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Aethlon Medical Announces Fiscal 2017 Second Quarter Results

SAN DIEGO, Nov. 10, 2016 /PRNewswire/ -- Aethlon Medical, Inc. (Nasdaq: AEMD), a developer of immunotherapeutic technologies to combat infectious disease and cancer, today announced results for its fiscal second quarter year ended September 30, 2016.

Aethlon's lead therapeutic candidate is the Aethlon Hemopurifier®, a first-in-class device that provides broad-spectrum elimination of infectious viruses and cancer-promoting exosomes from the circulatory system. In collaboration with its majority-owned Exosome Sciences, Inc. (ESI) subsidiary, the company is focused on the discovery of exosome-based biomarkers to diagnose and monitor a wide range of disease conditions.

Corporate activities during the quarter and the six months fiscal year to date include:

- Continued clinical advancement of the Aethlon Hemopurifier®, which the Company believes to be the first and only medical device being advanced in FDA approved studies as a broad-spectrum treatment countermeasure against infectious viral pathogens. The Company is advancing the Hemopurifier® to fulfill the broad-spectrum medical countermeasure goal of the U.S. Department of Health and Human Services 2015 Public Health Emergency Medical Countermeasure Enterprise (PHEMCE), which includes participation and support from the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the Department of Defense (DOD), the U.S. Department of Veterans Affairs (VA) and the Department of Homeland Security (DHS).
- During the quarter, the Company completed in vitro studies that demonstrated the capture of Zika virus by the Aethlon Hemopurifier.
- The Company further disclosed that it has completed in vitro studies that confirm the capture of Middle East Respiratory Syndrome Coronavirus (MERS-CoV) by the Hemopurifier. MERS-CoV was first reported in 2012, has spread to over 22 countries and has a mortality rate of 35%. Like Zika virus, there is no proven antiviral drug or vaccine to treat MERS-CoV.
- The Company disclosed that the FDA approved Hemopurifier feasibility study being conducted at DaVita Med Center in Houston is moving toward completion. As a result, the Company provided guidance related to 2017 U.S. clinical progression objectives. The 2017 guidance included the submission of a pivotal study protocol to FDA, the submission of one or more Humanitarian Use Device applications to FDA and the pursuit of Emergency-Use Authorization pathways that result from emerging pandemic outbreaks or bioterror events that become declared a national emergency by the Secretary of Health and Human Services. The Company previously received and maintains such authorization to treat Ebola virus in the United States and Canada.
- The Company achieved 29 of 29 milestone targets to complete a Department of Defense (DOD) Contract through the Defense Advanced Research Projects Agency

(DARPA), which generated overall revenues of approximately \$5.9 million.

- The Company disclosed that it has submitted responses to two new DOD infectious disease contract solicitations and also has submitted a contract response to the National Cancer Institute related to tumor-derived exosomes.
- Related to tumor-derived exosomes, the Company disclosed that the completion of the current Hemopurifier® feasibility study being conducted in Houston would be an impetus for discussions with FDA related to the potential first-in-human treatment of cancer patients with Hemopurifier therapy. Tumor-derived exosomes represent a significant unmet need in oncology as they promote the spread of metastasis, suppress the immune system and contribute to chemotherapy and immuno-oncology drug resistance. Management believes that reducing the presence of tumor-derived exosomes in circulation could improve the benefit of established cancer therapies, including immuno-oncology drugs and chemotherapeutic regimens.
- Future research endeavors includes the introduction of a prototype cerebral spinal fluid (CSF) therapeutic platform that leverages proprietary pathogen isolation techniques as a potential candidate to address CSF related viral, neurological and central nervous system disorders. The Company also indicated that it plans to introduce a study that would explore the potential use of Hemopurifier therapy in immune-suppressed sepsis and organ transplant patients.
- Disclosed that reported institutional and mutual fund ownership in the company has increased to over 22% with more than 25 such holders.
- The Company reported that it continues to maintain operational burn rates of approximately \$300,000 per month and has more than \$12 million of an original \$12.5 million "At The Market" financing facility available, which provides access to capital at prevailing market prices.
- Exosome Sciences (ESI) Subsidiary – The Company disclosed that the recruitment of former NFL players to participate in study supported by a \$16 million NIH grant awarded to collaborators at the Boston University CTE Center has begun. An objective of the study is to advance a test that could diagnose Chronic Traumatic Encephalopathy (CTE) in living individuals. ESI previously collaborated with the Boston University team to discover a TauSome biomarker, which is believed to be the first candidate biomarker to diagnose CTE in living individuals. In a 94-subject study, ESI measured TauSome levels to be approximately 9x higher in former NFL players as compared to same-age control subjects. ESI has agreed to provide continued TauSome testing analysis in the new NIH supported study. The Company further disclosed that ESI is exploring TauSome studies in other neurological conditions.

Financial Results

At September 30, 2016, the Company had a cash balance of approximately \$556 thousand. That cash position combined with capital generated under the \$12.5 million At-The-Market financing agreement will continue to be used to fund our FDA-approved feasibility study in the U.S. and operations.

The Company recorded revenues of \$387 thousand from its government contracts in the second quarter of fiscal 2017 compared to \$188 thousand in the second quarter of fiscal 2016. The increase was due to the achievement of two milestones under our DARPA contract in 2017 period compared to achieving one milestone in the prior year period.

Consolidated operating expenses were \$2.6 million in the second quarter of fiscal 2017 compared to \$1.3 million in the prior year period. This increase of \$1.3 million was due to increases in payroll and related expenses of \$1.2 million and in professional fees of \$122 thousand, which were partially offset by a reduction in general and administrative expenses of \$36 thousand.

The \$1.2 million increase in payroll and related expenses was due to a \$1.5 million increase in non-cash stock-based compensation, which was partially offset by a \$257 thousand decrease in cash-based compensation. The increase in stock-based compensation was the result of the RSU grants to our officers and directors in the three months ended September 30, 2016. The expense related to the RSU issuances was offset by an increase in our equity.

The Company had other expense of \$37 thousand in the second quarter of fiscal 2017 compared to \$127 thousand in the prior year period, a decrease of \$90 thousand. All of our other expense in both periods was interest expense. The most significant factor in the \$90 thousand decrease in interest expense was the \$74 thousand decrease in the amortization of note discounts, which related to the amortization against the discount on the convertible notes that we issued in November 2014. Other smaller factors in the change in our total interest were a \$20 thousand decrease in the amortization of deferred financing costs and a \$4 thousand increase in our contractual interest expense.

Overall, the net loss for the second quarter of fiscal 2017 was \$2.3 million, or \$0.29 per share, compared to a net loss of \$1.2 million, or \$0.16 per share in the prior year period.

The unaudited condensed consolidated balance sheet for September 30, 2016 and the unaudited condensed consolidated statements of operations for the three and six month periods ended September 30, 2016 and 2015 follow at the end of this release.

Conference Call

Aethlon will hold a conference call for investors on Thursday, November 10, 2016 at 1:30 p.m. PT (4:30 p.m. ET). Investors may access the call by dialing 844-836-8741 (domestic) or 412-317-5442 (International). A live webcast of the call will be available from the Investor Relations section of www.aethlonmedical.com. A recording of the call will also be available by calling 877-344-7529; access code 10096196 beginning approximately two hours after the call, and will be available for one week. A webcast replay from today's call will also be available from the Investor Relations section of www.aethlonmedical.com approximately one hour after the call and will be available for up to three months.

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. 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, 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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AETHLON MEDICAL, INC. AND SUBSIDIARIES**Condensed Consolidated Balance Sheet****ASSETS**

	September 30, 2016	March 31, 2016
CURRENT ASSETS		
Cash	\$556,352	\$2,123,737
Accounts receivable	193,719	199,471
Prepaid expenses	66,469	53,294
TOTAL CURRENT ASSETS	816,540	2,376,502
Property and equipment, net	22,969	36,038
Patents, net	89,579	94,161
Other assets	21,747	22,415
TOTAL NONCURRENT ASSETS	134,295	152,614
TOTAL ASSETS	\$950,835	\$2,529,116

LIABILITIES AND STOCKHOLDERS' EQUITY**CURRENT LIABILITIES**

Accounts payable	384,728	244,804
Due to related parties	58,362	145,112

Convertible notes payable, current portion	605,815	-
Other current liabilities	35,316	136,695
TOTAL CURRENT LIABILITIES	1,084,221	526,611
NONCURRENT LIABILITIES		
Convertible notes payable, net of current portion	-	500,139
TOTAL NONCURRENT LIABILITIES	-	500,139
TOTAL LIABILITIES	1,084,221	1,026,750
COMMITMENTS AND CONTINGENCIES		
EQUITY		
Common stock, par value of \$0.001, 30,000,000 shares authorized; 7,622,393 and 6,657,046 issued and outstanding	7,711	7,621
Additional paid in capital	90,811,302	88,047,142
Deficit accumulated during the development stage	(90,886,645)	(86,502,043)
TOTAL STOCKHOLDERS' EQUITY BEFORE NONCONTROLLING INTERESTS	(67,632)	1,552,720
Noncontrolling interests	(65,754)	(50,354)
TOTAL STOCKHOLDERS' EQUITY	(133,386)	1,502,366
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$950,835	\$2,529,116

AETHLON MEDICAL, INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations

For the three and six months ended September 30, 2016 and 2015

Three Months Three Months Six Months Six Months

	Ended 9/30/16	Ended 9/30/15	Ended 9/30/16	Ended 9/30/15
Government contract revenue	\$387,438	\$188,366	\$392,073	\$380,874
OPERATING EXPENSES				
Professional fees	510,982	389,207	1,078,731	927,433
Payroll and related	1,813,003	597,850	2,158,190	1,056,078
General and administrative	290,131	325,670	513,681	611,695
	2,614,116	1,312,727	3,750,602	2,595,206
OPERATING LOSS	(2,226,678)	(1,124,361)	(3,358,529)	(2,214,332)
OTHER (INCOME) EXPENSE				
Debt extinguishment expense	-	-	616,889	-
Warrant repricing expense	-	-	345,841	-
Interest and other debt expenses	36,576	127,245	78,743	253,933
	36,576	127,245	1,041,473	253,933
NET LOSS BEFORE NONCONTROLLING INTERESTS	\$(2,263,254)	\$(1,251,606)	\$(4,400,002)	\$(2,468,265)
Loss attributable to noncontrolling interests	(7,668)	(27,000)	(15,400)	(60,623)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$(2,255,586)	\$(1,224,606)	\$(4,384,602)	\$(2,407,642)
Basic and diluted net loss available to common stockholders per share	\$ (0.29)	\$ (0.16)	\$ (0.57)	\$ (0.34)
Weighted average number of common shares outstanding	7,756,883	7,610,459	7,690,369	7,167,903

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