

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

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2016

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

COMMISSION FILE NUMBER 001-37487

AETHLON MEDICAL, INC.
(Exact name of registrant as specified in its charter)

NEVADA
(State or other jurisdiction of incorporation or organization)

13-3632859
(I.R.S. Employer Identification No.)

9635 GRANITE RIDGE DRIVE, SUITE 100, SAN DIEGO, CA 92123
(Address of principal executive offices) (Zip Code)

(858) 459-7800
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES
NO

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (ss.232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES NO

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES NO

As of November 8, 2016, the registrant had outstanding 7,725,072 shares of common stock, \$.001 par value.

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

AETHLON MEDICAL, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2016 (Unaudited)	March 31, 2016
ASSETS		
Current assets		
Cash	\$ 556,352	\$ 2,123,737
Accounts receivable	193,719	199,471
Prepaid expenses and other current assets	66,469	53,294
Total current assets	<u>816,540</u>	<u>2,376,502</u>
Property and equipment, net	22,969	36,038
Patents and patents pending, net	89,579	94,161
Deposits	21,747	22,415
Total assets	<u>\$ 950,835</u>	<u>\$ 2,529,116</u>
LIABILITIES AND EQUITY		
Current liabilities		
Accounts payable	\$ 384,728	\$ 244,804
Due to related parties	58,362	145,112
Convertible notes payable, net - current portion	605,815	-
Other current liabilities	35,316	136,695
Total current liabilities	<u>1,084,221</u>	<u>526,611</u>
Convertible notes payable, net - less current portion	-	500,139
Total liabilities	<u>1,084,221</u>	<u>1,026,750</u>
Commitments and Contingencies (Note 13)		
Equity		
Aethlon Medical, Inc. Stockholders' (Deficit) Equity		
Common stock, par value \$0.001 per share; 30,000,000 shares authorized as of September 30, 2016 and March 31, 2016; 7,711,811 and 7,622,393 shares issued and outstanding as of September 30, 2016 and March 31, 2016, respectively	7,711	7,621
Additional paid-in capital	90,811,302	88,047,142
Accumulated deficit	(90,886,645)	(86,502,043)
Total Aethlon Medical, Inc. stockholders' (deficit) equity before noncontrolling interests	<u>(67,632)</u>	<u>1,552,720</u>
Noncontrolling interests	(65,754)	(50,354)
Total (deficit) equity	<u>(133,386)</u>	<u>1,502,366</u>
Total liabilities and equity	<u>\$ 950,835</u>	<u>\$ 2,529,116</u>

See accompanying notes.

AETHLON MEDICAL, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
For the Three and Six Month Periods Ended September 30, 2016 and 2015
(Unaudited)

	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Six Months Ended September 30, 2016	Six Months Ended September 30, 2015
REVENUES				
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 expenses	1,813,003	597,850	2,158,190	1,056,078
General and administrative	290,131	325,670	513,681	611,695
Total operating expenses	<u>2,614,116</u>	<u>1,312,727</u>	<u>3,750,602</u>	<u>2,595,206</u>
OPERATING LOSS	<u>(2,226,678)</u>	<u>(1,124,361)</u>	<u>(3,358,529)</u>	<u>(2,214,332)</u>
OTHER EXPENSE				
Interest and other debt expenses	36,576	127,245	78,743	253,933
Loss on debt extinguishment	-	-	616,889	-
Warrant repricing expense	-	-	345,841	-
Total other expense	<u>36,576</u>	<u>127,245</u>	<u>1,041,473</u>	<u>253,933</u>
NET LOSS BEFORE NONCONTROLLING INTERESTS	<u>(2,263,254)</u>	<u>(1,251,606)</u>	<u>(4,400,002)</u>	<u>(2,468,265)</u>
LOSS ATTRIBUTABLE TO NONCONTROLLING INTERESTS	<u>(7,668)</u>	<u>(27,000)</u>	<u>(15,400)</u>	<u>(60,623)</u>
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	<u>\$ (2,255,586)</u>	<u>\$ (1,224,606)</u>	<u>\$ (4,384,602)</u>	<u>\$ (2,407,642)</u>
BASIC AND DILUTED LOSS PER COMMON SHARE	<u>\$ (0.29)</u>	<u>\$ (0.16)</u>	<u>\$ (0.57)</u>	<u>\$ (0.34)</u>
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING – BASIC AND DILUTED	<u>7,756,883</u>	<u>7,610,459</u>	<u>7,690,369</u>	<u>7,167,903</u>

See accompanying notes.

AETHLON MEDICAL, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
For the Six Months Ended September 30, 2016 and 2015
(Unaudited)

	Six Months Ended September 30, 2016	Six Months Ended September 30, 2015
Cash flows from operating activities:		
Net loss	\$ (4,400,002)	\$ (2,468,265)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	20,612	18,676
Stock based compensation	1,573,991	101,421
Warrant repricing expense	345,841	-
Loss on debt extinguishment	616,889	-
Amortization of debt discount and deferred financing costs	46,639	225,717
Changes in operating assets and liabilities:		
Accounts receivable	5,752	6,533
Prepaid expenses and other current assets	(12,507)	(35,777)
Accounts payable and other current liabilities	125,842	(144,533)
Due to related parties	(86,750)	58,000
Net cash used in operating activities	<u>(1,763,693)</u>	<u>(2,238,228)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(2,961)	-
Net cash used in investing activities	<u>(2,961)</u>	<u>-</u>
Cash flows from financing activities:		
Proceeds from the issuance of common stock, net	266,612	5,591,988
Cash paid for tax withholding on vested restricted stock units	(67,343)	-
Net cash provided by financing activities	<u>199,269</u>	<u>5,591,988</u>
Net (decrease) increase in cash	(1,567,385)	3,353,760
Cash at beginning of period	<u>2,123,737</u>	<u>855,596</u>
Cash at end of period	<u>\$ 556,352</u>	<u>\$ 4,209,356</u>
Supplemental disclosures of non-cash investing and financing activities:		
Convertible note payable and accrued interest converted to common stock	<u>\$ 32,321</u>	<u>\$ -</u>
Debt discount on convertible notes payable	<u>\$ 75,994</u>	<u>\$ -</u>
Issuance of shares under vested restricted stock units	<u>\$ 30</u>	<u>\$ -</u>
Reclassification of accrued interest to convertible notes payable	<u>\$ 85,031</u>	<u>\$ -</u>
Cashless exercise of warrants	<u>\$ 3</u>	<u>\$ 5</u>

See accompanying notes.

AETHLON MEDICAL, INC. AND SUBSIDIARY
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
September 30, 2016

1. NATURE OF BUSINESS AND BASIS OF PRESENTATION

ORGANIZATION

Aethlon Medical, Inc. and subsidiary ("Aethlon", the "Company", "we" or "us") is a medical device company focused on creating innovative devices that address unmet medical needs in cancer, infectious disease and other life-threatening conditions. At the core of our developments is the Aethlon ADAPT™ (Adaptive Dialysis-Like Affinity Platform Technology) system, a medical device platform that converges single or multiple affinity drug agents with advanced plasma membrane technology to create therapeutic filtration devices that selectively remove harmful particles from the entire circulatory system without loss of essential blood components. On June 25, 2013, the United States Food and Drug Administration (FDA) approved an Investigational Device Exemption (IDE) that allows us to initiate human feasibility studies of the Aethlon Hemopurifier® in the U.S. Under the feasibility study protocol, we plan to enroll ten end-stage renal disease patients who are infected with the Hepatitis C virus (HCV) to demonstrate the safety of Hemopurifier therapy. Successful completion of this study will allow us the opportunity to initiate pivotal studies that are required for market clearance to treat HCV and other disease conditions in the U.S.

Successful outcomes of human trials will also be required by the regulatory agencies of certain foreign countries where we intend to sell this device. Some of our patents may expire before FDA approval or approval in a foreign country, if any, is obtained. However, we believe that certain patent applications and/or other patents issued more recently will help protect the proprietary nature of the Hemopurifier(R) treatment technology.

In October 2013, our majority owned subsidiary, Exosome Sciences, Inc. ("ESI"), commenced operations with a focus on advancing exosome-based strategies to diagnose and monitor the progression of cancer, infectious disease and other life-threatening conditions.

ESI is accounted for as a non-controlling interest as the Company has an 80% ownership interest in the subsidiary. Earnings or losses attributable to other stockholders of a consolidated affiliated company are classified separately as "noncontrolling interest" in the Company's consolidated statements of operations. Net loss attributable to noncontrolling interest reflects only its share of the after-tax earnings or losses of an affiliated company. Income taxes attributable to noncontrolling interest are determined using the applicable statutory tax rates in the jurisdictions where such operations are conducted. The Company's consolidated balance sheets reflect noncontrolling interests within the equity section of the consolidated balance sheets.

Our common stock is traded on the Nasdaq Capital Market under the symbol "AEMD."

SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

During the six months ended September 30, 2016, there have been no changes to our significant accounting policies as described in our Annual Report on Form 10-K for the fiscal year ended March 31, 2016.

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of the Securities and Exchange Commission (SEC) Regulation S-X. Accordingly, they should be read in conjunction with the audited financial statements and notes thereto for the year ended March 31, 2016, included in the Company's Annual Report on Form 10-K filed with the SEC on June 29, 2016. The accompanying unaudited condensed consolidated financial statements include the accounts of Aethlon Medical, Inc. and its majority-owned subsidiary. All significant inter-company transactions and balances have been eliminated in consolidation. The unaudited condensed consolidated financial statements contain all normal recurring accruals and adjustments that, in the opinion of management, are necessary to present fairly the condensed consolidated balance sheet of the Company at September 30, 2016, the condensed consolidated statements of operations for the three and six months ended September 30, 2016, and the condensed consolidated statement of cash flows for the six months ended September 30, 2016. Estimates were made relating to useful lives of fixed assets, valuation allowances, the fair value of warrants, impairment of assets, share-based compensation expense and accruals for clinical trial and research and development expenses. Actual results could differ materially from those estimates. Certain amounts previously reported in the financial statements have been reclassified to conform to the current presentation. Such reclassifications did not affect net loss, equity or cash flows. The accompanying condensed consolidated balance sheet at March 31, 2016 has been derived from the audited consolidated balance sheet at March 31, 2016, contained in the above referenced 10-K. The results of operations for the three and six months ended September 30, 2016 are not necessarily indicative of the results to be expected for the full year or any future interim periods.

On April 14, 2015, we completed a 1-for-50 reverse stock split. Accordingly, authorized common stock was reduced from 500,000,000 shares to 10,000,000 shares, and each 50 shares of outstanding common stock held by stockholders were combined into one share of common stock. The accompanying condensed consolidated financial statements and accompanying notes have been retroactively revised to reflect such reverse stock split as if it had occurred on April 1, 2015. All share and per share amounts have been revised accordingly.

On March 31, 2016, we filed a Certificate of Amendment to our Articles of Incorporation to increase our authorized common stock from 10,000,000 to 30,000,000 shares. Our stockholders approved the amendment at our annual meeting of stockholders held on March 29, 2016.

LIQUIDITY AND GOING CONCERN

The accompanying condensed consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the ordinary course of business. We have incurred continuing losses from operations and at September 30, 2016 had limited working capital and an accumulated deficit of approximately \$90,887,000. These factors, among other matters, raise substantial doubt about our ability to continue as a going concern. A significant amount of additional capital will be necessary to advance the development of our products to the point at which they may become commercially viable. We intend to fund operations, working capital and other cash requirements for the twelve month period subsequent to September 30, 2016 through debt and/or equity financing arrangements as well as through revenues and related cash receipts under our government contracts (see Note 11).

We are currently addressing our liquidity issue by seeking additional investment capital through issuances of common stock under our existing S-3 registration statement and by applying for grants issued by government agencies in the United States. We believe that our cash on hand and funds expected to be received from additional debt and equity financing arrangements will be sufficient to meet our liquidity needs for the twelve month period through September 30, 2017. However, no assurance can be given that we will receive any funds in addition to the funds we have received to date (see Note 14).

The successful outcome of future activities cannot be determined at this time and there is no assurance that, if achieved, we will have sufficient funds to execute our intended business plan or generate positive operating results.

The consolidated financial statements do not include any adjustments related to this uncertainty and as to the recoverability and classification of asset carrying amounts or the amount and classification of liabilities that might result should the Company be unable to continue as a going concern.

2. LOSS PER COMMON SHARE

Basic loss per share is computed by dividing net income available to common stockholders by the weighted average number of common shares outstanding during the period of computation. The weighted average number of common shares outstanding for the three and six months ended September 30, 2016 includes 184,500 vested restricted stock units that have not yet been issued. Diluted loss per share is computed similar to basic loss per share except that the denominator is increased to include the number of additional common shares that would have been outstanding if potential common shares had been issued, if such additional common shares were dilutive. Since we had net losses for all periods presented, basic and diluted loss per share are the same, and additional potential common shares have been excluded as their effect would be antidilutive.

As of September 30, 2016 and 2015, a total of 3,289,606 and 2,773,483 potential common shares, consisting of shares underlying outstanding stock options, warrants, unvested restricted stock units and convertible notes payable were excluded as their inclusion would be antidilutive.

3. RESEARCH AND DEVELOPMENT EXPENSES

Our research and development costs are expensed as incurred. We incurred research and development expenses during the three and six month periods ended September 30, 2016 and 2015, which are included in various operating expense line items in the accompanying condensed consolidated statements of operations. Our research and development expenses in those periods were as follows:

	September 30, 2016	September 30, 2015
Three months ended	<u>\$ 280,860</u>	<u>\$ 207,676</u>
Six months ended	<u>\$ 377,843</u>	<u>\$ 424,267</u>

4. SIGNIFICANT RECENT ACCOUNTING PRONOUNCEMENTS

During the six months ended September 30, 2016, we adopted Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") 2015-03, the new accounting standard on imputation of interest, simplifying the presentation of debt issuance costs. As a result of the adoption of that pronouncement, our deferred financing costs at March 31, 2016 were reclassified from current assets to an offset against our convertible notes.

Management is evaluating significant recent accounting pronouncements that are not yet effective for us, including the new accounting standard on improvements to employee share based payment accounting, ASU 2016-09 (Topic 718), the new accounting standard related to leases, ASU 2016-02 (Topic 842), the new accounting standard for recognition and measurement of financial assets and financial liabilities, ASU 2016-01, the new accounting standard on extraordinary and unusual items on income statements, ASU 2015-01, the new accounting standard related to presentation of financial statements - going concern qualifications, ASU 2014-15, and the new accounting standard on revenue recognition, ASU 2014-09 (Topic 606), and have not yet concluded whether any such pronouncements will have a significant effect on our future consolidated financial statements.

5. CONVERTIBLE NOTES PAYABLE

Convertible Notes Payable consisted of the following at September 30, 2016:

	Principal	Unamortized Discount	Net Amount	Accrued Interest
Convertible Notes Payable – Current Portion:				
November 2014 10% Convertible Notes	\$ 662,811	\$ (56,996)	\$ 605,815	\$ 17,486
Total Convertible Notes Payable	<u>\$ 662,811</u>	<u>\$ (56,996)</u>	<u>\$ 605,815</u>	<u>\$ 17,486</u>

During the six months ended September 30, 2016, we recorded interest expense of \$30,794 related to the contractual interest rates of our convertible notes, interest expense of \$27,641 related to the amortization of deferred financing costs and interest expense of \$18,998 related to the amortization of the note discount for a total interest expense of \$77,433 related to our convertible notes in the six months ended September 30, 2016. All of the unamortized discount at September 30, 2016 related to the note discount established upon the second amendment to the notes (see below).

Convertible Notes Payable consisted of the following at March 31, 2016 (our most recent fiscal year end):

	Principal	Unamortized Discount	Net Amount	Accrued Interest
Convertible Notes Payable – Non-Current Portion:				
November 2014 10% Convertible Notes	\$ 527,780	\$ (27,641)	\$ 500,139	\$ 74,036
Total Convertible Notes Payable	<u>\$ 527,780</u>	<u>\$ (27,641)</u>	<u>\$ 500,139</u>	<u>\$ 74,036</u>

The above table shows the retroactive application of \$27,641 in note discounts representing the deferred financing costs of that same amount on March 31, 2016 due to the application of related to the application of the new accounting standard ASU 2015-03. All of the unamortized discount at March 31, 2016 related to the deferred financing costs noted above.

During the six months ended September 30, 2015, we recorded interest expense of \$26,390 related to the contractual interest rates of our convertible notes, interest expense of \$186,276 related to the amortization of debt discount and interest expense of \$39,441 related to the amortization of deferred financing costs for a total interest expense of \$252,107 related to our convertible notes in the six months ended September 30, 2015.

NOVEMBER 2014 10% CONVERTIBLE NOTES

In November 2014, we entered into a subscription agreement with two accredited investors providing for the issuance and sale of (i) convertible promissory notes in the aggregate principal amount of \$527,780 (the “Notes”) and (ii) five year warrants to purchase up to 47,125 shares of common stock at a fixed exercise price of \$8.40 per share (the “Warrants”). These Notes bear interest at the annual rate of 10% and originally matured on April 1, 2016.

The aggregate gross cash proceeds to us were \$415,000 after subtracting legal fees of \$35,000, a \$27,780 due diligence fee and an original issuance discount of \$50,000. We recorded deferred financing costs of \$112,780 to reflect the legal fees, due diligence fee and original issuance discount and will amortize those costs over the life of the Notes using the effective interest method.

These Notes are convertible at the option of the holders into shares of our common stock at a fixed price of \$5.60 per share, for up to an aggregate of 94,246 shares of common stock. There are no registration requirements with respect to the shares of common stock underlying the Notes or the Warrants.

The estimated relative fair value of Warrants issued in connection with the Notes was recorded as a debt discount and is amortized as additional interest expense over the term of the underlying debt. We recorded debt discount of \$240,133 based on the relative fair value of these Warrants. In addition, as the effective conversion price of the Notes was less than market price of the underlying common stock on the date of issuance, we recorded an additional debt discount of \$287,647 related to the beneficial conversion feature.

Initial Amendment of the November 2014 10% Convertible Note Terms

On November 12, 2015, we entered into an amendment of terms (“Amendment of Terms”) with the two investors that participated in the November 2014 10% Convertible Notes. The Amendment of Terms modified the terms of the subscription agreement, Notes and Warrants held by those investors to, among other things, extended the maturity date of the Notes from April 1, 2016 to June 1, 2016, temporarily reduced the number of shares that we must reserve with respect to conversion of the Notes, and temporarily suspended the time period during which one of the investors may exercise its Warrants. In exchange for the investors’ agreements in the Amendment of Terms, we paid one of the investors a cash fee of \$90,000, which we recorded as deferred financing costs and amortized over the remaining term of the notes.

Second Amendment and Extension of the November 2014 10% Convertible Notes

On June 27, 2016, we and certain investors entered into further Amendments (the “Amendments”) to the Notes and the Warrants. The Amendments provide that the Maturity Date (as defined in the Notes) was extended from June 1, 2016 to July 1, 2017 and that the conversion price per share of the Notes was reduced from \$5.60 per share of common stock to \$5.00 per share of common stock. In addition, we reduced the purchase price (as defined in the Warrants) from \$8.40 per share to \$5.00 per share of common stock. In connection with these modifications, each of the investors signed a Consent and Waiver providing its consent under certain restrictive provisions, and waiving certain rights, including a right to participate in certain offerings made by us, under a Securities Purchase Agreement dated June 23, 2015, (the “2015 SPA”) to which we, the investors and certain other investors are parties, in order to facilitate an at-the-market equity program (see Note 6).

The Amendments also increase the principal amount of the Notes to \$692,811 (in the aggregate) to (i) include accrued and unpaid interest through June 15, 2016, and (ii) increase the principal amount by \$80,000 (in the aggregate) as an extension fee for the extended maturity date of the Notes. With respect to each Note, we entered into an Allonge to Convertible Promissory Note (each, an “Allonge”) reflecting the changes in the principal amount, Maturity Date and conversion price of the Note.

We also issued to the investors new warrants (the “New Warrants”) to purchase an aggregate of 30,000 shares of common stock with a Purchase Price (as defined in the New Warrants) of \$5.00 per share of common stock. We issued the New Warrants in substantially the same form as the prior Warrants, and the New Warrants will expire on November 6, 2019, the same date on which the prior Warrants will expire.

The modification of the Notes was evaluated under FASB Accounting Standards Codification (“ASC”) Topic No. 470-50-40, “Debt Modification and Extinguishments”. Therefore, according to the guidance, the instruments were determined to be substantially different, and the transaction qualified for extinguishment accounting. As a result, we recorded a loss on debt extinguishment of \$536,889 and recognized an extension fee expense of \$80,000, which are included in other expenses in the accompanying condensed consolidated statements of operations. The debt extinguishment is comprised from the fair value of prior warrants issued in connection with the Notes of \$287,676, as well as \$325,206 related to beneficial conversion feature and offset by debt discount of \$75,993. The beneficial conversion feature is a result of the effective conversion price of the new Notes being less than the market price of the underlying common stock on the date of modification.

The following table shows the changes to the principal balance of the November 2014 10% Convertible Notes:

Activity in the November 2014 10% Convertible Notes

Initial principal balance	\$	527,780
Increase in principal balance under the second amendment (see above)		165,031
Conversions during the six months ended September 30, 2016		<u>(30,000)</u>
Balance as of September 30, 2016	\$	<u>662,811</u>

6. EQUITY TRANSACTIONS IN THE SIX MONTHS ENDED SEPTEMBER 30, 2016

Common Stock Sales Agreement with H.C. Wainwright

On June 28, 2016, we entered into a Common Stock Sales Agreement (the “Agreement”) with H.C. Wainwright & Co., LLC (“H.C. Wainwright”) which establishes an at-the-market equity program pursuant to which we may offer and sell shares of our common stock from time to time as set forth in the Agreement. The Agreement provides for the sale of shares of our common stock having an aggregate offering price of up to \$12,500,000 (the “Shares”).

Subject to the terms and conditions set forth in the Agreement, H.C. Wainwright will use its commercially reasonable efforts consistent with its normal trading and sales practices to sell the Shares from time to time, based upon our instructions. We have provided H.C. Wainwright with customary indemnification rights, and H.C. Wainwright will be entitled to a commission at a fixed rate equal to three percent (3.0%) of the gross proceeds per Share sold. In addition, we have agreed to pay certain expenses incurred by H.C. Wainwright in connection with the Agreement, including up to \$50,000 of the fees and disbursements of their counsel. The Agreement will terminate upon the sale of all of the Shares under the Agreement unless terminated earlier by either party as permitted under the Agreement (see Note 14).

Sales of the Shares, if any, under the Agreement shall be made in transactions that are deemed to be “at the market offerings” as defined in Rule 415 under the Securities Act, including sales made by means of ordinary brokers’ transactions, including on the Nasdaq Capital Market, at market prices or as otherwise agreed with H.C. Wainwright. We have no obligation to sell any of the Shares, and, at any time, we may suspend offers under the Agreement or terminate the Agreement.

In July 2016, we commenced sales of common stock under our Common Stock Sales Agreement with H.C. Wainwright. In the three months ended September 30, 2016, we had raised net proceeds of \$266,612 (net of \$8,348 in commissions to H.C. Wainwright and \$3,319 in other offering expenses) utilizing the sales agreement through the sale of 50,163 shares at an average price of \$5.31 per share of net proceeds.

Warrant Issuances in July 2016

In July 2016, we issued an aggregate of 2,660 shares of common stock to three investors upon the exercise of previously issued warrants. The warrants were exercised on a cashless or “net” basis. Accordingly, we did not receive any proceeds from such exercises. The cashless exercise of such warrants resulted in the cancellation of previously issued warrants to purchase an aggregate of 19,563 shares of common stock.

Restricted Stock Unit Grants to Directors and Executive Officers

During the three months ended September 30, 2016, 30,131 Restricted Stock Units (“RSUs”) held by our outside directors were exchanged into the same number of shares of our common stock (see Note 9).

Amendment of November 2014 10% Convertible Notes

Under the Second Amendment and Extension of the November 2014 10% Convertible Notes dated June 27, 2016 (See Note 5), we reduced the purchase price of 47,125 Warrants from \$8.40 per share to \$5.00 per share.

We also issued to the investors new warrants to purchase an aggregate of 30,000 shares of common stock with a purchase price of \$5.00 per share of common stock. We issued the new warrants in substantially the same form as the prior Warrants, and the new warrants will expire on November 6, 2019, the same date on which the prior warrants will expire (See Note 5).

Amendment of December 2014 Warrants

On June 27, 2016, we and certain investors (the “Unit Investors”) entered into Consent and Waiver and Amendment agreements (the “CWAs”), relating to an aggregate of 264,000 Warrants to Purchase Common Stock (the “Unit Warrants”) we had issued to the Unit Investors on December 2, 2014 pursuant to a Securities Purchase Agreement dated November 26, 2014 (the “2014 SPA”). In the CWAs, each of the Unit Investors provided its consent under certain restrictive provisions, and waived certain rights, including a right to participate in certain offerings made by us, under the 2014 SPA in order to facilitate the at-the-market equity program described above. Pursuant to the CWAs, we reduced the Exercise Price (as defined in the Unit Warrants) from \$15.00 per share of common stock to \$5.00 per share of common stock. At any time that the shares of common stock underlying the Unit Warrants are covered by an effective registration statement that permits the public resale of the shares, if the Unit Investors exercise the Unit Warrants, they must do so by a cash exercise, which could yield up to \$1,320,000 in proceeds to us.

On June 27, 2016, each of the Unit Investors also entered into a Consent and Waiver providing its consent under certain provisions, and waiving certain rights, including a right to participate in certain offerings made by us, under the 2015 SPA in order to facilitate the at-the market equity program described above.

In accordance with GAAP, we measured the change in fair value that arose from the reduction in exercise price and recognized an expense of \$345,841, which is included in other expenses in the accompanying condensed consolidated statements of operations.

7. RELATED PARTY TRANSACTIONS

DUE TO RELATED PARTIES

Historically, certain of our officers and other related parties have advanced us funds, agreed to defer compensation and/or paid expenses on our behalf to cover working capital deficiencies. There were no such related party transactions during the fiscal year ended March 31, 2016 except that we had accrued unpaid Board fees of \$86,000 owed to our outside directors as of March 31, 2016. At September 30, 2016, we had unpaid Board fees of \$28,250.

8. OTHER CURRENT LIABILITIES

Other current liabilities were comprised of the following items:

	September 30, 2016	March 31, 2016
Accrued interest	\$ 17,486	\$ 74,038
Other accrued liabilities	17,830	62,657
Total other current liabilities	<u>\$ 35,316</u>	<u>\$ 136,695</u>

9. STOCK COMPENSATION

The following tables summarize share-based compensation expenses relating to Restricted Stock Units (“RSU”)s and options granted and the effect on basic and diluted loss per common share during the three and six month periods ended September 30, 2016 and 2015:

	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Six Months Ended September 30, 2016	Six Months Ended September 30, 2015
Vesting of stock options and restricted stock units	\$ 1,523,280	\$ 50,711	\$ 1,573,991	\$ 101,421
Total stock-based compensation expense	<u>\$ 1,523,280</u>	<u>\$ 50,711</u>	<u>\$ 1,573,991</u>	<u>\$ 101,421</u>
Weighted average number of common shares outstanding – basic and diluted	<u>7,756,883</u>	<u>7,610,459</u>	<u>7,690,369</u>	<u>7,167,903</u>
Basic and diluted loss per common share attributable to stock-based compensation expense	<u>\$ (0.20)</u>	<u>\$ (0.01)</u>	<u>\$ (0.20)</u>	<u>\$ (0.01)</u>

All of the stock-based compensation expense recorded during the six months ended September 30, 2016 and 2015, which totaled \$1,573,991 and \$101,421, respectively, is included in payroll and related expense in the accompanying condensed consolidated statements of operations. Stock-based compensation expense recorded during the six months ended September 30, 2016 and 2015 represented an impact on basic and diluted loss per common share of \$(0.20) in both periods.

We review share-based compensation on a quarterly basis for changes to the estimate of expected award forfeitures based on actual forfeiture experience. The cumulative effect of adjusting the forfeiture rate for all expense amortization is recognized in the period the forfeiture estimate is changed. The effect of forfeiture adjustments for the six months ended September 30, 2016 was insignificant.

Restricted Stock Unit Grants to Directors and Executive Officers

On August 9, 2016, our Board of Directors (the “Board”) granted RSUs to certain of our officers and directors as set forth below. The RSUs represent the right to be issued on a future date shares of our common stock for vested RSUs. Our Compensation Committee recommended the grants based on a compensation assessment provided by a third-party compensation consulting firm engaged by us that developed a peer group of companies for market assessment and analyzed compensation at such companies.

The consultant recommended beneficial ownership targets, which we previously disclosed in our Proxy Statement filed on February 23, 2016, in connection with our Annual Meeting of Stockholders held on March 29, 2016. In connection with the Annual Meeting, our stockholders approved our Amended 2010 Stock Incentive Plan, which included an increase in the number of shares available for grant under the plan in part to accommodate equity awards recommended by the Compensation Committee, and our stockholders approved our executive compensation as disclosed in the Proxy Statement pursuant to Item 402 paragraphs (m) through (q) of Regulation S-K.

To Mr. James A. Joyce, an aggregate of 634,000 RSUs valued at \$6.28 per share, based on the August 9, 2016 closing price of the common stock. 158,500 of the RSUs are deemed vested upon grant and an additional 39,625 RSUs will vest each quarter beginning on January 1, 2017. This grant is intended to increase Mr. Joyce’s beneficial ownership of our common stock to 9.0%, which target was recommended in 2015 and in June 2016 by the compensation consultant engaged by us. Previously, in 2004, the Board had approved a beneficial ownership target of 15% for Mr. Joyce. However, Mr. Joyce has agreed to the modified target of 9.0%.

To Mr. Rodney S. Kenley, an aggregate of 52,000 RSUs valued at \$6.28 per share, based on the August 9, 2016 closing price of the common stock. 13,000 of the RSUs are deemed vested upon grant and an additional 3,250 RSUs will vest each quarter beginning on January 1, 2017.

To Mr. James B. Frakes, an aggregate of 52,000 RSUs valued at \$6.28 per share, based on the August 9, 2016 closing price of the common stock. 13,000 of the RSUs are deemed vested upon grant and an additional 3,250 RSUs will vest each quarter beginning on January 1, 2017.

To each of our non-employee directors, Mr. Franklyn S. Barry, Jr., Mr. Edward G. Broenniman and Dr. Chetan S. Shah, 16,432 RSUs valued at an aggregate of \$105,000, based on the average of the closing prices of the common stock for the five trading days preceding and including August 9, 2016. These grants represent (a) \$70,000 worth of RSUs representing two years of grants under the amended 2012 Non-Employee Directors Compensation Program (the "2012 Program") because more than two years have elapsed since Messrs. Barry and Broenniman and Dr. Shah received grants under the program, all of which RSUs are deemed vested upon grant and (b) \$35,000 worth of RSUs representing the grant covering the fiscal year ending March 31, 2017, of which one-quarter are deemed vested upon grant and the remaining portion will vest ratably at September 30, 2016, at December 31, 2016 and at March 31, 2017.

The RSUs were granted under our Amended 2010 Stock Incentive Plan and we recorded expense of \$1,523,280 in the three months ended September 30, 2016 related to the RSU grants.

Changes to 2012 Non-Employee Directors Compensation Program

In July 2012, the Board approved the 2012 Program, which modified and superseded the 2005 Directors Compensation Program that had been in effect previously. On June 6, 2014, the Board approved certain changes to the 2012 Program, and on August 9, 2016, the Board approved further modifications to the program. Under the modified 2012 Program, in which only non-employee directors may participate, a new eligible director will receive an initial grant of \$50,000 worth of RSUs or, at the discretion of the Board, options to acquire shares of Common Stock. RSUs granted under this provision will be valued based on the average of the closing prices of the Common Stock for the five trading days preceding and including the date of grant and will vest at a rate determined by the Board in its discretion. Options granted under this provision will be valued at the exercise price, which will be based on the average of the closing prices of the Common Stock for the five trading days preceding and including the date of grant. Such options will have a term of ten years and will vest at a rate determined by the Board in its discretion.

At the beginning of each fiscal year, each existing director eligible to participate in the 2012 Program will receive a grant of \$35,000 worth of RSUs or, at the discretion of the Board, options to acquire shares of Common Stock. RSUs granted under this provision will be valued based on the average of the closing prices of the Common Stock for the five trading days preceding and including the first day of the fiscal year (or preceding and including the date of grant, if such grant is not made on the first day of the fiscal year) and will vest at a rate determined by the Board in its discretion. Options granted under this provision will be valued at the exercise price, which will be based on the average of the closing prices of the Common Stock for the five trading days preceding and including the first day of the fiscal year (or preceding and including the date of grant, if such grant is not made on the first day of the fiscal year). Such options will have a term of ten years and will vest at a rate determined by the Board in its discretion.

In lieu of per meeting fees, under the 2012 Program eligible directors will receive an annual Board retainer fee of \$30,000. The modified 2012 Program also provides for the following annual retainer fees: Audit Committee Chair - \$5,000, Compensation Committee chair - \$5,000, Nominating Committee Chair - \$5,000, Audit Committee member - \$4,000, Compensation Committee member - \$4,000 and Lead independent director (currently an open position) - \$15,000.

The RSU grants and the changes to the 2012 Program were approved and recommended by our Compensation Committee prior to approval by the Board.

RSUs outstanding that have vested and are expected to vest as of September 30, 2016 are as follows:

	<u>Number of RSUs</u>
Vested	184,500
Expected to vest	561,708
Total	<u>746,208</u>

During the three months ended September 30, 2016, 30,131 RSUs held by our outside directors were exchanged into the same number of shares of our common stock. As two of our three outside directors elected to return 40% of their RSU's in exchange for cash in order to pay their withholding taxes on the share issuances, 10,957 of the RSUs were cancelled and we paid a total of \$67,343 in cash to those two outside directors.

Stock Option Activity

There were no stock option grants during the six months ended September 30, 2016 or September 30, 2015.

Options outstanding that have vested and are expected to vest as of September 30, 2016 are as follows:

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term in Years</u>
Vested	417,047	\$ 11.20	4.77
Expected to vest	17,500	\$ 5.00	7.00
Total	<u>434,547</u>		

There was no stock option activity during the six months ended September 30, 2016 other than the expiration of 4,000 stock options during the period.

On September 30, 2016, our stock options had no intrinsic value since the closing price on that date of \$5.02 per share was below the weighted average exercise price of our stock options.

At September 30, 2016, there was approximately \$3,509,367 of unrecognized compensation cost related to share-based payments, which is expected to be recognized over a weighted average period of 2.87 years.

10. WARRANTS

During the six months ended September 30, 2016, we issued 30,000 warrants with an exercise price of \$5.00 per share. Those warrants were issued in connection with the Amendment of November 2014 Investment Documents (see Note 6).

A summary of warrant activity during the six months ended September 30, 2016 is presented below:

	<u>Amount</u>	<u>Range of Exercise Price</u>	<u>Weighted Average Exercise Price</u>
Warrants outstanding at March 31, 2016	2,164,094	\$2.10 - \$15.00	\$ 6.68
Exercised	(2,660)	\$6.25	\$ 6.25
Issued	30,000	\$5.00	\$ 5.00
Cancelled/Expired	(19,563)	\$6.25	\$ 6.25
Warrants outstanding at September 30, 2016	<u>2,171,871</u>	<u>\$2.10 - \$15.00</u>	<u>\$ 5.37</u>
Warrants exercisable at September 30, 2016	<u>2,171,871</u>	<u>\$2.10 - \$15.00</u>	<u>\$ 5.37</u>

The following outlines the significant weighted average assumptions used to estimate the fair value information presented, with respect to warrants utilizing the Binomial Lattice option pricing models at, and during the six months ended September 30, 2016:

Risk free interest rate	0.70%
Average expected life	3.5 years
Expected volatility	91.5%
Expected dividends	None

The expected volatility was based on the historic volatility. The expected life of options granted was based on the "simplified method" as described in the SEC's guidance due to changes in the vesting terms and contractual life of current option grants compared to our historical grants.

Based on the above assumptions, we valued the 30,000 new warrants issued during the six months ended September 30, 2016 at \$111,900 and classified that fair value as equity.

11. DARPA CONTRACT AND RELATED REVENUE RECOGNITION

We entered into a contract with the Defense Advanced Research Projects Agency, or DARPA, on September 30, 2011. Under the DARPA award, we have been engaged to develop a therapeutic device to reduce the incidence of sepsis, a fatal bloodstream infection that often results in the death of combat-injured soldiers. The award from DARPA was a fixed-price contract with potential total payments to us of \$6,794,389 over the course of five years. Fixed price contracts require the achievement of multiple, incremental milestones to receive the full award during each year of the contract. Under the terms of the contract, we performed certain incremental work towards the achievement of specific milestones against which we invoiced the government for fixed payment amounts.

Originally, only the base year (year one of the contract) was effective for the parties; however, DARPA subsequently exercised its option on the remaining years of the contract. The milestones were comprised of planning, engineering and clinical targets, the achievement of which in some cases required the participation and contribution of third party participants under the contract. We commenced work under the contract in October 2011.

In February 2014, DARPA reduced the scope of our contract in years three through five of the contract. The reduction in scope focused our research on exosomes, viruses and blood processing instrumentation. This scope reduction reduced the possible payments under the contract by \$858,469 over years three through five.

In the six months ended September 30, 2016, we invoiced the U.S. Government for the final two milestones under our DARPA contract in the aggregate amount of \$387,438.

The details of those milestones were as follows:

Milestone 2.6.1.3 - Quantify the degree to which the MERS virus can be extracted from circulation in vitro using miniature Hemopurifiers. The milestone payment was \$193,719. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We quantified the degree to which the MERS virus can be extracted from circulation in vitro using miniature Hemopurifiers. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter.

Milestone 2.6.1.4 - Prepare and present Final Report for DARPA. The milestone payment was \$193,719. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We prepared and presented the Final Report for DARPA. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter.

In the six months ended September 30, 2015, we invoiced the U.S. Government for two milestones under our DARPA contract in the amount of \$372,328.

The details of those milestones were as follows:

Milestone M6 - Define Aethlon's GMP manufacturing process and revise and upgrade Aethlon's quality procedures and policies to the current state of the art. The milestone payment was \$186,164. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We demonstrated that defined our GMP manufacturing process and that we revised and upgraded our quality procedures and policies to the current state of the art for a company of our size. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter.

Milestone 2.5.1.1 - Complete Aethlon's GMP procedure and establish and maintain all GMP documentation for the company. The milestone payment was \$186,164. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We demonstrated that we completed our GMP procedures and established and maintained all GMP documentation for the company. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter.

12. SEGMENTS

We operate our businesses principally through two reportable segments: Aethlon, which represents our therapeutic business activities, and ESI, which represents our diagnostic business activities. Our reportable segments have been determined based on the nature of the potential products being developed. We record discrete financial information for ESI and our chief operating decision maker reviews ESI's operating results in order to make decisions about resources to be allocated to the ESI segment and to assess its performance.

Aethlon's revenue is generated primarily from government contracts to date and ESI does not yet have any revenues. We have not included any allocation of corporate overhead to the ESI segment.

The following tables set forth certain information regarding our segments:

	Six Months Ended September 30,	
	2016	2015
Revenues:		
Aethlon	\$ 392,073	\$ 380,874
ESI	—	—
Total Revenues	<u>\$ 392,073</u>	<u>\$ 380,874</u>
Operating Losses:		
Aethlon	\$ (3,281,530)	\$ (1,911,219)
ESI	(76,999)	(303,113)
Total Operating Loss	<u>\$ (3,358,529)</u>	<u>\$ (2,214,332)</u>
Net Losses:		
Aethlon	\$ (4,323,003)	\$ (2,165,152)
ESI	(76,999)	(303,113)
Net Loss Before Non-Controlling Interests	<u>\$ (4,400,002)</u>	<u>\$ (2,468,265)</u>
Cash:		
Aethlon	\$ 553,884	\$ 4,208,554
ESI	2,468	802
Total Cash	<u>\$ 556,352</u>	<u>\$ 4,209,356</u>
Total Assets:		
Aethlon	\$ 914,179	\$ 4,677,989
ESI	36,656	27,486
Total Assets	<u>\$ 950,835</u>	<u>\$ 4,705,475</u>
Capital Expenditures:		
Aethlon	\$ 2,961	\$ —
ESI	—	—
Capital Expenditures	<u>\$ 2,961</u>	<u>\$ —</u>
Depreciation and Amortization:		
Aethlon	\$ 10,822	\$ 8,886
ESI	9,790	9,790
Total Depreciation and Amortization	<u>\$ 20,612</u>	<u>\$ 18,676</u>
Interest Expense:		
Aethlon	\$ (78,743)	\$ (253,933)
ESI	—	—
Total Interest Expense	<u>\$ (78,743)</u>	<u>\$ (253,933)</u>

13. COMMITMENTS AND CONTINGENCIES

LEASE COMMITMENTS

We currently rent approximately 2,600 square feet of executive office space at 9635 Granite Ridge Drive, Suite 100, San Diego, CA 92123 at the rate of \$6,054 per month on a four-year lease that expires in January 2019. We also rent approximately 1,700 square feet of laboratory space at 11585 Sorrento Valley Road, Suite 109, San Diego, California 92121 at the rate of \$4,394 per month on a one-year lease that was recently extended to an expiration date of November 30, 2017.

Our Exosome Sciences, Inc. subsidiary previously rented approximately 2,055 square feet of office and laboratory space at 11 Deer Park Drive, South Brunswick, NJ at the rate of \$3,917 per month on a one-year lease that expired in October 2015. In October 2015, ESI relocated to a different suite at the same office complex. That new suite was comprised of approximately 541 square feet of office and laboratory space and is located at 9 Deer Park Drive, South Brunswick, NJ at the rate of \$1,352 per month under a month to month lease basis. In January 2016, we exercised our 30-day notice to terminate the ESI lease in New Jersey as part of a consolidation of our laboratory operations in San Diego and the ESI lease was terminated effective February 29, 2016.

Rent expense, which is included in general and administrative expenses, approximated \$79,000 and \$90,000 for the six month periods ended September 30, 2016 and 2015, respectively.

LEGAL MATTERS

From time to time, claims are made against us in the ordinary course of business, which could result in litigation. Claims and associated litigation are subject to inherent uncertainties and unfavorable outcomes could occur, such as monetary damages, fines, penalties or injunctions prohibiting us from selling one or more products or engaging in other activities.

The occurrence of an unfavorable outcome in any specific period could have a material adverse effect on our results of operations for that period or future periods. We are not presently a party to any pending or threatened legal proceedings.

14. SUBSEQUENT EVENTS

Management has evaluated events subsequent to September 30, 2016 through the date that the accompanying condensed consolidated financial statements were filed with the Securities and Exchange Commission for transactions and other events which may require adjustment of and/or disclosure in such financial statements.

In October 2016, we collected \$193,719 from DARPA. That amount had been invoiced to DARPA for the achievement of a milestone in September 2016 and was classified as an account receivable as of September 30, 2016.

Subsequent to September 30, 2016, we continued selling common stock under our Common Stock Sales Agreement with H.C. Wainwright (see Note 6). Between the period of October 1, 2016 through November 8, 2016, we raised net proceeds of \$61,265 (after deducting \$1,919 in commissions to H.C. Wainwright and \$799 in other offering expenses) utilizing the sales agreement through the sale of 13,261 shares at an average price of \$4.62 per share of net proceeds.

On October 5, 2016, we entered into an amendment of the lease for our laboratory space at 11585 Sorrento Valley Road, Suite 109, San Diego, California 92121. Pursuant to the amendment, the lease term will be extended to November 30, 2017 and the rent will be \$4,394 per month.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion of our financial condition and results of operations should be read in conjunction with, and is qualified in its entirety by, the condensed consolidated financial statements and notes thereto included in Item 1 in this Quarterly Report on Form 10-Q. This item contains forward-looking statements that involve risks and uncertainties. Actual results may differ materially from those indicated in such forward-looking statements.

FORWARD LOOKING STATEMENTS

All statements, other than statements of historical fact, included in this Form 10-Q are, or may be deemed to be, "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Exchange Act. Such forward-looking statements involve assumptions, known and unknown risks, uncertainties and other factors which may cause the actual results, performance, or achievements of Aethlon Medical, Inc. ("we" or "us") to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements contained in this Form 10-Q. Such potential risks and uncertainties include, without limitation, completion of our capital-raising activities, U.S. Food and Drug Administration, or FDA, approval of our products, other regulations, patent protection of our proprietary technology, product liability exposure, uncertainty of market acceptance, competition, technological change, and other risk factors detailed herein and in other of our filings with the Securities and Exchange Commission (the "Commission"). The forward-looking statements are made as of the date of this Form 10-Q, and we assume no obligation to update the forward-looking statements, or to update the reasons actual results could differ from those projected in such forward-looking statements.

Overview

We are a medical device company focused on creating innovative devices that address unmet medical needs in cancer, infectious disease and other life-threatening conditions. At the core of our developments is the Aethlon ADAPT™ (Adaptive Dialysis-Like Affinity Platform Technology) system, a medical device platform that converges single or multiple affinity drug agents with advanced plasma membrane technology to create therapeutic filtration devices that selectively remove harmful particles from the entire circulatory system without loss of essential blood components.

In June 2013, the FDA approved our investigational device exemption application to initiate a ten-patient human clinical trial in one location in the U.S. to treat dialysis patients who are infected with the Hepatitis C virus. The principal investigator of that clinical trial recently began recruiting patients. Successful outcomes of that human trial as well as at least one follow-on human trial will be required by the FDA in order to commercialize our products in the U.S. The regulatory agencies of certain foreign countries where we intend to sell this device will also require one or more human clinical trials.

Some of our patents may expire before we receive FDA approval to market our products in the U.S. or we receive approval to market our products in a foreign country. However, we believe that certain patent applications and/or other patents issued more recently will help protect the proprietary nature of the Hemopurifier treatment technology.

Through Exosome Sciences, Inc. (ESI), our majority-owned subsidiary, we are also studying potential diagnostic techniques for identifying and monitoring neurological conditions and cancer. We consolidate ESI's activities in our consolidated financial statements.

Our common stock is traded on the Nasdaq Capital Market under the symbol "AEMD."

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the informational requirements of the Securities Exchange Act and must file reports, proxy statements and other information with the Commission. The reports, information statements and other information we file with the Commission can be inspected and copied at the Commission Public Reference Room, 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the Commission at (800) SEC-0330. The Commission also maintains a Web site (<http://www.sec.gov>) that contains reports, proxy and information statements and other information regarding registrants, like us, which file electronically with the Commission. Our headquarters are located at 9635 Granite Ridge Drive, Suite 100, San Diego, CA 92123. Our phone number at that address is (858) 459-7800. Our Web site is <http://www.aethlonmedical.com>.

RESULTS OF OPERATIONS

THREE MONTHS ENDED SEPTEMBER 30, 2016 COMPARED TO THE THREE MONTHS ENDED SEPTEMBER 30, 2015

Revenues

We recorded government contract revenue in the three months ended September 30, 2016 and 2015. This revenue arose from work performed under our government contract with the Defense Advanced Research Projects Agency, or DARPA, and our subcontract with Battelle Memorial Institute as follows:

	Three Months Ended 9/30/16	Three Months Ended 9/30/15	Change in Dollars
DARPA Contract	\$ 387,438	\$ 186,164	\$ 201,274
Battelle Subcontract	–	2,202	(2,202)
Total Government Contract Revenue	<u>\$ 387,438</u>	<u>\$ 188,366</u>	<u>\$ 199,072</u>

DARPA Contract

We entered into a contract with DARPA on September 30, 2011. Under the DARPA award, we have been engaged to develop a therapeutic device to reduce the incidence of sepsis, a fatal bloodstream infection that often results in the death of combat-injured soldiers. The award from DARPA was a fixed-price contract with potential total payments to us of \$6,794,389 over the course of five years. Fixed price contracts require the achievement of multiple, incremental milestones to receive the full award during each year of the contract. Under the terms of the contract, we performed certain incremental work towards the achievement of specific milestones against which we invoiced the government for fixed payment amounts.

Originally, only the base year (year one of the contract) was effective for the parties; however, DARPA subsequently exercised its option on the remaining years of the contract. The milestones were comprised of planning, engineering and clinical targets, the achievement of which in some cases required the participation and contribution of third party participants under the contract. We commenced work under the contract in October 2011.

In February 2014, DARPA reduced the scope of our contract in years three through five of the contract. The reduction in scope focused our research on exosomes, viruses and blood processing instrumentation. This scope reduction reduced the possible payments under the contract by \$858,469 over years three through five.

In the three months ended September 30, 2016, we invoiced the U.S. Government for the final two milestones under our DARPA contract in the aggregate amount of \$387,438. In the three months ended September 30, 2015, we invoiced the U.S. Government for one milestone under our DARPA contract in the amount of \$186,164.

Operating Expenses

Consolidated operating expenses for the three months ended September 30, 2016 were \$2,614,116 in comparison with \$1,312,727 for the comparable quarter a year ago. This increase of \$1,301,389, or 99.1%, was due to increases in payroll and related expenses of \$1,215,153 and in professional fees of \$121,775, which were partially offset by a reduction in general and administrative expenses of \$35,539.

The \$1,215,153 increase in payroll and related expenses was due to a \$1,472,570 increase in stock-based compensation, which was partially offset by a \$257,417 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 \$121,775 increase in our professional fees was primarily due to an increase in our non-DARPA-related professional fees of \$144,307, which was partially offset by decreases in our DARPA-related professional fees of \$22,166 and in our professional fees at ESI of \$366. The \$144,307 increase in our non-DARPA-related professional fees was due to a \$112,596 increase in scientific consulting fees, a \$51,000 increase in business development expenses, a \$9,665 increase in our accounting fees, a \$7,127 increase in investor relations fees and a \$5,942 increase in our public relations fees, which were partially offset by a \$43,044 decrease in legal fees.

The \$35,539 decrease in general and administrative expenses was the result of decreases of \$59,065 in our non-DARPA-related general and administrative expenses and of \$31,945 in our general and administrative expenses at ESI, which were partially offset by a \$55,470 increase in our DARPA-related general and administrative expenses.

Other Expense

Other expense in the three months ended September 30, 2016 and 2015 consisted of interest expense. Interest expense was \$36,576 for the three months ended September 30, 2016 compared to \$127,245 in the corresponding prior period, a decrease of \$90,669. The various components of our interest expense are shown in the following table:

	Quarter Ended 9/30/16	Quarter Ended 9/30/15	Change
Interest Expense	\$ 17,578	\$ 13,968	\$ 3,610
Amortization of Deferred Financing Costs	–	20,139	(20,139)
Amortization of Note Discounts	18,998	93,138	(74,140)
Total Interest Expense	<u>\$ 36,576</u>	<u>\$ 127,245</u>	<u>\$ (90,669)</u>

As noted in the above table, the most significant factor in the \$90,669 decrease in interest expense was the \$74,140 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 \$20,139 decrease in the amortization of deferred financing costs and a \$3,610 increase in our contractual interest expense.

Net Loss

As a result of the changes in revenues and expenses noted above, our net loss before noncontrolling interests increased from approximately \$1,252,000 in the quarter ended September 30, 2015 to approximately \$2,263,000 for the quarter ended September 30, 2016.

Basic and diluted loss attributable to common stockholders was (\$0.29) for the three month period ended September 30, 2016 and (\$0.16) for the three month period ended September 30, 2015.

SIX MONTHS ENDED SEPTEMBER 30, 2016 COMPARED TO THE SIX MONTHS ENDED SEPTEMBER 30, 2015

Revenues

We recorded government contract revenue in the six months ended September 30, 2016 and 2015. This revenue arose from work performed under our government contract with the Defense Advanced Research Projects Agency, or DARPA, and our subcontract with Battelle Memorial Institute as follows:

	Six Months Ended 9/30/16	Six Months Ended 9/30/15	Change in Dollars
DARPA Contract	\$ 387,438	\$ 372,328	\$ 15,110
Battelle Subcontract	4,635	8,546	(3,911)
Total Government Contract Revenue	<u>\$ 392,073</u>	<u>\$ 380,874</u>	<u>\$ 11,199</u>

DARPA Contract

We entered into a contract with DARPA on September 30, 2011. Under the DARPA award, we have been engaged to develop a therapeutic device to reduce the incidence of sepsis, a fatal bloodstream infection that often results in the death of combat-injured soldiers. The award from DARPA was a fixed-price contract with potential total payments to us of \$6,794,389 over the course of five years. Fixed price contracts require the achievement of multiple, incremental milestones to receive the full award during each year of the contract. Under the terms of the contract, we performed certain incremental work towards the achievement of specific milestones against which we invoiced the government for fixed payment amounts.

Originally, only the base year (year one of the contract) was effective for the parties; however, DARPA subsequently exercised its option on the remaining years of the contract. The milestones were comprised of planning, engineering and clinical targets, the achievement of which in some cases required the participation and contribution of third party participants under the contract. We commenced work under the contract in October 2011.

In February 2014, DARPA reduced the scope of our contract in years three through five of the contract. The reduction in scope focused our research on exosomes, viruses and blood processing instrumentation. This scope reduction reduced the possible payments under the contract by \$858,469 over years three through five.

In the six months ended September 30, 2016, we invoiced the U.S. Government for the final two milestones under our DARPA contract in the aggregate amount of \$387,438. In the six months ended September 30, 2015, we invoiced the U.S. Government for two milestones under our DARPA contract in the amount of \$372,328.

Operating Expenses

Consolidated operating expenses for the six months ended September 30, 2016 were \$3,750,602 in comparison with \$2,595,206 for the comparable quarter a year ago. This increase of \$1,155,396, or 44.5%, was due to increases in payroll and related expenses of \$1,102,112 and in professional fees of \$151,298, which were partially offset by a decrease in general and administrative expenses of \$98,014.

The \$1,102,112 increase in payroll and related expenses was primarily due to a \$1,472,570 increase in stock-based compensation, which was partially offset by a \$370,458 decrease in cash-based compensation. The increase in stock-based compensation was due to the RSU grants to our officers and directors in the three months ended September 30, 2016.

The \$151,298 increase in our professional fees was primarily due to an increase in our non-DARPA-related professional fees of \$202,114, which was partially offset by a reduction in our professional fees at ESI of \$4,918 and in our DARPA-related professional fees of \$45,898. The \$202,114 increase in our non-DARPA-related professional fees was due to a \$160,924 increase in scientific consulting fees, an \$85,000 increase in business development expenses, an \$8,851 increase in investor relations fees and a \$5,942 increase in our public relations fees, which were partially offset by a decreases of \$39,909 in accounting fees and \$19,953 in legal fees.

The \$98,014 decrease in general and administrative expenses was primarily due to decreases of \$103,221 in our non-DARPA-related general and administrative expenses and of \$49,373 in the general and administrative expenses at ESI, which were partially offset by an increase of \$54,580 in our DARPA-related general and administrative expenses.

Other Expense

Other expense during the six months ended September 30, 2016 and 2015 consisted primarily of losses on debt extinguishment, warrant repricing expense and interest expense. Other expense for the six months ended September 30, 2016 was other expense of \$1,041,473 in comparison with other expense of \$253,933 for the six months ended September 30, 2015.

The following table breaks out the various components of our other expense for both periods:

	Six Months Ended 9/30/16	Six Months Ended 9/30/15	Change
Loss on Debt Extinguishment	\$ 616,889	\$ -	\$ 616,889
Loss on Warrant Repricing	345,841	-	345,841
Interest Expense	78,743	253,933	(175,190)
Total Other Expense	<u>\$ 1,041,473</u>	<u>\$ 253,933</u>	<u>\$ 787,540</u>

Loss on Debt Extinguishment

This loss on debt extinguishment arose from the Amendments (the "Amendments") to our November 2014 convertible notes. The Amendments provided that the maturity date of the notes was extended from June 1, 2016 to July 1, 2017 and that the conversion price was reduced from \$5.60 per share of common stock to \$5.00 per share of common stock. In addition, we reduced the purchase price of warrants issued in connection with the notes from \$8.40 per share to \$5.00 per share. In connection with these modifications, each of the Investors signed a consent and waiver providing its consent under certain restrictive provisions, and waiving certain rights, including a right to participate in certain offerings made by us, under a securities purchase agreement dated June 23, 2015, (the "2015 SPA") to which we, the Investors and certain other investors are parties, in order to facilitate an at-the-market equity program described in the liquidity and capital resources section of this report below. This loss also included an \$80,000 fee to extend the November 2014 convertible notes from June 1, 2016 to July 1, 2017. The \$80,000 amount was not a cash payment but rather was added to the principal of the notes.

Loss on Warrant Repricing

On June 27, 2016, we and certain investors (the "Unit Investors") entered into Consent and Waiver and Amendment agreements (the "CWAs"), relating to an aggregate of 264,000 Warrants to Purchase Common Stock (the "Unit Warrants") we had issued to the Unit Investors on December 2, 2014 pursuant to a Securities Purchase Agreement dated November 26, 2014 (the "2014 SPA"). In the CWAs, each of the Unit Investors provided its consent under certain restrictive provisions, and waived certain rights, including a right to participate in certain offerings made by us, under the 2014 SPA in order to facilitate the at-the-market equity program described in the notes to the Financial Statements. Pursuant to the CWAs, we reduced the Exercise Price (as defined in the Unit Warrants) from \$15.00 per share of common stock to \$5.00 per share of common stock.

On June 27, 2016, each of the Unit Investors also entered into a Consent and Waiver providing its consent under certain provisions, and waiving certain rights, including a right to participate in certain offerings made by us, under the 2015 SPA in order to facilitate the at-the market equity program described in the notes to the Financial Statements.

We measured the change in fair value that arose from the reduction in exercise price from \$15.00 to \$5.00 and recorded a charge of \$345,841 to our other expense to reflect this change.

Interest Expense

Interest expense was \$78,743 for the six months ended September 30, 2016 compared to \$253,933 in the corresponding prior period, a decrease of \$175,190. The various components of our interest expense are shown in the following table:

	Six Months Ended 9/30/16	Six Months Ended 9/30/15	Change
Interest Expense	\$ 32,104	\$ 28,216	\$ 3,888
Amortization of Deferred Financing Costs	27,641	39,441	(11,800)
Amortization of Note Discounts	18,998	186,276	(167,278)
Total Interest Expense	<u>\$ 78,743</u>	<u>\$ 253,933</u>	<u>\$ (175,190)</u>

As noted in the above table, the most significant factor in the \$175,190 decrease in interest expense was the \$167,278 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 an \$11,800 decrease in the amortization of deferred financing costs and a \$3,888 increase in our contractual interest expense.

Net Loss

As a result of the changes in revenues and expenses noted above, our net loss before noncontrolling interests increased from approximately \$2,468,000 in the six month period ended September 30, 2015 to approximately \$4,400,000 for the six month period ended September 30, 2016.

Basic and diluted loss attributable to common stockholders were (\$0.57) for the six month period ended September 30, 2016 compared to (\$0.34) for the period ended September 30, 2015.

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2016, we had a cash balance of \$556,352 and negative working capital of \$267,681. This compares to a cash balance of \$2,123,737 and working capital of \$1,849,891 at March 31, 2016. The primary reason that we had negative working capital at September 30, 2016 was the presentation of \$605,815 in convertible notes as a current liability rather than as a long term liability as we did at March 31, 2016 since those notes have an expiration date of July 1, 2017, which is less than one year from the September 30, 2016 balance sheet date.

Significant additional financing must be obtained in order to provide a sufficient source of operating capital and to allow us to continue to operate as a going concern. In addition, we will need to raise capital to complete the approved human clinical trial in the U.S. We anticipate the primary source of this additional financing will be from proceeds of our at-the-market offering program.

We raised \$5,591,988 in net proceeds from a financing in June 2015. That amount, coupled with previously existing funds on hand and revenues from our government contracts, has financed our operations through the second quarter of the fiscal year ending March 31, 2017. However, we will require significant additional financing to complete the current and expected additional future clinical trials in the U.S., as well as fund all of our continued research and development activities for the Hemopurifier and products on our Aethlon ADAPT platform through the twelve month period ending June 30, 2017. In addition, as we expand our activities, our overhead costs to support personnel, laboratory materials and infrastructure will increase. Should the financing we require to sustain our working capital needs be unavailable to us on reasonable terms, if at all, when we require it, we may be unable to support our research and U.S. Food and Drug Administration, or FDA, clearance activities including our planned clinical trials. The failure to implement our research and clearance activities would have a material adverse effect on our ability to commercialize our products.

Future capital requirements will depend upon many factors, including progress with pre-clinical testing and clinical trials, the number and breadth of our clinical programs, the time and costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other proprietary rights, the time and costs involved in obtaining regulatory approvals, competing technological and market developments, as well as our ability to establish collaborative arrangements, effective commercialization, marketing activities and other arrangements. We expect to continue to incur increasing negative cash flows and net losses for the foreseeable future.

Going Concern

The accompanying condensed consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the ordinary course of business. We have incurred continuing losses from operations and at September 30, 2016 had limited working capital and an accumulated deficit of approximately \$90,887,000. These factors, among other matters, raise substantial doubt about our ability to continue as a going concern. A significant amount of additional capital will be necessary to advance the development of our products to the point at which they may become commercially viable. We intend to fund operations, working capital and other cash requirements for the twelve month period ending September 30, 2017 through debt and/or equity financing arrangements as well as through revenues and related cash receipts under our government contracts.

We are currently addressing our liquidity issue by seeking additional investment capital through issuances of common stock under our existing S-3 registration statement and by applying for additional grants issued by government agencies in the United States. We believe that our cash on hand and funds expected to be received from additional debt and equity financing arrangements will be sufficient to meet our liquidity needs for fiscal 2017. However, no assurance can be given that we will receive any funds in addition to the funds we have received to date (see Note 14).

In July 2016, we commenced sales of common stock under our Common Stock Sales Agreement with H.C. Wainwright. We raised \$266,612 under that sales agreement during the three months ended September 30, 2016 (after deducting \$8,348 in commissions to H.C. Wainwright and \$3,319 in other offering expenses) through the sale of 50,163 shares at an average price of \$5.31 per share of net proceeds. Subsequent to September 30, 2016, we continued selling common stock under our Common Stock Sales Agreement with H.C. Wainwright (see Note 6). Between the period of October 1, 2016 through November 8, 2016, we raised net proceeds of \$61,265 (after deducting \$1,919 in commissions to H.C. Wainwright and \$799 in other offering expenses) utilizing the sales agreement through the sale of 13,261 shares at an average price of \$4.62 per share of net proceeds.

In October 2016, we collected \$193,719 from DARPA. That amount had been invoiced to DARPA for the achievement of a milestone in September 2016 and was classified as an account receivable as of September 30, 2016.

The successful outcome of future activities cannot be determined at this time and there is no assurance that, if achieved, we will have sufficient funds to execute our intended business plan or generate positive operating results.

The consolidated financial statements do not include any adjustments related to this uncertainty and as to the recoverability and classification of asset carrying amounts or the amount and classification of liabilities that might result should we be unable to continue as a going concern.

Cash Flows

Cash flows from operating, investing and financing activities, as reflected in the accompanying Condensed Consolidated Statements of Cash Flows, are summarized as follows:

	(In thousands)	
	For the six months ended	
	September 30, 2016	September 30, 2015
Cash (used in) provided by:		
Operating activities	\$ (1,763)	\$ (2,238)
Investing activities	(3)	—
Financing activities	199	5,592
Net (decrease) increase in cash	<u>\$ (1,567)</u>	<u>\$ 3,354</u>

NET CASH USED IN OPERATING ACTIVITIES. We used cash in our operating activities due to our losses from operations. Net cash used in operating activities was approximately \$1,763,000 in the six months ended September 30, 2016 compared to \$2,238,000 in the six months ended September 30, 2015, a decrease of \$475,000.

NET CASH USED IN INVESTING ACTIVITIES. We used approximately \$3,000 of cash to purchase office equipment and fixtures in the six months ended September 30, 2016. There were no investing activities in the six months ended September 30, 2015.

NET CASH FROM FINANCING ACTIVITIES. In the six months ended September 30, 2015 we raised approximately \$5,592,000 through the sale of common stock. We raised approximately \$267,000 through the sale of common stock in the six months ended September 30, 2016, which was partially offset by approximately \$67,000 in cash paid for tax withholding on vested rights, for total cash from financing activities of approximately \$199,000.

At the date of this filing, we plan to invest significantly into purchases of our raw materials and into our contract manufacturing arrangement subject to successfully raising additional capital.

CRITICAL ACCOUNTING POLICIES

The preparation of condensed consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires us to make a number of estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements. Such estimates and assumptions affect the reported amounts of expenses during the reporting period. On an ongoing basis, we evaluate estimates and assumptions based upon historical experience and various other factors and circumstances. We believe our estimates and assumptions are reasonable in the circumstances; however, actual results may differ from these estimates under different future conditions.

We believe that the estimates and assumptions that are most important to the portrayal of our financial condition and results of operations, in that they require the most difficult, subjective or complex judgments, form the basis for the accounting policies deemed to be most critical to us. These critical accounting policies relate to revenue recognition, measurement of stock purchase warrants issued with notes payable, beneficial conversion feature of convertible notes payable, impairment of intangible assets and long lived assets, stock compensation, and the classification of warrant obligations, and evaluation of contingencies. We believe estimates and assumptions related to these critical accounting policies are appropriate under the circumstances; however, should future events or occurrences result in unanticipated consequences, there could be a material impact on our future financial condition or results of operations.

There have been no changes to our critical accounting policies as disclosed in our Form 10-K for the year ended March 31, 2016.

OFF-BALANCE SHEET ARRANGEMENTS

We have no obligations required to be disclosed herein as off-balance sheet arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

As a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and in Item 10(f)(1) of Regulation S-K, we are electing scaled disclosure reporting obligations and therefore are not required to provide the information requested by this item.

ITEM 4. CONTROLS AND PROCEDURES.

DISCLOSURE CONTROLS AND PROCEDURES

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of the end of the period covered by this Quarterly Report.

Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of the end of such period, our disclosure controls and procedures are effective in recording, processing, summarizing and reporting, on a timely basis, information required to be disclosed by us in the reports that we file or submit under the Exchange Act and are effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

There have been no changes in our internal control over financial reporting during the last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

From time to time, claims are made against us in the ordinary course of business, which could result in litigation. Claims and associated litigation are subject to inherent uncertainties and unfavorable outcomes could occur, such as monetary damages, fines, penalties or injunctions prohibiting us from selling one or more products or engaging in other activities.

The occurrence of an unfavorable outcome in any specific period could have a material adverse effect on our results of operations for that period or future periods. We are not presently a party to any pending or threatened legal proceedings.

ITEM 1A. RISK FACTORS.

As a smaller reporting company as defined by rule 12b-2 of the Exchange Act and in Item 10(f)(1) of Regulation S-K, we are electing scaled disclosure reporting obligations and therefore are not required to provide the information requested by this item.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

During the quarter ended September 30, 2016 and subsequent thereto through the date of filing this report, we issued the following securities which were not registered under the Securities Act of 1933, as amended. We did not employ any form of general solicitation or advertising in connection with the offer and sale of the securities described below. In addition, we believe the purchasers are “accredited investors” for the purpose of Rule 501 promulgated under the Securities Act. For these reasons, among others, the offer and sale of the following securities were made in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act or Regulation D promulgated by the Commission under the Securities Act.

On July 26, 2016, we issued an aggregate of 2,660 shares of common stock to three investors upon the exercise of previously issued warrants. The warrants were exercised on a cashless or “net” basis. Accordingly, we did not receive any proceeds from such exercises. The cashless exercise of such warrants resulted in the cancellation of previously issued warrants to purchase an aggregate of 19,563 shares of common stock.

On August 12, 2016, we issued 6,464 shares of common stock to the holder of a convertible note in exchange for the partial conversion of principal and interest in the aggregate amount of \$32,321 at a conversion price of \$5.00 per share.

On September 1, 2016, we issued an aggregate of 27,122 shares of common stock to our three outside directors in settlement of an aggregate of 27,122 restricted stock units, or RSUs, previously granted to them, which RSUs vested on August 9, 2016. On September 30, 2016, we issued an aggregate of 3,010 shares of common stock to our three outside directors in settlement of an aggregate of 3,010 RSUs previously granted to them, which RSUs vested on September 30, 2016.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

We have no disclosure applicable to this item.

ITEM 4. MINE SAFETY DISCLOSURES.

We have no disclosure applicable to this item.

ITEM 5. OTHER INFORMATION.

We have no disclosure applicable to this item.

ITEM 6. EXHIBITS.

(a) Exhibits. The following documents are filed as part of this report:

3.1	Articles of Incorporation of Aethlon Medical, Inc., as amended (1)
3.2	Bylaws of Aethlon Medical, Inc., as amended (2)
10.1	DARPA Contract dated September 30, 2011*
10.2	2012 Non-Employee Directors Compensation Program, as amended August 9, 2016 (3)
10.3	Stock Unit Agreement by and between Aethlon Medical, Inc. and James A. Joyce dated August 29, 2016*
10.4	Stock Unit Agreement by and between Aethlon Medical, Inc. and Rodney S. Kenley dated August 29, 2016*
10.5	Stock Unit Agreement by and between Aethlon Medical, Inc. and James B. Frakes dated August 29, 2016*
10.6	Stock Unit Agreement by and between Aethlon Medical, Inc. and Franklyn S. Barry, Jr. dated August 29, 2016*
10.7	Stock Unit Agreement by and between Aethlon Medical, Inc. and Edward G. Broenniman dated August 29, 2016*
10.8	Stock Unit Agreement by and between Aethlon Medical, Inc. and Chetan S. Shah, MD dated August 29, 2016*
10.9	Fourth Amendment to Standard Industrial Net Lease by and between AGP Sorrento Business Complex, L.P. and Aethlon Medical, Inc. dated October 5, 2016*
31.1	Certification of Principal Executive Officer pursuant to Securities Exchange Act rules 13a- 14(a) and 15d-14(a) as adopted pursuant to section 302 of the Sarbanes-Oxley Act of 2002*
31.2	Certification of Principal Financial Officer pursuant to Securities Exchange Act rules 13a- 14(a) and 15d-14(a) as adopted pursuant to section 302 of the Sarbanes-Oxley Act of 2002*
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002*
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002*
101	Interactive Data Files*
101.INS	XBRL Instance Document
101.SCH	XBRL Schema Document
101.CAL	XBRL Calculation Linkbase Document
101.DEF	XBRL Definition Linkbase Document
101.LAB	XBRL Label Linkbase Document
101.PRE	XBRL Presentation Linkbase Document

* Filed herewith.

- (1) Filed with the Company's Registration Statement on Form S-3 (File No. 333-211151) filed on May 5, 2016 and incorporated by reference.
- (2) Filed with the Company's Annual Report on Form 10-K filed on June 26, 2015 for the year ended March 31, 2015 and incorporated by reference.
- (3) Filed with the Company's Current Report on Form 8-K filed on August 10, 2016 and incorporated by reference.

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 thereunto duly authorized.

AETHLON MEDICAL, INC.

Date: November 10, 2016

By: /s/ JAMES B. FRAKES
JAMES B. FRAKES
CHIEF FINANCIAL OFFICER
CHIEF ACCOUNTING OFFICER

AWARD/CONTRACT		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		RATING	PAGE OF PAGES 1 43		
2. CONTRACT (Proc. Inv. Order) NO. N56001-11-C-4188		3. EFFECTIVE DATE 30 Sep 2011		4. REQUISITION/PURCHASE REQUEST/PROJECT NO. SEE SCHEDULE			
5. ISSUED BY SPAWAR SYSTEMS CENTER PACIFIC SEAN B. KEARNS, CODE 2250 SEAN KEARNS@NAVY.MIL 13250 HULL STREET SAN DIEGO CA 92152-5001		CODE N56001	6. ADMINISTERED BY (If other than item 5) DCMA SAN DIEGO 7635 PACOET ST SUITE 200 SAN DIEGO CA 92111-2241		CODE S0214A		
7. NAME AND ADDRESS OF CONTRACTOR (City, street, care, county, state and zip code) AETHLON MEDICAL INC DUNSR 06490865 8910 UNIVERSITY CTR LN STE 600 SAN DIEGO CA 92122-1027		8. DELIVERY <input type="checkbox"/> FOB ORIGIN <input checked="" type="checkbox"/> OTHER (See below)		9. DISCOUNT FOR PROMPT PAYMENT			
CODE 47A31		FACILITY CODE		10. SUBMIT INVOICES (If copies and/or references specified) TO THE ADDRESS SHOWN IN: ITEM Section G			
11. SHIP TO/MARK FOR CODE See Schedule		12. PAYMENT WILL BE MADE BY DFAS COLUMBUS CENTER DFAS-COMVEST ENTITLEMENT OPERATIONS P.O. BOX 162261 COLUMBUS OH 43216-2261		CODE H0039			
13. AUTHORITY FOR OTHER THAN FULL AND OPEN COMPETITION: <input checked="" type="checkbox"/> 10 U.S.C. 2304(c)(5) <input type="checkbox"/> 41 U.S.C. 253(c)()		14. ACCOUNTING AND APPROPRIATION DATA See Schedule					
15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT		
SEE SCHEDULE							
15G. TOTAL AMOUNT OF CONTRACT					\$1,975,047.00		
16. TABLE OF CONTENTS							
(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES			
X	A	SOLICITATION/ CONTRACT FORM	1	X	I	CONTRACT CLAUSES	32 - 42
X	B	SUPPLIES OR SERVICES AND PRICES/ COSTS	2 - 6	PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS			
X	C	DESCRIPTION/ SPECS/ WORK STATEMENT	7 - 14	X	J	LIST OF ATTACHMENTS	43
X	D	PACKAGING AND MARKING	15	PART IV - REPRESENTATIONS AND INSTRUCTIONS			
X	E	INSPECTION AND ACCEPTANCE	16	K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS		
X	F	DELIVERIES OR PERFORMANCE	17 - 18		L. INSTRS., CONDS., AND NOTICES TO OFFERORS		
X	G	CONTRACT ADMINISTRATION DATA	19 - 24	M. EVALUATION FACTORS FOR AWARD			
X	H	SPECIAL CONTRACT REQUIREMENTS	25 - 31				
CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE							
17. <input checked="" type="checkbox"/> CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and forward it to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications as are attached or incorporated by reference herein. (Attachments are listed below.)			18. <input type="checkbox"/> AWARD (Contractor is not required to sign this document.) Year offer on Solicitation Number				
19A. NAME AND TITLE OF SIGNER (Type or print) <i>Richard H. Tullie CEO/PI</i>			20A. NAME OF CONTRACTING OFFICER DAVID W. JENKINS				
19B. NAME OF CONTRACTOR BY: <i>Richard H. Tullie</i> <small>Signature of person conducting business</small>		19C. DATE SIGNED 9-30-11	20B. UNITED STATES OF AMERICA BY: <i>David W. Jenkins</i> <small>Signature of Contracting Officer</small>		20C. DATE SIGNED 30 SEP 2011		

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Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001		1	Lot	\$1,975,047.00	\$1,975,047.00

RESEARCH
FFP
Research IAW the SOW (Contained in section C).
FOB: Destination

NET AMT	\$1,975,047.00
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PURCHASE REQUEST NUMBER: 1300211787

000101	Funding Information			ACRN AA	\$938,583.00
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ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002	CDRLs				NSP

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003	RESEARCH	1	Lot	\$835,124.00	\$835,124.00
OPTION	FFP Research IAW the SOW (Contained in section C). FOB: Destination				
				NET AMT	<u>\$835,124.00</u>

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0004	CDRLs				NSP
OPTION					

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0005	Human and Animal Use	1	Lot	\$782,322.00	\$782,322.00
OPTION	FFP Tasking in SOW section 2.3.2 will not be funded until the contractor obtains all necessary IRB documentation and obtain both institutional and Government (SSC-Pacific) approval in accordance with IRB documentation submission guidance prior to conducting human or animal testing. FOB: Destination				
				NET AMT	<u>\$782,322.00</u>

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0006	RESEARCH	1	Lot	\$1,534,009.00	\$1,534,099.00
OPTION	FFP Research IAW the SOW (Contained in section C). FOB: Destination				
				NET AMT	<u>\$1,534,099.00</u>

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0007	CDRLs		Lot		NSP
OPTION					

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0008	Research	1	Lot	\$892,922.00	\$892,922.00
OPTION	FFP Research IAW the SOW (Contained in section C). FOB: Destination				
				NET AMT	<u>\$892,922.000</u>

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0009	CDRLs				NSP
OPTION					

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0010		1	Lot		NSP
OPTION					
	Hardware Deliverable				
	FFP				
	50 Prototype Optimized Cartridges				
	FOB: Destination				

NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0011		1	Lot		
OPTION					
	RESEARCH				
	FFP				
	Research IAW the SOW (Contained in section C).				
	FOB: Destination				

\$774,875.00 \$774,875.00

NET AMT

 \$774,875.000

ITEM NO 0012 OPTION	SUPPLIES/SERVICES CDRLs	QUANTITY	UNIT	UNIT PRICE	AMOUNT NSP
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STATEMENT OF WORK (SOW)

Statement of Work

Aethlon Medical, Inc.

DATE: 23 September 2011

TITLE: Broad Spectrum Countermeasures for Viral and Bacterial Sepsis using Dialysis-Like Devices

1. Scope

The scope of this effort is to use Aethlon's ADAPT System as the core technology within an extracorporeal blood purification device that would simultaneously remove: viruses, virally-derived immunosuppressive glycoproteins, and multiple classes of exosomes; complement activation, activation of virus growth (e.g. cytomegalovirus) and TLR activation, all of which have implications to the promotion of the well-being and recovery of wounded warfighters and the prevention of sepsis.

1.1 Introduction

This effort will use the adaptable dialysis-like platform (ADAPT) technology that allows for the selective removal of harmful agents from the entire circulatory system. This revolutionary advance overcomes the limitation of devices that indiscriminately adsorb or solely capture particles by molecule size. The platform will provide an expansive therapeutic filtration mechanism to immobilize multiple affinity agents directed toward precursors to sepsis, bacterial toxins, viral pathogens, and disease enhancing particles transported by exosomes. To insure benefit to wounded warfighters, this effort will advance an innovative strategy that will allow therapy administration without systemic anticoagulation.

The ADAPT platform has been previously used to create a broad-spectrum antiviral device that immobilized one lectin affinity agent, resulting in the effective capture of all tested Category A pathogens, as well as exosomes underlying tuberculosis and cancer. In human studies, this same device, known as the Hemopurifier, consistently provided greater than 50% average viral load reductions during four-hour treatment periods in both hepatitis-C and HIV infected individuals without antiviral drug therapy.

The resulting device would save thousands of military and civilian lives each year. Each of these technology advancements will be integrated into a single cartridge that will provide decision-free and life-saving medical care for the wounded warfighter.

1.2 Background

The goal of the DLT program is to develop a portable device that removes "dirty" blood from the body, separates harmful agents, and returns "clean" blood to the body in a manner similar to dialysis treatment of kidney failure. While the device could have an impact across multiple areas of medicine, the target application for this device is sepsis. The envisioned device can also provide early identification of the presence of a pathogen. Once the presence of pathogens has been confirmed, the DLT device will provide continuous "label-free" removal of pathogens, toxins and activated patient cells without pathogen identification or use of pathogen-specific binding chemistries. As a final step in the treatment process, the DLT device will enable closed-loop therapy based on continuous, reduced dimensionality modeling of patient health. Predictive modeling in this fashion will allow us to identify sepsis early, learn what we need to remove, and direct the most effective intervention to improve patient health. This cycle of sensing, adjustment, estimation, computation, and manipulation will modulate key health parameters faster than the underlying disease process and drive the patient towards a stable, healthy state.

2. Technical Requirements

2.1 Human and Animal use

Human use is anticipated in this effort, specifically related to the use of human blood. The contractor shall obtain all necessary Institutional Review Board (IRB) approvals, show proper assurance documentation, and obtain proper approval from the Government officials prior to human use testing. Funds associated with human subjected testing shall not be released until IRB documentation has been provided to SSC's HRPO and approval to release funds has been obtained.

Animal use is anticipated in this effort. The contractor shall obtain all necessary Institutional Animal Care and Utilization Committee (IACUC) approval and demonstrate this approval to the Government (**both** ACURO and SSC-Pacific) prior to beginning experimentation with animals. If animal use is no longer anticipated, or changes significantly from the approved IACUC then the Principal Investigator (PI) must submit a letter stating the discontinuation of animal use for this effort and/or receive appropriate authorization for IACUC changes of previously specified protocols. Unless prior approval by DARPA is given IACUC documentation must be provided prior to contract award.

2.2 Base Effort (Year 1)

2.2.1 Subtask 1a: Anticoagulant-free Hemopurification Device

- 2.2.1.1 Write requirements definition for the extracorporeal blood purification system and acquire necessary equipment.
- 2.2.1.2 Fabricate breadboard prototypes for anticoagulation-free anti-sepsis extracorporeal system (ASEPSYS) device. Fabricate prototype blood tubing sets. Acquire anti-thrombogenic surface-modified hollow fiber plasma separators.
- 2.2.1.3 Assemble and test breadboard ASEPSYS devices *ex vivo* with bovine blood. The test will most likely be conducted using a porcine model where the elapsed time to reach a pre-defined degree of clotting in the blood treatment device will be compared between the new device and two control groups; one using standard anticoagulant therapy and one using none. Determine contribution of the following techniques and approaches to eliminating anticoagulants:
 - (1) Backflushing at regular intervals, (2) Turbo loop, (3) Continuous pre-dilution loop using re-captured hydration fluid, (4) Linear vs pulsatile blood flow, (5) Elimination of air/blood interfaces in extracorporeal circuit, (6) Anti-thrombogenic derivatized plasma separation membrane, and (7) Ultra-short half-life anticoagulant nafamostat mesilate.
- 2.2.1.4 IRB Documentation Generation: The contractor shall obtain all necessary IRB documentation and obtain both institutional and Government (SSC-Pacific) approval in accordance with IRB documentation submission guidance prior to conducting human subject testing.

Milestones

- M1: Demonstrate the effectiveness of the prototype device in preventing platelet activation or clotting in at least a 2 hour blood pumping experiment at 100 mL/hr blood flow.

2.2.2 Subtask 2: Removal of Sepsis Precursors

- 2.2.2.1 Begin to develop a device based on Aethlon's ADAPT system to efficiently capture sepsis precursors identified as potentially important in killing patients undergoing sepsis. The strategy is takes advantage of the flexibility and rapidity of modification of our ADAPT platform system to test any sepsis precursor candidates that circulate in the blood. The sepsis precursors that will be targeted are shown in Table I, in order of importance. No test for the removal of bacterial toxins. No testing for removal of cytokines, since the evidence to date does not support a role for them in death due to sepsis. Additional factors may become known during the grant period and those will also be tested as time and budget permit.
-

2.2.2.2 Screening Capture Agents: Perform initial screening of the different proposed capture agents by measuring binding affinity and kinetics using surface plasmon resonance (SPR) or biolayer surface interferometry (BLI).

2.2.2.3 Perform quantitative real time PCR will also be used to measure viral load, and specific DNA or RNA targets.

Milestones

M2: Target capture > 50% in 24 hours for at least 1 target in blood or blood components

Table I Potential Target Sepsis Precursors and Broad Spectrum Binding Agents

Group	Factor	Proposed Binding Agents
Sepsis related Exosomes		
1. iNOS exosomes [1-3]	Inducible NO synthase containing exosomes implicated in sepsis	GNA lectin or iNOS Specific antibody
2. Platelet derived exosomes [4, 5]	Exosomes isolated from platelets associated with sepsis	GNA lectin or antibodies
3. Macrophage derived exosomes [6]	Exosomes from cultured macrophages	GNA lectin
Other Potential Sepsis Factors		
4. Complement Activation [7-9]	Humanized Cobra venom factor (CVF) from Incode, CVF is not a toxin	CVF is a stable analog of human complement that neutralizes C3a in animals
5. Bacterial DNA [13-15]	CpG rich DNA activates macrophages via Toll Like Receptors (TLR)	Antisense nuclease resistant DNA analogs, TLRs or specific antibodies
6. Common Sepsis associated Viruses including CMV	Virus blooms in trauma and burn patients [10]	GNA Lectin
7. Protease leakage through ischemic gut (e.g. trypsin) [11, 12]	Ischemia in the gut leads to protease leakage into the blood and the symptoms of sepsis (reperfusion injury)	Lima bean trypsin inhibitor, Soybean trypsin inhibitor

2.3 Option 1 (Year 2)

2.3.2 Subtask 1a: Anticoagulant-free Hemopurification Device

- 2.3.2.1 Demonstrate the effectiveness of the prototype device *in vivo* in animals preventing platelet activation or clotting in at least a 2 hour blood pumping experiment at 75 mL/min blood flow.
- 2.3.2.2 Formulate initial design based on work from previous phase. Begin to build and test selected instrument design and tubing sets.
- 2.3.2.3 Write and test software. Conduct ergonomic research. Begin discussions with System Integrator.

Milestone

- M3: Demonstrate the effectiveness of the prototype device in preventing platelet activation or clotting in at least a 8 hour blood pumping experiment at 500 mL/hr blood flow.

2.3.3 Subtask 2. Removal of Sepsis Precursors

- 2.3.3.1 Build the ADAPT capture cartridges with the identified affinity agents. Measure the rate of capture of the specific targets from *in vivo* recirculation experiments from cell culture and blood.
- 2.3.3.2 Cartridge construction with optimized affinity matrix design for each potential target. Complete all capture agents screening. Initiate *ex vivo* capture studies from blood using the optimized cartridges.

Milestones

- M4: Target capture > 50% in 24 hours for at least 5 targets in blood or blood components.
- M5: Milestone 5: Target capture > 90% in 24 hours for at least 3 targets in blood or blood components.

NOTE: TASK 2.3.2 SHALL NOT BE EXERCISED AND TASKING FUNDS RELEASED UNTIL IRB DOCUMENTATION AND PROPER IRB APPROVAL HAS BEEN OBTAINED.

2.4 Option 2 (Year 3)

2.4.1 Subtask 1a: Anticoagulant-free Hemopurification Device

- 2.4.1.1 Collaborate with System Integrator to build final prototypes for *in vivo* pig testing.
- 2.4.1.2 Perform animal tests to confirm the performance of the device *in vivo*.
- 2.4.1.3 Document all adverse events and long term effects of treatment.

Milestones

- M6: Demonstrate the effectiveness of the prototype device in preventing platelet activation or clotting in at least a 24 hour blood pumping experiment at 1250 mL/hr blood flow *in vivo* in pigs.

2.4.2 Subtask 4: Target Capture in Combined Agent Cartridge

- 2.4.2.1 Candidate cartridges that demonstrate >90% capture in 24 hours efficacy in binding to individual sepsis precursor targets will move to the next stage. These capture agents will be combined into a single cartridge and retested *ex vivo* in pig blood or blood components.
- 2.4.2.2 Optimize cartridge design in regard to fiber length, diameter and the use of prototype ASEPSYS system. Demonstrate increased capture rates 2-7 fold from the current system in blood or blood components. 2.4.2.3 Perform basic biocompatibility studies to confirm that the combination cartridge does not present any new patient risks that need to be addressed.

Milestones

- M7: Target capture > 50% in 24 hours for at least 5 of the 7 targets *ex vivo* in blood or blood components using the combination cartridge.
-

- M8: Optimize cartridge composition for target capture in a single cartridge demonstrating increased capture rates 2-7 fold from the current system in blood or blood components.
- M9: Target capture > 90% in 24 hours (12 months) for at least 5 of the 7 targets *ex vivo* in blood or blood components using the optimized cartridge
- M10: Pass biocompatibility tests for the combination ADAPT device.

2.5 Option 3 (Year 4)

2.5.1 Subtask 1a: Anticoagulant-free Hemopurification Device

- 2.5.1.1 System integrator implements design modifications emanating from pig experiments.
- 2.5.1.2 Collaborate with System Integrator in conducting verification and validation testing and collecting all remaining data required for IDE submission (e.g. biocompatibility, electromagnetic interference, electromagnetic susceptibility, software V&V, etc.).
- 2.5.1.3 Make additional cartridge or device modification as required by system integrator.

Milestones

- M11: Demonstrate the effectiveness of the newest device design in preventing blood clotting in a 24 hour blood pumping experiment at 1275 mL/hr blood flow *in vivo*.

2.5.2 Subtask 4: Target Capture in Combined Agent Cartridge

- 2.5.2.1 Determine the *in vivo* efficiency of an optimized combined clearance cartridge incorporating all the successful capture agents.
- 2.5.2.2 Finish construction and delivery of 50 prototype cartridges for testing by the system integrator. The cartridges will need to be made available (packaged, labeled, sterilized and qualified) to the system integrator.
- 2.5.2.3 Perform basic biocompatibility tests for the combination ADAPT device to confirm the combination cartridge does not present any new patient risk.

Milestones

- M12: Complete studies in septic pig models with optimized combination cartridge for >90% clearance of at least 4 of the 7 sepsis marker targets in 24 hours (12 months)
- M13: Construct and deliver of 50 prototype cartridges for testing by the system integrator.

2.6 Option 4 (Year 5)

2.6.1 Subtask 5: Testing of final product by System Integrator

- 2.6.1.1 System Integrator approval of ASEPSYS device for portable blood pump without the need for systemic anticoagulation.
- 2.6.1.2 System Integrator testing of the ADAPT treatment cartridge for reducing sepsis related death by >20% in a septic animal pig model.
- 2.6.1.3 Prepare and submit IDE proposal for sepsis treatment based on previously approved IDE.
- 2.6.1.4 Prepare and present Final report for DARPA.

Milestones

- M13: System Integrator approval of a sepsis precursor ADAPT treatment cartridge for reducing sepsis related death by >20% in a septic animal pig model.
 - M14: System integrator acceptance of the ASEPSYS anticoagulation device as the blood pump that can avoid the need for systemic anticoagulation.
-

3.0 Program Management and Reviews

3.1 Program Management Plan

The contractor shall develop a Program Management Plan. A graphical representation of this plan (Gantt chart is one example) identifying major tasks and their task leaders, milestones of the major task and their completion dates shall be generated. In addition, a graphical representation of budget shall be generated.

3.2 Kick-off Meeting

The contractor shall participate in a kick-off meeting within 60 days of contract award. The purpose of this meeting is to introduce key program personnel, discuss the proposed tasking, present the program schedule and milestones and the initial Program Management Plan.

3.3 Quarterly Reviews

The contractor shall hold quarterly reviews for the duration of this effort. The purpose of these reviews is to present a summary of work completed and milestones met, discuss any problems encountered, update the program schedule, present the program financial status, and discuss remaining work.

3.4 Final Contract Review

A final contract review held in place of the last quarterly review shall be hosted by the principal contractor. The purpose of this review is to present a summary of all work completed and milestones accomplished and to discuss any relevant future efforts similar to the contract that may be pursued.

4.0 Deliverables

The reports and presentation materials are to be delivered in accordance with the contract CDRLs.

CLAUSES INCORPORATED BY FULL TEXT

5252.227-9211 PROCEDURES FOR CONTROLLING TECHNICAL DOCUMENTS UNDER SPAWARSYSCEN PACIFIC CONTRACTS (NOV 2008)

The Contractor shall comply with DOD Directive 5230.25 and the information provided herein when the Government provides the Contractor with technical data.

- (a) Location of distribution statement, export warning notice, and destruction notice (classified and unclassified technical documents).
 - (1) Standard written or printed material with covers and/or title pages: Statement(s) to be printed, typed, or stamped on the front cover and title page.
 - (2) Technical documents without covers or title pages: Statement(s) to be typed, printed, or stamped on the first page of the document.
 - (3) Deck of punched or aperture cards: Statement(s) to be typed, printed, or stamped on face of first and last card and on top of deck.
 - (4) Magnetic tape, cassette, or disk: Statement(s) to be typed, stamped, or printed on a label applied to outside of material. The first page of the resulting hard-copy report or computer printout is also marked with applicable statement(s).
 - (5) Microfilm: Statement(s) to be typed, stamped, or printed on outside of jacket or canister housing the material. The first page of the resulting hard-copy report or first frame is also marked with applicable statement(s). The headers for microfiche must carry an abbreviated version of the statement(s).
 - (6) Drawings: Applicable statement(s) to be typed, stamped, or printed near the title block.
 - (b) Safeguarding of Unclassified, Limited-Access Documents (for classified documents see NOSCINST 5500.1A).
 - (1) Normal working hours: Limited-access documents and those that have not yet been reviewed cannot be left unattended in work areas accessible to non-DoD employees.
 - (2) After normal working hours: Limited-access documents and those that have not yet been reviewed should be placed in locked files, desks, or similar containers. If this is not possible, locked offices or buildings are adequate.
-

(3) Additional guidance for safeguarding limited-access media processed by an IT system, activity, or network can be found in OPNAVINST 5239.1A.

(c) Destruction of Unclassified, Limited-Access Documents. Destroy by any method that will prevent disclosure of contents or reconstruction of the material. Examples of such destruction methods follow:

- (1) Printed document, deck of punched or aperture cards, computer printout, and drawings: Destroy by tearing each copy into pieces to preclude reconstruction and placing the pieces in regular trash containers or send to the Mail Room Branch for destruction.
- (2) Magnetic tape, cassette, or disk: Destroy by erasing the magnetic storage media.
- (3) Microfilm: Destroy by cutting into small pieces or send to the mailroom for destruction.

(d) Safeguarding of Classified Documents: See NOSCINST 5500.1A.

(e) Destruction of Classified Documents: See NOSCINST 5500.1A.

(End of specification)

5252.237-9601 KEY PERSONNEL (DEC 1999)

(a) The offeror agrees to assign to this contract those key personnel listed in paragraph (d) below. No substitutions shall be made except in accordance with this clause.

(b) The offeror agrees that during the first 6 months of the contract performance period no personnel substitutions will be permitted unless such substitutions are necessitated by an individual's sudden illness, death or termination of employment. In any of these events, the contractor shall promptly notify the Contracting Officer and provide the information required by paragraph (c) below. After the initial 6 month period, all proposed substitutions must be submitted in writing, at least fifteen (15) days (thirty (30) days if a security clearance is to be obtained) in advance of the proposed substitutions to the contracting officer. These substitution requests shall provide the information required by paragraph (c) below.

(c) All requests for approval of substitutions under this contract must be in writing and provide a detailed explanation of the circumstances necessitating the proposed substitutions. They must contain a complete resume for the proposed substitute or addition, and any other information requested by the Contracting Officer or needed by him to approve or disapprove the proposed substitutions. All substitutions proposed during the duration of this contract must have qualifications of the person being replaced. The Contracting Officer or his authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof in writing.

(d) List of Key Personnel

NAME	CONTRACT LABOR CATEGORY
Richard H. Tullis, PhD	Chief Science Officer

(e) If the Contracting Officer determines that suitable and timely replacement of key personnel who have been reassigned, terminated or have otherwise become unavailable for the contract work is not reasonably forthcoming or that the resultant reduction of productive effort would be so substantial as to impair the successful completion of the contract or the service order, the contract may be terminated by the Contracting Officer for default or for the convenience of the Government, as appropriate. In addition, if the Contractor is found at fault for the condition, the Contracting Officer may elect to equitably decrease the contract price or fixed fee to compensate the Government for any resultant delay, loss or damage.

(f) If the offeror wishes to add personnel to be used in a labor category he shall employ the procedures outlined in paragraph (c) above. Adding personnel will only be permitted in the event of an indefinite quantity contract, where the Government has issued a delivery order for labor hours that would exceed a normal forty hour week if performed only by the number of employees originally proposed.

(End of clause)

Section D - Packaging and Marking

CLAUSES INCORPORATED BY FULL TEXT

252.235-7010 ACKNOWLEDGMENT OF SUPPORT AND DISCLAIMER (MAY 1995)

(a) The Contractor shall include an acknowledgment of the Government's support in the publication of any material based on or developed under this contract, stated in the following terms: This material is based upon work supported by the (name of contracting agency(ies)) under Contract No. (Contracting agency(ies) contract numbers(s)).

(b) All material, except scientific articles or papers published in scientific journals, must, in addition to any notices or disclaimers by the Contractor, also contain the following disclaimer: Any opinions, findings and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the (name of contracting agency(ies)).

(End of clause)

Section E - Inspection and Acceptance

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	Destination	Government	Destination	Government
0002	Destination	Government	Destination	Government
0003	Destination	Government	Destination	Government
0004	Destination	Government	Destination	Government
0005	Destination	Government	Destination	Government
0006	Destination	Government	Destination	Government
0007	Destination	Government	Destination	Government
0008	Destination	Government	Destination	Government
0009	Destination	Government	Destination	Government
0010	Destination	Government	Destination	Government
0011	Destination	Government	Destination	Government
0012	Destination	Government	Destination	Government

CLAUSES INCORPORATED BY REFERENCE

52.246-7 Inspection Of Research And Development Fixed Price
252.246-7000 Material Inspection And Receiving Report

AUG 1996
MAR 2008

Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	PERIOD OF PERFORMANCE	QUANTITY	SHIP TO ADDRESS	UIC
0001	12 MONTHS AFTER DATE OF CONTRACT AWARD	N/A	SPAWAR SYSTEMS CENTER RECEIVING OFFICER 4297 PACIFIC HIGHWAY, BLDG 7 SAN DIEGO CA 92110-5000 619-553-1251 FOB: Destination	N66001
0002	12 MONTHS AFTER DATE OF CONTRACT AWARD	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	N66001
0003	12 MONTHS AFTER DATE OF OPTION I AWARD	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	N66001
0004	12 MONTHS AFTER DATE OF OPTION I AWARD	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	N66001
0005	12 MONTHS AFTER DATE OF OPTION I AWARD	1	(SAME AS PREVIOUS LOCATION) FOB: Destination	N66001
0006	12 MONTHS AFTER DATE OF OPTION II AWARD	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	N66001
0007	12 MONTHS AFTER DATE OF OPTION II AWARD	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	N66001
0008	12 MONTHS AFTER DATE OF OPTION III AWARD	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	N66001
0009	12 MONTHS AFTER DATE OF OPTION III AWARD	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	N66001
0010	12 MONTHS AFTER DATE OF OPTION III AWARD	1	(SAME AS PREVIOUS LOCATION) FOB: Destination	N66001

0011	12 MONTHS AFTER DATE OF OPTION IV AWARD	(SAME AS PREVIOUS LOCATION) N/A FOB: Destination	N66001
0012	12 MONTHS AFTER DATE OF OPTION IV AWARD	(SAME AS PREVIOUS LOCATION) N/A FOB: Destination	N66001

CLAUSES INCORPORATED BY REFERENCE

52.242-15	Stop-Work Order	AUG 1989
52.242-15 Alt I	Stop-Work Order (Aug 1989) - Alternate I	APR 1984
52.247-34	F.O.B. Destination	NOV 1991

Section G - Contract Administration Data

ACCOUNTING AND APPROPRIATION DATA

AA: 9710400 1320 595 0P1D1 0 2525DP AM 179166 1101E S12136
AMOUNT: \$938,583.00
CIN 130021178700002: \$938,583.00

CLAUSES INCORPORATED BY FULL TEXT

252.204-0007 CONTRACT-WIDE: SEQUENTIAL ACRN ORDER. (SEP 2009)

The payment office shall make payment in sequential ACRN order within the contract or order, exhausting all funds in the previous ACRN before paying from the next ACRN using the following sequential order: alpha/alpha; alpha/numeric; numeric/alpha; and numeric/numeric.

(End of clause)

5252.201-9201 DESIGNATION OF CONTRACTING OFFICER'S REPRESENTATIVE (MAR 2006)

(a) The Contracting Officer hereby appoints the following individual as Contracting Officer's Representative(s) (COR) for this contract/order:

CONTRACTING OFFICER REPRESENTATIVE

Name: John Rockway
Code: 52260
Address: 53560 Hull Street, San Diego, CA 92152-5001

Phone Number: 619-204-0988
E-mail: john.rockway@navy.mil

(b) It is emphasized that only the Contracting Officer has the authority to modify the terms of the contract, therefore, in no event will any understanding agreement, modification, change order, or other matter deviating from the terms of the basic contract between the Contractor and any other person be effective or binding on the Government. When/If, in the opinion of the Contractor, an effort outside the existing scope of the contract is requested, the Contractor shall promptly notify the PCO in writing. No action shall be taken by the Contractor unless the Procuring Contracting Officer (PCO) or the Administrative Contracting Officer (ACO) has issued a contractual change.

5252.216-9210 TYPE OF CONTRACT (DEC 1999)

This is a Firm-Fixed Price (FFP) Completion contract.

(End of clause)

5252.227-9213 PATENT MATTERS POINT OF CONTACT (OCT 2008)

The Point of Contact regarding Patent Matters for this contract is:

OFFICE OF PATENT COUNSEL / CODE 360012
SPAWARSYSCEN
53560 HULL STREET
SAN DIEGO, CA 92152-5001
(619) 553-3001

Do not submit interim and final invention reports to this address. See the clause at 5252.227-9206 for the proper address.

(End of clause)

5252.232-9208 INVOICING INSTRUCTIONS FOR SERVICES USING WIDE AREA WORK FLOW (WAWF) (APR 2009)

(a) Invoices for services rendered under this contract shall be submitted electronically through the Wide Area Work Flow-Receipt and Acceptance (WAWF). The contractor shall submit invoices for payment per contract terms. The Government shall process invoices for payment per contract terms.

(b) The vendor shall have their Cage Code activated by calling 1-866-618-5988 and selecting option 2. Once activated, the vendor shall self-register at the WAWF website at <https://wawf.eb.mil>. Vendor training is available on the internet at <https://wawftraining.eb.mil>. WAWF Vendor "Quick Reference" Guides are located at the following web site: http://acquisition.navy.mil/rda/home/acquisitiononesource/ebusiness/donebusinesssolutions/wa_wfoverview/vendorinformation

(c) Cost back-up documentation (such as delivery receipts, labor hours & material/travel costs etc.) shall be included and attached to the invoice in WAWF. Attachments created with any Microsoft Office product or Adobe (.pdf files) are attachable to the invoice in WAWF. The total size limit for files per invoice is 5 megabytes. A separate copy shall be sent to the COR/TOM.

(d) Contractors approved by DCAA for direct billing will not process vouchers through DCAA, but may submit directly to DFAS. Vendors MUST still provide a copy of the invoice and any applicable cost back-up documentation supporting payment to the Acceptor/Contracting Officer's Representative (COR) if applicable. Additionally, a copy of the invoice(s) and attachment(s) at time of submission in WAWF shall also be provided to each point of contact identified in section (g) of this clause by email. If the invoice and/or receiving report are delivered in the email as an attachment it must be provided as a .PDF, Microsoft Office product or other mutually agreed upon form between the Contracting Officer and vendor.

- (e) A separate invoice will be prepared no more frequently than for every two weeks. Do not combine the payment claims for services provided under this contract.
- (f) The following information is provided for completion and routing of the invoice in WAWF:

WAWF Invoice Type	2-n-1 (Services Only)
Issuing Office DODAAC	See Block 5 of the SF26
Admin DODAAC	See Block 6 of the SF26
Inspector DODAAC (if applicable)	N66001
Inspector Contact Information	See Clause 5252.201-9201
Service Acceptor DODAAC	N66001
Acceptor Contact Information	See Clause 5252.201-9201
COR Contact Information	See Clause 5252.201-9201
DCAA Auditor DoDAAC :	N/A
Service Approver DoDAAC :	See Block 6 of the SF26
PAY DODAAC	See Block 12 of the SF26

- (g) After submitting the document(s) to WAWF, click on “Send More Email Notifications” and add the acceptor/receiver email addresses noted below in the email address blocks. The contractor shall, at a minimum, include the COR, Receiver, and Acceptor. This additional notification to the government is necessary to ensure that the acceptor/receiver is aware that the invoice documents have been submitted into WAWF:

Send Additional Email Notification(s) to:			
Name	Email	Phone	Role
See Clause 5252.201-9201			COR

(End of clause)

5252.243-9600 AUTHORIZED CHANGES ONLY BY THE CONTRACTING OFFICER (JAN 1992)

- (a) Except as specified in paragraph (b) below, no order, statement, or conduct of Government personnel who visit the Contractor’s facilities or in any other manner communicates with Contractor personnel during the performance of this contract shall constitute a change under the Changes clause of this contract.
- (b) The Contractor shall not comply with any order, direction or request of Government personnel unless it is issued in writing and signed by the Contracting Officer, or is pursuant to specific authority otherwise included as a part of this contract.
- (c) The Contracting Officer is the only person authorized to approve changes in any of the requirements of this contract and notwithstanding provisions contained elsewhere in this contract, the said authority remains solely the Contracting Officer’s. In the event the contractor effects any change at the direction of any person other than the Contracting Officer, the change will be considered to have been made without authority and no adjustment will be made in the contract price to cover any increase in charges incurred as a result thereof.

(End of clause)



ADMINISTRATIVE INSTRUCTIONS
INCORPORATION OF REPRESENTATIONS AND CERTIFICATIONS

All representations and certifications and other written statements made by the contractor in response to Section K of the solicitation or at the request of the contracting officer which are incident to the award of the contract or modification of this contract, are hereby incorporated by reference with the same force and effect as if they were given in full text.

(End of Instruction)

MARKING OF SHIPMENT

Each shipment of material and/or data shall be clearly marked to show the following information:

SHIP TO:
RECEIVING OFFICER

MARK FOR:
Contract #: N66001-11-C-4188
Item #: ALL
Receiving Officer Code: 56506

The receiving office is located at 4297 Pacific Highway, Bldg. 7, San Diego, CA 92110-5000 and is open for deliveries Monday through Thursday from 6:30 AM until 4:00 PM and Fridays 6:30 AM to 3:00 PM.

(End of Instruction)

AGREEMENT TO LICENSE--NO IMPLIED LICENSE

(a) Except as provided in paragraph (b) below:

(1) Aethlon Medical, Inc. shall obtain a license from the U.S. Government under the following U.S. patents, patent applications and all patents issuing thereon, and under all patents that may issue and patent applications that may be filed on the following invention disclosures, on reasonable terms and conditions, consistent with law, regulation, and Navy policy prior to any manufacture, use, sale, lease, license, or conveyance of any kind of any process, machine, manufacture, or composition of matter that would, absent such license, infringe any claim of such patent(s)/application(s):

NONE KNOWN AT THIS TIME

(2) Nothing in this contract shall release Aethlon Medical, Inc. from any obligation of or duty under any other Government contract; nor shall it grant to or confer upon Aethlon Medical, Inc. any rights, express or implied,

- (i) to any invention other than a Subject Invention,
- (ii) under any patent application or patent assigned to the U.S. Government that is dominant over a patent protecting a Subject Invention,
- (iii) under any patent application or patent assigned to the U.S. Government protecting an invention other than a Subject Invention, or
- (iv) under the U.S. patent(s)/patent application(s) identified in paragraph (a)(1) above.

(b) No license from the U.S. Government shall be required for research, development, test and evaluation to be performed by Aethlon Medical, Inc. under this contract.

(End of Instruction)

APPLICATION OF DFARS 252.227-7013 AND 252.227-7015 TECHNICAL DATA CLAUSES

The DFARS 252.227-7015, Technical Data--Commercial Items, clause applies to technical data that pertains to a "commercial item" as defined in the DFARS 252.227-7015 clause. The DFARS 252.227-7013, Rights in Technical Data--Noncommercial Items, clause applies to all other technical data.

(End of Instruction)

DISSEMINATION NOTICES FOR TECHNICAL DOCUMENTS PREPARED UNDER SPAWARSCEN
PACIFIC CONTRACTS (NOV 2008)

(a) Unless otherwise specified, all classified and unclassified technical documents generated under this contract must carry the following statements:

- (1) Do not distribute to DTIC or other data depositories.
- (2) Distribution authorized to DOD components only; premature dissemination [*Contractor to insert a date which will be determined by the Program Manager and affixed by the Contractor*]. Other requests shall be referred to the Space and Naval Warfare Systems Center, Code 2015, San Diego, CA 92152-5001.

(b) The Contractor shall place the above statements on the original and all copies before being delivered to the shipping address in Section F as follows:

- (1) Standard Written or Printed material with Covers and/or Title Pages: Statement(s) to be printed, typed, or stamped on front cover and title page.
- (2) Technical Documents Without Covers or Title Pages: Statement(s) to be typed, printed, or stamped on first page of the document.
- (3) Drawing: Applicable statement(s) to be typed, printed, or stamped near the title block.
- (4) Magnetic Tape, Cassette, or Disk: Statement(s) to be typed, printed, or stamped on a label applied to outside of material. The first page of the resulting hard-copy report or computer printout report is also marked with applicable statement(s).
- (5) Microfilm: Statement(s) typed, printed, or stamped on outside of jacket or canister housing the material. The first page of resulting hard-copy report or first frame is also marked with applicable statement(s). The headers for microfiche must carry an abbreviated version of the statement(s).
- (6) Deck of Punched or Aperture Cards: Statement(s) to be typed, stamped, or printed on face of first and last card and on top of deck.

(End of Instruction)

EXPORT CONTROL (DARPA)

Should this project develop beyond fundamental research (basic and applied research ordinarily published and shared broadly within the scientific community) with military or dual-use applications the following apply:

- (1) The Contractor shall comply with all U.S. export control laws and regulations, including the International Traffic in Arms Regulations (ITAR), 22 CFR Parts 120 through 130, and the Export Administration Regulations (EAR), 15 CFR Parts 730 through 799, in the performance of this contract. In the absence of available license exemptions/exceptions the Contractor shall be responsible for obtaining the appropriate licenses or other approvals, if required, for exports of (including deemed exports) hardware, technical data, and software, or for the provision of technical assistance.
- (2) The Contractor shall be responsible for obtaining export licenses, if required, before utilizing foreign persons in the performance of this contract, including instances where the work is to be performed on-site at any Government installation (whether in or outside the United States), where the foreign person will have access to export-controlled technologies, including technical data or software.
- (3) The Contractor shall be responsible for all regulatory record keeping requirements associated with the use of licenses and license exemptions/exceptions.
- (4) The Contractor shall be responsible for ensuring that the provisions of this clause apply to its subcontractors.

(End of instruction)

Section H - Special Contract Requirements

CLAUSES INCORPORATED BY FULL TEXT

5252.209-9206 EMPLOYMENT OF NAVY PERSONNEL RESTRICTED (DEC 1999)

In performing this contract, the Contractor will not use as a consultant or employ (on either a full or part-time basis) any active duty Navy personnel (civilian or military) without the prior approval of the Contracting Officer. Such approval may be given only in circumstances where it is clear that no law and no DOD or Navy instructions, regulations, or policies might possibly be contravened and no appearance of a conflict of interest will result.

(End of clause)

5252.227-9205 RIGHTS IN MASK WORKS (DEC 2002)

(a) *Definitions.*

As defined in 17 U.S.C. §901--

“Semiconductor chip product” is the final or intermediate form of any product--

(A) having two or more layers of metallic, insulating, or semiconductor material, deposited or otherwise placed on, or etched away or otherwise removed from, a piece of semiconductor material in accordance with a predetermined pattern; and

(B) intended to perform electronic circuit functions.

“Mask work” is a series of related images, however fixed or encoded--

(A) having, or representing the predetermined, three-dimensional pattern of metallic, insulating, or semiconductor material present or removed from the layers of a semiconductor chip product; and

(B) in which series the relation of the images to one another is that each image has the pattern of the surface of one form of the semiconductor chip product.

(b) For any and every mask work generated in the performance of work under this contract, the contractor grants to the Government a non-exclusive, irrevocable, royalty free, worldwide license to:

(1) reproduce or have reproduced the mask work by optical, electronic, or any other means; and

(2) import or distribute or have imported or distributed a semiconductor chip product in which the mask work is embodied.

(c) The contractor shall include this clause, suitably modified to replace “contractor” with “subcontractor” in all subcontracts, regardless of tier, in which a mask work is likely to be created in the performance of the work under the subcontract. The contractor shall not obtain rights in the subcontractor’s mask works as any part of the consideration for awarding the subcontract.

(d) This license is specific to mask work rights and shall not be construed to broaden any proprietary rights to technical data or computer software.

(End of clause)

5252.227-9206 SUBMISSION OF INTERIM AND FINAL INVENTION REPORTS AND NOTIFICATION OF ALL SUBCONTRACTS FOR EXPERIMENTAL, DEVELOPMENTAL, OR RESEARCH WORK (OCT 2008)

(a) This contract contains either FAR 52.227-11 "Patent Rights--Ownership by the Contractor" clause and DFARS 252.227-7039 "Patents--Reporting of Subject Inventions" or DFARS 252.227-7038 "Patent Rights--Ownership by the Contractor (Large Business)" clause, or FAR 52.227-13 "Patent Rights--Ownership by the Government" clause.

(b) Under these clauses, the Contractor is required to submit interim and final invention reports and notification to the Government of all subcontracts for experimental, developmental, or research work. The interim and final invention reports and notification of all subcontracts for experimental, developmental, or research work may be submitted on DD Form 882 "Report of Inventions and Subcontracts."

(c) The Contractor shall submit interim and final invention reports and notification of all subcontracts for experimental, developmental, or research work, including negative reports, to:

CONTRACT CLOSEOUT / CODE 23100
SPAWARSYSCEN PACIFIC
53560 HULL STREET
SAN DIEGO, CA 92152-5001

(d) The SPAWARSYSCEN Pacific Office of Patent Counsel, Code 360012, will represent the Contracting Officer with regard to invention reporting matters arising under the contract.

(End of clause)

5252.227-9207 LIMITED RELEASE OF CONTRACTOR CONFIDENTIAL BUSINESS INFORMATION (APRIL 2010)

(a) Definition.

"Confidential Business Information," (Information) as used in this clause, is defined as all forms and types of financial, business, economic or other types of information other than technical data or computer software/computer software documentation, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if -- (1) the owner thereof has taken reasonable measures to keep such Information secret, and (2) the Information derives independent economic value, actual or potential from not being generally known to, and not being readily ascertainable through proper means by, the public. Information does not include technical data, as that term is defined in DFARS 252.227-7013(a)(14), 252.227-7015(a)(4), and 252.227-7018(a)(19). Similarly, Information does not include computer software/computer software documentation, as those terms are defined in DFARS 252.227-7014(a)(4) and 252.227-7018(a)(4).

(b) The Space and Naval Warfare Systems Command (SPAWAR) may release to individuals employed by SPAWAR support contractors and their subcontractors Information submitted by the contractor or its subcontractors pursuant to the provisions of this contract. Information that would ordinarily be entitled to confidential treatment may be included in the Information released to these individuals. Accordingly, by submission of a proposal or execution of this contract, the offeror or contractor and its subcontractors consent to a limited release of its Information, but only for purposes as described in paragraph (c) of this clause.

(c) Circumstances where SPAWAR may release the contractor's or subcontractors' Information include the following:

(1) To other SPAWAR contractors and subcontractors, and their employees tasked with assisting SPAWAR in handling and processing Information and documents in the administration of SPAWAR contracts, such as file room management and contract closeout; and,

(2) To SPAWAR contractors and subcontractors, and their employees tasked with assisting SPAWAR in accounting support services, including access to cost-reimbursement vouchers.

(d) SPAWAR recognizes its obligation to protect the contractor and its subcontractors from competitive harm that could result from the release of such Information. SPAWAR will permit the limited release of Information under paragraphs (c)(1) and (c)(2) only under the following conditions:

- (1) SPAWAR determines that access is required by other SPAWAR contractors and their subcontractors to perform the tasks described in paragraphs (c)(1) and (c)(2);
- (2) Access to Information is restricted to individuals with a bona fide need to possess;
- (3) Contractors and their subcontractors having access to Information have agreed under their contract or a separate corporate non-disclosure agreement to provide the same level of protection to the Information that would be provided by SPAWAR employees. Such contract terms or separate corporate non-disclosure agreement shall require the contractors and subcontractors to train their employees on how to properly handle the Information to which they will have access, and to have their employees sign company non disclosure agreements certifying that they understand the sensitive nature of the Information and that unauthorized use of the Information could expose their company to significant liability. Copies of such employee non disclosure agreements shall be provided to the Government;
- (4) SPAWAR contractors and their subcontractors performing the tasks described in paragraphs (c)(1) or (c)(2) have agreed under their contract or a separate non-disclosure agreement to not use the Information for any purpose other than performing the tasks described in paragraphs (c)(1) and (c)(2); and,
- (5) Before releasing the Information to a non-Government person to perform the tasks described in paragraphs (c)(1) and (c)(2), SPAWAR shall provide the contractor a list of the company names to which access is being granted, along with a Point of Contact for those entities.

(e) SPAWAR's responsibilities under the Freedom of Information Act are not affected by this clause.

(f) The contractor agrees to include, and require inclusion of, this clause in all subcontracts at any tier that requires the furnishing of Information.

(End of clause)

5252.231-9200 REIMBURSEMENT OF TRAVEL COSTS (JAN 2006)

(a) Contractor Request and Government Approval of Travel

Any travel under this contract must be specifically requested in writing, by the contractor prior to incurring any travel costs. If this contract is a definite or indefinite delivery contract, then the written Government authorization will be by task/delivery orders issued by the Ordering Officer or by a modification to an issued task/delivery order. If this contract is not a definite or indefinite delivery contract, then the written Government authorization will be by written notice of approval from the Contracting Officer's Representative (COR). The request shall include as a minimum, the following:

- (1) Contract number
 - (2) Date, time, and place of proposed travel
 - (3) Purpose of travel and how it relates to the contract
 - (4) Contractor's estimated cost of travel
 - (5) Name(s) of individual(s) traveling and;
 - (6) A breakdown of estimated travel and per diem charges.
-

The contractor shall submit the travel request in writing to the Contracting Officer's Representative (COR). The COR shall review and approve/disapprove (as appropriate) all travel requests submitted giving written notice of such approval or disapproval to the contractor.

(b) General

(1) The costs for travel, subsistence, and lodging shall be reimbursed to the contractor only to the extent that it is necessary and authorized for performance of the work under this contract. The costs for travel, subsistence, and lodging shall be reimbursed to the contractor in accordance with the Federal Acquisition Regulation (FAR) 31.205-46, which is incorporated by reference into this contract. As specified in FAR 31.205-46(a) (2), reimbursement for the costs incurred for lodging, meals and incidental expenses (as defined in the travel regulations cited subparagraphs (b)(1)(i) through (b)(1)(iii) below) shall be considered to be reasonable and allowable only to the extent that they do not exceed on a daily basis the maximum per diem rates in effect at the time of travel as set forth in the following:

(i) Federal Travel Regulation prescribed by the General Services Administration for travel in the contiguous 48 United States;

(ii) Joint Travel Regulation, Volume 2, DoD Civilian Personnel, Appendix A, prescribed by the Department of Defense for travel in Alaska, Hawaii, The Commonwealth of Puerto Rico, and the territories and possessions of the United States; or

(iii) Standardized Regulations, (Government Civilians, Foreign Areas), Section 925, "Maximum Travel Per Diem Allowances in Foreign Areas" prescribed by the Department of State, for travel in areas not covered in the travel regulations cited in subparagraphs (b)(1)(i) and (b)(1)(ii) above.

(2) Personnel in travel status from and to the contractor's place of business and designated work site or vice versa, shall be considered to be performing work under the contract, and contractor shall bill such travel time at the straight (regular) time rate; however, such billing shall not exceed eight hours per person for any one person while in travel status during one calendar day.

(c) Per Diem

(1) The contractor shall not be paid per diem for contractor personnel who reside in the metropolitan area in which the tasks are being performed. Per diem shall not be paid on services performed at contractor's home facility and at any facility required by the contract, or at any location within a radius of 50 miles from the contractor's home facility and any facility required by this contract.

(2) Costs for subsistence and lodging shall be paid to the contractor only to the extent that overnight stay is necessary and authorized in writing by the Government for performance of the work under this contract per paragraph (a). When authorized, per diem shall be paid by the contractor to its employees at a rate not to exceed the rate specified in the travel regulations cited in FAR 31.205-46(a)(2) and authorized in writing by the Government. The authorized per diem rate shall be the same as the prevailing locality per diem rate.

(3) Reimbursement to the contractor for per diem shall be limited to payments to employees not to exceed the authorized per diem and as authorized in writing by the Government per paragraph (a). Fractional parts of a day shall be payable on a prorated basis for purposes of billing for per diem charges attributed to subsistence on days of travel. The departure day from the Permanent Duty Station (PDS) and return day to the PDS shall be 75% of the applicable per diem rate. The contractor shall retain supporting documentation for per diem paid to employees as evidence of actual payments, as required by the FAR 52.216-7 "Allowable Cost and Payment" clause of the contract.

(d) Transportation

(1) The contractor shall be paid on the basis of actual amounts paid to the extent that such transportation is necessary for the performance of work under the contract and is authorized in writing by the Government per paragraph (a).

(2) The contractor agrees, in the performance of necessary travel, to use the lowest cost mode commensurate with the requirements of the mission and in accordance with good traffic management principles. When it is necessary to use air or rail travel, the contractor agrees to use coach, tourist class or similar accommodations to the extent consistent with the successful and economical accomplishment of the mission for which the travel is being performed. Documentation must be provided to substantiate non-availability of coach or tourist if business or first class is proposed to accomplish travel requirements.

(3) When transportation by privately owned conveyance (POC) is authorized, the contractor shall be paid on a mileage basis not to exceed the applicable Government transportation rate specified in the travel regulations cited in FAR 31.205-46(a)(2) and is authorized in writing by the Government per paragraph (a).

(4) When transportation by privately owned (motor) vehicle (POV) is authorized, required travel of contractor personnel, that is not commuting travel, may be paid to the extent that it exceeds the normal commuting mileage of such employee. When an employee's POV is used for travel between an employee's residence or the Permanent Duty Station and one or more alternate work sites within the local area, the employee shall be paid mileage for the distance that exceeds the employee's commuting distance.

(5) When transportation by a rental automobile, other special conveyance or public conveyance is authorized, the contractor shall be paid the rental and/or hiring charge and operating expenses incurred on official business (if not included in the rental or hiring charge). When the operating expenses are included in the rental or hiring charge, there should be a record of those expenses available to submit with the receipt. Examples of such operating expenses include: hiring charge (bus, streetcar or subway fares), gasoline and oil, parking, and tunnel tolls.

(6) Definitions:

(i) "Permanent Duty Station" (PDS) is the location of the employee's permanent work assignment (i.e., the building or other place where the employee regularly reports for work.

(ii) "Privately Owned Conveyance" (POC) is any transportation mode used for the movement of persons from place to place, other than a Government conveyance or common carrier, including a conveyance loaned for a charge to, or rented at personal expense by, an employee for transportation while on travel when such rental conveyance has not been authorized/approved as a Special Conveyance.

(iii) "Privately Owned (Motor) Vehicle (POV)" is any motor vehicle (including an automobile, light truck, van or pickup truck) owned by, or on a long-term lease (12 or more months) to, an employee or that employee's dependent for the primary purpose of providing personal transportation, that:

(a) is self-propelled and licensed to travel on the public highways;

(b) is designed to carry passengers or goods; and

(c) has four or more wheels or is a motorcycle or moped.

(iv) "Special Conveyance" is commercially rented or hired vehicles other than a POC and other than those owned or under contract to an agency.

(v) "Public Conveyance" is local public transportation (e.g., bus, streetcar, subway, etc) or taxicab.

(iv) "Residence" is the fixed or permanent domicile of a person that can be reasonably justified as a bona fide residence.

EXAMPLE 1: Employee's one way commuting distance to regular place of work is 7 miles. Employee drives from residence to an alternate work site, a distance of 18 miles. Upon completion of work, employee returns to residence, a distance of 18 miles.

In this case, the employee is entitled to be reimbursed for the distance that exceeds the normal round trip commuting distance (14 miles). The employee is reimbursed for 22 miles ($18 + 18 - 14 = 22$).

EXAMPLE 2: Employee's one way commuting distance to regular place of work is 15 miles. Employee drives from residence to an alternate work site, a distance of 5 miles. Upon completion of work, employee returns to residence, a distance of 5 miles.

In this case, the employee is not entitled to be reimbursed for the travel performed (10 miles), since the distance traveled is less than the commuting distance (30 miles) to the regular place of work.

EXAMPLE 3: Employee's one way commuting distance to regular place of work is 15 miles. Employee drives to regular place of work. Employee is required to travel to an alternate work site, a distance of 30 miles. Upon completion of work, employee returns to residence, a distance of 15 miles.

In this case, the employee is entitled to be reimbursed for the distance that exceeds the normal round trip commuting distance (30 miles). The employee is reimbursed for 30 miles ($15 + 30 + 15 - 30 = 30$).

EXAMPLE 4: Employee's one way commuting distance to regular place of work is 12 miles. In the morning the employee drives to an alternate work site (45 miles). In the afternoon the employee returns to the regular place of work (67 miles). After completion of work, employee returns to residence, a distance of 12 miles.

In this case, the employee is entitled to be reimbursed for the distance that exceeds the normal round trip commuting distance (24 miles). The employee is reimbursed for 100 miles ($45 + 67 + 12 - 24 = 100$).

EXAMPLE 5: Employee's one way commuting distance to regular place of work is 35 miles. Employee drives to the regular place of work (35 miles). Later, the employee drives to alternate work site #1 (50 miles) and then to alternate work site #2 (25 miles). Employee then drives to residence (10 miles).

In this case, the employee is entitled to be reimbursed for the distance that exceeds the normal commuting distance (70 miles). The employee is reimbursed for 50 miles ($35 + 50 + 25 + 10 - 70 = 50$).

EXAMPLE 6: Employee's one way commuting distance to regular place of work is 20 miles. Employee drives to the regular place of work (20 miles). Later, the employee drives to alternate work site #1 (10 miles) and then to alternate work site #2 (5 miles). Employee then drives to residence (2 miles).

In this case, the employee is not entitled to be reimbursed for the travel performed (37 miles), since the distance traveled is less than the commuting distance (40 miles) to the regular place of work.

Section I - Contract Clauses

CLAUSES INCORPORATED BY REFERENCE

52.202-1	Definitions	JUL 2004
52.203-3	Gratuities	APR 1984
52.203-5	Covenant Against Contingent Fees	APR 1984
52.203-6	Restrictions On Subcontractor Sales To The Government	SEP 2006
52.203-7	Anti-Kickback Procedures	OCT 2010
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or JAN 1997 Improper Activity	
52.203-10	Price Or Fee Adjustment For Illegal Or Improper Activity	JAN 1997
52.203-12	Limitation On Payments To Influence Certain Federal Transactions	OCT 2010
52.204-4	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper	MAY 2011
52.204-7	Central Contractor Registration	APR 2008
52.209-6	Protecting the Government's Interest When Subcontracting DEC 2010 With Contractors Debarred, Suspended, or Proposed for Debarment	
52.215-2	Audit and Records--Negotiation	OCT 2010
52.215-8	Order of Precedence--Uniform Contract Format	OCT 1997
52.215-15	Pension Adjustments and Asset Reversions	OCT 2010
52.215-17	Waiver of Facilities Capital Cost of Money	OCT 1997
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits JUL 2005 (PRB) Other than Pensions	
52.215-19	Notification of Ownership Changes	OCT 1997
52.215-20 Alt II	Requirements for Cost or Pricing Data or Information Other OCT 1997 Than Cost or Pricing Data (Oct 2010) - Alternate II	
52.219-28	Post-Award Small Business Program Rerepresentation	APR 2009
52.222-3	Convict Labor	JUN 2003
52.222-21	Prohibition Of Segregated Facilities	FEB 1999
52.222-26	Equal Opportunity	MAR 2007
52.222-35	Equal Opportunity for Veterans	SEP 2010
52.222-36	Affirmative Action For Workers With Disabilities	OCT 2010
52.222-37	Employment Reports on Veterans	SEP 2010
52.222-40	Notification of Employee Rights Under the National Labor DEC 2010 Relations Act	
52.222-50	Combating Trafficking in Persons	FEB 2009
52.222-54	Employment Eligibility Verification	JAN 2009
52.223-6	Drug-Free Workplace	MAY 2001
52.223-18	Encouraging Contractor Policies To Ban Text Messaging While Driving	AUG 2011
52.225-13	Restrictions on Certain Foreign Purchases	JUN 2008
52.227-1	Authorization and Consent	DEC 2007
52.227-1 Alt I	Authorization And Consent (Dec 2007) - Alternate I	APR 1984
52.227-2	Notice And Assistance Regarding Patent And Copyright Infringement	DEC 2007
52.227-3	Patent Indemnity	APR 1984
52.227-11	Patent Rights--Ownership By The Contractor	DEC 2007
52.228-5	Insurance - Work On A Government Installation	JAN 1997
52.228-7	Insurance--Liability To Third Persons	MAR 1996
52.230-3	Disclosure And Consistency Of Cost Accounting Practices	OCT 2008

52.232-2	Payments Under Fixed-Price Research And Development Contracts	APR 1984
52.232-8	Discounts For Prompt Payment	FEB 2002
52.232-9	Limitation On Withholding Of Payments	APR 1984
52.232-17	Interest	OCT 2010
52.232-23	Assignment Of Claims	JAN 1986
52.232-23 Alt I	Assignment of Claims (Jan 1986) - Alternate I	APR 1984
52.232-25	Prompt Payment	OCT 2008
52.232-25 Alt I	Prompt Payment (Oct 2008) Alternate I	FEB 2002
52.232-33	Payment by Electronic Funds Transfer--Central Contractor OCT 2003 Registration	
52.233-1	Disputes	JUL 2002
52.233-3	Protest After Award	AUG 1996
52.233-3 Alt I	Protest After Award (Aug 1996) - Alternate I	JUN 1985
52.233-4	Applicable Law for Breach of Contract Claim	OCT 2004
52.237-2	Protection Of Government Buildings, Equipment, And Vegetation	APR 1984
52.242-13	Bankruptcy	JUL 1995
52.243-1 Alt I	Changes--Fixed Price (Aug 1987) - Alternate I	APR 1984
52.243-1 Alt V	Changes--Fixed-Price (Aug 1987) - Alternate V	APR 1984
52.244-6	Subcontracts for Commercial Items	DEC 2010
52.245-1	Government Property	AUG 2010
52.245-9	Use And Charges	AUG 2010
52.246-25	Limitation Of Liability--Services	FEB 1997
52.247-63	Preference For U.S. Flag Air Carriers	JUN 2003
52.249-2	Termination For Convenience Of The Government (Fixed- MAY 2004 Price)	
52.249-9	Default (Fixed-Priced Research And Development)	APR 1984
52.253-1	Computer Generated Forms	JAN 1991
252.201-7000	Contracting Officer's Representative	DEC 1991
252.203-7000	Requirements Relating to Compensation of Former DoD Officials	JAN 2009
252.203-7001	Prohibition On Persons Convicted of Fraud or Other Defense- DEC 2008 Contract-Related Felonies	
252.203-7002	Requirement to Inform Employees of Whistleblower Rights JAN 2009	
252.203-7002	Requirement to Inform Employees of Whistleblower Rights JAN 2009	
252.204-7003	Control Of Government Personnel Work Product	APR 1992
252.204-7004 Alt A C	entral Contractor Registration (52.204-7) Alternate A	SEP 2007
252.204-7006	Billing Instructions	OCT 2005
252.209-7004	Subcontracting With Firms That Are Owned or Controlled By DEC 2006 The Government of a Terrorist Country	
252.223-7006	Prohibition On Storage And Disposal Of Toxic And Hazardous Materials	APR 1993
252.225-7012	Preference For Certain Domestic Commodities	JUN 2010
252.226-7001	Utilization of Indian Organizations and Indian-Owned Economic Enterprises, and Native Hawaiian Small Business Concerns	SEP 2004
252.227-7012	Patent License And Release Contract	SEP 1999
252.227-7013	Rights in Technical Data--Noncommercial Items	MAR 2011
252.227-7014	Rights in Noncommercial Computer Software and Noncommercial Computer Software Documentation	MAR 2011
252.227-7015	Technical Data--Commercial Items	MAR 2011
252.227-7016	Rights in Bid or Proposal Information	JAN 2011
252.227-7019	Validation of Asserted Restrictions--Computer Software	JUN 1995
252.227-7027	Deferred Ordering Of Technical Data Or Computer Software APR 1988	

252.227-7030	Technical Data--Withholding Of Payment	MAR 2000
252.227-7037	Validation of Restrictive Markings on Technical Data	SEP 1999
252.231-7000	Supplemental Cost Principles	DEC 1991
252.232-7010	Levies on Contract Payments	DEC 2006
252.235-7011	Final Scientific or Technical Report	NOV 2004
252.242-7004	Material Management And Accounting System	MAY 2011
252.243-7001	Pricing Of Contract Modifications	DEC 1991
252.243-7002	Requests for Equitable Adjustment	MAR 1998
252.244-7000	Subcontracts for Commercial Items and Commercial Components (DoD Contracts)	NOV 2010
252.246-7000	Material Inspection And Receiving Report	MAR 2008

CLAUSES INCORPORATED BY FULL TEXT

52.215-19 NOTIFICATION OF OWNERSHIP CHANGES (OCT 1997)

(a) The Contractor shall make the following notifications in writing:

(1) When the Contractor becomes aware that a change in its ownership has occurred, or is certain to occur, that could result in changes in the valuation of its capitalized assets in the accounting records, the Contractor shall notify the Administrative Contracting Officer (ACO) within 30 days.

(2) The Contractor shall also notify the ACO within 30 days whenever changes to asset valuations or any other cost changes have occurred or are certain to occur as a result of a change in ownership.

(b) The Contractor shall--

(1) Maintain current, accurate, and complete inventory records of assets and their costs;

(2) Provide the ACO or designated representative ready access to the records upon request;

(3) Ensure that all individual and grouped assets, their capitalized values, accumulated depreciation or amortization, and remaining useful lives are identified accurately before and after each of the Contractor's ownership changes; and

(4) Retain and continue to maintain depreciation and amortization schedules based on the asset records maintained before each Contractor ownership change.

The Contractor shall include the substance of this clause in all subcontracts under this contract that meet the applicability requirement of FAR 15.408(k).

(End of clause)

52.217-9 OPTION TO EXTEND THE TERM OF THE CONTRACT (MAR 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within the period of performance of this contract; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed five years.

(End of clause)

52.232-32 PERFORMANCE-BASED PAYMENTS (AUG 2010)

(a) Amount of payments and limitations on payments. Subject to such other limitations and conditions as are specified in this contract and this clause, the amount of payments and limitations on payments shall be specified in the contract's description of the basis for payment.

(b) Contractor request for performance-based payment. The Contractor may submit requests for payment of performance-based payments not more frequently than monthly, in a form and manner acceptable to the Contracting Officer. Unless otherwise authorized by the Contracting Officer, all performance-based payments in any period for which payment is being requested shall be included in a single request, appropriately itemized and totaled. The Contractor's request shall contain the information and certification detailed in paragraphs (l) and (m) of this clause.

(c) Approval and payment of requests.

(1) The Contractor shall not be entitled to payment of a request for performance-based payment prior to successful accomplishment of the event or performance criterion for which payment is requested. The Contracting Officer shall determine whether the event or performance criterion for which payment is requested has been successfully accomplished in accordance with the terms of the contract. The Contracting Officer may, at any time, require the Contractor to substantiate the successful performance of any event or performance criterion which has been or is represented as being payable.

(2) A payment under this performance-based payment clause is a contract financing payment under the Prompt Payment clause of this contract and not subject to the interest penalty provisions of the Prompt Payment Act. The designated payment office will pay approved requests on the 30th day after receipt of the request for performance-based payment by the designated payment office. However, the designated payment office is not required to provide payment if the Contracting Officer requires substantiation as provided in paragraph (c)(1) of this clause, or inquires into the status of an event or performance criterion, or into any of the conditions listed in paragraph (e) of this clause, or into the Contractor certification. The payment period will not begin until the Contracting Officer approves the request.

(3) The approval by the Contracting Officer of a request for performance-based payment does not constitute an acceptance by the Government and does not excuse the Contractor from performance of obligations under this contract.

(d) Liquidation of performance-based payments.

(1) Performance-based finance amounts paid prior to payment for delivery of an item shall be liquidated by deducting a percentage or a designated dollar amount from the delivery payment. If the performance-based finance payments are on a delivery item basis, the liquidation amount for each such line item shall be the percent of that delivery item price that was previously paid under performance-based finance payments or the designated dollar amount. If the performance-based finance payments are on a whole contract basis, liquidation shall be by either predesignated liquidation amounts or a liquidation percentage.

(2) If at any time the amount of payments under this contract exceeds any limitation in this contract, the Contractor shall repay to the Government the excess. Unless otherwise determined by the Contracting Officer, such excess shall be credited as a reduction in the unliquidated performance-based payment balance(s), after adjustment of invoice payments and balances for any retroactive price adjustments.

(e) Reduction or suspension of performance-based payments. The Contracting Officer may reduce or suspend performance-based payments, liquidate performance-based payments by deduction from any payment under the contract, or take a combination of these actions after finding upon substantial evidence any of the following conditions:

(1) The Contractor failed to comply with any material requirement of this contract (which includes paragraphs (h) and (i) of this clause).

(2) Performance of this contract is endangered by the Contractor's --

(i) Failure to make progress; or

(ii) Unsatisfactory financial condition.

(3) The Contractor is delinquent in payment of any subcontractor or supplier under this contract in the ordinary course of business.

(f) Title.

(1) Title to the property described in this paragraph (f) shall vest in the Government. Vestiture shall be immediately upon the date of the first performance-based payment under this contract, for property acquired or produced before that date. Otherwise, vestiture shall occur when the property is or should have been allocable or properly chargeable to this contract

(2) "Property," as used in this clause, includes all of the following described items acquired or produced by the Contractor that are or should be allocable or properly chargeable to this contract under sound and generally accepted accounting principles and practices:

(i) Parts, materials, inventories, and work in process;

(ii) Special tooling and special test equipment to which the Government is to acquire title;

(iii) Nondurable (i.e., noncapital) tools, jigs, dies, fixtures, molds, patterns, taps, gauges, test equipment and other similar manufacturing aids, title to which would not be obtained as special tooling under subparagraph (f)(2)(ii) of this clause; and

(iv) Drawings and technical data, to the extent the Contractor or subcontractors are required to deliver them to the Government by other clauses of this contract.

(3) Although title to property is in the Government under this clause, other applicable clauses of this contract (e.g., the termination or clauses) shall determine the handling and disposition of the property.

(4) The Contractor may sell any scrap resulting from production under this contract, without requesting the Contracting Officer's approval, provided that any significant reduction in the value of the property to which the Government has title under this clause is reported in writing to the Contracting Officer.

(5) In order to acquire for its own use or dispose of property to which title is vested in the Government under this clause, the Contractor shall obtain the Contracting Officer's advance approval of the action and the terms. If approved, the basis for payment (the events or performance criteria) to which the property is related shall be deemed to be not in compliance with the terms of the contract and not payable (if the property is part of or needed for performance), and the Contractor shall refund the related performance-based payments in accordance with paragraph (d) of this clause.

(6) When the Contractor completes all of the obligations under this contract, including liquidation of all performance-based payments, title shall vest in the Contractor for all property (or the proceeds thereof) not --

- (i) Delivered to, and accepted by, the Government under this contract; or
 - (ii) Incorporated in supplies delivered to, and accepted by, the Government under this contract and to which title is vested in the Government under this clause.
- (7) The terms of this contract concerning liability for Government-furnished property shall not apply to property to which the Government acquired title solely under this clause.
- (g) Risk of loss. Before delivery to and acceptance by the Government, the Contractor shall bear the risk of loss for property, the title to which vests in the Government under this clause, except to the extent the Government expressly assumes the risk. If any property is lost, stolen, damaged or destroyed, the basis of payment (the events or performance criteria) to which the property is related shall be deemed to be not in compliance with the terms of the contract and not payable (if the property is part of or needed for performance), and the Contractor shall refund the related performance-based payments in accordance with paragraph (d) of this clause.
- (h) Records and controls. The Contractor shall maintain records and controls adequate for administration of this clause. The Contractor shall have no entitlement to performance-based payments during any time the Contractor's records or controls are determined by the Contracting Officer to be inadequate for administration of this clause.
- (i) Reports and Government access. The Contractor shall promptly furnish reports, certificates, financial statements, and other pertinent information requested by the Contracting Officer for the administration of this clause and to determine that an event or other criterion prompting a financing payment has been successfully accomplished. The Contractor shall give the Government reasonable opportunity to examine and verify the Contractor's records and to examine and verify the Contractor's performance of this contract for administration of this clause.
- (j) Special terms regarding default. If this contract is terminated under the Default clause,
- (1) the Contractor shall, on demand, repay to the Government the amount of unliquidated performance-based payments, and
 - (2) title shall vest in the Contractor, on full liquidation of all performance-based payments, for all property for which the Government elects not to require delivery under the Default clause of this contract. The Government shall be liable for no payment except as provided by the Default clause.
- (k) Reservation of rights.
- (1) No payment or vesting of title under this clause shall --
 - (i) Excuse the Contractor from performance of obligations under this contract; or
 - (ii) Constitute a waiver of any of the rights or remedies of the parties under the contract.
 - (2) The Government's rights and remedies under this clause --
 - (i) Shall not be exclusive, but rather shall be in addition to any other rights and remedies provided by law or this contract; and
 - (ii) Shall not be affected by delayed, partial, or omitted exercise of any right, remedy, power, or privilege, nor shall such exercise or any single exercise preclude or impair any further exercise under this clause or the exercise of any other right, power, or privilege of the Government.
- (l) Content of Contractor's request for performance-based payment. The Contractor's request for performance-based payment shall contain the following:
-

- (1) The name and address of the Contractor;
- (2) The date of the request for performance-based payment;
- (3) The contract number and/or other identifier of the contract or order under which the request is made;
- (4) Such information and documentation as is required by the contract's description of the basis for payment; and
- (5) A certification by a Contractor official authorized to bind the Contractor, as specified in paragraph (m) of this clause.

(m) Content of Contractor's certification. As required in paragraph (l)(5) of this clause, the Contractor shall make the following certification in each request for performance-based payment:

I certify to the best of my knowledge and belief that --

- (1) This request for performance-based payment is true and correct; this request (and attachments) has been prepared from the books and records of the Contractor, in accordance with the contract and the instructions of the Contracting Officer;
- (2) (Except as reported in writing on _____), all payments to subcontractors and suppliers under this contract have been paid, or will be paid, currently, when due in the ordinary course of business;
- (3) There are no encumbrances (except as reported in writing on _____) against the property acquired or produced for, and allocated or properly chargeable to, the contract which would affect or impair the Government's title;
- (4) There has been no materially adverse change in the financial condition of the Contractor since the submission by the Contractor to the Government of the most recent written information dated _____; and
- (5) After the making of this requested performance-based payment, the amount of all payments for each deliverable item for which performance-based payments have been requested will not exceed any limitation in the contract, and the amount of all payments under the contract will not exceed any limitation in the contract.

(End of Clause)

52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

<http://farsite.hill.af.mil>
<http://www.acquisition.gov>

(End of clause)

52.252-6 AUTHORIZED DEVIATIONS IN CLAUSES (APR 1984)

(a) The use in this solicitation or contract of any Federal Acquisition Regulation (48 CFR Chapter 1) clause with an authorized deviation is indicated by the addition of " (DEVIATION)" after the date of the clause.

(b) The use in this solicitation or contract of any Defense Federal Acquisition Regulation Supplement (48 CFR Chapter 2) clause with an authorized deviation is indicated by the addition of "(DEVIATION)" after the name of the regulation.

(End of clause)

252.204-7008 EXPORT-CONTROLLED ITEMS (APR 2010)

(a) Definition. Export-controlled items, as used in this clause, means items subject to the Export Administration Regulations (EAR) (15 CFR parts 730-774) or the International Traffic in Arms Regulations (ITAR) (22 CFR parts 120-130). The term includes:

(1) Defense items, defined in the Arms Export Control Act, 22 U.S.C. 2778(j)(4)(A), as defense articles, defense services, and related technical data, and further defined in the ITAR, 22 CFR part 120.

(2) Items, defined in the EAR as "commodities, software, and technology," terms that are also defined in the EAR, 15 CFR 772.1.

(b) The Contractor shall comply with all applicable laws and regulations regarding export-controlled items, including, but not limited to, the requirement for Contractors to register with the Department of State in accordance with the ITAR. The Contractor shall consult with the Department of State regarding any questions relating to compliance with the ITAR and shall consult with the Department of Commerce regarding any questions relating to compliance with the EAR.

(c) The Contractor's responsibility to comply with all applicable laws and regulations regarding export-controlled items exists independent of, and is not established or limited by, the information provided by this clause.

(d) Nothing in the terms of this contract adds to, changes, supersedes, or waives any of the requirements of applicable Federal laws, Executive orders, and regulations, including but not limited to--

(1) The Export Administration Act of 1979, as amended (50 U.S.C. App. 2401, et seq.);

(2) The Arms Export Control Act (22 U.S.C. 2751, et seq.);

(3) The International Emergency Economic Powers Act (50 U.S.C. 1701, et seq.);

(4) The Export Administration Regulations (15 CFR parts 730-774);

(5) The International Traffic in Arms Regulations (22 CFR parts 120-130); and

(6) Executive Order 13222, as extended.

(e) The Contractor shall include the substance of this clause, including this paragraph (e), in all subcontracts. (End of clause)

252.232-7003 ELECTRONIC SUBMISSION OF PAYMENT REQUESTS AND RECEIVING REPORTS (MAR 2008)

(a) Definitions. As used in this clause--

(1) Contract financing payment and invoice payment have the meanings given in section 32.001 of the Federal Acquisition Regulation.

(2) Electronic form means any automated system that transmits information electronically from the initiating system to all affected systems. Facsimile, e-mail, and scanned documents are not acceptable electronic forms for submission of payment requests. However, scanned documents are acceptable when they are part of a submission of a payment request made using Wide Area WorkFlow (WAWF) or another electronic form authorized by the Contracting Officer.

(3) Payment request means any request for contract financing payment or invoice payment submitted by the Contractor under this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests and receiving reports using WAWF, in one of the following electronic formats that WAWF accepts: Electronic Data Interchange, Secure File Transfer Protocol, or World Wide Web input. Information regarding WAWF is available on the Internet at <https://wawf.eb.mil/>.

(c) The Contractor may submit a payment request and receiving report using other than WAWF only when--

(1) The Contracting Officer authorizes use of another electronic form. With such an authorization, the Contractor and the Contracting Officer shall agree to a plan, which shall include a timeline, specifying when the Contractor will transfer to WAWF;

(2) DoD is unable to receive a payment request or provide acceptance in electronic form;

(3) The Contracting Officer administering the contract for payment has determined, in writing, that electronic submission would be unduly burdensome to the Contractor. In such cases, the Contractor shall include a copy of the Contracting Officer's determination with each request for payment; or

(4) DoD makes payment for commercial transportation services provided under a Government rate tender or a contract for transportation services using a DoD-approved electronic third party payment system or other exempted vendor payment/invoicing system (e.g., PowerTrack, Transportation Financial Management System, and Cargo and Billing System).

(d) The Contractor shall submit any non-electronic payment requests using the method or methods specified in Section G of the contract.

(e) In addition to the requirements of this clause, the Contractor shall meet the requirements of the appropriate payment clauses in this contract when submitting payments requests.

(End of clause)

252.247-7024 Notification of Transportation of Supplies by Sea (MAR 2000)

(a) The Contractor has indicated by the response to the solicitation provision, Representation of Extent of Transportation by Sea, that it did not anticipate transporting by sea any supplies. If, however, after the award of this contract, the Contractor learns that supplies, as defined in the Transportation of Supplies by Sea clause of this contract, will be transported by sea, the Contractor --

(1) Shall notify the Contracting Officer of that fact; and

- (2) Hereby agrees to comply with all the terms and conditions of the Transportation of Supplies by Sea clause of this contract.
- (b) The Contractor shall include this clause; including this paragraph (b), revised as necessary to reflect the relationship of the contracting parties--
- (1) In all subcontracts under this contract, if this contract is a construction contract; or
- (2) If this contract is not a construction contract, in all subcontracts under this contract that are for--
- (i) Noncommercial items; or
- (ii) Commercial items that--
- (A) The Contractor is reselling or distributing to the Government without adding value (generally, the Contractor does not add value to items that it subcontracts for f.o.b. destination shipment);
- (B) Are shipped in direct support of U.S. military contingency operations, exercises, or forces deployed in humanitarian or peacekeeping operations; or
- (C) Are commissary or exchange cargoes transported outside of the Defense Transportation System in accordance with 10 U.S.C. 2643.
- (End of clause)
-

Section J - List of Documents, Exhibits and Other Attachments

Exhibit/Attachment Table of Contents

DOCUMENT TYPE	DESCRIPTION	PAGES	DATE
Exhibit A	Base Period CDRLs	4	26-SEP-2011
Exhibit B	Option I CDRLs	4	26-SEP-2011
Exhibit C	Option II CDRLs	4	26-SEP-2011
Exhibit D	Option III CDRLs	4	26-SEP-2011
Exhibit E	Option IV CDRLs	4	26-SEP-2011
Attachment 1	Performance Based Payments Schedule	5	26-SEP-2011
Attachment 2	Clause 252.227-7017	2	28-SEP-2011

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT ID CODE J	PAGE OF PAGES 1 11
2. AMENDMENT/MODIFICATION NO. P00010	3. EFFECTIVE DATE 12-Mar-2015	4. REQUISITION/PURCHASE REQ. NO. SEE SCHEDULE		5. PROJECT NO. (If applicable)
6. ISSUED BY SPAWAR SYSTEMS CENTER PACIFIC LYNN BIEDERMANN CODE 22530 LYNN.BIEDERMANN@NAVY.MIL 55500 HULL STREET SAN DIEGO CA 92152-5001	CODE N86001	7. ADMINISTERED BY (If other than item 4) DCMA SAN DIEGO 7575 DRAGET ST SUITE 203 SAN DIEGO CA 92111-2241		CODE S0514A SCD: C
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) AETHLON MEDICAL INC DUNBAR 05963095 8840 UNIVERSITY CTR LN STE 600 SAN DIEGO CA 92122-1027			9A. AMENDMENT OF SOLICITATION NO.	
			9B. DATED (SEE ITEM 11)	
			X 10A. MOD. OF CONTRACT/ORDER NO. N86001-11-C-4186	
			X 10B. DATED (SEE ITEM 13) 30-Sep-2011	
CODE 47A31	FACILITY CODE			
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS				
<input type="checkbox"/> The above numbered solicitation is amended as set forth in item 14. The hour and date specified for receipt of offer <input type="checkbox"/> is extended. <input type="checkbox"/> is not extended. Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.				
12. ACCOUNTING AND APPROPRIATION DATA (If required)				
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACT ORDERS IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.				
A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.				
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).				
X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: Mutual Agreement of the Parties				
D. OTHER (Specify type of modification and authority)				
E. IMPORTANT: Contractor <input type="checkbox"/> is not. <input checked="" type="checkbox"/> is required to sign this document and return <u>1</u> copies to the issuing office.				
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by URF section headings, including solicitation/contract subject matter where feasible) Modification Control Number: biederH151242 This modification incorporates an updated Statement of Work and Schedule of Milestone Payments. Please see following page(s).				
Except as provided herein, all terms and conditions of the document referenced in item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.				
15A. NAME AND TITLE OF SIGNER (Type or print) <i>Ruby Kenley Principal Investigator</i>			16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) TEL: <i>Larry Hartpence</i> EMAIL:	
15B. CONTRACT/ORDER NO. <i>[Signature]</i> (Signature of person authorized to sign)			16B. UNITED STATES OF AMERICA BY: <i>[Signature]</i> (Signature of Contracting Officer)	
15C. DATE SIGNED <i>3/12/2015</i>			16C. DATE SIGNED <i>12 MAR 2015</i>	

EXCEPTION TO SF 30
APPROVED BY OIRM 11-84

30-105-04

STANDARD FORM 30 (Rev. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

SUMMARY OF CHANGES

SECTION C - DESCRIPTIONS AND SPECIFICATIONS

The following have been modified: STATEMENT OF WORK (SOW)

Aethlon Medical, Inc.

DATE: 11 December 2013, Revised: 12 March 2015

TITLE: Broad Spectrum Countermeasures for Viral and Bacterial Sepsis using Dialysis-Like Devices

1.0 Scope

The scope of this effort is to use Aethlon's Hemopurifier as the core technology within an extracorporeal blood purification device that would simultaneously remove: viruses, virally-derived immunosuppressive glycoproteins, and multiple classes of exosomes; complement activation, activation of virus growth (e.g. cytomegalovirus) and TLR activation, all of which have implications to the promotion of the well-being and recovery of wounded warfighters and the prevention of sepsis.

1.1 Introduction

This effort will create an adaptable dialysis-like platform (ADAPT) technology that allows for the selective removal of harmful agents from the entire circulatory system. This revolutionary advance overcomes the limitation of devices that indiscriminately adsorb or solely capture particles by molecule size. The platform will provide an expansive therapeutic filtration mechanism to immobilize multiple affinity agents directed toward precursors to sepsis, bacterial toxins, viral pathogens, and disease enhancing particles transported by exosomes. To insure benefit to wounded warfighters, this effort will advance an innovative strategy that will allow therapy administration without systemic anticoagulation.

The ADAPT platform has been shown previously to create a broad-spectrum antiviral device that immobilized one lectin affinity agent, resulting in the effective capture of all tested Category A pathogens, as well as exosomes underlying tuberculosis and cancer. In human studies, this same device, known as the Hemopurifier, consistently provided greater than 50% average viral load reductions during four-hour treatment periods in both hepatitis-C and HIV infected individuals without antiviral drug therapy.

The resulting device would save thousands of military and civilian lives each year. Each of these technology advancements will be integrated into a single cartridge that will provide decision-free and life-saving medical care for the wounded warfighter.

1.2 Background

The goal of the DLT program is to develop a portable device that removes "dirty" blood from the body, separates harmful agents, and returns "clean" blood to the body in a manner similar to dialysis treatment of kidney failure. While the device could have an impact across multiple areas of medicine, the target application for this device is sepsis. The envisioned device will persistently interrogate the entire blood volume, providing early identification of the presence of a pathogen. Once the presence of pathogens has been confirmed, the DLT device will provide continuous "label-free" removal of pathogens, toxins and activated patient cells without pathogen identification or use of pathogen-specific binding chemistries. As a final step in the treatment process, the DLT device will enable closed-loop therapy based on continuous, reduced dimensionality modeling of patient health. Predictive modeling in this fashion will allow us to identify sepsis early, learn what we need to remove, and direct the most effective intervention to improve patient health. This cycle of sensing, adjustment, estimation, computation, and manipulation will modulate key health parameters faster than the underlying disease process and drive the patient towards a stable, healthy state.

2.0 Technical Requirements

2.1 Human and Animal use

Human use is anticipated in this effort, specifically related to the use of human blood. The grantee shall obtain all necessary Institutional Review Board (IRB) approvals, show proper assurance documentation, and obtain proper approval from the Government officials prior to human use testing. Funds associated with human subjected testing shall not be released until IRB documentation has been provided to SSC's HRPO and approval to release funds has been obtained.

Animal use is anticipated in this effort. The contractor shall obtain all necessary Institutional Animal Care and Utilization Committee (IACUC) approval and demonstrate this approval to the Government (**both** ACURO and SSC-Pacific) prior to beginning experimentation with animals. If animal use is no longer anticipated, or changes significantly from the approved IACUC then the Principal Investigator (PI) must submit a letter stating the discontinuation of animal use for this effort and/or receive appropriate authorization for IACUC changes of previously specified protocols. Unless prior approval by DARPA is given IACUC documentation must be provided prior to contract award.

2.2 Base Effort (Year 1)

2.2.1 Subtask 1a: Anticoagulant-free Hemopurification Device

- 2.2.1.1 Write requirements definition for the extracorporeal blood purification system and acquire necessary equipment.
- 2.2.1.2 Fabricate breadboard prototypes for anticoagulation-free anti-sepsis extracorporeal system (ASEPSYS) device. Fabricate prototype blood tubing sets. Acquire anti-thrombogenic surface-modified hollow fiber plasma separators.
- 2.2.1.3 Assemble and test breadboard ASEPSYS devices *ex vivo* with bovine blood. The test will most likely be conducted using a porcine model where the elapsed time to reach a pre-defined degree of clotting in the blood treatment device will be compared between the new device and two control groups; one using standard anticoagulant therapy and one using none. Determine contribution of the following techniques and approaches to eliminating anticoagulants:
 - (1) Backflushing at regular intervals, (2) Turbo loop, (3) Continuous pre-dilution loop using re-captured hydration fluid, (4) Linear vs pulsatile blood flow, (5) Elimination of air/blood interfaces in extracorporeal circuit, (6) Anti-thrombogenic derivatized plasma separation membrane, and (7) Ultra-short half-life anticoagulant nafamostat mesilate.
- 2.2.1.4 **IRB Documentation Generation: The contractor shall obtain all necessary IRB documentation and obtain both institutional and Government (SSC-Pacific) approval in accordance with IRB documentation submission guidance prior to conducting human subject testing.**

Milestones

M1: Demonstrate the effectiveness of the prototype device in preventing platelet activation or clotting in at least a 2 hour blood pumping experiment at 100 mL/hr blood flow.

2.2.2 Subtask 2: Removal of Sepsis Precursors

- 2.2.2.1 Begin to develop a device based on Aethlon's ADAPT system to efficiently capture sepsis precursors identified as potentially important in killing patients undergoing sepsis. The strategy is takes advantage of the flexibility and rapidity of modification of our ADAPT platform system to test any sepsis precursor candidates that circulate in the blood. The sepsis precursors that will be targeted are shown in Table I, in order of importance. No test for the removal of bacterial toxins. No testing for removal of cytokines, since the evidence to date does not support a role for them in death due to sepsis. Additional factors may become known during the grant period and those will also be tested as time and budget permit.

- 2.2.2.2 Screening Capture Agents: Perform initial screening of the different proposed capture agents by measuring binding affinity and kinetics using surface plasmon resonance (SPR) or biolayer surface interferometry (BLI).
- 2.2.2.3 Perform quantitative real time PCR will also be used to measure viral load, and specific DNA or RNA targets.

Milestones

M2: Target capture > 50% in 24 hours for at least 1 target in blood or blood components

Table I Potential Target Sepsis Precursors and Broad Spectrum Binding Agents

Septic Exosomes	Removal Agent
INOS exosomes	GNA
Viruses Associated with Sepsis	
Dengue Fever virus	GNA
H1N1 Flu virus	GNA
Cytomegalovirus **	GNA
Herpes viruses – e.g. HSV 1	GNA
Poxviruses - e.g. Vaccina (model for small pox)	GNA
Activation of Innate Immunity	
LPS endotoxins	GNA
LTA endotoxins	GNA

2.3 Option 1 (Year 2)

2.3.2 Subtask 1a: Anticoagulant-free Hemopurification Device

- 2.3.2.1 Demonstrate the effectiveness of the prototype device in vivo in animals preventing platelet activation or clotting in at least a 2 hour blood pumping experiment at 75 mL/min blood flow.
- 2.3.2.2 Formulate initial design based on work from previous phase. Begin to build and test selected instrument design and tubing sets.
- 2.3.2.3 Write and test software. Conduct ergonomic research. Begin discussions with System Integrator.
- 2.3.2.4 Complete fabrication and testing of prototype instrument.
- 2.3.2.5 Research literature and patent database for technical options for an on-line/in-line sensor with the ability to quantify the clearance of citrate and/or calcium in effluent dialysate.
- 2.3.2.6 Collect feasibility data on at least one sensor option.
- 2.3.2.7 Conduct a series of 21 experiments aimed at characterizing the contribution of several alternate fluidic designs and methods of perfusing plasma filters and affinity columns in the performance of affinity plasmapheresis.

2.3.3 Subtask 2. Removal of Sepsis Precursors

- 2.3.3.1 Build the ADAPT capture cartridges with the identified affinity agents. Measure the rate of capture of the specific targets from in ex vivo recirculation experiments from cell culture and blood.
- 2.3.3.2 Cartridge construction with optimized affinity matrix design for each potential target. Complete all capture agents screening. Initiate *ex vivo* capture studies from blood using the optimized cartridges.

Milestones

M4: Target capture > 50% in 24 hours for at least 5 targets in blood or blood components.

M5: Milestone 5: Target capture > 90% in 24 hours for at least 3 targets in blood or blood components.

NOTE: TASK 2.3.2 SHALL NOT BE EXERCISED AND TASKING FUNDS RELEASED UNTIL IRB DOCUMENTATION AND PROPER IRB APPROVAL HAS BEEN OBTAINED.

2.4 Option 2 (Year 3)

2.4.1 Subtask 1a: Anticoagulant-free Hemopurification Device

2.4.1.1 Design and fabricate optimized configuration(s) of hemopurification device(s) that contain(s) a combination of hemofilters, plasma filters, and affinity columns.

Milestones

M6: Define Aethlon's GMP manufacturing process and revise and upgrade Aethlon's quality procedures and policies to the current state of the art. ~~Demonstrate the safety of at least one prototype device within an optimized fluidic circuit architecture preventing clotting in a 24 hour experiment *in vivo* at a blood flow rate of 200 ml/min using either pigs or dogs.~~

2.4.2 Subtask 4: Target Capture in Combined Agent Cartridge

2.4.2.1 Evaluate contribution of manufacturing process variables to binding capacity of affinity resin.

2.4.2.2 Determine capacity requirements of affinity resin to multiple simultaneous targets.

2.4.2.3 Perform basic biocompatibility tests for the combination ADAPT device to confirm the combination cartridge does not present additional risk.

2.4.2.4 Finish construction and delivery of 25 experimental cartridges for testing by the system integrator.

Milestones

M7: Target capture > 90% in 24 hours (12 months) for at least 3 targets ex vivo in blood or blood components using the optimized cartridge.

M8: Pass biocompatibility tests for the combination ADAPT device.

M9: Construct and deliver of 25 prototype cartridges for testing by the system integrator.

2.5 Option 3 (Year 4)

2.5.1 Subtask 1a: Anticoagulant-free Hemopurification Device

2.5.1.1 ~~Complete Aethlon's GMP procedure and establish and maintain all GMP documentation for the company. Revise and upgrade Aethlon's quality procedures and policies to the current state of the art and establish and maintain all GMP documentation for the company. Develop additional optimized configuration(s) of hemopurification device(s) that contain(s) a combination of hemofilters, plasma filters, and affinity columns.~~

Milestones

M11: ~~Develop a strategic plan for developing an alternate method of producing GNA by cloning the gene into an alternate vector and identify potential partners for such production. Demonstrate the safety of an additional prototype device within an optimized fluidic circuit architecture preventing clotting in a 24 hour experiment *in vivo* at a blood flow rate of 200 ml/min using either pigs or dogs.~~

2.5.2 Subtask 4: Target Capture in Combined Agent Cartridge

2.5.2.2 Finish construction and delivery of 50 prototype cartridges for testing by the system integrator. The cartridges will need to be made available (packaged, labeled, sterilized and qualified) to the system integrator.

Milestones

M13: Construct and deliver of 50 prototype cartridges for testing by the system integrator.

2.6 Option 4 (Year 5)

2.6.1 Subtask 5: Testing of final product by System Integrator

2.6.1.1 System integrator acceptance of the hemofilter device.

2.6.1.3 Prepare and submit IDE proposal for sepsis treatment.

2.6.1.4 Prepare and present Final report for DARPA.

Milestones

M12: System Integrator approval of a sepsis precursor ADAPT treatment cartridge

3.0 Program Management and Reviews

3.1 Program Management Plan

The contractor shall develop a Program Management Plan. A graphical representation of this plan (Gantt chart is one example) identifying major tasks and their task leaders, milestones of the major task and their completion dates shall be generated. In addition, a graphical representation of budget shall be generated.

3.2 Kick-off Meeting

The contractor shall participate in a kick-off meeting within 60 days of contract award. The purpose of this meeting is to introduce key program personnel, discuss the proposed tasking, present the program schedule and milestones and the initial Program Management Plan.

3.3 Quarterly Reviews

The contractor shall hold quarterly reviews for the duration of this effort. The purpose of these reviews is to present a summary of work completed and milestones met, discuss any problems encountered, update the program schedule, present the program financial status, and discuss remaining work.

3.4 Final Contract Review

A final contract review held in place of the last quarterly review shall be hosted by the principal contractor. The purpose of this review is to present a summary of all work completed and milestones accomplished and to discuss any relevant future efforts similar to the contract that may be pursued.

4.0 Deliverables

The reports and presentation materials are to be delivered in accordance with the attached Data Delivery Matrix.

(End of SOW).

SECTION G - CONTRACT ADMINISTRATION DATA

The following have been modified:

SCHEDULE OF PAYMENT MILESTONES

12 month duration base period (Year 1)

Milestone	Month	Payable Milestone	GOVT CONTRIBUTION
Subtask 1a		Anticoagulant-free Hemopurification Device	(\$908,384)
2.2.1.1	1	Write requirements definition for the extracorporeal blood purification system and acquire necessary equipment.	(\$358,284)
2.2.1.2	3	Fabricate breadboard prototypes for anticoagulation-free anti-sepsis extracorporeal system (ASEPSYS) device. Fabricate prototype blood tubing sets. Acquire anti- thrombogenic surface-modified hollow fiber plasma separators.	(\$183,367)
2.2.1.3	6	Assemble and test breadboard ASEPSYS devices. Evaluate the use of different techniques and approaches to eliminating anticoagulants.	(\$183,367)
2.2.1.4	12	Obtain all necessary IRB documentation and obtain both institutional and Government (SSC-Pacific) approval in accordance with IRB documentation submission guidance prior to conducting human or animal testing.	(\$183,367)
Subtask 2 & 4		Removal of Sepsis Precursors	(\$1,066,663)
2.2.2.1	2	Begin to develop the Aethlon's ADAPT device to efficiently capture sepsis precursors and acquire important equipment and supplies	(\$416,424)
2.2.2.2	5	Perform initial screening of the different proposed capture agents by measuring binding affinity and kinetics using surface plasmon resonance (SPR) or biolayer surface interferometry (BLI).	(\$216,747)
2.2.2.3	8	Perform preliminary quantitative real time PCR to measure viral load, and specific DNA or RNA targets.	(\$216,747)
M2	12	Target capture > 50% in 24 hours for at least 1 target in blood or blood components	(\$216,747)
Total			(\$1,975,047)

12 month duration option #1 period (Year2)

Milestone	Month	Payable Milestone	GOVT CONTRIBUTION
Subtask 1a		Anticoagulant-free Hemopurification Device	(\$782,322)
2.3.2.1	15	Demonstrate the effectiveness of the prototype device in vivo in animals preventing platelet activation or clotting in at least a 2 hour blood pumping experiment at 75 mL/min blood flow.	(\$195,581)
2.3.2.2	18	Formulate initial design based on work from previous phase. Begin to build and test selected instrument design and tubing sets.	(\$195,581)
2.3.2.3	21	Write and test software. Conduct ergonomic research. Begin discussions with System Integrator.	(\$195,581)
M3	24	Complete fabrication and testing of prototype instrument. Research literature and patent database for technical.	(\$195,581)
Subtask 2		Removal of Sepsis Precursors	(\$835,124)
2.3.3.1	15	Build the ADAPT capture cartridges with the identified affinity agents. Measure the rate of capture of the specific targets from in ex vivo recirculation experiments from cell culture and blood.	(\$208,781)
M4	18	Target capture > 50% in 24 hours for at least 5 targets in blood or blood components.	(\$208,781)
2.3.3.2	21	Cartridge construction with optimized affinity matrix design for each potential target. Complete the capture agent screening.	(\$208,781)
M5	24	Target capture > 90% in 24 hours for at least 3 targets in blood or blood components.	(\$208,781)
Total			(\$1,617,446)

12 month duration option #2 period (Year 3)

Milestone	Month	Payable Milestone	GOVT CONTRIBUTION
Subtask 1a		Anticoagulant-free Hemopurification Device	(\$372,328)
2.4.1.1	27	Design and fabricate optimized configuration(s) of hemopurification device(s) that contain(s) a combination of hemofilters, plasma filters, and affinity columns.	(\$186,164)
M6	36	Define Aethlon's GMP manufacturing process and revise and upgrade Aethlon's quality procedures and policies to the current state of the art.	(\$186,164)
Subtask 2+4		Target Capture in Combined Agent Cartridge	(\$720,726)
2.4.2.1	27	Evaluate contribution of manufacturing process variables to binding capacity of affinity resin.	(\$197,362)
2.4.2.2	33	Determine capacity requirements of affinity resin to multiple simultaneous targets.	(\$197,362)
2.4.2.3	30	Perform biocompatibility tests for the combination ADAPT device to confirm the combination cartridge does not present additional risk.	(\$78,641)
2.4.2.4	36	Finish construction and delivery of 25 experimental cartridges for testing by the system integrator	(\$50,000)
M9	36	Target capture > 90% in 24 hours (12 months) for at least 3 targets ex vivo in blood or blood components using the optimized cartridge.	(\$197,361)
Total			(\$1,093,054)

12 month duration option #3 period (Year 4)



Milestone	Month	Payable Milestone	GOVT CONTRIBUTION
Subtask 1a		Anticoagulant-free Hemopurification Device	(\$276,172)
2.5.1.1	45	Complete Aethlon's GMP procedure and establish and maintain all GMP documentation for the company.	(\$90,008)
M11	48	Develop a strategic plan for developing an alternate method of producing GNA by cloning the gene into an alternate vector and identify potential partners for such production.	(\$186,164)
Subtask 2+4		Target Capture in Combined Agent Cartridge	(\$296,964)
2.5.2.2	48	Finish construction and begin delivery of 50 prototype cartridges for testing by the system integrator.	(\$296,964)
Total			(\$573,136)

12 month duration option #4 period (Year 5)

Milestone	Month	Payable Milestone	GOVT CONTRIBUTION
Subtask 5		Testing of final product by System Integrator	(\$581,157)
2.6.1.1	51	System integrator acceptance of the hemofilter device.	(\$193,719)
2.6.1.3	57	Prepare and submit IDE proposal for sepsis treatment.	(\$193,719)
2.6.1.4	60	Prepare and present Final Report for DARPA.	(\$193,719)
Total			(\$581,157)

(End of Milestone Schedule)

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT ID CODE	PAGE OF PAGES	
			J	1	10
2. AMENDMENT/MODIFICATION NO. P00013	3. EFFECTIVE DATE 09-Aug-2016	4. REQUESTION/PURCHASE REQ. NO. SEE SCHEDULE	5. PROJECT NO. (If applicable)		
6. ISSUED BY SPAWAR SYSTEMS CENTER PACIFIC LYNN BIEDERMAN CODE 2250 LYNN BIEDERMAN@NAVY.MIL 5280 HULL STREET SAN DIEGO CA 92152-5001	CODE N66001	7. ADMINISTERED BY (If other than item 6) DCMA SAN DIEGO 7676 DAGGET ST SUITE 200 SAN DIEGO CA 92111-2241	CODE S0514A SCD C		
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) AETHLON MEDICAL, INC. DUNSM 2640000 9000 GRANITE RIDGE DR STE 100 SAN DIEGO CA 92123-2678			9A. AMENDMENT OF SOLICITATION NO.		
			9B. DATED (SEE ITEM 11)		
			X 10A. MOD. OF CONTRACT ORDER NO. N66001-11-C-4188		
			X 10B. DATED (SEE ITEM 13) 30-Sep-2011		
CODE 47A31	FACILITY CODE				
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS					
<input type="checkbox"/> The above numbered solicitation is amended as set forth in item 14. The hour and date specified for receipt of offer <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended. Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter make reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.					
12. ACCOUNTING AND APPROPRIATION DATA (If required)					
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACT'S ORDERS IT MODIFIES THE CONTRACT ORDER NO. AS DESCRIBED IN ITEM 14.					
A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.					
B. THE ABOVE NUMBERED CONTRACT ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).					
X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: Mutual Agreement of the Parties.					
D. OTHER (Specify type of modification and authority)					
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input checked="" type="checkbox"/> is required to sign this document and return <u>1</u> copies to the issuing office.					
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible) Modification Control Number: dledem1162563 This modification incorporates a revised Statement of Work into Section C and a revised Milestone Payment Schedule into Section G. Please see the following page(s).					
Except as provided herein, all terms and conditions of the document referenced in item 9A or 10A, as heretofore changed, remain unchanged and in full force and effect.					
15A. NAME AND TITLE OF SIGNER (Type or print) Rodney S. Kenley			16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) Digitally signed by JENKINS, DAVID W. 104 2016.08.09		
15B. CONTRACTOR/OFFEROR  (Signature of person authorized to sign)		15C. DATE SIGNED 8/9/2016	16B. UNITED STATES OF AMERICA BY  (Signature of Contracting Officer) Date: 2016.08.09 10:34:59 -07'00'		
EXCEPTION TO SF 30 APPROVED BY OIRM 11-84		30-101-04	STANDARD FORM 30 (Rev. 10-83) Prescribed by GSA FAR (48 CFR) 53.243		

SUMMARY OF CHANGES

SECTION A - SOLICITATION/CONTRACT FORM

The standard size code 1,000 has been added.
The NAICS code 541711 has been added.

SECTION C - DESCRIPTIONS AND SPECIFICATIONS

The following have been modified:

STATEMENT OF WORK (SOW)

Aethlon Medical, Inc.

DATE: 12 March 2015; Modified: 15 July 2016

TITLE: Broad Spectrum Countermeasures for Viral and Bacterial Sepsis using Dialysis-Like Devices

1.0

Scope

The scope of this effort is to use Aethlon's Hemopurifier as the core technology within an extracorporeal blood purification device that would simultaneously remove: viruses, virally-derived immunosuppressive glycoproteins, and multiple classes of exosomes; complement activation, activation of virus growth (e.g. cytomegalovirus) and TLR activation, all of which have implications to the promotion of the well-being and recovery of wounded warfighters and the prevention of sepsis.

1.1

Introduction

This effort will create an adaptable dialysis-like platform (ADAPT) technology that allows for the selective removal of harmful agents from the entire circulatory system. This revolutionary advance overcomes the limitation of devices that indiscriminately adsorb or solely capture particles by molecule size. The platform will provide an expansive therapeutic filtration mechanism to immobilize multiple affinity agents directed toward precursors to sepsis, bacterial toxins, viral pathogens, and disease enhancing particles transported by exosomes. To insure benefit to wounded warfighters, this effort will advance an innovative strategy that will allow therapy administration without systemic anticoagulation.

The ADAPT platform has been shown previously to create a broad-spectrum antiviral device that immobilized one lectin affinity agent, resulting in the effective capture of all tested Category A pathogens, as well as exosomes underlying tuberculosis and cancer. In human studies, this same device, known as the Hemopurifier, consistently provided greater than 50% average viral load reductions during four-hour treatment periods in both hepatitis-C and HIV infected individuals without antiviral drug therapy.

The resulting device would save thousands of military and civilian lives each year. Each of these technology advancements will be integrated into a single cartridge that will provide decision-free and life-saving medical care for the wounded warfighter.

1.2 Background

The goal of the DLT program is to develop a portable device that removes “dirty” blood from the body, separates harmful agents, and returns “clean” blood to the body in a manner similar to dialysis treatment of kidney failure. While the device could have an impact across multiple areas of medicine, the target application for this device is sepsis. The envisioned device will persistently interrogate the entire blood volume, providing early identification of the presence of a pathogen. Once the presence of pathogens has been confirmed, the DLT device will provide continuous “label-free” removal of pathogens, toxins and activated patient cells without pathogen identification or use of pathogen-specific binding chemistries. As a final step in the treatment process, the DLT device will enable closed-loop therapy based on continuous, reduced dimensionality modeling of patient health. Predictive modeling in this fashion will allow us to identify sepsis early, learn what we need to remove, and direct the most effective intervention to improve patient health. This cycle of sensing, adjustment, estimation, computation, and manipulation will modulate key health parameters faster than the underlying disease process and drive the patient towards a stable, healthy state.

2.0 Technical Requirements

2.1 Human and Animal use

Human use is anticipated in this effort, specifically related to the use of human blood. The grantee shall obtain all necessary Institutional Review Board (IRB) approvals, show proper assurance documentation, and obtain proper approval from the Government officials prior to human use testing. Funds associated with human subjected testing shall not be released until IRB documentation has been provided to SSC’s HRPO and approval to release funds has been obtained.

Animal use is anticipated in this effort. The contractor shall obtain all necessary Institutional Animal Care and Utilization Committee (IACUC) approval and demonstrate this approval to the Government (both ACURO and SSC-Pacific) prior to beginning experimentation with animals. If animal use is no longer anticipated, or changes significantly from the approved IACUC then the Principal Investigator (PI) must submit a letter stating the discontinuation of animal use for this effort and/or receive appropriate authorization for IACUC changes of previously specified protocols. Unless prior approval by DARPA is given IACUC documentation must be provided prior to contract award.

2.2 Base Effort (Year 1)

2.2.1 Subtask 1a: Anticoagulant-free Hemopurification Device

2.2.1.1 Write requirements definition for the extracorporeal blood purification system and acquire necessary equipment.

2.2.1.2 Fabricate breadboard prototypes for anticoagulation-free anti-sepsis extracorporeal system (ASEPSYS) device. Fabricate prototype blood tubing sets. Acquire anti-thrombogenic surface-modified hollow fiber plasma separators.

2.2.1.3 Assemble and test breadboard ASEPSYS devices *ex vivo* with bovine blood. The test will most likely be conducted using a porcine model where the elapsed time to reach a pre-defined degree of clotting in the blood treatment device will be compared between the new device and two control groups; one using standard anticoagulant therapy and one using none. Determine contribution of the following techniques and approaches to eliminating anticoagulants:

- (1) Backflushing at regular intervals, (2) Turbo loop, (3) Continuous pre-dilution loop using re-captured hydration fluid, (4) Linear vs pulsatile blood flow, (5) Elimination of air/blood interfaces in extracorporeal circuit, (6) Anti-thrombogenic derivatized plasma separation membrane, and (7) Ultra-short half-life anticoagulant nafamostat mesilate.

2.2.1.4 IRB Documentation Generation: The contractor shall obtain all necessary IRB documentation and obtain both institutional and Government (SSC-Pacific) approval in accordance with IRB documentation submission guidance prior to conducting human subject testing.

Milestones

M1: Demonstrate the effectiveness of the prototype device in preventing platelet activation or clotting in at least a 2 hour blood pumping experiment at 100 mL/hr blood flow.

2.2.2 Subtask 2: Removal of Sepsis Precursors

2.2.2.1 Begin to develop a device based on Aethlon’s ADAPT system to efficiently capture sepsis precursors identified as potentially important in killing patients undergoing sepsis. The strategy is takes advantage of the flexibility and rapidity of modification of our ADAPT platform system to test any sepsis precursor candidates that circulate in the blood. The sepsis precursors that will be targeted are shown in Table I, in order of importance. No test for the removal of bacterial toxins. No testing for removal of cytokines, since the evidence to date does not support a role for them in death due to sepsis. Additional factors may become known during the grant period and those will also be tested as time and budget permit

2.2.2.2 Screening Capture Agents: Perform initial screening of the different proposed capture agents by measuring binding affinity and kinetics using surface plasmon resonance (SPR) or biolayer surface interferometry (BLI).

2.2.2.3 Perform quantitative real time PCR will also be used to measure viral load, and specific DNA or RNA targets.

Milestones

M2: Target capture > 50% in 24 hours for at least 1 target in blood or blood components

Table I Potential Target Sepsis Precursors and Broad Spectrum Binding Agents

Septic Exosomes	Removal Agent
INOS exosomes	GNA
Viruses Associated with Sepsis	
Dengue Fever virus	GNA
H1N1 Flu virus	GNA
Cytomegalovirus **	GNA
Herpes viruses – e.g. HSV 1	GNA
Poxviruses - e.g. Vaccinia (model for small pox)	GNA
Activation of Innate Immunity	
LPS endotoxins	GNA
LTA endotoxins	GNA

2.3 Option 1 (Year 2)

2.3.2 Subtask 1a: Anticoagulant-free Hemopurification Device

2.3.2.1 Demonstrate the effectiveness of the prototype device in vivo in animals preventing platelet activation or clotting in at least a 2 hour blood pumping experiment at 75 mL/min blood flow.

2.3.2.2 Formulate initial design based on work from previous phase. Begin to build and test selected instrument design and tubing sets.

2.3.2.3 Write and test software. Conduct ergonomic research. Begin discussions with System Integrator.

2.3.2.4 Complete fabrication and testing of prototype instrument.

2.3.2.5 Research literature and patent database for technical options for an on-line/in-line sensor with the ability to quantify the clearance of citrate and/or calcium in effluent dialysate.

2.3.2.6 Collect feasibility data on at least one sensor option.

2.3.2.7 Conduct a series of 21 experiments aimed at characterizing the contribution of several alternate fluidic designs and methods of perfusing plasma filters and affinity columns in the performance of affinity plasmapheresis.

2.3.3 Subtask 2. Removal of Sepsis Precursors

2.3.3.1 Build the ADAPT capture cartridges with the identified affinity agents. Measure the rate of capture of the specific targets from in ex vivo recirculation experiments from cell culture and blood.

2.3.3.2 Cartridge construction with optimized affinity matrix design for each potential target. Complete all capture agents screening. Initiate *ex vivo* capture studies from blood using the optimized cartridges.

Milestones

M4: Target capture > 50% in 24 hours for at least 5 targets in blood or blood components.

M5: Milestone 5: Target capture > 90% in 24 hours for at least 3 targets in blood or blood components.

NOTE: TASK 2.3.2 SHALL NOT BE EXERCISED AND TASKING FUNDS RELEASED UNTIL IRB DOCUMENTATION AND PROPER IRB APPROVAL HAS BEEN OBTAINED.

2.4 Option 2 (Year 3)

2.4.1 **Subtask 1a: Anticoagulant-free Hemopurification Device**

2.4.1.1 Design and fabricate optimized configuration(s) of hemopurification device(s) that contain(s) a combination of hemofilters, plasma filters, and affinity columns.

Milestones

M6: Define Aethlon's GMP manufacturing process and revise and upgrade Aethlon's quality procedures and policies to the current state of the art.

2.4.2 **Subtask 4: Target Capture in Combined Agent Cartridge**

2.4.2.1 Evaluate contribution of manufacturing process variables to binding capacity of affinity resin.

2.4.2.2 Determine capacity requirements of affinity resin to multiple simultaneous targets.

2.4.2.3 Perform basic biocompatibility tests for the combination ADAPT device to confirm the combination cartridge does not present additional risk.

2.4.2.4 Finish construction and delivery of 25 experimental cartridges for testing by the system integrator.

Milestones

M7: Target capture > 90% in 24 hours (12 months) for at least 3 targets ex vivo in blood or blood components using the optimized cartridge.

M8: Pass biocompatibility tests for the combination ADAPT device.

M9: Construct and deliver of 25 prototype cartridges for testing by the system integrator.

2.5 Option 3 (Year 4)

2.5.1 **Subtask 1a: Anticoagulant-free Hemopurification Device**

2.5.1.1 Complete Aethlon's GMP procedure and establish and maintain all GMP documentation for the company.

Milestones

M11: Develop a strategic plan for developing an alternate method of producing GNA by cloning the gene into an alternate vector and identify potential partners for such production.

2.5.2 **Subtask 4: Target Capture in Combined Agent Cartridge**

2.5.2.2 Finish construction and delivery of 50 prototype cartridges for testing by the system integrator. The cartridges will need to be made available (packaged, labeled, sterilized and qualified) to the system integrator.

Milestones

M13: Construct and deliver of 50 prototype cartridges for testing by the system integrator.

2.6 Option 4 (Year 5)

2.6.1 **Subtask 5: Testing of final product by System Integrator**

2.6.1.1 System integrator acceptance of the hemofilter device.

2.6.1.3 Quantify the degree to which the MERS virus can be extracted from circulation *in vitro* using miniature Hemopurifiers.

2.6.1.4 Prepare and present Final report for DARPA.

Milestones

M12: System Integrator approval of a sepsis precursor ADAPT treatment cartridge

3.0 Program Management and Reviews

3.1 Program Management Plan

The contractor shall develop a Program Management Plan. A graphical representation of this plan (Gantt chart is one example) identifying major tasks and their task leaders, milestones of the major task and their completion dates shall be generated. In addition, a graphical representation of budget shall be generated.

3.2 Kick-off Meeting

The contractor shall participate in a kick-off meeting within 60 days of contract award. The purpose of this meeting is to introduce key program personnel, discuss the proposed tasking, present the program schedule and milestones and the initial Program Management Plan.

3.3 Quarterly Reviews

The contractor shall hold quarterly reviews for the duration of this effort. The purpose of these reviews is to present a summary of work completed and milestones met, discuss any problems encountered, update the program schedule, present the program financial status, and discuss remaining work.

3.4 Final Contract Review

A final contract review held in place of the last quarterly review shall be hosted by the principal contractor. The purpose of this review is to present a summary of all work completed and milestones accomplished and to discuss any relevant future efforts similar to the contract that may be pursued.

4.0 Deliverables

The reports and presentation materials are to be delivered in accordance with the attached Data Delivery Matrix.

(End of SOW).

SECTION G - CONTRACT ADMINISTRATION DATA

The following have been modified:

SCHEDULE OF PAYMENT MILESTONES

12 month duration base period (Year 1)

Milestone	Month	Payable Milestone	GOVT CONTRIBUTION
Subtask 1a		Anticoagulant-free Hemopurification Device	(\$908,384)
2.2.1.1	1	Write requirements definition for the extracorporeal blood purification system and acquire necessary equipment.	(\$358,284)
2.2.1.2	3	Fabricate breadboard prototypes for anticoagulation-free anti-sepsis extracorporeal system (ASEPSYS) device. Fabricate prototype blood tubing sets. Acquire anti- thrombogenic surface-modified hollow fiber plasma separators.	(\$183,367)
2.2.1.3	6	Assemble and test breadboard ASEPSYS devices. Evaluate the use of different techniques and approaches to eliminating anticoagulants.	(\$183,367)
2.2.1.4	12	Obtain all necessary IRB documentation and obtain both institutional and Government (SSC-Pacific) approval in accordance with IRB documentation submission guidance prior to conducting human or animal testing.	(\$183,367)
Subtask 2 & 4		Removal of Sepsis Precursors	(\$1,066,663)
2.2.2.1	2	Begin to develop the Aethlon's ADAPT device to efficiently capture sepsis precursors and acquire important equipment and supplies	(\$416,424)
2.2.2.2	5	Perform initial screening of the different proposed capture agents by measuring binding affinity and kinetics using surface plasmon resonance (SPR) or biolayer surface interferometry (BLI).	(\$216,747)
2.2.2.3	8	Perform preliminary quantitative real time PCR to measure viral load, and specific DNA or RNA targets.	(\$216,747)
M2	12	Target capture > 50% in 24 hours for at least 1 target in blood or blood components	(\$216,747)
Total			(\$1,975,047)

12 month duration option #1 period (Year2)

Milestone	Month	Payable Milestone	GOVT CONTRIBUTION
Subtask 1a		Anticoagulant-free Hemopurification Device	(\$782,322)
2.3.2.1	15	Demonstrate the effectiveness of the prototype device in vivo in animals preventing platelet activation or clotting in at least a 2 hour blood pumping experiment at 75 mL/min blood flow.	(\$195,581)
2.3.2.2	18	Formulate initial design based on work from previous phase. Begin to build and test selected instrument design and tubing sets.	(\$195,581)
2.3.2.3	21	Write and test software. Conduct ergonomic research. Begin discussions with System Integrator.	(\$195,581)
M3	24	Complete fabrication and testing of prototype instrument. Research literature and patent database for technical.	(\$195,581)
Subtask 2		Removal of Sepsis Precursors	(\$835,124)
2.3.3.1	15	Build the ADAPT capture cartridges with the identified affinity agents. Measure the rate of capture of the specific targets from in ex vivo recirculation experiments from cell culture and blood.	(\$208,781)
M4	18	Target capture > 50% in 24 hours for at least 5 targets in blood or blood components.	(\$208,781)
2.3.3.2	21	Cartridge construction with optimized affinity matrix design for each potential target. Complete the capture agent screening.	(\$208,781)
M5	24	Target capture > 90% in 24 hours for at least 3 targets in blood or blood components.	(\$208,781)
Total			(\$1,617,446)

12 month duration option #2 period (Year 3)

Milestone	Month	Payable Milestone	GOVT CONTRIBUTION
Subtask 1a		Anticoagulant-free Hemopurification Device	(\$372,328)
2.4.1.1	27	Design and fabricate optimized configuration(s) of hemopurification device(s) that contain(s) a combination of hemofilters, plasma filters, and affinity columns.	(\$186,164)
M6	36	Define Aethlon's GMP manufacturing process and revise and upgrade Aethlon's quality procedures and policies to the current state of the art.	(\$187,164)
Subtask 2+4		Target Capture in Combined Agent Cartridge	(\$720,726)
2.4.2.1	27	Evaluate contribution of manufacturing process variables to binding capacity of affinity resin.	(\$197,362)
2.4.2.2	33	Determine capacity requirements of affinity resin to multiple simultaneous targets.	(\$197,362)
2.4.2.3	30	Perform biocompatibility tests for the combination ADAPT device to confirm the combination cartridge does not present additional risk.	(\$78,641)
2.4.2.4	36	Finish construction and delivery of 25 experimental cartridges for testing by the system integrator	(\$50,000)
M9	36	Target capture > 90% in 24 hours (12 months) for at least 3 targets ex vivo in blood or blood components using the optimized cartridge.	(\$197,361)
Total			(\$1,093,054)

12 month duration option #3 period (Year 4)

Milestone	Month	Payable Milestone	GOVT CONTRIBUTION
Subtask 1a		Anticoagulant-free Hemopurification Device	(\$276,172)
2.5.1.1	45	Complete Aethlon's GMP procedure and establish and maintain all GMP documentation for the company.	(\$90,008)
M11	48	Develop a strategic plan for developing an alternate method of producing GNA by cloning the gene into an alternate vector and identify potential partners for such production.	(\$186,164)
Subtask 2+4		Target Capture in Combined Agent Cartridge	(\$296,964)
2.5.2.2	48	Finish construction and begin delivery of 50 prototype cartridges for testing by the system integrator.	(\$296,964)
Total			(\$759,300)

12 month duration option #4 period (Year 5)

Milestone	Month	Payable Milestone	GOVT CONTRIBUTION
Subtask 5		Testing of final product by System Integrator	(\$581,157)
2.6.1.1	51	System integrator acceptance of the hemofilter device.	(\$193,719)
2.6.1.3	57	Quantify the degree to which the MERS virus can be extracted from circulation <i>in vitro</i> using miniature Hemopurifiers.	(\$193,719)
2.6.1.4	60	Prepare and present Final Report for DARPA.	(\$193,719)
Total			(\$581,157)

(End of Milestone Schedule)

(End of Summary of Changes)

EXHIBIT 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a), AS ADOPTED
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, James Joyce, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aethlon Medical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2016

/s/ JAMES A. JOYCE
JAMES A. JOYCE
CHIEF EXECUTIVE OFFICER
(PRINCIPAL EXECUTIVE OFFICER)

EXHIBIT 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a), AS ADOPTED
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, James Frakes, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aethlon Medical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2016

/s/ JAMES B. FRAKES
JAMES B. FRAKES
CHIEF FINANCIAL OFFICER
(PRINCIPAL FINANCIAL OFFICER)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Aethlon Medical, Inc. (the "Registrant") on Form 10-Q for the six-month period ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof, I, James A. Joyce, Chief Executive Officer of the Registrant, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Quarterly Report on Form 10-Q fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and
2. The information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Aethlon Medical, Inc.

Dated: November 10, 2016

/s/ JAMES A. JOYCE

James A. Joyce
Chief Executive Officer
Aethlon Medical, Inc.

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Aethlon Medical, Inc. and will be retained by Aethlon Medical, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

EXHIBIT 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Aethlon Medical, Inc. (the "Registrant") on Form 10-Q for the six-month period ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof, I, James B. Frakes, Chief Financial Officer of the Registrant, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Quarterly Report on Form 10-Q fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and
2. The information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Aethlon Medical, Inc.

Dated: November 10, 2016

/s/ JAMES B. FRAKES

James B. Frakes
Chief Financial Officer
Aethlon Medical, Inc.

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Aethlon Medical, Inc. and will be retained by Aethlon Medical, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.