Quidel Receives FDA Approval to Market Osteoporosis Device

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SAN DIEGO, Aug. 8 /PRNewswire/ -- Quidel Corporation (Nasdaq: QDEL) today announced that it has received Premarket Approval (PMA) from the U.S. Food and Drug Administration (FDA) to market the QUS(TM)-2 Calcaneal Ultrasonometer. The QUS-2 is a portable device that uses ultrasound to assess the density (quality) of bone in the heel of a person's foot. Approval from the FDA allows Quidel to begin marketing the device for diagnostic use in the United States and initiates the registration process in certain other countries. Physicians can use the quantitative results from the QUS-2 to aid in diagnosing osteoporosis and determining the risk of atraumatic (fragility) fractures associated with this common "brittle bone" disease. The QUS-2 is manufactured in an ISO 9001 certified facility and is approved to carry a CE mark, allowing distribution in Europe. The QUS-2 is also commercially available in certain Asia-Pacific and Latin American countries. The device incorporates technology covered by eight issued U.S. patents, and additional patents are pending.

"This approval is a significant advance in the bone health strategy we began with the acquisition of Metra Biosystems last year," said Andre de Bruin, President & Chief Executive Officer of Quidel Corporation. "Our current biochemical bone marker tests - Alkphase-B(R) and Pyrilinks(R)-D - are increasingly being used by physicians for assessing bone "turnover," the dynamic process of bone breakdown and formation. Together, the biochemical tests and the QUS-2 offer osteoporosis management solutions to the primary care, wellness and specialist communities."

Osteoporosis is most often diagnosed through the use of large, expensive, X-ray-based bone density machines or after a fracture has occurred. The portable QUS-2 brings a new level of convenience to the physician and patient. At seven pounds, this self-contained, battery-operated device can be used virtually anywhere. The QUS-2 incorporates unique, dry scanning technology that precisely locates an optimal measurement site within the heel, ensuring a high level of clinical performance. "We found that the QUS-2 is a reliable and reproducible method for identifying women with osteoporosis," commented Susan Greenspan M.D. of the University of Pittsburgh School of Medicine, a principal investigator for multicenter clinical trials conducted with the QUS-2. "Its ability to discriminate fracture status is similar to that of X-ray bone density techniques of the spine and hip. Because an osteoporotic fracture is predicted to occur in 50% of women over age 50, this is a disease that needs to be assessed in a large patient population." Dr. Greenspan concluded, "The QUS-2 provides a portable, comfortable tool to assess bone status, allowing for earlier initiation of prevention and treatment for this common, silent disease."

Quidel is a market leader in point-of-care, rapid diagnostics, providing simple, accurate and cost-effective diagnostic tests to physicians and/or consumers. Quidel's Test and Treat products are easy to use and provide results in minutes, facilitating rapid treatment and improved health outcomes, lower costs, and increased patient satisfaction. Its core products address issues relating to a woman's health throughout her life including reproductive status, pregnancy management and osteoporosis. In addition, the Company provides diagnostic products for all family members for common health problems and infectious diseases, including influenza A and B, strep throat, H. pylori infection, chlamydia and infectious mononucleosis. Quidel's products are sold to healthcare professionals for use in physicians' offices, clinical laboratories, pharmacies and wellness screening centers. Quidel also manufactures a line of products sold to consumers through organizations that provide store-branded products.

This press release contains forward-looking statements regarding Quidel's future activities within the meaning of the federal securities laws. These forward-looking statements involve material risks and uncertainties. Many possible factors could affect the future results and performance of Quidel's products, such that actual results and performance may differ materially. If Quidel's products fail to perform as expected, or if there is lower demand for these products than expected, Quidel's financial condition and operating results may be materially and adversely affected. Quidel's financial condition and operating results may also be materially and adversely affected by a number of other factors, including, without limitation, seasonality, adverse changes in competitive and economic conditions, currency fluctuations, actions by the Company's distributors, manufacturing and production delays or difficulties and adverse actions or delays in product reviews by the FDA. Please see the discussion of these and other factors in Quidel's annual reports on Form 10-K and subsequent quarterly reports on Form 10-Q. For more information, please visit Quidel's web site at http://www.quidel.com.

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