



**Meridian**  
**Bioscience, Inc.**  
Inspired Science. Trusted Solutions.®

## INFORMATION

For Immediate Release

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Contact: 513.271.3700

John A. Kraeutler, Chief Executive Officer

### **Meridian Bioscience, Inc. Receives FDA Clearance for New Molecular Test for the Detection of *Mycoplasma pneumoniae***

CINCINNATI, June 16, 2016 (GLOBE NEWSWIRE) -- Meridian Bioscience, Inc. (NASDAQ: VIVO) today announced that it has received FDA clearance for a new molecular diagnostic test for *Mycoplasma pneumoniae* (*M. pneumoniae*). The new and improved *illumigene*® Mycoplasma Direct assay, launched earlier this year in Europe, features a simplified 3-step procedure. The new procedure will significantly expand Meridian's customer base by eliminating the need for specialized techniques and training, as well as providing definitive results in less than one hour.

Often referred to as "walking pneumonia", *M. pneumoniae* is associated with up to 40% of community-acquired pneumonias and accounts for approximately two million infections annually in the United States. Due to the lack of cell wall in Mycoplasma, typical antibiotics like penicillin and cephalosporin are not effective. *illumigene* Mycoplasma Direct accurately detects infection on the first day of symptoms and provides the ability to avoid treating patients empirically to reduce the administration of broad spectrum antibiotics and the likelihood of antimicrobial resistance.

The *illumigene* Mycoplasma Direct test utilizes throat swabs and provides highly sensitive and specific results. It requires no expensive capital equipment or service contracts. The test relies upon a simple 3-step procedure that takes less than two minutes of hands-on time. The simplicity of this technology, along with its cost efficiency and small footprint, makes this innovative test ideal for enabling a more rapid diagnosis; providing earlier identification of outbreaks and prevention of secondary cases through implementation of control measures.

Mike Shaughnessy, Executive Vice President and President of Meridian Global Diagnostics stated, "As the market share leader for *Mycoplasma pneumoniae* testing, we are pleased to be able to offer our customers an improved molecular assay for *Mycoplasma pneumoniae*. By simplifying the procedure of *illumigene* Mycoplasma we are able to address a larger customer base with a superior diagnostic tool that will dramatically improve patient care. Traditional methods of diagnosis include serology and X-Ray which may have as low as 25% and 41% sensitivity respectively, making rapid, targeted detection for specific treatment difficult. Our *illumigene* molecular platform does not require cumbersome capital equipment or costly hidden service contracts. We believe *illumigene* is the best value choice for molecular detection in infectious disease."

*illumigene* Mycoplasma Direct, now available for order immediately in the U.S., adds to the already broad *illumigene* menu that includes molecular assays for *C. difficile*, Group A Streptococcus, Group B Streptococcus, HSV 1&2 and Pertussis in the United States as well as Chlamydia, Gonorrhea and Malaria outside of the U.S.

## **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. All statements that address operating performance or events or developments that Meridian expects or anticipates will occur in the future, including, but not limited to, statements relating to per share diluted earnings and revenue, are forward-looking statements. Such statements, whether expressed or implied, are based upon current expectations of the Company and speak only as of the date made. Specifically, Meridian’s forward-looking statements are, and will be, based on management’s then-current views and assumptions regarding future events and operating performance. Meridian 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, and its ability to effectively sell such products. 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. Meridian relies on proprietary, patented and licensed technologies, and the Company’s ability to protect its intellectual property rights, as well as the potential for intellectual property litigation, would impact its results. 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, including those 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. The international scope of Meridian’s operations, including changes in the relative strength or weakness of the U.S. dollar and general economic conditions in foreign countries, can impact results and make them difficult to predict. One of Meridian’s 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 will be successfully integrated into Meridian’s operations. There may be risks that acquisitions may disrupt operations and may pose potential difficulties in employee retention and there may be additional risks with respect to Meridian’s ability to recognize the benefits of acquisitions, including potential synergies and cost savings or the failure of acquisitions to achieve their plans and objectives. Meridian cannot predict the possible impact of U.S. health care legislation enacted in 2010 – the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act – and any modification or repeal of any of the provisions thereof, and any similar initiatives in other countries on its results of operations. Efforts to reduce the U.S. federal deficit, breaches of Meridian’s information technology systems and natural disasters and other events could have a materially adverse effect on Meridian’s results of operations and revenues. 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 develops, 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 health care. 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, diagnostics manufacturers and biotech companies in more than 70 countries around the world. The Company’s shares are traded on the NASDAQ Global Select Market, symbol VIVO. Meridian’s website address is [www.meridianbioscience.com](http://www.meridianbioscience.com).

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