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# Passage of the 21st Century Cures Act and its Potential Implications on Biodefense

SAN DIEGO, Dec. 21, 2016 /PRNewswire/ -- Aethlon Medical, Inc. (Nasdaq: AEMD), today released the following note authored by its Chairman and CEO, Jim Joyce.

Last week, President Obama signed the 21st Century Cures Act into law. The $6.3 billion bill establishes new rules that direct the United States Food and Drug Administration (FDA) to approve drugs and devices with greater urgency. Specific to medical devices, the Act requires the FDA to establish a priority review program for "breakthrough" devices, or for devices that target diseases for which no FDA-cleared or approved alternatives are available.

A significant void in healthcare is the lack of FDA-cleared therapies to defend against infectious pathogens that emerge naturally or are created by man as agents of bioterrorism. At present, U.S. citizens are naked against most of these threats. As an example, only a small number of the 300+ viruses known to be infectious to man are addressed with an FDA-cleared drug or vaccine.

With the Cures Act now signed into law, the incoming Trump administration has an opportunity to advance the broad-spectrum medical countermeasure goal set forth by the U.S. Department of Health and Human Services (HHS) 2015 Public Health Emergency Medical Countermeasure Enterprise, otherwise known as PHEMCE. If achieved, the PHEMCE broad-spectrum goal would spur the advancement of innovative therapeutics to defend against the many pathogens that are not addressed with traditional disease-specific drugs or vaccines approved by the FDA.

At Aethlon Medical, we are advancing our Hemopurifier® to fulfill the HHS broad-spectrum objective. As a medical device, we believe the Hemopurifier is the first therapeutic candidate of its kind to be advanced in FDA-approved studies. Based on previous pre-clinical and human clinical outcomes, we also believe that our Hemopurifier is a leading broad-spectrum countermeasure (additional details at the end of this note) against virulent viral pathogens that remain beyond the reach of drug and vaccine therapies.

In the case of pathogen threats, there is often an assumption that sufficient government spending will yield drug and vaccine cures. However, our government has spent an estimated $80 billion since 2001 on biodefense initiatives, yet just one of 13 viruses classified as "Category A" are addressed with an approved therapy. "Category A" pathogens are biological threats that pose the highest risk to national security and public health. In the meantime, a confluence of global warming, urban crowding and global travel are expected to fuel increased occurrences of pandemic outbreaks in the future.

Leveraging the Cures Act to advance the HHS broad-spectrum objective should be a priority

initiative for the incoming administration, as historic attempts to align a disease-specific drug or vaccine with a pathogen threat have proven to be an immensely challenging feat that fails far more often than it succeeds. While a safe and effect vaccine would provide the greatest protection against a virulent pathogen, we recognize that it is statistically improbable for such a disease-specific countermeasure to be developed, proven effective, manufactured, and then delivered within a time frame necessary to combat an emerging life-threatening pathogen. In the case of highly virulent pathogens, it is often not feasible to conduct controlled human studies that are necessary to demonstrate the benefit of a disease-specific drug or vaccine. As pathogen outbreaks are also unpredictable, there is limited commercial incentive for researchers to develop disease-specific therapies prior to an outbreak.

Ebola and Zika virus are recent examples of pathogen threats that were known to be infectious to man for decades. Yet, when they suddenly emerged, no proven antiviral drug or vaccine was available. The broad-spectrum goal of HHS offers to inspire therapeutic innovation that could overcome the challenge of aligning a therapy with each and every pathogen threat. Instead of inhibiting the replication of a specific pathogen, broad-spectrum therapies would stimulate or protect the immune system's ability to combat a wide range of pandemic infections. In the treatment of cancer, similar strategies are already being advanced through the development of immuno-oncology devices and drugs.

Then, there is the issue of bioterrorism. Last month, the President's Council of Advisors on Science and Technology (PCAST), which consists of 18 scientists and policy experts in various disciplines, issued a letter to President Obama to recommend the implementation of new countermeasures to deal with artificially engineered pathogens as they have the potential to be even more dangerous than naturally occurring pandemic threats. PCAST was especially concerned with the emergence and availability of CRISPR gene-editing technology, which provides a platform to alter and enhance a pathogen to more lethal. The PCAST recommendation further reinforces the immense value that a broad-spectrum countermeasure could have in protecting U.S. citizens.

The recently published book "Pandemic: Tracking Contagions from Cholera to Ebola and Beyond," cites a survey by Dr. Larry Brilliant in which 90 percent of epidemiologists predict that a pandemic event will sicken 1 billion individuals, kill up to 165 million, and trigger a global recession at some point in the next two generations. While such a prediction may seem dire, an outbreak of similar magnitude did occur in the last century. In 1918 and 1919, a virulent strain of influenza virus was estimated to have infected one-third of the world's population and killed an approximate 50 million people. Since that outbreak, the world population has grown from 1.8 billion to 7.4 billion individuals.

We applaud the passage of the 21st Century Cures Act and encourage the incoming administration to leverage the mandates of the Act to advance the HHS broad-spectrum vision before the next large-scale pandemic.

**About the Aethlon Hemopurifier®**

The Aethlon Hemopurifier® is a first-in-class medical technology currently being advanced in FDA approved studies as a broad-spectrum treatment countermeasure against infectious viral pathogens. Named a "Top 25 Invention" and one of the "Eleven Most Remarkable Advances in Healthcare," by TIME Magazine, the Hemopurifier® has previously been administered to individuals infected with Ebola virus, Hepatitis C virus and the Human

Immunodeficiency virus, which leads to HIV AIDS.

Beyond human treatment experiences, pre-clinical Hemopurifier studies have validated the capture of Chikungunya, Dengue, Middle East Respiratory Syndrome Coronavirus, West Nile and Zika virus, as well as Vaccinia and Monkey pox, which serve as models for human Smallpox infection. Specific to pandemic influenza threats, Aethlon has validated the capture of H5N1 avian flu, H1N1 swine flu, and the reconstructed 1918 influenza virus, which represents a model for the strain of influenza that killed an estimated 50 million victims in 1918 and 1919. To validate treatment performance, the Hemopurifier is supported by the HP Virus Capture Assay, which quantifies the number of viruses captured within the Hemopurifier and no longer circulating in the patient.

**About Aethlon Medical**

Aethlon Medical (Nasdaq: AEMD) is a leading developer of immunotherapeutic technologies to combat infectious disease and cancer. To augment the body's natural immune defenses, the Aethlon Hemopurifier® eliminates life-threatening disease targets that are often shielded from the immune system and not well addressed by traditional drug therapies. The technology captures circulating viruses, bacterial toxins and cancer promoting exosomes through affinity attachment to a unique structure that cloaks these targets from immune detection. At present, the Hemopurifier® is being advanced under an FDA approved clinical study. Aethlon is also the majority owner of Exosome Sciences, Inc., a company focused on the discovery of exosomal biomarkers to diagnose and monitor life-threatening diseases. Aethlon is part of the Russell Microcap® Index. Additional information can be found online at www.AethlonMedical.com or you can connect with us on Twitter, LinkedIn, Facebook and Google+.

*This press release contains 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 that involve risks and uncertainties. Statements containing words such as "may," "believe," "anticipate," "expect," "intend," "plan," "project," "will," "projections," "estimate," or similar expressions constitute forward-looking statements. Such forward-looking statements are subject to significant risks and uncertainties and actual results may differ materially from the results anticipated in the forward-looking statements. Factors that may contribute to such differences include, without limitation, the Company's ability to maintain its listing on the Nasdaq Capital Market, or any other national securities exchange, that the Company or its subsidiary will not be able to commercialize its products, that the FDA will not approve the initiation or continuation of the Company's clinical programs or provide market clearance of the Company's products, including clearance through the 21st Century Cures Act, the Company's ability to raise capital when needed, the Company's ability to complete the development of its planned products, the Company's ability to manufacture its products either internally or through outside companies, the impact of government regulations, patent protection on the Company's proprietary technology, the ability of the Company to meet the milestones contemplated in its contract with DARPA, product liability exposure, uncertainty of market acceptance, competition, technological change, and other risk factors. The foregoing list of risks and uncertainties is illustrative, but is not exhaustive. Additional factors that could cause results to differ materially from those anticipated in forward-looking statements can be found under the caption "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended March 31, 2016, and in the Company's other filings with*

*the Securities and Exchange Commission. Except as may be required by law, the Company does not intend, nor does it undertake any duty, to update this information to reflect future events or circumstances.*

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