

# Aethlon Medical Announces First Quarter Financial Results and Provides Corporate Update

SAN DIEGO, Aug. 9, 2022 /PRNewswire/ -- Aethlon Medical, Inc. (Nasdaq: AEMD), a medical therapeutic company focused on developing products to diagnose and treat cancer and life threatening infectious diseases, today reported financial results for its first quarter ended June 30, 2022 and provided an update on recent developments.

# **Company Updates**

Aethlon Medical is continuing the research and clinical development of its Hemopurifie®, a therapeutic blood filtration system that can bind and remove life-threatening viruses and harmful exosomes from blood. This action has potential applications in cancer, where cancer associated exosomes may promote immune suppression and metastasis, and in life-threatening infectious diseases, including removal of COVID-19 virus, associated variants, and related exosomes.

We recently published a peer-reviewed manuscript demonstrating that Aethlon's proprietary GNA affinity resin, a key component of the Hemopurifier, was able to bind seven clinically relevant SARS-CoV-2 variants *in vitro*, including the Delta and Omicron variants. Viral capture efficiency with the GNA affinity resin ranged from 53% to 89% for all variants tested. The findings from this paper suggest that the Hemopurifier should be able to bind any future SARS-CoV-2 variants that may potentially arise. The manuscript is titled "Removal of Clinically Relevant SARS-CoV-2 Variants by An Affinity Resin Containing Galanthus Nivalis Agglutinin" and was published in *PLOS ONE* on July 28, 2022.

We continue to advance our severe COVID-19 clinical trial for the Hemopurifier under our open Investigational Device Exemption (IDE) for life-threatening viral infections. Since our last update, the first patient has completed the study. Our active sites continue to actively screen patients along with our contract research organization (CRO), PPD, Inc. On July 6, 2022, the U.S. Food and Drug Administration (FDA) approved a supplement to our COVID-19 trial. The newly approved protocol supplement eliminates the inclusion criteria that patients must have a dialysis catheter in place and have tolerated dialysis at the time of screening. This change should improve the feasibility of enrolling new patients into our study. The active sites are currently submitting this supplement to their IRBs, and we expect to have their approvals in August and September 2022.

Medanta Medicity Hospital, a multi-specialty hospital in Delhi NCR, India, has enrolled one patient in our COVID-19 trial in India and continues to actively screen patients. Our CRO, Qualtran LLC, has identified additional potential sites for the trial in India and is currently assessing feasibility.

In addition to our work with COVID-19, we continue to screen patients for our IDE clinical trial in head and neck cancer. We have submitted a protocol supplement to the FDA to request the inclusion of patients who have failed platinum chemotherapy in the trial. If accepted by the FDA, this change would increase the eligible population for the study. We are currently drafting a protocol for a new clinical trial to allow us to examine the effects of the Hemopurifier in multiple tumor types where the cancer has progressed, following a twomonth period of checkpoint inhibitor therapy.

Given the ongoing outbreak of monkeypox virus (MPXV), Aethlon is commissioning a newin *vitro* binding experiment to confirm that the Hemopurifier effectively captures the current strain of that virus. In 2008, we conducted an *in vitro* study that demonstrated that the Hemopurifier effectively bound and removed MPXV. We believe that the Hemopurifier's ability to bind the current MPXV strain should not be affected because the mutations present in this strain do not change the mannose sugar in the viral envelope, which is recognized by the GNA within the Hemopurifier resin.

For more context regarding the 2008 study, we commissioned Battelle Memorial Institute to run an MPXV in vitro study using a miniature version of our Hemopurifier. This study demonstrated that high concentrations of MPXV, approximately 35,000s GPUs per mil, were rapidly depleted from cell culture fluids when circulated through the Hemopurifier. The study indicated that the Hemopurifier removed 44% of monkeypox virus in the first hour of testing, 82% after six hours, and 98% after 20 hours. The studies were conducted in triplicate and data verification was provided by real time polymerase chain reaction (PCR).

We continue to monitor MPXV caseload and disease severity. We have contacted the FDA and confirmed the process by which we could provide the Hemopurifier to requesting physicians for single patient emergency use. On August 4, 2022, the U.S. Department of Health and Human Services (DHHS) officially declared Monkeypox a health emergency. An Emergency Use Authorization (EUA) declaration has not yet been made. We plan to submit a pre-EUA package to the FDA so as to be prepared in the event this declaration occurs.

# Financial Results for the First Quarter Ended June 30, 2022

As of June 30, 2022, Aethlon Medical had a cash balance of approximately \$14.9 million.

Consolidated operating expenses for the three months ended June 30, 2022, were approximately \$2.91 million, compared to \$2.23 million for the three months ended June 30, 2021. This increase of approximately \$680,000, or 30%, in the 2022 period was due to increases in our general and administrative expenses of approximately \$402,000, in our professional fees of approximately \$261,000 and in our payroll and related expenses of approximately \$13,000.

The \$402,000 increase in our general and administrative expenses in the June 30, 2022, quarter was primarily due to the combination of a \$161,000 increase in our clinical trial expenses, a \$97,000 increase in supplies, a \$91,000 increase in our rent expense and a \$27,000 increase in our insurance expense.

The \$261,000 increase in our professional fees was primarily due to the combination of a \$154,000 increase in our contract labor expense associated with product development and analytical services and a \$95,000 increase in professional fees associated with regulatory

#### strategy services

The \$13,000 increase in our payroll and related expenses was due to an increase in our stock-based compensation expense of \$95,000. Our cash-based compensation expense decreased by \$82,000 because our CEO received a \$215,000 bonus in the June 2021 period for achieving certain contractual milestones in his employment agreement and there were no bonuses paid out in the June 2022 period.

Aethlon did not record any revenue related to our government contracts with the NIH in the three months ended June 30, 2022, compared to approximately \$132,000 in the three months ended June 30, 2021. As of June 30, 2022, the Company had approximately \$459,000 of deferred revenue related to those contracts as a result of not achieving certain milestones in those contracts.

As a result of the changes in revenues and expenses noted above, Aethlon's net loss before noncontrolling interests increased to approximately \$2.9 million for the three months ended June 30, 2022, from approximately \$2.1 million for the three months ended June 30, 2021.

During the three months ended June 30, 2022, the Company raised approximately \$619,000 in net proceeds under our ATM agreement with H.C. Wainwright & Co., pursuant to sales of our common stock. In July and August 2022 to date, the Company raised approximately \$8.3 million under our ATM agreement through sales of our common stock.

The unaudited condensed consolidated balance sheet for June 30, 2022, and the unaudited condensed consolidated statements of operations for the three months ended June 30, 2022 and 2021 follow at the end of this release.

# **Conference Call**

The Company will hold a conference call today, Tuesday, Aug. 9, 2022, at 4:30 p.m. EDT to review financial results and recent corporate developments. Following management's formal remarks, there will be a question-and-answer session.

Interested parties can register for the conference by navigating to <u>https://dpregister.com/sreg/10170206/f3fcc2ec44</u>

Please note that registered participants will receive their dial in number upon registration.

Interested parties without internet access or unable to pre-register may dial in by calling:

PARTICIPANT DIAL IN (TOLL FREE): 1-844-836-8741 PARTICIPANT INTERNATIONAL DIAL IN: 1-412-317-5442

All callers should ask for the Aethlon Medical, Inc. conference call.

A replay of the call will be available approximately one hour after the end of the call through July 28, 2022. The replay can be accessed via Aethlon Medical's website or by dialing 1-877-344-7529 (domestic) or 1-412-317-0088 (international) or Canada Toll Free at 1-855-669-9658. The replay conference ID number is 2740523.

# About Aethlon and the Hemopurifier®

Aethlon Medical is a medical therapeutic company developing the Hemopurifier, a therapeutic blood filtration system indicated for infectious diseases and cancer. In human studies, the Hemopurifier has demonstrated the removal of life-threatening viruses and harmful exosomes from blood utilizing a proprietary lectin-based technology. This action has potential applications in cancer, where exosomes may promote immune suppression and metastasis, and in life-threatening infectious diseases.

The Hemopurifier is a U.S. Food and Drug Administration (FDA) designated Breakthrough Device indicated for the treatment of individuals with advanced or metastatic cancer who are either unresponsive to or intolerant of standard of care therapy, and with cancer types in which exosomes have been shown to participate in the development or severity of the disease. Under an Investigational Device Exemption (IDE) application, the FDA approved a single site, open-label Early Feasibility Study (EFS) to evaluate the Hemopurifier for reducing cancer-associated exosomes prior to the administration of standard-of-care pembrolizumab (KEYTRUDA®) in patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck. The EFS is being conducted at the University of Pittsburgh Medical Center Hillman Cancer Center.

The Hemopurifier also holds an FDA Breakthrough Device designation and an open IDE application related to the treatment of life-threatening viruses that are not addressed with approved therapies. A recent amendment to the IDE will enable Aethlon to implement a new EFS protocol to treat up to 40 COVID-19 patients at up to 20 clinical sites in the U.S. In two case studies of patients treated under Emergency Use (EU), the Hemopurifier demonstrated binding of SARS-CoV-2 spike protein and removal of SARS-CoV-2 virus from the circulation of a human patient.

Additional information can be found at www.AethlonMedical.com.

# **Forward-Looking Statements**

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," "potentially" 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. These forwardlooking statements are based upon Aethlon's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Factors that may contribute to such differences include, without limitation, the Company's ability to enroll additional sites for its clinical trials, IRB approval of and the timing of IRB approval of the new protocol for the Hemopurifier use in COVID trials; the Company's ability to submit to the FDA and have the FDA approve an EUA for the MPVX, the Company's ability to enroll patients in and successfully complete its trials in COVID-19 patients and in its head and neck cancer trials, the Company's ability to successfully treat patients under any Emergency Use pathway, the Company's ability to successfully complete development of its Hemopurifier, the Company's ability to raise additional funds, the Company's ability to obtain Emergency Use authorization from the FDA for use of the Hemopurifier to treat patients with the MPXV; the Company's ability expand its clinical trials into other areas of cancer, and other potential risks. 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, 2022, and in the Company's other filings with the Securities and Exchange Commission, including its quarterly Reports on Form 10-Q. All forward-looking statements contained in this press release speak only as of the date on which they were made. 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 SUBSIDIARY Condensed Consolidated Balance Sheets

ASSETS	June 30, 2022	March 31, 2022
CURRENT ASSETS		
Cash	\$14,921,775	\$17,072,419
Accounts receivable	114,849	127,965
Prepaid expenses	857,287	956,623
TOTAL CURRENT ASSETS	15,893,911	18,157,007
Property and equipment, net	451,894	441,238
Right-of-use lease asset	663,539	696,698
Patents, net	2,063	2,200
Restricted cash	87,506	87,506
Deposits	33,305	33,305
TOTAL ASSETS	\$17,132,218	\$19,417,954
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	439.745	499,962
Due to related parties	162,045	155,742
Deferred revenue	459,396	344,547
Lease liability, current portion	136,730	126,905
Other current liabilities	446,783	696,893
TOTAL CURRENT LIABILITIES	1,644,699	1,824,049
Lease liability, less current portion	567,321	602,505
TOTAL LIABILITIES	2,212,020	2,426,554
COMMITMENTS AND CONTINGENCIES		
EQUITY		
Common stock, par value of \$0.001, 30,000,000 shares		
authorized; 15,993,723 and 15,419,163 issued and outstanding	15,996	15,421
Additional-paid in capital	148,281,172	147,446,868
Accumulated deficit	(133,234,849)	(130,329,181
TOTAL STOCKHOLDERS' EQUITY BEFORE NONCONTROLLING INTERESTS	15,062,319	17,133,108
Noncontrolling interests	(142,121)	(141,708
TOTAL STOCKHOLDERS' EQUITY	14,920,198	16,991,400

#### AETHLON MEDICAL, INC. AND SUBSIDIARY Condensed Consolidated Statements of Operations For the three month periods ended June 30, 2022 and 2021

	Three Months Ended 6/30/22	Three Months Ended 6/30/21
Government contract revenue	\$-	\$131,966
OPERATING COSTS AND EXPENSES Professional fees Payroll and related General and administrative	844,028 1,029,686 1,032,367 2,906,081	583,469 1,016,742 630,193 2,230,404
OPERATING LOSS	(2,906,081)	(2,098,438)
NET LOSS	\$(2,906,081)	\$(2,098,438)
Loss attributable to noncontrolling interests	(413)	(1,135)
NET LOSS ATTRIBUTABLE TO AETHLON MEDICAL, INC	\$(2,905,668)	\$(2,097,303)
Basic and diluted net loss available to common stockholders per share	\$ (0.19)	\$ (0.16)
Weighted average number of common shares outstanding	15,486,621	12,828,816

<sup>C</sup> View original content:<u>https://www.prnewswire.com/news-releases/aethlon-medical-announces-first-quarter-financial-results-and-provides-corporate-update-301602739.html</u>

SOURCE Aethlon Medical, Inc.