



DexCom Schedules Conference Call to Discuss FDA Warning Letter

SAN DIEGO, Jun 01, 2010 (BUSINESS WIRE) -- DexCom, Inc. (NASDAQ:DXCM) announced today that it has received a warning letter from the U.S. Food & Drug Administration (FDA) resulting from an inspection of DexCom's facility in San Diego, CA by the Los Angeles District Office earlier this year. Due to the volume of inquiries received by the company concerning the warning letter, which was posted on the FDA's web site this morning, management will hold a conference call starting at 4:15 p.m. (Eastern Time) today to discuss the company's intended response and answer questions. To listen to the conference call, please dial (800) 447-0521 (US/Canada) or (847) 413-3238 (International) and use the confirmation number "27189814" approximately five minutes prior to the start time. The conference call will be concurrently webcast. The link to the webcast will be available on the DexCom, Inc. website at www.dexcom.com under the investor webcast section and will be archived for future reference.

The warning letter cites a deviation related to MDR reporting for complaints involving sensor wire fractures underneath a patient's skin and recommends some specific changes to the company's warning and precaution statements in its product labeling. With respect to the MDR reporting deviation, DexCom has historically evaluated the reportability of sensor wire fractures under the Medical Device Reporting Regulations (21 C.F.R. Part 803). The company's analysis led it to conclude that these events were not reportable. However, as discussed with the FDA during the facility inspection, DexCom committed to reporting sensor wire fractures as MDRs going forward. With respect to the recommended labeling changes, DexCom believes the labeling information requested by the FDA is adequately set forth in the precautions statement section of the company's FDA-approved product labeling, however the company expects to revise its labeling and move certain portions of its precautions statement to the warnings statement section of its product labeling. We intend to work cooperatively with the FDA to obtain the necessary approval for those labeling changes.

DexCom does not expect this matter will have any impact on production or on future product approvals. The company expects to respond to the FDA within the time frame set forth in the warning letter.

About DexCom, Inc.

DexCom, Inc., headquartered in San Diego, California, is developing and marketing continuous glucose monitoring systems for ambulatory use by patients and by healthcare providers in the hospital.

Cautionary Statement Regarding Forward Looking Statements

This media release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which involve risks and uncertainties. These forward-looking statements include statements regarding the company's proposed response to the FDA, and the impact of the warning letter on production and future product approvals. DexCom's actual results may differ materially from those anticipated in these forward-looking statements. Factors that might contribute to such differences include, among others, our ability to respond in a timely manner acceptable to the FDA, other factors affecting production, including possible future FDA actions, and other issues affecting the company's product approval applications. DexCom is a medical device company with a limited operating history. Successful commercialization of the company's products is subject to numerous risks and uncertainties, including a lack of acceptance in the marketplace by physicians and patients, the inability to manufacture products in commercial quantities at an acceptable cost, possible delays in the company's development programs, the inability of patients to receive reimbursement from third-party payors and inadequate financial and other resources. Certain of these risks and uncertainties, in addition to other risks, are more fully described in the company's annual report on Form 10-Q for the period ending March 31, 2010, as filed with the Securities and Exchange Commission on May 5, 2010.

SOURCE: DexCom, Inc.

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