

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K
CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **November 14, 2022**

AETHLON MEDICAL, INC.

(Exact name of Registrant as Specified in Its Charter)

Nevada
(State or Other Jurisdiction of Incorporation)

001-37487
(Commission File Number)

13-3632859
(IRS Employer Identification No.)

11555 Sorrento Valley Road, Suite 203
San Diego, California
(Address of Principal Executive Offices)

92121
(Zip Code)

Registrant's Telephone Number, Including Area Code: **(619) 941-0360**

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	AEMD	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On November 14, 2022, Aethlon Medical, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2022. A copy of this press release is attached hereto as Exhibit 99.1.

The information in this Item 2.02 and the exhibit hereto are being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated November 14, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 14, 2022

Aethlon Medical, Inc.

By: /s/ James B. Frakes
Name: James B. Frakes
Chief Financial Officer



Aethlon Medical Announces Second Quarter Financial Results and Provides Corporate Update

SAN DIEGO, Nov. 14, 2022 -- 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 second quarter ended September 30, 2022 and provided an update on recent developments.

Company Updates

Aethlon Medical is continuing the research and clinical development of its Hemopurifier®, a therapeutic blood filtration system that can bind and remove harmful exosomes and life-threatening viruses 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.

- Due to a scarcity of COVID patients in intensive care units eligible for enrollment into our U.S. COVID trial, we recently decided to terminate the agreement with our contract research organization (CRO). As a result, while our Investigational Device Exemption (IDE) related to severe viral infections remains open, we are discontinuing U.S. COVID clinical trial activity. We expect this decision to save the company up to \$5 million over the next twelve months, which we intend to allocate towards advancing the study of our Hemopurifier in oncology.
- Due to lack of patient enrollment by the University of Pittsburgh Medical Center (UPMC) in our head and neck cancer safety trial, we and UPMC have terminated this study. We are planning a new clinical trial in oncology that will potentially include more tumor types, enabling us to build our safety database in oncology and provide data to help direct the development of our Hemopurifier as a treatment option in oncology. We are in the latter stages of selecting a new CRO to supervise this new oncology study.
- In October 2022, we launched a wholly owned subsidiary in Australia, formed to conduct clinical research, seek regulatory approval, and commercialize our Hemopurifier in that country. The subsidiary will initially focus on the oncology market in Australia. Once selected, it is likely that our new CRO will oversee planned oncology studies in both the U.S. and Australia.
- Our COVID-19 trial site in India remains open with the goal of enrolling additional COVID-19 patients. We are considering opening an oncology trial in India as well.
- The addition of a second supplier for Galanthus nivalis agglutinin (GNA), used in the resin of our Hemopurifier, is delayed in the U.S., pending approval by the U.S. Food and Drug Administration (FDA) of the supplement to our IDE required to enact this manufacturing change. In our opinion, the FDA has mandated unexpectedly high testing requirements for a product in the safety and feasibility stage of development. The additional data requested by FDA may take us several months to obtain. We are escalating our concerns with the FDA decision by engaging the FDA's ombudsman. However, there can be no assurance that this escalation will accelerate our development timelines.
- Regulatory authorities in India have accepted this manufacturing change and, as a result, we will ship new cartridges to the site in India for use in our clinical trials there.
- We have engaged a major testing lab, Battelle (Columbus, OH), to perform *in vitro* study to examine the binding of the current Monkeypox strain to a miniature version of our Hemopurifier.

Financial Results for the Second Quarter Ended September 30, 2022

As of September 30, 2022, Aethlon Medical had a cash balance of approximately \$19.6 million.

Consolidated operating expenses for the three months ended September 30, 2022 were approximately \$3.67 million, compared to \$2.14 million for the three months ended September 30, 2021. This increase of \$1.53 million, or 71%, in the 2022 period was due to increases in our general and administrative expenses of \$863,000, in our professional fees of \$354,000 and in our payroll and related expenses of \$307,000.

The \$863,000 increase in our general and administrative expenses was primarily due to the combination of a \$384,000 increase in our clinical trial expenses, a \$258,000 increase in supplies, primarily for manufacturing Hemopurifiers, a \$140,000 increase in subcontract expenses related to our government contracts, a \$50,000 increase in our rent expense and a \$32,000 increase in our insurance expense.

The \$354,000 increase in our professional fees was primarily due to the combination of a \$152,000 increase in our contract labor expense associated with product development and analytical services, a \$136,000 increase in our legal fees and a \$61,000 increase in our investor relations expenses, primarily related to solicitation expenses associated with our 2022 annual meeting of stockholders.

The \$307,000 increase in our payroll and related expenses was due to an increase in our stock-based compensation expense of \$112,000. Our cash-based compensation expense increased by \$195,000 due to our increased headcount.

In September 2022, the Board of Directors of Exosome Sciences, Inc. (ESI) and Aethlon, as the majority stockholder of ESI, approved the dissolution of ESI. As a result of this dissolution, we recorded a non-cash charge of \$142,121 as other expense in the three months ended September 30, 2022.

Aethlon did not record any revenue related to our government contract with the NIH in the three months ended September 30, 2022, compared to approximately \$132,000 in the three months ended September 30, 2021. As of September 30, 2022, the Company had approximately \$574,000 of deferred revenue related to those contracts as a result of not achieving certain milestones in those contracts. The NIH award contract ended on September 15, 2022 and we presented the required final report to the NCI. Once the NCI completes the close out review of the contract, we expect to recognize as revenue the \$574,000 currently recorded as deferred revenue on our September 30, 2022 balance sheet.

As a result of the changes in revenues and expenses noted above, our net loss increased to approximately \$3.8 million in the three months ended September 30, 2022, from approximately \$2.0 million in the three months ended September 30, 2021.

During the six months ended September 30, 2022, the Company raised approximately \$8.9 million in net proceeds under our ATM agreement with H.C. Wainwright & Co., pursuant to sales of our common stock.

The unaudited condensed consolidated balance sheet for September 30, 2022, and the unaudited condensed consolidated statements of operations for the three and six months

ended September 30, 2022 and 2021 follow at the end of this release.

Conference Call

The Company will hold a conference call today, Monday, Nov. 14, 2022, at 4:30 p.m. EST 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 <https://dpregrister.com/sreg/10172901/f4fe08e0d7>

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

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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 December 14, 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 2753791.

About Aethlon and the Hemopurifier®

Aethlon Medical is a medical therapeutic company developing the Hemopurifier, a therapeutic blood filtration system indicated for cancer and infectious diseases. 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 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. 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 forward-looking 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 launch its clinical trials in Australia and expand its trials in India, the Company's ability to obtain FDA approval of its new GNA supplier in a timely manner, the Company's ability to submit to the FDA and have the FDA approve an EUA for the MPVX, 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 MPVX; 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
Consolidated Balance Sheets

September 30,
2022

March 31,
2022

ASSETS

CURRENT ASSETS			
Cash		\$ 19,604,025	\$ 17,072,419
Accounts receivable		114,849	127,965
Prepaid expenses		784,638	956,623
TOTAL CURRENT ASSETS		<u>20,503,512</u>	<u>18,157,007</u>
Property and equipment, net		1,138,623	441,238
Right-of-use lease asset		1,282,328	696,698
Patents, net		1,925	2,200
Restricted cash		87,506	87,506
Deposits		33,305	33,305
TOTAL ASSETS		<u>\$ 23,047,199</u>	<u>\$ 19,417,954</u>
LIABILITIES AND STOCKHOLDERS' EQUITY			
CURRENT LIABILITIES			
Accounts payable		\$ 361,001	\$ 499,962
Due to related parties		177,527	155,742
Deferred revenue		574,245	344,547
Lease liability, current portion		247,144	126,905
Other current liabilities		741,529	696,893
TOTAL CURRENT LIABILITIES		<u>2,101,446</u>	<u>1,824,049</u>
Lease liability, less current portion		1,077,529	602,505
TOTAL LIABILITIES		<u>3,178,975</u>	<u>2,426,554</u>
COMMITMENTS AND CONTINGENCIES			
EQUITY			
Common stock, par value of \$0.001, 60,000,000 shares authorized; 22,946,232 and 15,419,163 issued and outstanding		22,948	15,421
Additional-paid in capital		156,887,555	147,446,868
Accumulated deficit		(137,042,279)	(130,329,181)
TOTAL STOCKHOLDERS' EQUITY BEFORE NONCONTROLLING INTERESTS		<u>19,868,224</u>	<u>17,133,108</u>
Noncontrolling interests		–	(141,708)
TOTAL STOCKHOLDERS' EQUITY		<u>19,868,224</u>	<u>16,991,400</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY		<u>\$ 23,047,199</u>	<u>\$ 19,417,954</u>

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

	<u>Three Months Ended 9/30/22</u>	<u>Three Months Ended 9/30/21</u>	<u>Six Months Ended 9/30/22</u>	<u>Six Months Ended 9/30/21</u>
Government contract revenue	\$ –	\$ 131,966	\$ –	\$ 263,932
OPERATING COSTS AND EXPENSES				
Professional fees	1,003,870	649,460	1,847,899	1,232,929
Payroll and related	1,112,955	805,608	2,142,641	1,822,350
General and administrative	1,548,484	685,702	2,582,505	1,315,895
Total operating expenses	<u>3,665,309</u>	<u>2,140,770</u>	<u>6,573,045</u>	<u>4,371,174</u>
OPERATING LOSS	<u>(3,665,309)</u>	<u>(2,008,804)</u>	<u>(6,573,045)</u>	<u>(4,107,242)</u>
OTHER EXPENSE				
Loss on dissolution of subsidiary	142,121	–	142,121	–
NET LOSS	<u>\$ (3,807,430)</u>	<u>\$ (2,008,804)</u>	<u>\$ (6,715,166)</u>	<u>\$ (4,107,242)</u>
Loss attributable to noncontrolling interests	–	(825)	–	(1,960)
NET LOSS ATTRIBUTABLE TO AETHLON MEDICAL, INC.	<u>\$ (3,807,430)</u>	<u>\$ (2,007,979)</u>	<u>\$ (6,715,166)</u>	<u>\$ (4,105,282)</u>
Basic and diluted net loss available to common stockholders per share	<u>\$ (0.18)</u>	<u>\$ (0.13)</u>	<u>\$ (0.37)</u>	<u>\$ (0.29)</u>

Weighted average number of common shares outstanding

20,744,999

15,386,486

18,130,177

14,114,639