

Biomerica Reports Fiscal 2021 Second Quarter Financial Results and Provides Business Update

- **Biomerica expects completion of enrollment of its Irritable Bowel Syndrome Diagnostic-Guided Therapy clinical trial by end of April, 2021**
- **FDA actively reviewing Company's EUA submission for its first of its kind "at-home" Blood Collection kit used with the Biomerica COVID-19 IgG ELISA Lab Test system**
- **Simple to use 15-minute COVID-19 Antigen Rapid Test, which now has CE Mark, receives first large orders**

IRVINE, California, January 15, 2021 -- Biomerica, Inc. (Nasdaq: BMRA), a global provider of advanced medical products, today announced financial results for its second quarter of fiscal year 2021, which ended November 30, 2020.

The Company reported second quarter worldwide revenue of \$1.373 million as compared to \$1.596 million for the same period in the previous year. The decrease in sales during the quarter was primarily due lower sales in Asia. However, sales in Asia have substantially increased in the first half of the third fiscal quarter. Net loss was \$1.485 million for the second fiscal quarter compared to a net loss of \$0.485 million for the same period in the previous fiscal year. The increase in net loss was primarily due to higher research and development expense, largely related to the development of several COVID-19 tests, and higher general and administrative expenses, mainly due to increases in legal fees, reserves and personnel/consulting costs. Cash and cash equivalents were \$5.684 million, and current assets were \$11.947 million, at the end of the second fiscal quarter.

The Company announced that the U.S. Food and Drug Administration ("FDA") is now actively reviewing the Company's Emergency Use Authorization ("EUA") application for its COVID-19 IgG ELISA Test along with the Company's professional use and at-home Whole Blood Collection Card system. If EUA clearance is granted, it would be the first for an in-home blood sample collection system combined with an ELISA test kit. This collection system offers the simplicity of a finger-prick blood sample which can be easily collected in multiple settings such as homes, schools, workplace, community care and healthcare settings, and have these samples sent back to a lab to be run on the Company's highly accurate ELISA test. In clinical studies, the finger-prick blood collected samples demonstrated 100% specificity for detecting IgG antibodies to the spike protein of SARS-CoV-2 and 0% cross-reactivity with many common diseases. The Company's COVID-19 IgG ELISA test uses modified trimeric spike protein from the SARS-CoV-2 virus, which is known to be the target of neutralizing antibodies that prevent the virus from entering cells.¹

The Company also recently announced that it has received a CE mark for its new antigen rapid test. The Company has already received its first large European orders and plans to ship the first part of these orders in the coming weeks. The Company will now begin marketing this product broadly in Europe and other regions outside of the U.S. Biomerica's new COVID-19 Antigen Rapid Test is highly portable, affordable and provides results in approximately 15 minutes with no equipment required to perform or read the test. This test can be performed by doctors, nurses, school nurses, medical assistants, and trained medical specialists. In independent testing at clinics in three different countries outside of the U.S., the Biomerica COVID-19 Rapid Antigen Test demonstrated an overall performance of 94.7% positive agreement (sensitivity) and 99.7% negative agreement (specificity) as compared to lab-based molecular PCR tests. A simple nasal swab is used to collect specimens from people

suspected of having an active infection. Patient samples should be tested immediately and should not be diluted or used with viral transport media or frozen specimens.

Also, as previously announced, the Company is nearing completion of patient enrollment in the endpoint clinical trial for its InFoods® Irritable Bowel Syndrome (“IBS”) diagnostic-guided therapy (“DGT”). This double-blinded, randomized, controlled clinical trial is validating the Biomerica InFoods® IBS test to manage the debilitating pain and suffering of patients diagnosed with IBS. Utilizing an antibody guided blood test, the InFoods® IBS product identifies patient-specific foods that may alleviate IBS symptoms when eliminated from the patient’s diet. Mayo Clinic, Beth Israel Deaconess Medical Center, Inc., a Harvard Medical School Teaching Hospital, Houston Methodist, University of Texas Health Science Center at Houston, and the University of Michigan are participating in this study. Biomerica expects to complete patient enrollment at these centers by the end of April, 2021, and to have summary analysis results from the clinical trial by the end of July, 2021.

“We have worked to differentiate our COVID-19 products from the competition by focusing on proprietary methods of sample collection. For example, by using our simple finger-prick blood collection device we can enable a simple collection of a blood sample virtually anywhere (at home, at the office, or virtually any other location). At the same time, we are now launching our point of care 15-minute antigen test. Most importantly, we are very excited about nearing completion of patient enrollment in our endpoint clinical trial for its InFoods® IBS diagnostic-guided therapy. While we are proud to be helping with the current global pandemic, it is important to note that our primary long-term focus continues to be on validation and commercialization of products based on our patented InFoods® technology platform. We continue to believe our InFoods products could revolutionize the way people are diagnosed and treated for a variety of gastrointestinal diseases, while offering Biomerica sizable revenue opportunities,” stated Zackary Irani, CEO of Biomerica.

About Biomerica (NASDAQ: BMRA)

Biomerica, Inc. (www.biomerica.com) is a global biomedical technology company that develops, patents, manufactures and markets advanced diagnostic and therapeutic products used at the point of care (in home and in physicians' offices) and in hospital/clinical laboratories for detection and/or treatment of medical conditions and diseases. The Company's products are designed to enhance the health and well-being of people, while reducing total healthcare costs. Biomerica’s primarily focus is on gastrointestinal and inflammatory diseases where the Company has multiple diagnostic and therapeutic products in development.

About InFoods®

The Biomerica InFoods® IBS product is designed to allow physicians to identify patient-specific foods (e.g., eggs, broccoli, wheat, potatoes, corn, etc.), that when removed from the diet, may alleviate or improve an individual's IBS symptoms including, but not limited to, constipation, diarrhea, bloating, pain and indigestion. This patented, diagnostic-guided therapy is designed to allow for a patient-specific, guided dietary regimen to improve IBS outcomes. The point-of-care product is being developed to allow physicians to perform the test in-office using a finger stick blood sample while a clinical lab version of the product is expected to be the first for which the Company will seek regulatory approval. A billable CPT code that can be used by both clinical labs and physicians' offices is already available for InFoods® diagnostic products. Since the InFoods® product is a diagnostic-guided therapy, and not a drug, it has no drug type side effects. An estimated 45 million people in America currently suffer from IBS making it a leading cause for patient doctor visits.

The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for forward-looking statements. Certain information included in this press release (as well as information included in oral statements or other written statements made or to be made by Biomerica) contains statements that are forward-looking, such as statements relating to the efficacy of the Company’s COVID-19 tests, FDA clearance, EUA clearance, the rapidity of testing results, uniqueness of a product, accuracy of products, pricing of the Company’s test kits, demand for international orders, availability of the Company’s COVID-19 test kits, and patent protection on the test technology. Such forward-looking information involves important risks and uncertainties that could significantly



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affect anticipated results in the future, including, without limitation: results of studies testing the efficacy of the Company's COVID-19 tests; regulatory approvals necessary prior to commercialization of the Company's COVID-19 tests; availability of the Company's COVID-19 test kits; capacity, resource and other constraints on our suppliers; dependence on our third party manufacturers; dependence on international shipping carriers; governmental import/export regulations; demand for our various COVID-19 tests; competition from other similar products and from competitors that have significantly more financial and other resources available to them; governmental virus control regulations that make it difficult or impossible for the company to maintain current operations; regulations and the Company's ability to obtain patent protection on any aspects of its rapid test technology. Accordingly, such results may differ materially from those expressed in any forward-looking statements made by or on behalf of Biomerica. Additionally, potential risks and uncertainties include, among others, fluctuations in the Company's operating results due to its business model and expansion plans, downturns in international and or national economies, the Company's ability to raise additional capital, the competitive environment in which the Company will be competing, and the Company's dependence on strategic relationships. The Company is under no obligation to update any forward-looking statements after the date of this release.

1. medRxiv preprint doi: <https://doi.org/10.1101/2020.03.30.20047365>. Accessed 15Jun20

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