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# ZIVO Reports that USDA Claims Regulatory Jurisdiction for New Coccidiosis Treatment

*Regulatory Clarity Enables ZIVO to Focus and Optimize Development Strategy*

BLOOMFIELD HILLS, Mich.--(BUSINESS WIRE)-- **ZIVO Bioscience, Inc. (NASDAQ: ZIVO) (the “Company”)**, a biotech/agtech R&D company engaged in the development of therapeutic, medicinal and nutritional product candidates derived from proprietary algal cultures, announces receipt of a letter from the U.S. Department of Agriculture’s (USDA) Center for Veterinary Biologics (CVB) affirming that the agency has claimed jurisdiction for reviewing the Company’s novel immune-modulating biologic for treating coccidiosis in broiler chickens.

Coccidiosis is a parasitic disease of the intestinal tract caused by coccidian protozoa and is one of the largest health and animal welfare problems facing poultry flocks. The global poultry industry spends more than \$1.5 billion annually on coccidiosis control, primarily using decades-old compounds that face growing anticoccidial drug resistance. Coccidiosis is a common disease for chickens, especially among young chicks, and can be fatal or result in compromised digestion.

“I’m delighted with today’s announcement that demonstrates ZIVO’s commitment to advancing our product candidate toward commercialization and provides regulatory clarity. This jurisdictional decision is significant, allowing us to expedite our approval path. With regulatory jurisdiction now confirmed, we will advance discussions with the CVB on the final product development plan, regulatory strategy and data requirements for licensure. This clarity enables us to shape our path more concretely toward realizing our product’s market potential,” stated John Payne, Chief Executive Officer of ZIVO Bioscience.

ZIVO is developing a product candidate for use in poultry feed that is designed to boost immune response, allowing birds to effectively combat coccidiosis and reduce the negative effects of the disease without the use antimicrobial compounds. ZIVO’s biologic features a first-in-class novel mechanism of action (MOA) that differentiates it from existing products by qualifying for the regulatory approval process of the CVB.

Following a comprehensive review of data from several of ZIVO’s efficacy studies, MOA studies and manufacturing processes, the CVB verified ZIVO’s product is of biological origin and functions through an immune-modulating MOA that has no direct antimicrobial activity, and therefore is subject to their regulatory review. While other products for the control of coccidiosis delivered in feed are regulated by the U.S. FDA’s Center for Veterinary Medicine,

CVB's jurisdictional announcement removes regulatory ambiguity while providing a path for a comprehensive review.

### **About ZIVO Bioscience, Inc.**

ZIVO Bioscience is a research and development company operating in both the biotech and agtech sectors, with an intellectual property portfolio comprised of proprietary algal and bacterial strains, biologically active molecules and complexes, production techniques, cultivation techniques and patented or patent-pending inventions for applications in human and animal health. Please visit [www.zivobioscience.com](http://www.zivobioscience.com) for more information.

### **Forward Looking Statements**

Except for any historical information, the matters discussed in this press release contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Although ZIVO believes that we have a reasonable basis for each forward-looking statement, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. Our actual future results may be materially different from what we expect due to factors largely outside our control, including risks that our strategic partnerships may not facilitate the commercialization or market acceptance of our products; risks that our products may not be ready for commercialization in a timely manner or at all; risks that our products will not perform as expected based on results of our pre-clinical and clinical trials; our ability to raise additional funds; uncertainties inherent in the development process of our products; changes in regulatory requirements or decisions of regulatory authorities; the size and growth potential of the markets for our products; the results of clinical trials, our ability to protect our intellectual property rights and other risks, uncertainties and assumptions, including those described under the heading "Risk Factors" in our filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release and ZIVO undertakes no obligation to revise or update any forward-looking statements for any reason, even if new information becomes available in the future.

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