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The Dilemma in Funding Zika and Other Pandemic Therapies

SAN DIEGO, Sept. 9, 2016 /PRNewswire/ -- Aethlon Medical, Inc. (Nasdaq: AEMD), today released the following note authored by its Chairman and CEO, Jim Joyce.

After a seven-week vacation, the U.S. Congress and Senate returned to work on Tuesday and immediately restarted the fight to advance a Zika virus funding program. Beyond normal political posturing, government officials face the dilemma of whether to allocate resources to support the advancement of traditional drugs and vaccines or emerging broad-spectrum therapies. As it relates to viral pandemics, there is often an assumptive complacency that drug and vaccine cures are just a matter of spending sufficient capital resources. In reality, the effort to align a disease-specific drug or vaccine with an emerging pandemic threat is immensely challenging and not often successful. Especially in the case of a virulent pathogen that may prohibit human studies from being conducted to demonstrate treatment efficacy.

Emerging pandemics represent significant threats to mankind and Zika is just one of many active pathogen threats not addressed with a traditional drug and vaccine. Beyond pathogens known to be infectious to man, a proliferation of international travel, urban crowding and global warming are expected to accelerate the emergence of new pandemic threats in the future. Then, there is the issue of pathogens created and released by man as agents of bioterrorism.

Our government has an opportunity to inspire the biotechnology industry to fuel innovation through the development of broad-spectrum treatment countermeasures that can cross the boundaries of treating different strains, species and families of life-threatening viral pathogens. The facts underlying the challenge of aligning a disease-specific drug or vaccine with each pathogen threat reinforces the need for broad-spectrum therapeutic innovation.

Statistical Improbability

It is statistically improbable for traditional pathogen-specific drugs and vaccines to be developed, proven to be effective, manufactured and then delivered in a timeframe necessary to combat a life-threatening bioterror or pandemic threat. As pathogen outbreaks cannot be predicted, the current universe of therapeutic developers is extremely limited as there is no commercial incentive to develop such countermeasures from a business model perspective.

Conversely, the U.S. Food and Drug Administration (FDA) reports that hundreds and sometimes thousands of chemical drug compounds must be made and tested to find one that can achieve a desirable result without serious side effects. To further support this statement, the FDA website reports that the Pharmaceutical Research and Manufacturers of

America estimates that only 5 in 5,000 compounds that enter preclinical testing make it to human testing, and only 1 of those 5 may be safe and effective enough to be approved. Beyond those statistics, expectations for traditional countermeasures should further be tempered as each pathogen threat may require multiple drug mechanisms to address the corresponding pathogen threat. In regards to Zika, there are likely no more than a handful of candidate drug compounds that have been proposed to treat the virus.

Too Many Threats

Of the more than 300 viruses known to be infectious to man, only a small fraction are addressed with a proven antiviral drug or vaccine countermeasure. It has been estimated that our government has spent more than $80 billion to defend against biological threats since 2001. Yet, just one of 13 viruses classified as "Category A" have been addressed with a treatment countermeasure. The National Institute for Allergy and Infectious Diseases (NIAID) considers "Category A" pathogens to be biological agents that pose the highest risk to national security and public health as they are easily disseminated, result in high mortality rates, and cause public panic and social disruption. Furthermore, the development of disease-specific drug and vaccine countermeasure against unknown viral threats is not possible until the pathogen has either emerged naturally or been released by man as an agent of bioterrorism.

Inability to Demonstrate Effectiveness

Perhaps the greatest challenge in advancing a disease-specific drug or vaccine is the inability to ethically or feasibly conduct controlled human studies that demonstrate treatment efficacy against a virulent threat. As a result, treatment efficacy is required to be demonstrated in animal models, which in many cases either don't exist or don't equate to treatment efficacy in humans. As a result, at-risk populations (those most likely to need protection) such as pregnant women (a primary treatment target for Zika), children, elderly adults and those with other underlying medical conditions are not recommended to receive therapeutic candidates that are not proven to be effective in humans studies.

A Shift Towards Broad-Spectrum Treatment Countermeasures

The challenge of aligning a drug and vaccine with each pathogen threat has already established an impetus for U.S. government health agencies to support innovative therapeutic mechanisms that can be deployed against a wide-range of pathogen threats. Such evidence is best reflected in the 2015 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan (SIP), which describes the priorities that the U.S. Department of Health and Human Services (HHS) will implement over the next five years to protect against bioterror and emergency pandemic threats. A primary objective of the PHEMCE SIP includes the advancement of platform technology medical countermeasures with broad-spectrum capabilities. We are working to establish the Aethlon Hemopurifier®, which is being advanced clinically in an FDA approved study, as a leading broad-spectrum treatment countermeasure.

The Hemopurifier® is an immunotherapeutic technology designed for the single-use elimination of infectious viruses from the circulatory system. The technology provides a post-exposure treatment strategy to mitigate illness, suffering, and death resulting from exposure to virulent viral pathogens that are often beyond the reach of drug and vaccine therapies. In

addition to Zika virus, in vitro studies have validated the broad-spectrum capture of numerous viral threats. These include: Chikungunya, Dengue and West Nile virus, which is currently spreading in the U.S. and is responsible for numerous deaths. Vaccinia and Monkey pox, which serve as models for human Smallpox infection, have also been validated. Specific to pandemic influenza threats, we have validated the capture of H5N1 avian flu, H1N1 swine flu, and the reconstructed 1918 influenza virus, which killed as many as 50 million individuals. In regards to human studies, Hemopurifier therapy has been successfully administered to individuals infected with Ebola virus, Hepatitis C virus (HCV) and the Human Immunodeficiency virus (HIV).

Additional studies are currently being conducted to validate the capture of Middle East Respiratory Syndrome Coronavirus (MERS-CoV), which has a fatality rate of approximately 40%, and Marburg Virus, which is classified as a "Category A" bioterror and pandemic threat with a fatality rate exceeding 50%.

Zika and other emerging pandemic viruses represent a significant threat to mankind. We believe that broad-spectrum treatment countermeasures that cross the boundaries of different strains, species and families of viruses, should be the basis for life-saving innovation that will be necessary to combat emerging pandemic threats around the globe. With Congress and the Senate now back at work, the political debate of how to protect against Zika and other pandemics can now continue.

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+.

The Hemopurifier® in Cancer

Upwards of ninety percent of all cancer-related deaths are attributed to metastasis; the spread of cancer from a primary site of origin to other organs or areas of the body. The mechanism of how tumors metastasize to distant sites in the body has long been one of cancer's greatest mysteries. That mystery was recently solved when circulating particles known as tumor-derived exosomes were discovered to be the seeds that promote the spread and growth of cancer metastasis.

Aethlon initiated its tumor-derived exosome research at a time when the medical community believed exosomes were merely cellular debris with no biological function. Today, a therapeutic to address tumor-derived exosomes represents a significant unmet need in cancer care. Aethlon has demonstrated that the affinity mechanism of the Hemopurifier®

can capture tumor-derived exosomes underlying several forms of cancer, including breast, ovarian and metastatic melanoma.

Beyond their role in metastasis, researchers have also published mounting evidence that tumor-derived exosomes contribute to tumorigenesis (the formation of cancer), cancer progression, angiogenesis (creation of blood vessels to fuel tumor growth), immune evasion, and resistance to radiation and chemotherapeutic drugs. Recent discoveries also reveal that exosomes may contribute to bacterial and viral pathogenesis, the progression of Alzheimer and Parkinson's diseases, the spread of prion proteins, and numerous inflammatory conditions.

The Hemopurifier® in Infectious Disease

Emerging pathogens pose a significant threat to mankind. Of the hundreds of viral pathogens known to be infectious to man, only a few are addressed with proven antiviral drug or vaccine therapies. Beyond the looming threat of bioterrorism, a proliferation of international travel, urban crowding and global warming is expected to accelerate the emergence of future pandemics. In response, the U.S. Department of Health and Human Services (HHS) has established an initiative to support platform technology medical countermeasures with broad-spectrum capabilities. Based on preclinical studies and human treatment experiences, the Aethlon Hemopurifier® defines this initiative.

To date, Hemopurifier therapy has been administered to individuals infected with Ebola virus, Hepatitis C virus (HCV) and the Human Immunodeficiency virus (HIV). In the case of Ebola, a remarkable response to a single administration of Hemopurifier therapy (comatose physician with multiple organ failure at the time), led to Time Magazine naming the Hemopurifier to be one of the "Top 25 Inventions" as well as one of the "Eleven Most Remarkable Advances in Healthcare."

Beyond human treatment experiences, pre-clinical Hemopurifier studies have validated the broad-spectrum capture of numerous viral threats. These include: Chikungunya, Dengue and West Nile 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. *In vitro* studies of other viral threats are ongoing.

Aethlon has also demonstrated that the Hemopurifier captures the bacteria toxins lipopolysaccharide (LPS) and lipoteichoic acid (LTA). These studies were conducted under a contract with the Defense Advanced Research Projects Agency (DARPA) related to the treatment of sepsis.

About Exosome Sciences

Exosome Sciences, Inc., in collaboration with majority shareholder Aethlon Medical (Nasdaq: AEMD), is focused on the discovery of exosomal biomarker candidates to diagnose and monitor life-threatening diseases. The proprietary Enzyme-Linked Lectin-Specific Assay (ELLSA™) serves as a platform to isolate exosomal biomarkers from a wide-range of bodily fluids. In preliminary studies, ELLSA™ demonstrated the ability to isolate exosomes from urine, which resulted in high-sensitivity detection of HIV-infection. Specific to

neurological disorders, Exosome Sciences discovered TauSome™, an exosomal biomarker that may be the first non-invasive candidate to detect Chronic Traumatic Encephalopathy (CTE) in living individuals. In a study of former National Football League (NFL) players, TauSome levels were found to be significantly higher as compared to athlete control subjects who participated in non-contact sports. TauSome levels also correlated with cognitive decline based standardized tests of memory and psychomotor speed. Visit www.exosomesciences.com for additional details.

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 any products relating to the Zika virus, 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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