

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 9, 2021

AETHLON MEDICAL, INC.
(Exact name of Registrant as Specified in Its Charter)

| | | |
|--|---|---|
| <u>Nevada</u> (State or Other Jurisdiction of Incorporation) | <u>001-37487</u> (Commission File Number) | <u>13-3632859</u> (IRS Employer Identification No.) |
|--|---|---|

| | |
|--|----------------------------|
| <u>11555 Sorrento Valley Road, Suite 203</u> <u>San Diego, California</u> (Address of Principal Executive Offices) | <u>92121</u> (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:

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

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 9, 2021, Aethlon Medical, Inc. (the "Registrant") issued a press release announcing its financial results for the quarter ended September 30, 2021. A copy of the press release is attached hereto as Exhibit 99.1.

The information provided in this Item 2.02 of this Current Report on Form 8-K, including the exhibits, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any of the Registrant's filings under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 99.1 | Press Release of the Registrant dated November 9, 2021. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

SIGNATURES

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.

AETHLON MEDICAL, INC.

Date: November 9, 2021

By: /s/ James B. Frakes

James B. Frakes
Chief Financial Officer



Aethlon Medical Announces Second Quarter Financial Results and Provides Corporate Update

SAN DIEGO Nov. 9, 2021 -- Aethlon Medical, Inc. (Nasdaq: AEMD), a company developing medical technology to treat cancer and life-threatening infectious diseases, today reported financial results for its second quarter ended September 30, 2021 and provided an update on recent developments.

Company Updates

Aethlon Medical is continuing the research and clinical development of the Hemopurifier™, our 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.

As disclosed in our last earnings release on August 9, 2021, the Aethlon Hemopurifier™ has demonstrated binding of SARS-CoV-2 spike protein and, as reported in a peer reviewed publication, the binding and removal from circulation of SARS-CoV-2 virus from a human patient. This is in addition to the Hemopurifier's previously demonstrated binding of numerous pathogenic viruses. The new information about the Hemopurifier in COVID-19 has stimulated clinical researchers to express interest in joining our ongoing clinical trial investigating the Hemopurifier for the treatment of patients with SARS-CoV-2/COVID-19 infection. This trial is being conducted under the open Investigational Device Exemption (IDE) for the Hemopurifier in life threatening viral infections. The trial is designed to allow for up to 40 of these patients to be treated under an Early Feasibility Study protocol at up to 20 clinical sites in the U.S.

During the recent quarter, we entered into an agreement with PPD, Inc., a leading global contract research organization (CRO), to oversee our U.S. clinical studies investigating the Hemopurifier for critically ill COVID-19 patients.

Together with PPD, we continue to advance site readiness at Cooper Medical Center, Loma Linda Medical Center, University of California Davis, Virginia Commonwealth University Medical Center, LSU Health Shreveport, University of Miami Medical Center, and Thomas Jefferson Medical Center. Additionally, we obtained institutional research board approval and have entered into a clinical trial agreement with Stanford Hospital. We are in discussions to bring on board other key U.S. medical centers.

We also recently obtained ethics review board approval and entered into a clinical trial agreement with Medanta Medicity Hospital, a multi-specialty hospital in Delhi NCR, India, for a COVID-19 clinical trial at that location. On-site training is expected to take place in November 2021.

"The opportunity to help critically ill, ICU patients with COVID-19 continues in both the U.S. and India," said Steven LaRosa, M.D., Chief Medical Officer.

"In addition to our work with COVID-19, we remain very optimistic about the use of our Hemopurifier for the treatment of Head and Neck Cancer. We acknowledge that the enrollment of our Head and Neck Cancer trial has been delayed, primarily due to the COVID-19 pandemic. We are exploring additional avenues to investigate our Hemopurifier in patients with cancer," said Charles J. Fisher, Jr., M.D., CEO.

Financial Results for the Second Quarter Ended September 30, 2021

At September 30, 2021, Aethlon Medical had a cash balance of approximately \$23.2 million.

Aethlon recorded approximately \$115,000 of government contract revenue on its Phase 2 Melanoma Cancer Contract in the three months ended September 30, 2021. We also recorded approximately \$17,000 of revenue related to our cost reimbursable subaward arrangement with the University of Pittsburgh in connection with an NIH contract entitled "Depleting Exosomes to Improve Responses to Immune Therapy in HNNCC." As a result, the Company recorded total government contract revenue of approximately \$132,000 in the three months ended September 30, 2021. Aethlon did not record any government contract revenue in the three months ended September 30, 2020.

Consolidated operating expenses for the three months ended September 30, 2021 were approximately \$2.1 million, compared to approximately \$1.8 million for the three months ended September 30, 2020. This increase of approximately \$300,000, or 20%, in the 2021 period was due to increases in payroll and related expenses of approximately \$200,000 and in general and administrative expenses of approximately \$100,000.

The \$200,000 increase in payroll and related expenses was primarily due to the combination of a \$101,000 increase in our research and development payroll as the result of hiring additional scientists and, a \$100,000 increase in general and administrative payroll expense as the result of additional headcount.

The \$100,000 increase in general and administrative expenses was primarily due to a \$72,000 increase in our rent expense, a \$54,000 increase in our amortization expense and a \$46,000 increase in our insurance expenses, which were partially offset by a \$57,000 decrease in our clinical trial expenses.

As a result of the changes in revenues and expenses noted above, the Company's net loss before noncontrolling interests increased to approximately \$2.0 million for the three months ended September 30, 2021, from approximately \$1.8 million for the three months ended September 30, 2020.

The unaudited condensed consolidated balance sheet for September 30, 2021 and the unaudited condensed consolidated statements of operations for the three and six month periods ended September 30, 2021 and 2020 follow at the end of this release.

Conference Call

The Company will hold a conference call today, Tuesday, November 9, 2021 at 4:30 p.m. Eastern Time 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/10161862/ef905aZede>. 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

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 9, 2021. 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 10162862.

About Aethlon and the Hemopurifier®

Aethlon Medical is a biotechnology 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 enabled 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.

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 enroll additional sites for its clinical trials, 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, 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, 2021, 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.

Company Contact:

Jim Frakes
Chief Financial Officer
Aethlon Medical, Inc.
jfrakes@aethlonmedical.com

Media Contact:

Tony Russo, Ph.D.
Russo Partners, LLC
tony.russo@russopartnersllc.com
212-845-4251

Investor Contact:

Susan Noonan
S.A. Noonan Communications, LLC
susan@sanoonan.com
212-966-3650

AETHLON MEDICAL, INC. AND SUBSIDIARIES Condensed Consolidated Balance Sheet

| | September 30, 2021 | March 31, 2021 |
|----------------------|-----------------------|-------------------|
| ASSETS | | |
| CURRENT ASSETS | | |
| Cash | \$ 23,224,925 | \$ 9,861,575 |
| Accounts receivable | 131,966 | 149,082 |
| Prepaid expenses | 212,308 | 341,081 |
| | <u>23,569,199</u> | <u>10,351,738</u> |
| TOTAL CURRENT ASSETS | | |

| | | |
|--|----------------------|----------------------|
| Property and equipment, net | 213,625 | 160,976 |
| Right-of-use lease asset | – | 40,363 |
| Patents, net | 2,476 | 56,954 |
| Restricted cash | 46,726 | 46,726 |
| Deposits | 42,159 | 12,159 |
| TOTAL ASSETS | \$ 23,874,185 | \$ 10,668,916 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| CURRENT LIABILITIES | | |
| Accounts payable | 254,176 | 337,678 |
| Due to related parties | 134,207 | 118,520 |
| Deferred revenue | 114,849 | 114,849 |
| Lease liability | – | 42,543 |
| Other current liabilities | 471,117 | 761,636 |
| TOTAL CURRENT LIABILITIES | 974,349 | 1,375,226 |
| TOTAL LIABILITIES | 974,349 | 1,375,226 |
| COMMITMENTS AND CONTINGENCIES | | |
| EQUITY | | |
| Common stock, par value of \$0.001, 30,000,000 shares authorized; 15,397,299 and 12,150,597 issued and outstanding | 15,399 | 12,152 |
| Additional paid-in capital | 147,041,683 | 129,331,542 |
| Accumulated deficit | (124,018,372) | (119,913,090) |
| TOTAL STOCKHOLDERS' EQUITY BEFORE NONCONTROLLING INTERESTS | 23,038,710 | 9,430,604 |
| Noncontrolling interests | (138,874) | (136,914) |
| TOTAL STOCKHOLDERS' EQUITY | 22,899,836 | 9,293,690 |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | \$ 23,874,185 | \$ 10,668,916 |

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AETHLON MEDICAL, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations
For the three and six months ended September 30, 2021 and 2020

| | Three Months Ended 9/30/21 | Three Months Ended 9/30/20 | Six Months Ended 9/30/21 | Six Months Ended 9/30/20 |
|---|---------------------------------------|---------------------------------------|-------------------------------------|-------------------------------------|
| Government contract revenue | \$ 131,966 | \$ – | \$ 263,932 | \$ – |
| OPERATING COSTS AND EXPENSES | | | | |
| Professional fees | 649,460 | 656,396 | 1,232,929 | 1,220,680 |
| Payroll and related | 805,608 | 560,244 | 1,822,350 | 997,155 |
| General and administrative | 685,702 | 554,749 | 1,315,895 | 964,700 |
| | <u>2,140,770</u> | <u>1,771,389</u> | <u>4,371,174</u> | <u>3,182,535</u> |
| OPERATING LOSS | (2,008,804) | (1,771,389) | (4,107,242) | (3,182,535) |
| NET LOSS | (2,008,804) | (1,771,389) | (4,107,242) | (3,182,535) |
| Loss attributable to noncontrolling interests | (825) | (825) | (1,960) | (1,688) |
| NET LOSS ATTRIBUTABLE TO AETHLON MEDICAL, INC. | \$ (2,007,979) | \$ (1,770,564) | \$ (4,105,282) | \$ (3,180,847) |
| Basic and diluted net loss available to common stockholders per share | <u>\$ (0.13)</u> | <u>\$ (0.15)</u> | <u>\$ (0.29)</u> | <u>\$ (0.29)</u> |
| Weighted average number of common shares outstanding | <u>15,386,486</u> | <u>12,070,592</u> | <u>14,114,639</u> | <u>10,845,049</u> |

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