverse actions or delays in product reviews by the U.S. Food and Drug Administration (the "FDA"); 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; the loss of key personnel; international risks, including but not limited to, compliance with product registration requirements, exposure to currency exchange fluctuations, 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 failure to maintain adequate internal control over financial reporting; 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," and similar words, although some forward-looking statements are expressed differently. The risks described under "Risk Factors" in reports and registration statements that we file with the Securities and Exchange Commission (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 the forward-looking statements, except as required by law.

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