

Meridian Bioscience Submits New illumigene(TM) Molecular C. difficile Test to U.S. FDA for Marketing Clearance

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CINCINNATI, Mar 22, 2010 (BUSINESS WIRE) -- Meridian Bioscience, Inc. announced today that it has submitted a 510(k) application to the United States Food and Drug Administration for marketing clearance of its new, simple molecular diagnostic test, illumigene(TM) C. difficile. illumigene is a simplified new technology platform, based upon loop amplification (LAMP) that makes molecular diagnostic testing possible for any size laboratory. The technology is isothermal and therefore requires no costly capital equipment. Clostridium difficile is a major cause of antibiotic associated diarrhea and it is the primary cause of pseudomembranous colitis. C. difficile bacteria can produce toxins that attack the cell walls of an infected patient's intestines causing serious and often life-threatening damage. This first molecular amplification test from Meridian, illumigene C. difficile, detects and amplifies a pathogenic DNA region common to all toxin-producing strains of C. difficile. The test is performed on a small sample of the patient's stool and the entire procedure can be completed in less than one hour.

John A. Kraeutler, Chief Executive Officer, said, "Our R&D team has worked diligently for the past four years to refine and simplify this technology. The workflow is straight-forward so that the benefits of molecular diagnostics can be made available to any lab. The clinical trials that support the performance of *illumigene* were thorough and we are pleased with the performance of the test. We look forward to receiving clearance from the FDA and to the U.S. market introduction later this year."

Forward Looking Statements

The Private Securities Litigation Reform Act of 1995 provides a safe harbor from civil litigation for forward-looking statements accompanied by meaningful cautionary statements. Except for historical information, this report 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, which may be identified by words such as "estimates," "anticipates," "projects," "plans," "seeks," "may," "will," "expects," "intends," "believes," "should" and similar expressions or the negative versions thereof and which also may be identified by their context. Such statements, whether expressed or implied, are based upon current expectations of the Company and speak only as of the date made. The Company assumes no obligation to publicly update or revise any forward-looking statements even if experience or future changes make it clear that any projected results expressed or implied therein will not be realized. These statements are subject to various risks, uncertainties and other factors that could cause actual results to differ materially, including, without limitation, the following: Meridian's continued growth depends, in part, on its ability to introduce into the marketplace enhancements of existing products or new products that incorporate technological advances, meet customer requirements and respond to products developed by Meridian's competition. While Meridian has introduced a number of internally developed products, there can be no assurance that it will be successful in the future in introducing such products on a timely basis. Ongoing consolidations of reference laboratories and formation of multi-hospital alliances may cause adverse changes to pricing and distribution. Recessionary pressures on the economy and the markets in which our customers operate, as well as adverse trends in buying patterns from customers can change expected results. Costs and difficulties in complying with laws and regulations administered by the United States Food and Drug Administration can result in unanticipated expenses and delays and interruptions to the sale of new and existing products. Changes in the relative strength or weakness of the U.S. dollar can also change expected results. One of Meridian's main growth strategies is the acquisition of companies and product lines. There can be no assurance that additional acquisitions will be consummated or that, if consummated, will be successful and the acquired businesses successfully integrated into Meridian's operations. The Company cannot predict the possible effects of potential healthcare reform in the United States and similar initiatives in other countries on its results of operations. In addition to the factors described in this paragraph, Part I, Item 1A Risk Factors of our Form 10-K contains a list and description of uncertainties, risks and other matters that may affect the Company.

Meridian is a fully integrated life science company that manufactures, markets and distributes a broad range of innovative diagnostic test kits, purified reagents and related products and offers biopharmaceutical enabling technologies. Utilizing a variety of methods, these products and diagnostic tests provide accuracy, simplicity and speed in the early diagnosis and treatment of common medical conditions, such as gastrointestinal, viral and respiratory infections. Meridian's diagnostic products are used outside of the human body and require little or no special equipment. The Company's products are designed to enhance patient well-being while reducing the total outcome costs of healthcare. Meridian has strong market positions in the areas of gastrointestinal and upper respiratory infections, serology, parasitology and fungal disease diagnosis. In addition, Meridian is a supplier of rare reagents, specialty biologicals and related technologies used by biopharmaceutical companies engaged in research for new drugs and vaccines. The Company markets its products and technologies to hospitals, reference laboratories, research centers, veterinary testing centers, physician offices, diagnostics manufacturers and biotech companies in more than 60 countries around the world. The Company's shares are traded through NASDAQ's Global Select Market, symbol VIVO. Meridian's website address is <http://www.meridianbioscience.com/>.

SOURCE: Meridian Bioscience, Inc.

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