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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, 2019

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	13-3632859
(State or other jurisdiction of incorporation or organization)	(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)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock	AEMD	The Nasdaq Capital Market

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES ☒ NO ☐

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

Large accelerated filer ☐
Non-accelerated filer ☐
Accelerated filer ☐
Smaller reporting company ☒
Emerging growth company ☐

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

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 October 31, 2019, the registrant had outstanding 1,441,275 shares of common stock, $0.001 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, 2019 (Unaudited)	March 31, 2019
ASSETS		
Current assets		
Cash	$ 785,658	$ 3,828,074
Prepaid expenses and other current assets	114,036	210,042
Total current assets	899,694	4,038,116
Property and equipment, net	124,833	6,021
Right-of-use lease asset	183,018	–
Patents, net	62,086	66,668
Deposits	12,159	12,159
Total assets	$ 1,281,790	$ 4,122,964
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 586,960	$ 131,931
Due to related parties	101,462	83,654
Convertible notes payable, net	–	962,301
Deferred revenue	100,000	–
Lease liability, current portion	94,885	–
Other current liabilities	285,211	646,000
Total current liabilities	1,168,518	1,823,886
Lease liability, less current portion	92,600	–
Total liabilities	1,261,118	1,823,886
Commitments and Contingencies (Note 13)		
Stockholders' Equity		
Common stock, par value $0.001 per share; 30,000,000 shares authorized; 1,337,259 and 1,266,979 shares issued and outstanding as of September 30, 2019 and March 31, 2019, respectively	1,338	1,267
Additional paid-in capital	109,571,708	108,076,275
Accumulated deficit	(109,423,894)	(105,652,433)
Total Aethlon Medical, Inc. stockholders' equity before noncontrolling interests	149,152	2,425,109
Noncontrolling interests	(128,480)	(126,031)
Total stockholders' equity	20,672	2,299,078
Total liabilities and stockholders' equity	$ 1,281,790	$ 4,122,964

See accompanying notes.

AETHLON MEDICAL, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
For the Three and Six Month Periods Ended September 30, 2019 and 2018
(Unaudited)

	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Six Months Ended September 30, 2019	Six Months Ended September 30, 2018
REVENUES				
Government contract revenue	$ –	$ –	$ 30,000	$ 149,625
OPERATING EXPENSES				
Professional fees	762,337	403,044	1,369,915	852,479
Payroll and related expenses	597,526	672,279	1,203,521	1,274,844
General and administrative	342,339	271,631	724,955	466,528
Total operating expenses	1,702,202	1,346,954	3,298,391	2,593,851
OPERATING LOSS	(1,702,202)	(1,346,954)	(3,268,391)	(2,444,226)
OTHER EXPENSE				
Interest and other debt expenses	21	55,106	54,106	110,210
Loss on share for warrant exchanges	4,403	–	4,403	–
Loss on debt extinguishment	–	–	447,011	–
Total other expense	4,424	55,106	505,520	110,210
NET LOSS	(1,706,626)	(1,402,060)	(3,773,911)	(2,554,436)
LOSS ATTRIBUTABLE TO NONCONTROLLING INTERESTS	(1,589)	(8,715)	(2,450)	(14,864)
NET LOSS ATTRIBUTABLE TO AETHLON MEDICAL, INC.	$ (1,705,037)	$ (1,393,345)	$ (3,771,461)	$ (2,539,572)
BASIC AND DILUTED LOSS PER COMMON SHARE	$ (1.29)	$ (1.17)	$ (2.91)	$ (2.14)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING – BASIC AND DILUTED	1,317,418	1,185,949	1,294,206	1,184,795

See accompanying notes.

AETHLON MEDICAL, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Three and Six Months Ended September 30, 2019 and 2018
(Unaudited)

	ATTRIBUTABLE TO AETHLON MEDICAL, INC.					
	COMMON STOCK		ADDITIONAL PAID IN	ACCUMULATED	NON-CONTROLLING	TOTAL
	SHARES	AMOUNT	CAPITAL	DEFICIT	INTERESTS	EQUITY
BALANCE - MARCH 31, 2019	1,266,979	$ 1,267	$ 108,076,275	$ (105,652,433)	$ (126,031)	$ 2,299,078
Issuances of common stock for cash under at the market program	3,087	3	36,619	–	–	36,622
Loss on debt extinguishment	–	–	447,011	–	–	447,011
Issuance of common shares upon vesting of restricted stock units	3,539	4	(23,775)	–	–	(23,771)
Stock-based compensation expense	–	–	326,536	–	–	326,536
Net loss	–	–	–	(2,066,424)	(860)	(2,067,284)
BALANCE - JUNE 30, 2019	1,273,605	$ 1,274	$ 108,862,666	$ (107,718,857)	(126,891)	$ 1,018,192
Issuances of common stock for cash under the market program	59,340	60	386,552	–	–	386,612
Issuance of common shares upon vesting of restricted stock units	3,236	3	(8,448)	–	–	(8,445)
Issuances of common stock upon warrant exchanges	1,078	1	4,402	–	–	4,403
Stock-based compensation expense	–	–	326,536	–	–	326,536
Net loss	–	–	–	(1,705,037)	(1,589)	(1,706,626)
BALANCE - SEPTEMBER 30, 2019	1,337,259	$ 1,338	$ 109,571,708	$ (109,423,894)	$ (128,480)	$ 20,672
BALANCE - MARCH 31, 2018	1,182,634	$ 1,183	$ 105,590,571	$ (99,457,714)	$ (101,246)	$ 6,032,794
Issuance of common shares upon vesting of restricted stock units	1,446	1	(32,738)	–	–	(32,737)
Stock-based compensation expense	–	–	263,162	–	–	263,162
Net loss	–	–	–	(1,146,228)	(6,148)	(1,152,376)
BALANCE - JUNE 30, 2018	1,184,080	$ 1,184	$ 105,820,995	$ (100,603,942)	$ (107,394)	$ 5,110,843
Issuance of common shares upon vesting of restricted stock units	3,897	4	(53,036)	–	–	(53,032)
Common stock issued for services	1,000	1	19,349	–	–	19,350
Stock-based compensation expense	–	–	336,496	–	–	336,496
Net loss	–	–	–	(1,393,345)	(8,715)	(1,402,060)
BALANCE - SEPTEMBER 30, 2018	1,188,977	$ 1,189	$ 106,123,804	$ (101,997,287)	$ (116,109)	$ 4,011,597

See accompanying notes.

AETHLON MEDICAL, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
For the Six Months Ended September 30, 2019 and 2018
(Unaudited)

	Six Months Ended September 30, 2019	Six Months Ended September 30, 2018
Cash flows used in operating activities:		
Net loss	$ (3,773,911)	$ (2,554,436)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	5,751	16,040
Stock based compensation	653,072	599,658
Loss on debt extinguishment	447,011	–
Loss on share for warrant exchanges	4,403	–
Amortization of debt discount	30,287	60,574
Common stock issued for services	–	19,350
Noncash lease expense	45,676	–
Changes in operating assets and liabilities:		
Accounts receivable	–	74,813
Prepaid expenses and other current assets	96,006	93,163
Accounts payable and other current liabilities	97,947	(127,358)
Change in lease liability	(44,916)	–
Deferred revenue	100,000	–
Due to related parties	17,808	8,500
Net cash used in operating activities	(2,320,866)	(1,809,696)
Cash flows used in investing activities:		
Purchases of property and equipment	(119,981)	–
Net cash used in investing activities	(119,981)	–
Cash flows (used in) provided by financing activities:		
Proceeds from the issuance of common stock, net	423,234	–
Principal payments on convertible notes	(992,591)	–
Tax withholding payments or tax equivalent payments for net share settlement of restricted stock units	(32,212)	(85,769)
Net cash used in financing activities	(601,569)	(85,769)
Net decrease in cash	(3,042,416)	(1,895,465)
Cash at beginning of period	3,828,074	6,974,070
Cash at end of period	$ 785,658	$ 5,078,605
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Interest	$ 83,332	$ 95,388
Supplemental disclosures of non-cash investing and financing activities:		
Initial recognition of right-of-use lease asset and lease liability	$ 228,694	$ –
Par value of shares issued for vested restricted stock units	$ 7	$ 4

See accompanying notes.

1. NATURE OF BUSINESS AND BASIS OF PRESENTATION

ORGANIZATION

Aethlon Medical, Inc. and its subsidiary (collectively, "Aethlon", the "Company", "we" or "us"), is a medical device technology company focused on developing products to diagnose and treat life and organ threatening diseases. The Aethlon Hemopurifier® is a clinical-stage immunotherapeutic device designed to combat cancer and life-threatening viral infections. In cancer, the Hemopurifier depletes the presence of circulating tumor-derived exosomes that promote immune suppression, seed the spread of metastasis and inhibit the benefit of leading cancer therapies. The U.S. Food and Drug Administration, or FDA, has designated the Hemopurifier as a "Breakthrough Device" for two independent indications:

- the treatment of individuals with advanced or metastatic cancer who are either unresponsive to or intolerant of standard of care therapy, and with cancer types in which exosomes have been shown to participate in the development or severity of the disease; and
- the treatment of life-threatening viruses that are not addressed with approved therapies.

We believe the Hemopurifier can be a substantial advance in the treatment of patients with advanced and metastatic cancer through the clearance of exosomes that promote the growth and spread of tumors through multiple mechanisms. We are currently preparing for the initiation of clinical trials in patients with advanced and metastatic cancers. We are initially focused on the treatment of solid tumors, including head and neck cancer, gastrointestinal cancers and other cancers.

On October 4, 2019, the FDA approved our Investigational Device Exemption, or IDE, application to initiate an Early Feasibility Study, or EFS, of the Hemopurifier in patients with head and neck cancer in combination with standard of care pembrolizumab (Keytruda). The primary endpoint for the EFS, which will enroll 10-12 subjects at a single center, will be safety, with secondary endpoints including measures of exosome clearance and characterization, as well as response and survival rates. The IDE approval is subject to FDA approval of Informed Consent documents from the trial site.

We also believe the Hemopurifier can be a part of the broad-spectrum treatment of life-threatening highly glycosylated, or carbohydrate coated, viruses that are not addressed with an already approved treatment. In small-scale or early feasibility human studies, the Hemopurifier has been used to treat individuals infected with HIV, hepatitis-C, and Ebola. Additionally, *in vitro,* the Hemopurifier has been demonstrated to capture Zika virus, Lassa virus, MERS-CoV, cytomegalovirus, Epstein-Barr virus, Herpes simplex virus, Chikungunya virus, Dengue virus, West Nile virus, smallpox-related viruses, H1N1 swine flu virus, H5N1 bird flu virus, and the reconstructed Spanish flu virus of 1918. In several cases, these studies were conducted in collaboration with leading government or non-government research institutes.

We are also the majority owner of Exosome Sciences, Inc., or ESI, a company focused on the discovery of exosomal biomarkers to diagnose and monitor life-threatening diseases. Included among ESI's activities is the advancement of a TauSome™ biomarker candidate to diagnose chronic traumatic encephalopathy, or CTE, in the living. ESI previously documented TauSome levels in former NFL players to be nine times higher than same age-group control subjects. Through ESI, we are also developing exosome based biomarkers in patients with, or at risk for, a number of cancers. We consolidate ESI's activities in our consolidated financial statements.

We also recently announced the execution of a cross-licensing and development agreement with SeaStar Medical, Inc., which will be focused on co-development of our Hemopurifier cartridge with SeaStar's proprietary cartridges and the development of a closed system for the Hemopurifier using the SeaStar pump and cassettes. This collaboration may allow the deployment of the Hemopurifier into settings that lack dialysis infrastructure, such as chemotherapy infusion centers and field operations for life threatening viral epidemics.

Successful outcomes of human trials will also be required by the regulatory agencies of certain foreign countries where we plan to sell the Hemopurifier. 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 treatment technology.

Our executive offices are located at 9635 Granite Ridge Drive, Suite 100, San Diego, California 92123. Our telephone number is (858) 459-7800. Our website address is www.aethlonmedical.com.

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

REVERSE STOCK SPLIT

On October 14, 2019, the Company completed a 1-for-15 reverse stock split. Accordingly, 15 shares of outstanding common stock held by stockholders were combined into one share of common stock. Any fractional shares resulting from the reverse split were rounded up to the next whole share. Authorized common stock remained at 30,000,000 shares (see Note 14). The accompanying unaudited 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, 2018. All shares and per share amounts have been revised accordingly.

SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

During the six months ended September 30, 2019, 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, 2019 except as described below.

Leases

At lease commencement, the Company records a lease liability based on the present value of lease payments over the expected lease term. The Company calculates the present value of lease payments using the discount rate implicit in the lease, unless that rate cannot be readily determined. In that case, the Company uses its incremental borrowing rate, which is the rate of interest that the Company would have to pay to borrow on a collateralized basis an amount equal to the lease payments over the expected lease term. The Company records a corresponding right-of-use lease asset based on the lease liability, adjusted for any lease incentives received and any initial direct costs paid to the lessor prior to the lease commencement date.

After lease commencement, the Company measures its leases as follows: (i) the lease liability based on the present value of the remaining lease payments using the discount rate determined at lease commencement; and (ii) the right-of-use lease asset based on the remeasured lease liability, adjusted for any unamortized lease incentives received, any unamortized initial direct costs and the cumulative difference between rent expense and amounts paid under the lease agreement. Rent expense is recorded on a straight-line basis over the expected lease term (See Note 4).

Basis of Presentation and Use of Estimates

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 8 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 fiscal year ended March 31, 2019, included in the Company's Annual Report on Form 10-K filed with the SEC on July 1, 2019. 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 financial statements as of and for the three and six months ended September 30, 2019, and the condensed consolidated statement of cash flows for the six months ended September 30, 2019. Estimates were made relating to useful lives of fixed assets, 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. The accompanying condensed consolidated balance sheet at March 31, 2019 has been derived from the audited consolidated balance sheet at March 31, 2019, contained in the above referenced 10-K. The results of operations for the three and six months ended September 30, 2019 are not necessarily indicative of the results to be expected for the full year or any future interim periods.

Reclassifications

Certain prior year balances within the unaudited condensed consolidated financial statements have been reclassified to conform to the current year presentation.

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, 2019 had an accumulated deficit of approximately $109,424,000. These factors, among other matters, raise substantial doubt about our ability to continue as a going concern for the twelve months from the issuance of these financial statements. 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 through at least twelve months from the issuance date of these condensed consolidated financial statements through equity and/or debt financing arrangements as well as through revenues and related cash receipts under our government contracts (see Note 11).

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 and to meet our liquidity needs for a twelve month period from the date of this filing. In addition, we will need to raise capital to complete anticipated future human clinical trials in the U.S. We anticipate the primary sources of this additional financing will be from proceeds of our at-the-market offering program, pursuant to our Form S-3 Registration Statement, debt financing and other forms of equity placements. However, no assurance can be given that we will receive any funds in addition to the funds we have received to date.

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 unaudited condensed 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 loss 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, 2019 and 2018 included common shares underlying 2,857 and 3,075 vested restricted stock units, respectively. Diluted loss per share is computed similar to basic loss per share except that the denominator is increased to include the number of additional dilutive 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, 2019 and 2018, an aggregate of 386,220 and 437,113 potential common shares, respectively, 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, 2019 and 2018, 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, 2019	September 30, 2018
Three months ended	$ 222,857	$ 178,800
Six months ended	$ 470,882	$ 402,566

4. RECENT ACCOUNTING PRONOUNCEMENTS

The Company adopted ASU Topic 842 on April 1, 2019 utilizing the alternative transition method allowed for under this guidance. As a result, the Company recorded lease liabilities and right-of-use lease assets of $228,694 on its balance sheet as of April 1, 2019. The lease liabilities represent the present value of the remaining lease payments of the Company's corporate headquarters lease (see Note 13), discounted using the Company's incremental borrowing rate as of April 1, 2019. The corresponding right-of-use lease assets are recorded based on the lease liabilities and the cumulative difference between rent expense and amounts paid under its corporate headquarters lease. The Company also elected the short-term lease recognition exemption for its laboratory lease. For the laboratory lease that qualified as short-term, the Company did not recognize ROU assets or lease liabilities at adoption. The adoption of ASU 2016-02 did not have a material impact on either the statement of operations or statement of cash flows for the six months ended September 30, 2019.

Topic 842 also allows lessees and lessors to elect certain practical expedients. The Company elected the following practical expedients:

- Transitional practical expedients, which must be elected as a package and applied consistently to all of the Company's leases:
  - The Company need not reassess whether any expired or existing contracts are or contain leases.
  - The Company need not reassess the lease classification for any expired or existing leases (that is, all existing leases that were classified as operating leases in accordance with the previous guidance will be classified as operating leases, and all existing leases that were classified as capital leases in accordance with the previous guidance will be classified as finance leases).
  - The Company need not reassess initial direct costs for any existing leases.
- Hindsight practical expedient. The Company elected the hindsight practical expedient in determining the lease term (that is, when considering lessee options to extend or terminate the lease and to purchase the underlying asset) and in assessing impairment of the Company's right-of-use assets.

5. CONVERTIBLE NOTES PAYABLE, NET

In July 2019, we paid off our Convertible Notes Payable. We paid the remaining principal balance of $892,591 and accrued interest of $11,352. As a result, we did not incur any interest expense related to the Convertible Notes in the three months ended September 30, 2019.

For the six months ended September 30, 2019, we recorded interest expense of $23,759 related to the contractual interest rates of our convertible notes and interest expense of $30,287 related to the amortization of the note discount for a total interest expense of $54,046 related to our convertible notes.

Convertible Notes Payable, Net consisted of the following at March 31, 2019:

	Principal	Unamortized Discount	Net Amount	Accrued Interest
Convertible Notes Payable, Net:				
November 2014 10% Convertible Notes (due July 1, 2019)	$ 612,811	$ (18,701)	$ 594,110	$ 37,309
December 2016 10% Convertible Notes (due July 1, 2019)	379,780	(11,589)	368,191	22,264
Total Convertible Notes Payable, Net	$ 992,591	$ (30,290)	$ 962,301	$ 59,573

During the six months ended September 30, 2018, we recorded interest expense of $49,630 related to the contractual interest rates of our convertible notes and interest expense of $60,574 related to the amortization of the note discount for a total interest expense of $110,204 related to our convertible notes in the six months ended September 30, 2018. All of the unamortized discount at September 30, 2018 related to the note discount established upon the June 2017 amendment to the November 2014 10% Convertible Notes and to the December 2016 10% Convertible Notes.

6. EQUITY TRANSACTIONS IN THE SIX MONTHS ENDED SEPTEMBER 30, 2019

Common Stock Sales Agreement with H.C. Wainwright

On June 28, 2016, we entered into a Common Stock Sales Agreement, or the Agreement, with H.C. Wainwright & Co., LLC, or H.C. Wainwright, which established 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, or the Shares.

On August 6, 2019, we executed Amendment No. 1 to the Agreement with H.C. Wainwright, effective as of August 5, 2019. The amendment provides that references in the Agreement to the registration statement shall refer to the registration statement on Form S-3 (File No. 333-231397), originally filed with the Securities and Exchange Commission on May 10, 2019, declared effective by the Securities and Exchange Commission on August 1, 2019.

Subject to the terms and conditions set forth in the Agreement, H.C. Wainwright agreed to 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 is entitled to a commission at a fixed rate equal to three percent (3.0%) of the gross proceeds per Share sold. In addition, we 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.

Sales of the Shares, if any, under the Agreement will 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 the six months ended September 30, 2019, we raised aggregate net proceeds of $423,234 (net of $13,213 in commissions to H.C. Wainwright and $3,997 in other offering expenses) under this Agreement through the sale of 62,427 shares at an average price of $6.78 per share of net proceeds.

Restricted Stock Unit Grants

Our Board of Directors established the 2012 Non-Employee Directors Compensation Program, as amended through August 2016, or the Non-Employee Directors Plan, pursuant to which, in addition to cash compensation, directors of the Company who are not also employees may be granted stock-based compensation in the form of restricted stock units, or RSU's. The RSUs represent the right to be issued on a future date shares of our common stock for RSUs which have then vested.

In April 2019, pursuant to the Non-Employee Directors Plan, we issued RSUs with a value of $35,000 to each of our non-employee directors, as the stock-based compensation element of their overall directors' compensation, for the fiscal year ending March 31, 2020. Those grants were based on the closing price of our common stock on the one business day prior to the grant date, $14.25 per share. Therefore, 2,456 RSUs were issued to each of our five non-employee directors, for a total of 12,280 RSUs. All of the RSUs are subject to vesting in equal quarterly installments on June 30, 2019, September 30, 2019, December 31, 2019 and March 31, 2020.

In April 2019, 2,859 vested RSUs held by our current and former executive officers were exchanged for the same number of shares of our common stock. As these executives elected to net settle a portion of their vested RSUs in exchange for the Company paying the related withholding taxes of $18,318 on the share issuance, 1,512 of the vested RSUs were cancelled and we issued a net 1,347 shares to the executives and former executive.

In June 2019, 3,075 vested RSUs held by our non-employee directors were exchanged into the same number of shares of our common stock. Four of our five non-employee directors elected to return 40% of their vested RSUs in exchange for cash, in order to pay their withholding taxes on the share issuances, resulting in 984 of the vested RSUs being cancelled in exchange for $5,453 in aggregate cash proceeds to those independent directors.

In July 2019, 2,861 vested RSUs held by our current and former executive officers were exchanged for the same number of shares of our common stock. As these executives elected to net settle a portion of their vested RSUs in exchange for the Company paying the related withholding taxes of $4,979 on the share issuance, 1,510 of the vested RSUs were cancelled and we issued a net 1,351 shares to the executives and former executive.

In September 2019, 3,075 vested RSUs held by our non-employee directors were exchanged into the same number of shares of our common stock. Four of our five non-employee directors elected to return 40% of their vested RSUs in exchange for cash, in order to pay their withholding taxes on the share issuances, resulting in 984 of the vested RSUs being cancelled in exchange for $3,463 in aggregate cash proceeds to those independent directors.

RSUs outstanding that have vested as of, and are expected to vest subsequent to, September 30, 2019 are as follows:

	Number of RSUs
Vested	2,857
Expected to vest	8,997
Total	11,854

Common Stock for Warrant Cancellation

During the six months ended September 30, 2019, we agreed with five accredited investors to issue 1,078 shares of our common stock to these investors in exchange for the cancellation of outstanding warrants then held by the investors to purchase 10,759 shares of our common stock. We measured the fair value of the shares issued and the fair value of the warrants exchanged for those shares and recorded a loss of $4,403 on those exchanges based on the changes in fair value between the instruments exchanged.

7. RELATED PARTY TRANSACTIONS

During the three months ended September 30, 2019, we accrued unpaid fees of $69,750 owed to our non-employee directors as of September 30, 2019. For the six months ended September 30, 2019, we recorded $139,500 in fees to our non-employee directors.

Amounts due to related parties were comprised of the following items:

	September 30, 2019	March 31, 2019
Accrued Board fees	$ 69,750	$ 69,750
Accrued vacation to all employees	31,712	13,904
Total due to related parties	$ 101,462	$ 83,654

8. OTHER CURRENT LIABILITIES

Other current liabilities were comprised of the following items:

	September 30, 2019	March 31, 2019
Accrued interest	$ –	$ 59,573
Accrued separation expenses for former executives	109,930	355,189
Accrued professional fees	175,281	231,238
Total other current liabilities	$ 285,211	$ 646,000

9. STOCK COMPENSATION

The following tables summarize share-based compensation expenses relating to RSUs and stock options and the effect on basic and diluted loss per common share during the three and six month periods ended September 30, 2019 and 2018:

	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Six Months Ended September 30, 2019	Six Months Ended September 30, 2018
Vesting of stock options and restricted stock units	$ 326,536	$ 336,496	$ 653,072	$ 599,658
Total stock-based compensation expense	$ 326,536	$ 336,496	$ 653,072	$ 599,658
Weighted average number of common shares outstanding – basic and diluted	1,317,418	1,185,949	1,294,206	1,184,795
Basic and diluted loss per common share attributable to stock-based compensation expense	$ (0.25)	$ (0.28)	$ (0.50)	$ (0.51)

All of the stock-based compensation expense recorded during the six months ended September 30, 2019 and 2018, which totaled $653,072 and $599,658, 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, 2019 and 2018 represented an impact on basic and diluted loss per common share of $(0.50) and $(0.51), respectively.

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, 2019 was insignificant.

Stock Option Activity

We did not issue any stock options during the six months ended September 30, 2019 and September 30, 2018.

Options outstanding that have vested and are expected to vest as of September 30, 2019 are as follows:

	Number of Shares	**Weighted Average Exercise Price**	**Weighted Average Remaining Contractual Term in Years**
Vested	13,684	$ 113.27	3.21
Expected to vest	37,440	$ 18.85	8.24
Total	51,124		

A summary of stock option activity during the six months ended September 30, 2019 is presented below:

	Amount	Range of Exercise Price	Weighted Average Exercise Price
Stock options outstanding at March 31, 2019	59,111	$ 18.75 - 187.50	$ 56.85
Adjustment for reverse split	14	n/a	n/a
Exercised	–	$ –	$ –
Granted	–	$ –	$ –
Cancelled/Expired	(8,001)	$ 75.00 - 142.50	$ 138.75
Stock options outstanding at September 30, 2019	51,124	$ 18.75 - 187.50	$ 44.12
Stock options exercisable at September 30, 2019	13,684	$ 25.20 - 187.50	$ 113.27

On September 30, 2019, our stock options had no intrinsic value since the closing price on that date of $3.45 per share was below the weighted average exercise price of our outstanding stock options.

At September 30, 2019, there was approximately $1,520,729 of unrecognized compensation cost related to share-based payments, which is expected to be recognized over a weighted average period of 1.2 years.

10. WARRANTS

During the six months ended September 30, 2019 and 2018, we did not issue any warrants. During the six months ended September 30, 2019, we agreed with five accredited investors to issue 1,078 shares of our common stock to these investors in exchange for the cancellation of outstanding warrants then held by the investors to purchase 10,759 shares of our common stock. We measured the fair value of the shares issued and the fair value of the warrants exchanged for those shares and recorded a loss of $4,403 on those exchanges based on the changes in fair value between the instruments exchanged.

A summary of warrant activity during the six months ended September 30, 2019 is presented below:

	Amount	Range of Exercise Price	Weighted Average Exercise Price
Warrants outstanding at March 31, 2019	342,992	$ 16.50 - 180.75	$ 38.10
Adjustment for reverse split	73	n/a	n/a
Cancelled/Expired	(19,823)	$ 64.50 - 180.75	$ 99.85
Warrants outstanding at September 30, 2019	323,242	$ 16.50 - 135.00	$ 38.26
Warrants exercisable at September 30, 2019	323,242	$ 16.50 - 135.00	$ 38.26

11. GOVERNMENT CONTRACTS AND RELATED REVENUE RECOGNITION

We have entered into the following three contracts/grants with the National Cancer Institute, or NCI, part of the National Institutes of Health, or NIH, over the past two years:

Phase 2 Melanoma Cancer Contract

On September 12, 2019, the NCI awarded to us an SBIR Phase II Award Contract, for NIH/NCI Topic 359, entitled "A Device Prototype for Isolation of Melanoma Exosomes for Diagnostics and Treatment Monitoring", or the Award Contract. The Award Contract amount is $1,860,561 and runs for the period from September 16, 2019 through September 15, 2021.

The work to be performed pursuant to this Award Contract will focus on melanoma exosomes. This work follows from our completion of a Phase I contract for the Topic 359 solicitation that ran from September 2017 through June 2018 (see Phase 1 Melanoma Cancer Contract below). Following on the Phase I work, the deliverables in the Phase II program will involve the design and testing of a pre-commercial prototype of a more advanced version of the exosome isolation platform.

No revenue was recognized under this contract in the three and six month periods ended September 30, 2019.

Phase 1 Melanoma Cancer Contract

We entered into a contract with the NIH on September 15, 2017. This award was under the NIH's SBIR program which is designed to fund early stage small businesses that are seeking to commercialize innovative biomedical technologies. The title of the award is SBIR Topic 359 Phase 1 Device Strategy for Selective Isolation of Oncosomes and Non-Malignant Exosomes. The award from NIH was a firm, fixed-price contract with potential total payments to us of $299,250 over the course of nine months.

Fixed price contracts require the achievement of multiple, incremental milestones to receive the full award during each period of the contract. The NIH also had the unilateral right to require us to perform additional work under an option period for an additional fixed amount of $49,800. Under the terms of the contract, we were required to perform certain incremental work toward the achievement of specific milestones against which we invoiced the government for fixed payment amounts.

In the six months ended September 30, 2018, we performed work under the contract covering the remainder of the technical objectives of the contract Aim 1: To validate the Hemopurifier as a device for capture and recovery of melanoma exosomes from plasma, and Aim 2: To validate a method of melanoma exosome isolation consisting of the Hemopurifier followed by mab-based immunocapture to select out the tumor-derived exosomes from non-malignant exosomes and Aim 3: To evaluate the functional integrity of melanoma exosomes purified by the Hemopurifier and immunocapture isolation steps. As a result, we invoiced NIH for $149,625 during the six months ended September 30, 2018. The Phase 1 Melanoma Cancer Contract is now completed.

Breast Cancer Grant

In September 2018, the NCI awarded us a government grant (number 1R43CA232977-01). The title of this SBIR Phase I grant is "The Hemopurifier Device for Targeted Removal of Breast Cancer Exosomes from the Blood Circulation."

This NCI Phase I grant period originally ran from September 14, 2018 through August 31, 2019. In August 2019, we applied for and received a no cost, twelve month extension on this grant, so the expiration date was extended to August 31, 2020. The total amount of the firm grant is $298,444. The grant calls for two subcontractors to work with us. Those subcontractors are University of Pittsburgh and Massachusetts General Hospital. During the six months ended September 30, 2019, we recognized $30,000 in government contract revenue under this grant as a result of the work involved in one of the three technical objectives of the contract (Aim 2. "Elution of a population of breast cancer exosomes from Hemopurifier cartridges that bear the signatures of malignancy based on expression of CSPG4 and HER2, for triple-negative or HER2-overexpressing cancers, respectively"). We also invoiced the NCI an additional $100,000 in the six month period ended September 30, 2019 in order to pay our subcontractors under the contract. As we did not complete any of the technical objectives beyond Aim 2 noted above during the September period, we recorded this $100,000 as deferred revenue as of September 30, 2019.

12. SEGMENTS

We operate our businesses principally through two reportable segments: Aethlon, which represents our therapeutic business activities, and Exosome Sciences, Inc., or 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,	
	2019	2018
Revenues:		
Aethlon	$ 30,000	$ 149,625
ESI	–	–
Total Revenues	$ 30,000	$ 149,625
Operating Losses:		
Aethlon	$ (3,256,142)	$ (2,369,907)
ESI	(12,249)	(74,319)
Total Operating Loss	$ (3,268,391)	$ (2,444,226)
Net Losses:		
Aethlon	$ (3,761,662)	$ (2,480,117)
ESI	(12,249)	(74,319)
Net Loss Before Non-Controlling Interests	$ (3,773,911)	$ (2,554,436)
Cash:		
Aethlon	$ 785,461	$ 5,076,872
ESI	197	1,733
Total Cash	$ 785,658	$ 5,078,605
Total Assets:		
Aethlon	$ 1,281,593	$ 5,270,690
ESI	197	1,733
Total Assets	$ 1,281,790	$ 5,272,423
Capital Expenditures:		
Aethlon	$ 119,981	$ –
ESI	–	–
Capital Expenditures	$ 119,981	$ –
Depreciation and Amortization:		
Aethlon	$ 5,751	$ 16,040
ESI	–	–
Total Depreciation and Amortization	$ 5,751	$ 16,040
Interest Expense:		
Aethlon	$ (54,106)	$ (110,210)
ESI	–	–
Total Interest Expense	$ (54,106)	$ (110,210)

13. COMMITMENTS AND CONTINGENCIES

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

There have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations-Contractual Obligations and Commitments" as contained in our Annual Report on Form 10-K for the year ended March 31, 2019 filed by us with the SEC on July 1, 2019.

LEASE COMMITMENTS

We currently lease approximately 2,600 square feet of executive office space at 9635 Granite Ridge Drive, Suite 100, San DiegoCalifornia 92123 under a 39-month gross plus utilities lease that commenced on December 1, 2014 and expires on August 31, 2021 the "Granite Ridge Lease." The current rental rate under the lease extension is $8,265 per month. We believe this leased facility will be satisfactory for our office needs over the term of the lease.

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 $4,700 per month on a one-year lease that expires on November 30, 2019. In October 2019, we entered into a lease extension for an additional twelve months running from December 1, 2019 through November 30, 2020 at the rate of $5,961 per month (see Note 14).

Rent expense, which is included in general and administrative expenses, approximated $47,000 and $34,000 for the three month periods ended September 30, 2019 and 2018, respectively. For the six month periods ended September 30, 2019 and 2018, rent expense approximated $87,000 and $84,000, respectively.

Future minimum lease payments under the Granite Ridge Lease as of September 30, 2019, are as follows:

October 1, 2019 through March 31, 2020	$	49,591
April 1, 2020 through March 31, 2021		102,074
April 1, 2021 through August 31, 2021		43,670
Total future minimum lease payments		195,335
Less: discount		(7,850)
Total lease liability	$	187,485

On April 1, 2019, we recorded a lease liability and ROU lease asset for the Granite Ridge Lease based on the present value of lease payments over the expected remaining lease term of 2.2 years, discounted using our estimated incremental borrowing rate of 4%. For the six months ended September 30, 2019, reduction of the right-of-use lease asset was $45,676 and reduction of the lease liability was $44,916, which resulted in a net increase in the right-of-use lease asset of $760 during the period (See Note 4).

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, 2019 through the date that the accompanying condensed consolidated financial statements were filed with the SEC for transactions and other events which may require adjustment of and/or disclosure in such financial statements.

Reverse Split – Following the approval of a reverse stock split at our Annual Stockholders' Meeting held on October 14, 2019, our Board of Directors approved a 1-for-15 reverse stock split. Accordingly, each 15 shares of outstanding common stock held by stockholders were combined into one share of common stock. Our authorized common stock remained at 30,000,000 shares. As the result of the rounding up of fractional shares related to the reverse split, we have issued an additional 3,946 shares to our shareholders in October 2019.

FDA Approval of IDE for Oncology Indications – On October 4, 2019, the FDA approved our Investigational Device Exemption (IDE) application to initiate an Early Feasibility Study, or EFS of the Hemopurifier in patients with head and neck cancer in combination with standard of care pembrolizumab (Keytruda). The primary endpoint for the EFS, which will enroll 10-12 subjects at a single center, will be safety, with secondary endpoints including measures of exosome clearance and characterization, as well as response and survival rates. The IDE approval is subject to FDA approval of Informed Consent documents from the trial site.

Restricted Stock Unit ("RSU") Issuances – In October 2019, 2,859 RSUs held by our current and former executives were exchanged into the same number of shares of our common stock. As our executives elected to net settle a portion of their RSU's in exchange for us paying the related withholding taxes on the share issuance, 1,511 of the RSUs were cancelled and we issued a net 1,348 shares of common stock to our executives.

ATM Sales – In October 2019, we sold 98,722 shares of our common stock under our Common Stock Sales Agreement with H.C. Wainwright (see Note 6) and from those sales raised net proceeds of $472,798 (after deducting $14,682 in commissions to H.C. Wainwright and $1,932 in other offering expenses), at an average price of $4.79 per share of net proceeds.

Government Contract Funding – In October 2019, we billed the NCI for $206,729 after achieving the first milestone in our Phase 2 Melanoma Cancer Contract.

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, or 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 our actual results, performance, or achievements 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, our ability to maintain our Nasdaq listing, U.S. Food and Drug Administration, 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, or 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

Aethlon Medical, Inc. and its subsidiary (collectively, “Aethlon”, the “Company”, “we” or “us”) is a medical device technology company focused on developing products to diagnose and treat life and organ threatening diseases. The Aethlon Hemopurifier® is a clinical-stage immunotherapeutic device designed to combat cancer and life-threatening viral infections. In cancer, the Hemopurifier depletes the presence of circulating tumor-derived exosomes that promote immune suppression, seed the spread of metastasis and inhibit the benefit of leading cancer therapies. The U.S. Food and Drug Administration, or the FDA, has designated the Hemopurifier as a "Breakthrough Device" for two independent indications:

- the treatment of individuals with advanced or metastatic cancer who are either unresponsive to or intolerant of standard of care therapy, and with cancer types in which exosomes have been shown to participate in the development or severity of the disease; and
- the treatment of life-threatening viruses that are not addressed with approved therapies.

We believe the Hemopurifier can be a substantial advance in the treatment of patients with advanced and metastatic cancer through the clearance of exosomes that promote the growth and spread of tumors through multiple mechanisms. We are currently preparing for the initiation of clinical trials in patients with advanced and metastatic cancers. We are initially focused on the treatment of solid tumors, including head and neck cancer, gastrointestinal cancers and other cancers.

On October 4, 2019, the FDA approved our Investigational Device Exemption, or IDE, application to initiate an Early Feasibility Study, or EFS, of the Hemopurifier in patients with head and neck cancer in combination with standard of care pembrolizumab (Keytruda). The primary endpoint for the EFS, which will enroll 10-12 subjects at a single center, will be safety, with secondary endpoints including measures of exosome clearance and characterization, as well as response and survival rates. The IDE approval is subject to FDA approval of Informed Consent documents from the trial site.

We also believe the Hemopurifier can be a part of the broad-spectrum treatment of life-threatening highly glycosylated viruses that are not addressed with an already approved treatment. In small-scale or early feasibility human studies, the Hemopurifier has been used to treat individuals infected with HIV, hepatitis-C, and Ebola. Additionally, *in vitro,* the Hemopurifier has been demonstrated to capture Zika virus, Lassa virus, MERS-CoV, cytomegalovirus, Epstein-Barr virus, Herpes simplex virus, Chikungunya virus, Dengue virus, West Nile virus, smallpox-related viruses, H1N1 swine flu virus, H5N1 bird flu virus, and the reconstructed Spanish flu virus of 1918. In several cases, these studies were conducted in collaboration with leading government or non-government research institutes.

We are also the majority owner of Exosome Sciences, Inc., or ESI, a company focused on the discovery of exosomal biomarkers to diagnose and monitor life-threatening diseases. Included among ESI's activities is the advancement of a TauSome™ biomarker candidate to diagnose chronic traumatic encephalopathy, or CTE, in the living. ESI previously documented TauSome levels in former NFL players to be nine times higher than same age-group control subjects. Through ESI we are also developing exosome based biomarkers in patients with, or at risk for, a number of cancers. We consolidate ESI's activities in our consolidated financial statements.

We also recently announced the execution of a cross-licensing and development agreement with SeaStar Medical, Inc., which will be focused on co-development of our Hemopurifier cartridge with SeaStar's proprietary cartridges and the development of a closed system for the Hemopurifier using the SeaStar pump and cassettes. This collaboration may allow the deployment of the Hemopurifier into settings that lack dialysis infrastructure, such as chemotherapy infusion centers and field operations for life threatening viral epidemics.

Successful outcomes of human trials will also be required by the regulatory agencies of certain foreign countries where we plan to sell the Hemopurifier. 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 treatment technology.

Our common stock is listed 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 of 1934, as amended, and must file reports, proxy statements and other information with the Commission. The Commission 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, 2019 COMPARED TO THE THREE MONTHS ENDED SEPTEMBER 30, 2018

Government Contract Revenues

We did not record any government contract revenue in the three months ended September 30, 2019 and 2018.

We have entered into the following three contracts/grants with the National Cancer Institute, or NCI, part of the National Institutes of Health, or NIH, over the past two years:

Phase 2 Melanoma Cancer Contract

On September 12, 2019, the NCI awarded to us an SBIR Phase II Award Contract, for NIH/NCI Topic 359, entitled "A Device Prototype for Isolation of Melanoma Exosomes for Diagnostics and Treatment Monitoring", or the Award Contract. The Award Contract amount is $1,860,561 and runs for the period from September 16, 2019 through September 15, 2021.

The work to be performed pursuant to this Award Contract will focus on melanoma exosomes. This work follows from our completion of a Phase I contract for the Topic 359 solicitation that ran from September 2017 through June 2018 (see Phase 1 Melanoma Cancer Contract below). Following on the Phase I work, the deliverables in the Phase II program will involve the design and testing of a pre-commercial prototype of a more advanced version of the exosome isolation platform.

No revenue was recognized under this contract in the three months and six months ended September 30, 2019.

Phase 1 Melanoma Cancer Contract

We entered into a contract with the NCI in September 2017. This award was under the NIH's SBIR program. The title of the award is "SBIR Topic 359 Phase 1 Device Strategy for Selective Isolation of Oncosomes and Non-Malignant Exosomes." The award from NIH was a firm, fixed-price contract with potential total payments to us of $299,250 over the course of nine months.

Fixed price contracts require the achievement of multiple, incremental milestones to receive the full award during each period of the contract. The NIH also had the unilateral right to require us to perform additional work under an option period for an additional fixed amount of $49,800.

Under the terms of the contract, we were required to perform certain incremental work towards the achievement of specific milestones against which we will invoice the government for fixed payment amounts. The Phase 1 Melanoma Cancer Contract was completed in June 2018.

Breast Cancer Grant

In September 2018, the NCI awarded us a government grant (number 1R43CA232977-01). The title of this SBIR Phase I grant is "The Hemopurifier Device for Targeted Removal of Breast Cancer Exosomes from the Blood Circulation."

This NCI Phase I grant period originally ran from September 14, 2018 through August 31, 2019. In August 2019, we applied for and received a no cost, twelve month extension on this grant, so the expiration date was extended to August 31, 2020. The total amount of the firm grant is $298,444. The grant calls for two subcontractors to work with us. Those subcontractors are University of Pittsburgh and Massachusetts General Hospital.

While we did not record any revenue from this grant during the three months ended September 30, 2019, we did invoice the NCI for $100,000 during the period in order to pay our subcontractors under the contract. As we did not complete any of the technical objectives during the September period, we recorded this $100,000 as deferred revenue.

Operating Expenses

Consolidated operating expenses for the three months ended September 30, 2019 were $1,702,202, in comparison with $1,346,954 for the comparable period ended September 30, 2018. This increase of $355,248, or 26%, in 2019 was due to increases in professional fees of $359,293 and in general and administrative expenses of $70,708, which were partially offset by a decrease in payroll and related expenses of $74,753.

The $359,293 increase in our professional fees in 2019 was primarily due to a $278,892 increase in our legal fees, a $68,715 increase in our accounting fees and a $65,000 payment to the University of Pittsburgh, a subcontractor on our Breast Cancer grant related to their work on that grant. The increase in legal and accounting fees related to increased activity in our registration statement filings and in intellectual property actions, among other matters.

The $70,708 increase in general and administrative expenses in 2019 was primarily due to the combination of a $21,264 increase in our clinical trial expense, primarily costs associated with the manufacturing of Hemopurifiers for an expected clinical trial in the cancer space and a $44,999 increase in our lab supplies expense, primarily related to our breast cancer grant and lab work related to our IDE application.

The $74,753 decrease in payroll and related expenses was due to the combination of a $64,793 reduction in our cash-based compensation expense and a $9,960 decrease in stock-based compensation.

Other Expense

Other expense during the three months ended September 30, 2019 consisted of interest expense and a loss on share for warrant exchanges and during the three months ended September 30, 2018, consisted of interest expense only. Other expense for the three months ended September 30, 2019 was $4,424, in comparison with other expense of $55,106 for the three months ended September 30, 2018.

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

	Three Months Ended 9/30/19	Three Months Ended 9/30/18	Change
Loss on Share for Warrant Exchanges	$ 4,403	$ –	$ 4,403
Interest Expense	21	55,106	(55,085)
Total Other Expense	$ 4,424	$ 55,106	$ (50,682)

Loss on Common Stock for Warrant Cancellation

During the three months ended September 30, 2019, we agreed with five accredited investors to issue 1,078 shares of our common stock to these investors in exchange for the cancellation of outstanding warrants then held by the investors to purchase 10,759 shares of our common stock. We measured the fair value of the shares issued and the fair value of the warrants exchanged for those shares and recorded a loss of $4,403 on those exchanges based on the changes in fair value between the instruments exchanged.

Interest Expense

Interest expense was $21 for the three months ended September 30, 2019, and $55,106 for the three months ended September 30, 2018, a decrease of $55,085 in 2019. The various components of our interest expense are shown in the following table:

	Three Months Ended 9/30/19	Three Months Ended 9/30/18	Change
Interest Expense	$ 21	$ 24,819	$ (24,798)
Amortization of Note Discounts	–	30,287	(30,287)
Total Interest Expense	$ 21	$ 55,106	$ (55,085)

The $55,085 decrease in our interest expense was due to the payoff of our convertible notes in July 2019.

Net Loss

As a result of the changes in revenues and expenses noted above, our net loss increased from approximately $1,402,000 in the three month period ended September 30, 2018 to $1,707,000 in the three month period ended September 30, 2019.

Basic and diluted loss attributable to common stockholders were ($1.29) for the three month period ended September 30, 2019, compared to ($1.17) for the three month period ended September 30, 2018.

RESULTS OF OPERATIONS

SIX MONTHS ENDED SEPTEMBER 30, 2019 COMPARED TO THE SIX MONTHS ENDED SEPTEMBER 30, 2018

Government Contract Revenues

We recorded government contract revenue in the six months ended September 30, 2019 and 2018. This revenue resulted from work performed under our government contracts with the NIH as follows:

	Six Months Ended 9/30/19	Six Months Ended 9/30/18	Change in Dollars
Melanoma Cancer Contract	$ –	$ 149,625	$ (149,625)
Breast Cancer Grant	30,000	–	30,000
Total Government Contract and Grant Revenue	$ 30,000	$ 149,625	$ (119,625)

We have entered into the following three contracts/grants with the NCI, part of the NIH over the past two years:

Phase 2 Melanoma Cancer Contract

On September 12, 2019, the NCI awarded to us the Award Contract. The Award Contract amount is $1,860,561 and runs for the period from September 16, 2019 through September 15, 2021.

The work to be performed pursuant to this Award Contract will focus on melanoma exosomes. This work follows from our completion of a Phase I contract for the Topic 359 solicitation that ran from September 2017 through June 2018 (see Phase 1 Melanoma Cancer Contract below). Following on the Phase I work, the deliverables in the Phase II program will involve the design and testing of a pre-commercial prototype of a more advanced version of the exosome isolation platform.

No revenue was recognized under this contract in the six months ended September 30, 2019.

Phase 1 Melanoma Cancer Contract

We entered into a contract with the NIH on September 15, 2017. This award was under the NIH's SBIR program which is designed to fund early stage small businesses that are seeking to commercialize innovative biomedical technologies. The title of the award is SBIR Topic 359 Phase 1 Device Strategy for Selective Isolation of Oncosomes and Non-Malignant Exosomes. The award from NIH was a firm, fixed-price contract with potential total payments to us of $299,250 over the course of nine months.

Fixed price contracts require the achievement of multiple, incremental milestones to receive the full award during each period of the contract. The NIH also had the unilateral right to require us to perform additional work under an option period for an additional fixed amount of $49,800. Under the terms of the contract, we were required to perform certain incremental work toward the achievement of specific milestones against which we invoiced the government for fixed payment amounts.

In the six months ended September 30, 2018, we performed work under the contract covering the remainder of the technical objectives of the contract (Aim 1: To validate the Hemopurifier as a device for capture and recovery of melanoma exosomes from plasma and Aim 2: To validate a method of melanoma exosome isolation consisting of the Hemopurifier followed by mab-based immunocapture to select out the tumor-derived exosomes from non-malignant exosomes and Aim 3: To evaluate the functional integrity of melanoma exosomes purified by the Hemopurifier and immunocapture isolation steps). As a result, we invoiced NIH for $149,625 during the six months ended September 30, 2018. The Phase 1 Melanoma Cancer Contract is now completed.

Breast Cancer Grant

In September 2018, the NCI awarded us a government grant (number 1R43CA232977-01). The title of this Small Business Innovation Research (SBIR) Phase I grant is “The Hemopurifier Device for Targeted Removal of Breast Cancer Exosomes from the Blood Circulation.”

This NCI Phase I grant period originally ran from September 14, 2018 through August 31, 2019. In August 2019, we applied for and received a no cost, twelve month extension on this grant, so the expiration date was extended to August 31, 2020. The total amount of the firm grant is $298,444. The grant calls for two subcontractors to work with us. Those subcontractors are University of Pittsburgh and Massachusetts General Hospital.

During the six months ended September 30, 2019, we recognized $30,000 in government contract revenue under this grant as a result of the work involved in one of the three technical objectives of the contract (Aim 2. “Elution of a population of breast cancer exosomes from Hemopurifier cartridges that bear the signatures of malignancy based on expression of CSPG4 and HER2, for triple-negative or HER2-overexpressing cancers, respectively”). We also invoiced the NCI for an additional $100,000 during the six month period ended September 30, 2019 in order to pay our subcontractors under the contract. As we did not complete any additional technical objectives beyond Aim 2 noted above during the period, we recorded this $100,000 as deferred revenue as of September 30, 2019.

Operating Expenses

Consolidated operating expenses for the six months ended September 30, 2019 were $3,298,391, in comparison with $2,593,851 for the comparable period ended September 30, 2018. This increase of $704,540, or 27%, in 2019 was due to increases professional fees of $517,436 and in general and administrative expenses of $258,427, which were partially offset by a reduction in and payroll and related expenses of $71,323.

The $517,436 increase in our professional fees in 2019 was primarily due to a $421,145 increase in our legal fees, a $125,804 increase in our accounting fees and a $65,000 payment to the University of Pittsburgh, a subcontractor on our Breast Cancer grant related to their work on that grant. The increase in legal and accounting fees related to increased activity in our registration statement filings and in intellectual property actions among other matters.

The $258,427 increase in general and administrative expenses in 2019 was primarily due to the combination of a $140,792 increase in our clinical trial expense, primarily costs associated with the manufacturing of Hemopurifiers for an expected clinical trial in the cancer space, a $83,520 increase in our lab supplies expense, primarily related to our breast cancer grant and lab work related to our IDE application and a $58,520 increase in travel expense.

The $71,323 decrease in payroll and related expenses was due to the combination of a $124,737 reduction in our cash-based compensation expense and a $53,414 increase in stock-based compensation.

Other Expense

Other expense during the six months ended September 30, 2019 consisted of interest expense, a loss on share for warrant exchanges and a loss on debt extinguishment and during the six months ended September 30, 2018, consisted of interest expense only. Other expense for the six months ended September 30, 2019 was $505,520, in comparison with other expense of $110,210 for the six months ended September 30, 2018.

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

	Six Months Ended 9/30/19	Six Months Ended 9/30/18	Change
Loss on Debt Extinguishment	$ 447,011	$ –	$ 447,011
Loss on Share for Warrant Exchanges	4,403	–	4,403
Interest Expense	54,106	110,210	(56,104)
Total Other Expense	$ 505,520	$ 110,210	$ 395,310

Loss on Debt Extinguishment

During the six months ended September 30, 2019, we reduced the conversion price on our outstanding convertible notes from $45.00 per share to $10.20 per share. The modification of the convertible notes was evaluated under ASC 470-50-40 and the instruments were determined to be substantially different, and the transaction qualified for extinguishment accounting. Under the extinguishment accounting we recorded a loss on debt extinguishment of $447,011.

Loss on Common Stock for Warrant Cancellation

During the three months ended September 30, 2019, we agreed with five accredited investors to issue 1,078 shares of our common stock to these investors in exchange for the cancellation of outstanding warrants then held by the investors to purchase 10,759 shares of our common stock. We measured the fair value of the shares issued and the fair value of the warrants exchanged for those shares and recorded a loss of $4,403 on those exchanges based on the changes in fair value between the instruments exchanged.

Interest Expense

Interest expense was $54,106 for the six months ended September 30, 2019, and $110,210 for the six months ended September 30, 2018, a decrease of $56,104 in 2019. The various components of our interest expense are shown in the following table:

	Six Months Ended 9/30/19	Six Months Ended 9/30/18	Change
Interest Expense	$ 23,819	$ 49,636	$ (25,817)
Amortization of Note Discounts	30,287	60,574	(30,287)
Total Interest Expense	$ 54,106	$ 110,210	$ (56,104)

The $56,104 decrease in our interest expense was due to the payoff of our convertible notes in July 2019.

Net Loss

As a result of the changes in revenues and expenses noted above, our net loss increased from approximately $2,554,000 in the six month period ended September 30, 2018 to $3,774,000 in the six month period ended September 30, 2019.

Basic and diluted loss attributable to common stockholders were ($2.91) for the six month period ended September 30, 2019, compared to ($2.14) for the six month period ended September 30, 2018.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2019, we had a cash balance of $785,658 and negative working capital of $268,824. This compares to a cash balance of $3,828,074 and working capital of $2,214,230 at March 31, 2019. 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 anticipated future human clinical trials in the U.S. We anticipate the primary sources of this additional financing will be from proceeds of our at-the-market offering program, debt financing and other forms of equity placements.

Our primary source of capital during the six months ended September 30, 2019 was the Agreement with H.C. Wainwright & Co., LLC, or H.C. Wainwright. The cash raised from that activity is noted below:

Common Stock Sales Agreement with H.C. Wainwright

On June 28, 2016, we entered into a Common Stock Sales Agreement, or the Agreement, with H.C. Wainwright & Co., LLC, or H.C. Wainwright, which established 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, or the Shares.

On August 6, 2019, we executed Amendment No. 1 to the Agreement with H.C. Wainwright, effective as of August 5, 2019. The amendment provides that references in the Agreement to the registration statement shall refer to the registration statement on Form S-3 (File No. 333-231397), originally filed with the Securities and Exchange Commission on May 10, 2019, declared effective by the Securities and Exchange Commission on August 1, 2019.

Subject to the terms and conditions set forth in the Agreement, H.C. Wainwright agreed to 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 is entitled to a commission at a fixed rate equal to three percent (3.0%) of the gross proceeds per Share sold. In addition, we 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.

Sales of the Shares, if any, under the Agreement will 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 the six months ended September 30, 2019, we raised aggregate net proceeds of $423,234 (net of $13,213 in commissions to H.C. Wainwright and $3,997 in other offering expenses) under this Agreement through the sale of 62,427 shares at an average price of $6.78 per share of net proceeds.

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.

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, 2019	September 30, 2018
Cash used in:		
Operating activities	$ (2,321)	$ (1,809)
Investing activities	(120)	–
Financing activities	(601)	(86)
Net decrease in cash	$ (3,042)	$ (1,895)

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 $2,321,000 in the six month period ended September 30, 2019 compared to approximately $1,895,000 in the six month period ended September 30, 2018. The primary driver in this increase of approximately $512,000 in 2019 in cash used in operating activities was the $1,220,000 increase in our net loss which was partially offset by the non-cash debt extinguishment expense of approximately $447,000, an increase in our non-cash stock-based compensation of approximately $53,000, and the receipt of $100,000 under our Breast Cancer Grant that we recorded as deferred revenue.

NET CASH USED IN INVESTING ACTIVITIES. We used approximately $120,000 of cash to purchase laboratory and office equipment in the six months ended September 30, 2019. We had no investing activities in the three months ended September 30, 2018.

NET CASH USED IN FINANCING ACTIVITIES. During the six months ended September 30, 2019, we raised approximately $423,000 from the issuance of common stock. That source of cash from our financing activities was more than offset by the use of approximately $993,000 to partially pay down our convertible notes and the use of approximately $32,000 to pay for the tax withholding on restricted stock units for an aggregate use of cash in financing activities of approximately $602,000. During the six months ended September 30, 2018, we used approximately $86,000 to pay for the tax withholding on restricted stock units.

As of 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

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America, or GAAP, 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. These 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 estimates relate to revenue recognition, stock purchase warrants issued with notes payable, beneficial conversion feature of convertible notes payable, impairment of intangible assets and long lived assets, stock compensation, deferred tax asset valuation allowance, and contingencies.

There have been no changes to our critical accounting policies as disclosed in our Form 10-K for the year ended March 31, 2019 , except for the leases policy disclosed in Note 4 to the accompanying unaudited condensed consolidated financial statements included in Item 1 of this Quarterly Report on Form 10-Q.

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 Securities Exchange Act of 1934, as amended, and are effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, 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. For a discussion of our potential risks and uncertainties, please see the information listed in the item captioned "Risk Factors" in our Annual Report on Form 10-K for the year ended March 31, 2019. Except as provided below, there have been no material changes to the risk factors as disclosed in the Form 10-K. You should carefully consider the risk factors discussed below and in our Annual Report on Form 10-K for the year ended March 31, 2019, which could materially affect our business, financial position and results of operations.

Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a de-listing of our common stock.

If we fail to satisfy the continued listing requirements of The Nasdaq Capital Market, or Nasdaq, such as the minimum stockholders' equity requirement or the minimum closing bid price requirement, Nasdaq may take steps to de-list our common stock. In May 2019, we received a letter from Nasdaq indicating that Nasdaq has determined that we failed to comply with the minimum bid price requirement of Nasdaq Listing Rule 5550(a)(2). Nasdaq Listing Rule 5550(a)(2) requires that companies listed on the Nasdaq Capital Market maintain a minimum closing bid price of at least $1.00 per share. Although we currently are in compliance with the minimum bid price requirement, it is possible that we may not be in the future. In July 2019, we received another letter from Nasdaq indicating that Nasdaq has determined that we failed to comply with the minimum stockholder's equity requirement of Nasdaq Listing Rule 5550(b)(1). Nasdaq Listing Rule 5550(b)(1) requires that companies listed on the Nasdaq Capital Market maintain a minimum of $2,500,000 in stockholder's equity. If we fail to regain and maintain compliance with these, or any other of the continued listing requirements of The Nasdaq Capital Market, Nasdaq may take steps to de-list our common stock. A de-listing of our common stock would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a de-listing, we would take actions to restore our compliance with Nasdaq's listing requirements, but any such action taken by us may not be successful.

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

In July, August and September 2019, an aggregate of 844 shares of our common stock were issued to five accredited investors in exchange for the cancellation of outstanding warrants previously held by these investors to purchase an aggregate of 8,442 shares of our common stock.

The offers, sales and issuances of the securities described in paragraphs (1) and (2) were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) in that the issuance of securities to the accredited investors did not involve a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. No underwriters were involved in these transactions.

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:

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	SEC File No.	Exhibit Number	Date	
3.1	Articles of Incorporation.	S-3	333-211151	3.1	May 5, 2016	
3.2	Amended and Restated Bylaws of the Company.	8-K	001-37487	3.1	September 12, 2019	
4.1	Form of Common Stock Certificate.	S-1	333-201334	4.1	December 31, 2014	
4.2	Form of Common Stock Purchase Warrant dated August 29, 2012.	8-K	000-21846	4.1	September 6, 2012	
4.3	Form of Common Stock Purchase Warrant dated October, November and December 2012.	10-Q	000-21846	4.1	February 13, 2013	
4.4	Form of Common Stock Purchase Warrant dated June 14, 2013.	10-Q	000-21846	4.1	August 13, 2013	
4.5	Form of Common Stock Purchase Warrant dated June 24, 2014.	8-K	000-21846	4.1	June 30, 2014	
4.6	Form of Common Stock Purchase Warrant dated July 24, 2014.	8-K	000-21846	4.1	July 28, 2014	
4.7	Form of Common Stock Purchase Warrant dated August and September 2014.	10-Q	000-21846	4.3	November 10, 2014	
4.8	Form of Warrant to Purchase Common Stock dated June 25, 2015.	8-K	000-21846	4.1	June 24, 2015	

4.9	Form of Purchase Agent Warrant dated June 25, 2015.	8-K	000-21846	4.1	June 26, 2015	
4.10	Form of Warrant Agreement dated March 27, 2017.	8-K	001-37487	4.1	March 22, 2017	
4.11	Form of Warrant dated _____, 2017.	S-1/A	333-219589	4.29	September 18, 2017	
4.12	Form of Placement Agent Warrant dated _____, 2017.	S-1/A	333-219589	4.30	September 22, 2017	
10.1	Seventh Amendment to Standard Industrial Net Lease, dated September 9, 2019, between Aethlon Medical Inc. and San Diego Inspire 1, LLC.					X
10.2	SBIR Phase II Award Contract, effective as of September 12, 2019, by and among Aethlon Medical, Inc., the National Institutes of Health and the National Cancer Institute.					X
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.					X
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.					X
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.					X
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.					X
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					

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 1, 2019

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

EXHIBIT 10.1

SEVENTH AMENDMENT TO STANDARD INDUSTRIAL NET LEASE
BETWEEN
SAN DIEGO INSPIRE 1, LLC
AND
AETHLON MEDICAL, INC.

THIS SEVENTH AMENDMENT TO STANDARD INDUSTRIAL NET LEASE (this "**Seventh Amendment**") is dated as of September 9, 2019, by and between **SAN DIEGO INSPIRE 1, LLC**, a Delaware limited liability company ("**Landlord**"), and **AETHLON MEDICAL, INC.**, a Nevada corporation ("**Tenant**").

RECITALS

A. Landlord (as successor-in-interest to AGP Sorrento Business Complex, L.P., a Delaware limited partnership, who, in turn, is successor-in-interest to Sorrento Business Complex, a California limited partnership) and Tenant are parties to that certain Standard Industrial Net Lease dated as of September 28, 2009 (the "**Original Lease**"), as amended by that certain (i) First Amendment to Standard Industrial Net Lease dated as of October 4, 2011 (the "**First Amendment**"), (ii) Second Amendment to Standard Industrial Net Lease dated as of October 10, 2014 (the "**Second Amendment**"), (iii) Third Amendment to Standard Industrial Net Lease dated as of October 21, 2015 (the "**Third Amendment**"), (iv) Fourth Amendment to Standard Industrial Net Lease dated as of October 5, 2016 (the "**Fourth Amendment**"), (v) Fifth Amendment to Standard Industrial Net Lease dated October 16, 2017 (the "**Fifth Amendment**"), and (vi) Sixth Amendment to Standard Industrial Net Lease dated September 18, 2018 (the "**Sixth Amendment**") (all such lease amendments together with the Original Lease, hereinafter simply the "**Lease**"), with respect to certain premises containing approximately 1,703 rentable square feet (the "**Premises**") identified as Suite 109 in that certain building located at 11585 Sorrento Valley Road, San Diego, California 92121 (the "**Building**"), which is part of a larger complex known as Inspire 1 consisting of the Building and other buildings (the "**Project**").

B. Pursuant to the Sixth Amendment, the Expiration Date was previously extended from December 1, 2018 to November 30, 2019 (such extended term referred to in the Sixth Amendment as the "**Sixth Amendment Extended Term**").

C. Landlord and Tenant now desire to amend the Lease to extend the Lease Term for an additional twelve (12) months and modify other provisions of the Lease, all as more particularly set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant agree that the Lease is amended as follows:

1. **Defined Terms**. Capitalized terms used and not otherwise defined herein shall have the same meanings ascribed to them in the Lease.

2. **Term of the Lease**. Effective as of the date hereof, the Lease Term is hereby extended for an additional twelve (12) months (which period may be referred to as the "**Seventh Amendment Extended Term**") so that the Seventh Amendment Extended Term shall commence December 1, 2019 and expire unless terminated sooner pursuant to the terms of the Lease, November 30, 2020 (the "**Seventh Amendment Extended Expiration Date**"). All references to "**Lease Term**" in the Lease and this Seventh Amendment shall be deemed references to the Lease Term as extended by this Seventh Amendment and all references to "**Expiration Date**" shall be deemed references to the Seventh Amendment Extended Expiration Date. Tenant shall not have any right to extend the Lease Term beyond the Seventh Amendment Extended Expiration Date.

3. **Condition of the Premises**. Landlord shall have no obligation whatsoever to construct leasehold improvements for Tenant or to repair or refurbish the Premises. Tenant hereby agrees to continue to accept the Premises in its "**AS IS**" condition, and Tenant hereby acknowledges that the Premises is suited for the use intended by Tenant and is in good and satisfactory condition as of the date of this Amendment. Tenant acknowledges that neither Landlord nor Landlord's agents has made any representation or warranty as to the condition of the Premises or the Building or its suitability for Tenant's purposes. Tenant represents and warrants to Landlord that (a) its sole intended use of the Premises is for uses set forth in Section 1.8 of the Original Lease, and (b) it does not intend to use the Premises for any other purpose.

4. **Base Rent**. In addition to Additional Rent and all other costs and expenses payable by Tenant pursuant to the Lease, Tenant shall pay the following Minimum Monthly Rent (as defined in the Lease) for the Premises during the Seventh Amendment Extended Term in accordance with the terms of Article 4 of the Original Lease:

SEVENTH AMENDMENT EXTENDED TERM	MINIMUM MONTHLY INSTALLMENT OF RENT	MINIMUM MONTHLY RENT PER RENTABLE SQUARE FOOT
12/1/19 – 11/30/20	$5,960.50	$3.50

5. **Additional Rent**. During the Seventh Amendment Extended Term and in addition to the monthly Base Rent set forth inSection 4 of this Seventh Amendment, Tenant shall continue to pay all Additional Rent for the Premises, including without limitation, Tenant's Share of Operating Costs in accordance with the terms of Article 6 of the Original Lease.

6. **Security Deposit**. Tenant has previously deposited with Landlord the sum of Three Thousand Two Hundred Fifty Dollars and Sixty-Five Cents ($3,250.65) as a Security Deposit under the Lease. Landlord shall continue to hold such Security Deposit during the Second Amendment Extended Term in accordance with the terms and conditions of Article 5 of the Original Lease.

7. **Address for Rent Payment**. Section 4.5 of the Original Lease is hereby amended and restated as follows: Tenant shall make all payments of Minimum Monthly Rent, Additional Rent and other amounts due under the Lease in immediately available funds or by wire transfer of funds. Such payments all be initiated by Tenant to an account designated from time to time by Landlord no later than 12:00 noon, San Diego, California time on the date such sums or payments are respectively due. Any payment received after such time shall be deemed to have been made after the due date. Tenant shall use the following address for rent payments:

San Diego Inspire 1, LLC
P.O. Box 894412
Los Angeles, CA 90189-4412
Or Tenant may wire rent payments to:

Citibank NA, New York
Account Name: San Diego Inspire Holdings, LLC
Account Number: 6794041847
Routing Number: 021000089
Origin is outside the U.S.: Swift code CITIUS33

8. **Address**. Section 1.1 and Section 24.19 of the Original Lease are hereby amended to provide that notices to Landlord shall be given at the following addresses:

Address of Landlord:	SAN DIEGO INSPIRE 1, LLC c/o Longfellow Real Estate Partners 260 Franklin Street, Suite 1920 Boston, MA 02141 Attn: Asset Management
	With copies to:
	San Diego Inspire 1, LLC c/o Longfellow Real Estate Partners 11772 Sorrento Valley Rd., Suite 125 San Diego, CA 92121 Attn: Property Management

9. **Brokers**. Tenant represents and warrants to Landlord that it has not engaged any broker, finder or other person who would be entitled to any commission or fees in respect of the negotiation, execution or delivery of this Seventh Amendment, other than Newmark of Southern California, Inc., dba Newmark Knight Frank ("**Newmark Knight Frank**") serving as Landlord's agent and Grant Schoneman of JLL Life Sciences Group ("**JLL**") serving as Tenant's agent and whose commissions shall be paid by Landlord pursuant to a separate agreement. Tenant shall indemnify, defend and hold harmless Landlord against any loss, cost, liability or expense incurred by Landlord as a result of any claim asserted by any broker (other than Newmark Knight Frank and JLL), finder or other person on the basis of any arrangements or agreements made or alleged to have been made by or on behalf of Tenant.

10. **Disclosures and Utility Usage Information**. For purposes of Section 1938(a) of the California Civil Code, Landlord hereby discloses to Tenant, and Tenant hereby acknowledges, that the Premises have not undergone inspection by a Certified Access Specialist (CASp). As required by Section 1938(e) of the California Civil Code, Landlord hereby states as follows: "A Certified Access Specialist (CASp) can inspect the subject premises and determine whether the subject premises comply with all of the applicable construction-related accessibility standards under state law. Although state law does not require a CASp inspection of the subject premises, the commercial property owner or lessor may not prohibit the lessee or tenant from obtaining a CASp inspection of the subject premises for the occupancy or potential occupancy of the lessee or tenant, if requested by the lessee or tenant. The parties shall mutually agree on the arrangements for the time and manner of the CASp inspection, the payment of the fee for the CASp inspection, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the premises." In furtherance of the foregoing, Landlord and Tenant hereby agree as follows: (a) any CASp inspection requested by Tenant shall be conducted, at Tenant's sole cost and expense, by a CASp designated by Landlord, subject to Landlord's reasonable rules and requirements; (b) Tenant, at its sole cost and expense, shall be responsible for making any improvements or repairs within the Premises to correct violations of construction-related accessibility standards; and (c) if anything done by or for Tenant in its use or occupancy of the Premises shall require any improvements or repairs to the Building or the Center (outside the Premises) to correct violations of construction-related accessibility standards, then Tenant shall reimburse Landlord upon demand, as Additional Rent, for the cost to Landlord of performing such improvements or repairs. If Tenant is billed directly by a public utility with respect to Tenant's electrical usage at the Premises, upon request, Tenant shall provide monthly electrical utility usage for the Premises to Landlord for the period of time requested by Landlord (in electronic or paper format) or, at Landlord's option, provide any written authorization or other documentation required for Landlord to request information regarding Tenant's electricity usage with respect to the Premises directly from the applicable utility company.

11. **Continuing Effectiveness**. The Lease, except as amended hereby, remains unamended, and, as amended hereby, remains in full force and effect.

12. **Counterparts**. This Seventh Amendment may be executed in counterparts, each of which shall constitute an original, and all of which, together, shall constitute one document. This Seventh Amendment may be executed by a party's signature transmitted by facsimile ("**fax**") or email and copies of this Seventh Amendment executed and delivered by means of faxed or emailed signatures shall have the same force and effect as copies hereof executed and delivered with original signatures. All parties hereto may rely upon faxed or emailed signatures as if such signatures were originals. Any party executing and delivering this Seventh Amendment by fax or email shall promptly thereafter deliver a counterpart signature page of this Seventh Amendment containing said party's original signature. All parties hereto agree that a faxed or emailed signature page may be introduced into evidence in any proceeding arising out of or related to this Seventh Amendment as if it were an original signature page.

13. **Execution by Both Parties**. Submission of this instrument for examination or signature by Tenant does not constitute a reservation of or option to lease, and it is not effective as an amendment to lease or otherwise until execution by and delivery to both Landlord and Tenant, and execution and delivery hereof.

14. **No Further Modification**. Except as set forth in this Seventh Amendment, all of the terms and provisions of the Lease shall remain unmodified and in full force and effect. This Seventh Amendment contains the entire understanding between the parties with respect to the matters contained herein. In the event of any conflict between the terms and conditions of the Lease and the terms and conditions of this Seventh Amendment, the terms and conditions of this Seventh Amendment shall prevail. No representations, warranties, covenants or agreements have been made concerning or affecting the subject matter of this Seventh Amendment, except as are contained herein and in the Lease. This Seventh Amendment may not be changed orally, but only by an agreement in writing signed by the party against whom enforcement of any waiver, change or modification or discharge is sought.

15. **Authorization** The parties signing on behalf of Tenant each hereby represents and warrants that such party has the capacity set forth on the signature pages hereof and has full power and authority to bind Tenant to the terms hereof. Two (2) authorized officers must sign on behalf of the Tenant and this Amendment must be executed by the president or vice-president and the secretary or assistant secretary of Tenant, unless the bylaws or a resolution of the board of directors shall otherwise provide. In such case, the bylaws or a certified copy of the resolution of Tenant, as the case may be, must be furnished to Landlord.

(SIGNATURES ON NEXT PAGE)

IN WITNESS WHEREOF, the parties hereto have executed this Seventh Amendment as of the date first above written.

"LANDLORD"

SAN DIEGO INSPIRE 1, LLC,
a Delaware limited liability company

By: /s/ Jamison Peschel

Print Name: Jamison Peschel

Title: Authorized Signatory

"**TENANT"**

AETHLON MEDICAL, INC.,
a Nevada corporation

By: /s/ Timothy Rodell

Print Name: Timothy Rodell

Title: CEO

By: /s/ James B. Frakes

Print Name: James B. Frakes

Title: Chief Financial Officer

EXHIBIT 10.2

AWARD/CONTRACT

1\. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)

RATING

PAGE OF PAGES

2\. CONTRACT (Proc. Inst. Ident.) NO.
75N91019C000J2

3\. EFFECTIVE DATE: See [illegible]

4\. REQUISITION/PURCHASE REQUEST/PROJECT NO.: [illegible]

5\. ISSUED BY — CODE: [illegible]

[illegible]
National Cancer Institute
[illegible]

6\. ADMINISTERED BY (If other than Item 5) — CODE: [illegible]

National Institutes of Health
National Cancer Institute
Bethesda, MD [illegible]-7511

SCD-C

7\. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)

AETHLON MEDICAL, INC.: [illegible] 6382
9635 GRANITE RIDGE DRIVE SUITE 100
SAN DIEGO CA 92123:678

CODE — FACILITY CODE

8\. DELIVERY
FOB ORIGIN — OTHER (See below)

9\. DISCOUNT FOR PROMPT PAYMENT

10\. SUBMIT INVOICES (copies unless otherwise specified) TO THE ADDRESS SHOWN IN ▶

11\. SHIP TO/MARK FOR — CODE: MEDICAL CENTER DR

9609 Medical Center Drive, Rockvill
9609 Medical Center Drive
Rockville [illegible] 50

12\. PAYMENT WILL BE MADE BY — CODE: [illegible]

Approved By, NCI Branch A Invoices
Paid By: NIH Commercial Accounting Br
2115 East Jefferson St, [illegible] 8500
Room 4B-[illegible]
Bethesda, MD 20892-8500

13\. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION
[ ] 10 U.S.C. 2304(c)( ) [ ] 41 U.S.C. 3304(a)( )

14\. ACCOUNTING AND APPROPRIATION DATA
See Schedule

15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued				

15G. TOTAL AMOUNT OF CONTRACT ▶ [illegible]

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(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	24
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	5			PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
X	C	DESCRIPTION/SPECS./WORK STATEMENT	6	X	J	LIST OF ATTACHMENTS	35
X	D	PACKAGING AND MARKING	11			PART IV - REPRESENTATIONS AND INSTRUCTIONS	
X	E	INSPECTION AND ACCEPTANCE	12	X	K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	36
X	F	DELIVERIES OR PERFORMANCE	13				
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CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17\. [X] CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return [illegible] copies 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 herein.)

18\. [ ] SEALED-BID AWARD (Contractor is not required to sign this document.) Your bid on Solicitation Number [illegible] including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

19A. NAME AND TITLE OF SIGNER (Type or print)

20A. NAME OF CONTRACTING OFFICER
TIFFANY D. CHADWICK

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
BY [signature] (Signature of person authorized to sign)	9/11/19	Tiffany D. Chadwick -S — Digitally signed by Tiffany D. Chadwick -S Date: 2019.09.12 11:29:56 -04'00' (Signature of the Contracting Officer)	9/12/19

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Previous edition is NOT usable

STANDARD FORM 26 (REV. [illegible])
Prescribed by GSA - FAR (48 CFR) 53.214(a)

NAME OF OFFEROR OR CONTRACTOR
AETHLON MEDICAL, INC.:1296382

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
1	Topic 359: A Device Prototype for Isolation of Melanoma Exosomes for Diagnostics and Treatment Monitoring Obligated Amount: $1,860,561.00 Product/Service Code: AN13 Product/Service Description: R&D- MEDICAL: BIOMEDICAL (ADVANCED DEVELOPMENT) Project Data: 125132.1.HNC1 NCI OD OFFICE OF THE DIRECTOR.2555 RESEARCH AND DEVELOPMENT.09/03/2019 Accounting Info: 08024920191DA0.2019.03.C100.HNC1000000C.E.00014.406.SBIR.2555.610001.9999.9999.9999 Funded: $1,860,561.00				1,860,561.00

CONTRACT TABLE OF CONTENTS

PART I - THE SCHEDULE

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

Topic 359: Technologies for Differential Isolation of Exosomes and Oncosomes

Title of Project: A Device Prototype for Isolation of Melanoma Exosomes for Diagnostics and Treatment Monitoring

The contractor will develop a pre-commercial prototype of an exosome isolation device to be used in clinical diagnostic laboratories.

ARTICLE B.2. PRICES

1. The total fixed price of this contract is $1,860,561.
2. Upon delivery and acceptance of the services described in SECTION C of this contract and identified in the schedule of charges below, the Government shall pay to the Contractor the unit price(s) set forth below:

PAYMENT SCHEDULE

Description	Amount ($)
Kick-Off Presentation	$206,729
Quarterly Report 1	$206,729
Quarterly Report 2	$206,729
Quarterly Report 3	$206,729
Quarterly Report 4, SBIR Program Life Cycle Certification, Annual Updated Commercialization Plan	$206,729
Quarterly Report 5	$206,729
Quarterly Report 6	$206,729
Quarterly Report 7	$206,729
Final Report, Contract Outcomes Report, Final presentation, and all other contract deliverables	$206,729
TOTAL FIXED PRICE	$1,860,561

ARTICLE B.3. ADVANCE UNDERSTANDINGS

a. Contract Number Designation

On all correspondence submitted under this contract, the Contractor agrees to clearly identify the contract number that appears on the face page of the contract.

b. SBIR Funding Agreement Certification

The SBIR Funding Agreement Certification form, located in SECTION J, must be completed at the time of award prior to the performance of work under this contract, in accordance with the SBIR Policy Directive issued by SBA (May 2, 2019).

For additional information, see NIH Policy Notice NOT-OD-13-116, entitled, "New Program Certifications Required for SBIR and STTR Awards," located at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-116.html.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

a. Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services,qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work, dated August 28, 2019, set forth in SECTION J-List of Attachments, attached hereto and made a part of this contract.

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format via e-mail, as attachments, to the following designated NCI Branch Distribution Mailbox: NCIbranchainvoices@mail.nih.gov .

Each e-mail submission shall contain only one deliverable. If the attached file for the deliverable exceeds 50 MB, the Contractor shall divide the deliverable into files of 50 MB each. All deliverables shall be limited to five file attachments or less.

The subject line of the e-mail shall read as follows: **Deliverable_** *Contract Number_ Vendor's Name_ Deliverable Description_ Due Date.*

All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

a. Technical Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with the DELIVERIES Article in SECTION F of this contract:

Note: The Contractor shall include, in any technical progress report submitted, the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.

1. Kick-Off Presentation

The Contractor shall prepare and submit a kick-off presentation. Slides shall be prepared and presentation of the slides shall occur either in-person or through webinar or teleconference. The presentation shall cover the following:

a. Discussion of the Contractor's organization and project status, particularly changes that occurred since the proposal submission;

b. Contractor's recent achievements (patents, publications, sales, regulatory approvals, partnerships, awards, etc.);

c. Status of the field;

d. Status of commercial and academic competitors;

e. Where the proposed project is positioned against the state of the art;

f. Intellectual property landscape;

g. Refresher on the proposed technology/R&D;

h. Detailed plan for the first budget period of the contract;

i. Milestones (technical and commercial) to be achieved by the end of the first budget period of the contract;

j. Discussion of anticipated technical risks and alternative approaches;

k. Questions to the NCI.

2. Quarterly Reports

The Contractor shall submit Quarterly Reports, which shall include:

a. Summary of technical objectives with status of each objective clearly marked (*e.g.* previously completed, completed during this reporting period, not started, etc);

b. Clear description of activities accomplished in the quarter;

c. Analysis of experimental data and presentation of selected data;

d. Comments regarding the timeliness of performance;

e. Brief explanation of objectives/activities to be pursued in the next reporting period.

This report shall generally be no longer than five (5) pages, excluding tables, figures, images and graphs used to present data.

3. Annual Updated Commercialization Plan

The Contractor shall submit an updated commercialization plan which shall include.

a. Value of the SBIR Project, Expected Outcomes, and Impact
Describe, in layperson's terms, the proposed project and its key technology objectives. State the product, process, or service to be developed in Phases II and III. Clarify the need addressed, specifying weaknesses in the current approaches to meet this need. In addition, describe the commercial applications of the research and the innovation inherent in this application. Be sure to also specify the potential societal, educational, and scientific benefits of this work. Explain the non-commercial impacts to the overall significance of the project. Explain how the SBIR contract integrates with the overall business plan of the company.

b. Organization
Give a brief description of the Contractor's organization, including corporate objectives, core competencies, present size (annual sales level and number and types of employees), history of previous Federal and non-Federal funding, regulatory experience and subsequent commercialization, and any current products/services that have significant sales. Include a short description of the origins of the Contractor's organization. Indicate the Contractor's vision for the future, how the Contractor will grow/maintain a sustainable business entity, and how the Contractor will meet critical management functions as the Contractor's organization evolves from a small technology R&D business to a successful commercial entity.

c. Market, Customer, and Competition
Describe the market and/or market segments being targeted and provide a brief profile of the potential customer. Tell what significant advantages the Contractor's innovation will bring to the market - *e.g.*, better performance, lower cost, faster, more efficient or effective, new capability. Explain the hurdles the Contractor will have to overcome in order to gain market/customer acceptance of the Contractor's innovation. Describe any strategic alliances, partnerships, or licensing agreements the Contractor has in place to get FDA approval (if required) and to market

and sell the Contractor's product. Briefly describe the Contractor's marketing and sales strategy. Give an overview of the current competitive landscape and any potential competitors over the next several years.

d. Intellectual Property (IP) Protection
Describe how the Contractor is going to protect the IP that results from the Contractor's innovation. Also, note other actions the Contractor may consider taking that will constitute at least a temporal barrier to others aiming to provide a solution similar to the Contractor's.

e. Finance Plan
Describe the necessary financing the Contractor will require to commercialize the innovation and when it will be required. Describe the Contractor's plans to raise the requisite financing to launch the Contractor's innovation into Phase III and begin the revenue stream. Plans for this financing stage may be demonstrated in one or more of the following ways:

- Letter of commitment of funding.
- Letter of intent or evidence of negotiations to provide funding, should the Phase II project be successful and the market need still exist.
- Letter of support for the project and/or some in-kind commitment, *e.g.*, to test or evaluate the innovation.
- Specific steps the Contractor is going to take to secure Phase III funding.

f. Production and Marketing Plan
Describe how the production of the Contractor's product/process/service will occur (*e.g.*, in-house manufacturing, contract manufacturing). Describe the steps the Contractor will take to market and sell the Contractor's product/process/service. For example, explain plans for licensing, Internet sales, etc.

g. Revenue Stream
Explain how the Contractor plans to generate a revenue stream for the Contractor's organization should this project be a success. Examples of revenue stream generation include, but are not limited to; manufacture and direct sales, sales through value added resellers or other distributors, joint venture, licensing, service. Describe how the Contractor's staffing will change to meet the Contractor's revenue expectations.

4. Draft Final Report

The Contractor shall submit a Draft Final Report. The Government Contracting Officer's Representative (COR) will review and provide comments on the Draft Final Report, which the Contractor shall incorporate into a revised Final Report (- see Reporting Requirement Item 5).

The Draft Final Report shall include the following three sections:

Section 1: Summary of Salient Results

The Summary of Salient Results shall summarize in 200 words or less the salient results achieved during performance of the contract.

Section 2: Final Technical Report

The Final Technical Report shall set forth the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved.

Section 3: Commercialization Plan

The Commercialization Plan shall be in the same format as described above for the Annual Updated Commercialization Plan (- see Reporting Requirement Item 3).

5. **Final Report**

   The Contractor shall submit a Final Report. This document shall incorporate revisions in response to the comments provided by the Government COR after review of the Draft Final Report (- see Reporting Requirements Item 4).

6. **Contract Outcomes Report**

   The Contractor shall submit a Contract Outcomes Report using a fillable PDF form to be provided by the Government. The Contract Outcomes Report must be provided as a filled-in version of the PDF form provided and not as a printed or scanned copy of this document.

7. **Final Presentation**

   The Contractor shall prepare and submit a final presentation. Slides shall be prepared and presentation of the slides shall occur either in-person or through webinar or teleconference. The presentation shall cover the following:

   a. Discussion of the Contractor's organization and project status;
   b. Contractor's achievements during the performance period (patents, publications, sales, regulatory approvals, partnerships, awards, etc.);
   c. Detailed results of the performed research and development;
   d. Discussion of proposed milestones and whether they were achieved during the contract performance;
   e. Summary of progress towards commercialization;
   f. Questions to the NCI.

a. Other Reports/Deliverables

1. **Reporting of Financial Conflict of Interest (FCOI)**

   All reports and documentation required by 45 CFR Part 94, Responsible Prospective Contractors including, but not limited to, the New FCOI Report, Annual FCOI Report, Revised FCOI Report, and the Mitigation Report, shall be submitted to the Contracting Officer in Electronic format. Thereafter, reports shall be due in accordance with the regulatory compliance requirements in 45 CFR Part 94.

   45 CFR Part 94 is available at: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45. See Part 94.5, Management and reporting of financial conflicts of interest for complete information on reporting requirements.

   (Reference subparagraph g. of the INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST Article in SECTION H of this contract.)

2. **NIH Small Business Innovation Research (SBIR) Program Life Cycle Certification**

In accordance with the SBIR/STTR Reauthorization Act of 2011, the contractor shall complete and submit the NIH Small Business Innovation Research (SBIR) Life Cycle Certification form, located in SECTION J, of the contract to the Contracting Officer. This certification is required to ensure the contractor is meeting the program's requirements during the life cycle of the contract.

The Life Cycle Certification form shall be submitted as follows:

- Phase I SBIR Contractors shall submit the Certification at the time of receiving final payment or disbursement.
- Phase II SBIR Contractors shall submit the Certification prior to receiving more than 50% of the total contract amount **AND** prior to final payment or disbursement.

The Contracting Officer, may, at any time after ward request further clarifications and supporting documentation in order to assist in the verification of any information provided by the contractor.

For additional information, see NIH Policy Notice NOT-OD-13-116, entitled, "New Program Certifications Required for SBIR and STTR Awards, " located at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-116.html.

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

A 'subject invention' is defined as "any invention of the contractor made in the performance of work under a Government contract." See FAR 27.301.

All reports and documentation required for subject inventions by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed to the Division of Extramural Inventions and Technology Resources (DEITR), OPERA, OER, NIH, 6705 Rockledge Drive, Suite 310, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986).

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is required as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

In addition, a final invention statement, listing all subject inventions or stating that there were none, shall be submitted to the Contracting Officer and the Contracting Officer's Representative (COR) on or before the completion date of the contract.

SECTION D - PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this SECTION, the Contracting Officer's Representative (COR) designated in SECTION G is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at:

National Cancer Institute
9609 Medical Center Drive
Rockville, MD 20850

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause **52.246-9, Inspection of Research and Development (Short Form)** (April 1984).

FAR Clause **52.246-16, Responsibility for Supplies** (April 1984).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of this contract shall be from September 16, 2019 through September 15, 2021.

ARTICLE F.2. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

1. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below:

Item	Description	Delivery Schedule
(1)	SBIR Funding Agreement Certification	Due at time of award, prior to performance of any work under this contract.
(2)	Financial Conflict of Interest Reports	Prior to performance of any work under this contract, the contractor must either submit an initial report or submit a statement that no such conflicts exist. Thereafter, initial and ongoing reports are due in accordance with 45 CFR Part 94.
(3)	Kick-off Presentation	Due on or before 30 calendar days following the effective date of this contract.
(4)	Quarterly Reports	Due on or before 15 calendar days following completion of each reporting period. A Quarterly Report shall not be due when the Final Report is due.
(5)	SBIR Program Life Cycle Certification 1	Due upon submission of invoice requesting at least 50% of the total fixed price.
(6)	Annual Updated Commercialization Plan	Due on or before 1 year after the effective date of this contract.
(7)	Draft Final Report	Due on or before 1 month prior to the completion date of the contract.
(8)	Final Report	Due on or before the completion date of the contract.
(9)	Contract Outcomes Report	Due on or before the completion date of the contract.
(10)	Final Presentation	Due on or before the completion date of the contract.
(11)	SBIR Program Life Cycle Certification 2	Due on or before the completion date of the contract.
(12)	Final Invention Statement	Due on or before the completion date of the contract.
(13)	Invention Disclosure Report & Annual Invention Utilization Reports	In accordance with FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor, for any subject invention(s).

2. The above items shall be addressed and delivered to:

Addressee	Deliverables
NCI Contracting Officer ncibranchainvoices@mail.nih.gov	Items 1-12, in electronic format
OPERA, OEH, NIH 6705 Rockledge Drive, Suite 310, MSC 7980 Bethesda, MD 20892-7980	Item 13, via http://www.iedison.gov

ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: https://www.acquisition.gov/?q=browsefar.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE: **52.242-15, Stop Work Order** (August 1989)

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) will represent the Government for the purpose of this contract:

Jian Lou

The COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract; or (6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of the contract

The Government may unilaterally change its COR designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.237-75 (December 2015)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to the contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the contractor is terminated for cause or separates from the contractor voluntarily with less than thirty days notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

(End of Clause)

The following individual(s) is/are considered to be essential to the work being performed hereunder:

Name	Title
Annette Marleau, PhD	Principal Investigator

ARTICLE G.3. INVOICE SUBMISSION

a. Invoice Instructions for NIH Fixed-Price Type Contracts, NIH(RC)-2, are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**

1. The original invoice shall be submitted to the following **designated billing office**:

   National Institutes of Health
   Office of Financial Management
   Commercial Accounts
   2115 East Jefferson Street, Room 4B-432, MSC 8500
   Bethesda, MD 20892-8500

2. One courtesy copy of the original invoice shall be submitted electronically as follows:

   1. The Contractor shall scan the original payment request (invoice) in Adobe Portable Document Format (PDF) along with the necessary supporting documentation as one single attachment.

   2. Save the single attachment (scanned invoice along with any supporting documentation) in the following format: YourVendorName_Invoice number (e.g., if you are submitting Invoice 123456, save the single attachment as "Contractor Name_Invoice 123456"). [Note: Please do not use special characters (such as #, $, %, *, &, !) when saving your attachment. Only the underscore symbol (_) is permitted.]

   3. Transmit the saved single attachment via e-mail to the appropriate branch's Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NCI OA Branch A - ncibranchainvoices@mail.nih.gov. Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contract Number_Contract Title_Contractor's Name_unique Invoice number.

   Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office listed in subparagraph a., above, to meet the requirements of a "proper invoice." Also, the Contractor must certify on the payment request that the electronic courtesy copy is a duplicate of the original invoice mailed to NIH's Office of Financial Management.

2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:

   a. Name of the Office of Acquisitions: The National Cancer Institute.

   b. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

   c. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the System for Award Management (SAM) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

   d. Invoice Matching Option. This contract requires a two-way match.

   e. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

   f. The contract period of performance.

   g. The contract number and the contract title.

b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6452.

ARTICLE G.4. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (December 2013)

a. Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.

b. The acceleration of payments under this clause does not provide any new rights under the prompt Payment Act.

c. Include the substance of this clause, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

(End of Clause)

ARTICLE G.5. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and Final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The Final performance evaluation will be prepared at the time of completion of work. In addition to the Final evaluation, Interim evaluation(s) will be prepared Annually, on or around the anniversary of the effective date of the contract.

Interim and Final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted sixty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors may access evaluations through a secure Web site for review and comment at the following address: http://www.cpars.gov.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

ARTICLE H.2. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310).

ARTICLE H.3. NIH POLICY ON ENHANCING REPRODUCIBILITY THROUGH RIGOR AND TRANSPARENCY

Contractors shall adhere to the NIH policy of enhancing reproducibility through rigor and transparency by addressing each of the four areas of the policy in performance of the Statement of Work and in publications, as applicable: 1) Scientific Premise; 2) Scientific Rigor; 3) Consideration of Relevant Biological Variables, including Sex; and 4) Authentication of Key Biological and/or Chemical Resources. This policy applies to all NIH funded research and development, from basic through advanced clinical studies. See NIH Guide Notice, NOT-OD-15-103, "Enhancing Reproducibility through Rigor and Transparency" and NOT-OD-15-102, "Consideration of Sex as a Biological Variable in NIH-funded Research" for more information. In addition, publications are expected to follow the guidance at http://www.nih.gov/research-training/rigor-reproducibility/principles-guidelines-reporting-preclinical-research, whether preclinical or otherwise, as appropriate. More information is available at http://grants.nih.gov/reproducibility/index.htm, including FAQs and a General Policy Overview.

ARTICLE H.4. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

NIH-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will

preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

Additional information is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-071.html and http://publicaccess.nih.gov.

ARTICLE H.5. ACKNOWLEDGEMENT OF FEDERAL FUNDING

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

ARTICLE H.6. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (December 2015)

a. Before undertaking performance of any contract involving animal-related activities where the species is regulated by the United Sates Department of Agriculture (USDA), the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.

b. The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1 2.11, or from a source that is exempt from licensing under those sections.

c. The Contractor agrees that the care, use, and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard shall govern.

d. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c)above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with Animal Welfare Assurances.

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (Email: ace@aphis.usda.gov; Web site: (http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare).

(End of clause)

ARTICLE H.7. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy can be accessed at: http://grants1.nih.gov/grants/olaw/references/phspol.htm

In addition, the research involving live vertebrate animals shall be conducted in accordance with the description set forth in the Vertebrate Animal Section (VAS) of the contractor's technical proposal, as confirmed in the Final Proposal Revision (FPR), dated September 9, 2019, which is incorporated by reference.

ARTICLE H.8. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS

The Contractor shall not use contract funds to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

ARTICLE H.9. GUN CONTROL

The Contractor shall not use contract funds in whole or in part, to advocate or promote gun control.

ARTICLE H.10. LIMITATIONS ON SUBCONTRACTING - SBIR

The Contractor shall perform a minimum off one-half of the research and/or analytical effort conducted under this contract, as measured by total contract dollars. Any deviation from this requirement must be approved in writing by the Contracting Officer.

ARTICLE H.11. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Institution (includes any contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under NIH contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: : http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45
As required by 45 CFR Part 94, the Institution shall, at a minimum:

a. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request. A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

    1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. Included are payments and equity interests;

    2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or

3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

Significant financial interests do not include the following:

1. Income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and
2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

b. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any NIH-funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.

c. Designate an official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the NIH-funded research.

d. Require that each Investigator who is planning to participate in the NIH-funded research disclose to the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for NIH-funded research. Require that each Investigator who is participating in the NIH-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution during the period of the award as well as within thirty days of discovering or acquiring a new significant financial interest.

e. Provide guidelines consistent with the regulations for the designated official(s) to determine whether an Investigator's significant financial interest is related to NIH-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to NIH-funded research when the Institution, thorough its designated official(s), reasonably determines that the significant financial interest: Could be affected by the NIH-funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

f. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).

g. Provide initial and ongoing FCOI reports to the Contracting Officer pursuant to Part 94.5(b).

h. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

j. Complete the certification in Section K - Representations, Certifications, and Other Statements of Offerors titled "Certification of Institutional Policy on Financial Conflicts of Interest".

If the failure of an Institution to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the NIH-funded research, the Institution must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the NIH-funded research project.

The Contracting Officer and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests.. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the NIH-funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that NIH-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

ARTICLE H.12. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, under Contract No.75N91019C00042"

a. **Advanced Copies of Press Releases**

Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The Contractor shall not publish a press release related to this contract without receiving prior concurrence from the Contracting Officer. The Contractor shall submit an advance copy of the press release to the Contracting Officer and Contracting Officer's Representative (COR). Upon acknowledgment of receipt, the Contracting Officer will have five (5) working days to respond with concurrence or comments. In the event that the Contracting Officer does not communicate concurrence or comments to the Contractor within five (5) working days following acknowledgement of receipt of the press release advance copy, concurrence may be presumed.

ARTICLE H.13. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477)**. All telephone calls will be handled confidentially. The website to file a complaint on-line is: http://oig.hhs.gov/fraud/hotline/ and the mailing address is:

US Department of Health and Human Services

Office of Inspector General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.14. SHARING RESEARCH DATA

The Contractor agrees to adhere to the data sharing plan submitted with its final proposal revision and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Privacy Rule at http://www.hhs.gov/ocr/). The rights and privacy of people who participate in NIH-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A FIXED-PRICE RESEARCH AND DEVELOPMENT SBIR PHASE II CONTRACT

This contract incorporates the following 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 as follows: FAR Clauses at: http://www.acquisition.gov/far/. HHSAR Clauses at: http://www.hhs.gov/policies/hhsar/subpart352.html.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Nov 2013	Definitions (Over the Simplified Acquisition Threshold)
52.203-3	Apr 1984	Gratuities (Over the Simplified Acquisition Threshold)
52.203-5	May 2014	Covenant Against Contingent Fees (Over the Simplified Acquisition Threshold)
52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government (Over the Simplified Acquisition Threshold)
52.203-7	May 2014	Anti-Kickback Procedures (Over the Simplified Acquisition Threshold)
52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)
52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)
52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions (Over $150,000)
52.203-17	Apr 2014	Contractor Employee Whistleblower Rights and Requirements to Inform Employees of Whistleblower Rights (Over the Simplified Acquisition Threshold)
52.203-99	Feb 2015	Prohibition on Contracting with Entities That Require Certain Internal Confidentiality Agreements (DEVIATION)
52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper(Over the Simplified Acquisition Threshold)
52.204-10	Oct 2016	Reporting Executive Compensation and First-Tier Subcontract Awards ($30,000 or more)
52.204-13	Oct 2016	System for Award Management Maintenance
52.209-6	Oct 2015	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $35,000)
52.215-2	Oct 2010	Audit and Records - Negotiation [Note: Applies to ALL contracts funded in whole or in part with Recovery Act funds, regardless of dollar value, AND contracts over the Simplified Acquisition Threshold funded exclusively with non-Recovery Act funds.]
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data (Over $750,000)

FAR CLAUSE NO.	DATE	TITLE
52.215-12	Oct 2010	Subcontractor Cost or Pricing Data (Over $750,000)
52.215-14	Oct 2010	Integrity of Unit Prices (Over the Simplified Acquisition Threshold)
52.215-15	Oct 2010	Pension Adjustments and Asset Reversions (Over $750,000)
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications
52.219-6	Nov 2011	Notice of Total Small Business Set-Aside
52.219-8	Nov 2016	Utilization of Small Business Concerns (Over the Simplified Acquisition Threshold)
52.219-14	Jan 2017	Limitations on Subcontracting
52.222-3	Jun 2003	Convict Labor
52.222-21	Apr 2015	Prohibition of Segregated Facilities
52.222-26	Sep 2016	Equal Opportunity
52.222-35	Oct 2015	Equal Opportunity for Veterans ($150,000 or more)
52.222-36	Jul 2014	Equal Opportunity for Workers with Disabilities
52.222-37	Feb 2016	Employment Reports on Veterans ($150,000 or more)
52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act (Over the Simplified Acquisition Threshold)
52.222-50	Mar 2015	Combating Trafficking in Persons
52.222-54	Oct 2015	Employment Eligibility Verification (Over the Simplified Acquisition Threshold)
52.223-6	May 2001	Drug-Free Workplace
52.223-18	Aug 2011	Encouraging Contractor Policies to Ban Text Messaging While Driving
52.225-1	May 2014	Buy American - Supplies
52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
52.227-1	Dec 2007	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
52.227-11	May 2014	Patent Rights - Ownership by the Contractor (Note: In accordance with FAR 27.303(b)(2), paragraph (e) is modified to include the requirements in FAR 27.303(b)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-20	May 2014	Rights in Data - SBIR Program
52.229-3	Feb 2013	Federal, State and Local Taxes (Over the Simplified Acquisition Threshold)
52.232-2	Apr 1984	Payments under Fixed-Price Research and Development Contracts
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	May 2014	Interest (Over the Simplified Acquisition Threshold)
52.232-23	May 2014	Assignment of Claims
52.232-25	Jan 2017	Prompt Payment
52.232-33	Jul 2013	Payment by Electronic Funds Transfer--System for Award Management
52.232-39	Jun 2013	Unenforceability of Unauthorized Obligations

FAR CLAUSE NO.	DATE	TITLE
52.233-1	May 2014	Disputes
52.233-3	Aug 1996	Protest After Award
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.242-13	Jul 1995	Bankruptcy (Over the Simplified Acquisition Threshold)
52.243-1	Aug 1987	Changes - Fixed Price, Alternate V (Apr 1984)
52.244-5	Dec 1996	Competition in Subcontracting (Over the Simplified Acquisition Threshold)
52.244-6	Nov 2017	Subcontracts for Commercial Items
52.246-25	Feb 1997	Limitation of Liability - Services (Over the Simplified Acquisition Threshold)
52.249-2	Apr 2012	Termination for the Convenience of the Government (Fixed-Price)
52.249-9	Apr 1984	Default (Fixed-Price Research and Development)(Over the Simplified Acquisition Threshold)
52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

HHSAR CLAUSE NO.	DATE	TITLE
352.203-70	Dec 2015	Anti-Lobbying
352.222-70	Dec 2015	Contractor Cooperation in Equal Employment Opportunity Investigations
352.227-70	Dec 2015	Publications and Publicity
352.237-75	Dec 2015	Key Personnel

[End of GENERAL CLAUSES FOR A FIXED-PRICE RESEARCH AND DEVELOPMENT SBIR PHASE II CONTRACT- Rev. 11/2017].

ARTICLE I.2. AUTHORIZED SUBSTITUTION OF CLAUSES

ARTICLE I.1. of this SECTION is hereby modified as follows:

a. THERE ARE NO APPLICABLE CLAUSES IN THIS SECTION.

ARTICLE I.3. Additional Contract Clauses

This contract incorporates the following 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.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. FAR Clause **52.204-14**, **Service Contract Reporting Requirements** (October 2016).

2. FAR Clause **52.204-18 Commercial and Government Entity Code Maintenance** (July 2016)

3. FAR Clause **52.209-10, Prohibition on Contracting With Inverted Domestic Corporations** (November 2015).

4. FAR Clause **52.219-28, Post-Award Small Business Program Rerepresentation** (July 2013).

a. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

1. HHSAR Clause **352.208-70, Printing and Duplication** (December 2015)

2. HHSAR Clause **352.223-70, Safety and Health** (December 2015)

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

This contract incorporates the following clauses in full text.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. FAR Clause 52.204-21, **Basic Safeguarding of Covered Contractor Information Systems** (June 2016)

a. Definitions . As used in this clause--

"Covered contractor information system" means an information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information.

"Federal contract information" means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government, but not including information provided by the Government to the public (such as on public Web sites) or simple transactional information, such as necessary to process payments.

"Information" means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

"Information system" means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

"Safeguarding" means measures or controls that are prescribed to protect information systems.

b. Safeguarding requirements and procedures.

1.The Contractor shall apply the following basic safeguarding requirements and procedures to protect covered contractor information systems. Requirements and procedures for basic safeguarding of covered contractor information systems shall include, at a minimum, the following security controls:

i.Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).

ii.Limit information system access to the types of transactions and functions that authorized users are permitted to execute.

iii. Verify and control/limit connections to and use of external information systems.

iv.Control information posted or processed on publicly accessible information systems.

v.Identify information system users, processes acting on behalf of users, or devices.

vi.Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.

vii.Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.

viii.Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.

ix.Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.

x.Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.

xi.Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.

xii.Identify, report, and correct information and information system flaws in a timely manner.

xiii.Provide protection from malicious code at appropriate locations within organizational information systems.

xiv.Update malicious code protection mechanisms when new releases are available.

xv.Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

2. *Other requirements.* This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal agencies and departments relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.

c. *Subcontracts.* The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial items, other than commercially available off-the-shelf items), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

(End of clause)

2. FAR Clause 52.204-25 **Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.** (AUG 2019)

a. Definitions . As used in this clause-

Covered foreign country means The People's Republic of China.

Covered telecommunications equipment or services means-

1. Telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities);
2. For the purpose of public safety, security of Government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities);

3. Telecommunications or video surveillance services provided by such entities or using such equipment; or

4. Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.

Critical technology means-

1. Defense articles or defense services included on the United States Munitions List set forth in the International Traffic in Arms Regulations under subchapter M of chapter I of title 22, Code of Federal Regulations;

2. Items included on the Commerce Control List set forth in Supplement No. 1 to part 774 of the Export Administration Regulations under subchapter C of chapter VII of title 15, Code of Federal Regulations, and controlled-

   i. Pursuant to multilateral regimes, including for reasons relating to national security, chemical and biological weapons proliferation, nuclear nonproliferation, or missile technology; or

   ii. For reasons relating to regional stability or surreptitious listening;

3. Specially designed and prepared nuclear equipment, parts and components, materials, software, and technology covered by part 810 of title 10, Code of Federal Regulations (relating to assistance to foreign atomic energy activities);

4. Nuclear facilities, equipment, and material covered by part 110 of title 10, Code of Federal Regulations (relating to export and import of nuclear equipment and material);

5. Select agents and toxins covered by part 331 of title 7, Code of Federal Regulations, part 121 of title 9 of such Code, or part 73 of title 42 of such Code; or

6. Emerging and foundational technologies controlled pursuant to section 1758 of the Export Control Reform Act of 2018 (50 U.S.C. 4817).

Substantial or essential component means any component necessary for the proper function or performance of a piece of equipment, system, or service.

b. Prohibition. Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. The Contractor is prohibited from providing to the Government any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in Federal Acquisition Regulation 4.2104.

c. Exceptions. This clause does not prohibit contractors from providing-

   i. A service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

   ii. Telecommunications equipment that cannot route or redirect user data traffic or permit visibility into any user data or packets that such equipment transmits or otherwise handles.

d. Reporting requirement.

1. In the event the Contractor identifies covered telecommunications equipment or services used as a substantial or essential component of any system, or as critical technology as part of any system, during contract performance, or the Contractor is notified of such by a subcontractor at any tier or by any other source, the Contractor shall report the information in paragraph (d)(2) of this clause to the Contracting Officer, unless elsewhere in this contract are established procedures for reporting the information; in the case of the Department of Defense, the Contractor shall report to the website at https://dibnet.dod.mil. For indefinite delivery contracts, the Contractor shall report to the Contracting Officer for the indefinite delivery contract and the Contracting Officer(s) for any affected order or, in the case of the Department of Defense, identify both the indefinite delivery contract and any affected orders in the report provided at https://dibnet.dod.mil.

2. The Contractor shall report the following information pursuant to paragraph (d)(1) of this clause:

   i. Within one business day from the date of such identification or notification: the contract number; the order number(s), if applicable; supplier name; supplier unique entity identifier (if known); supplier Commercial and Government Entity (CAGE) code (if known); brand; model number (original equipment manufacturer number, manufacturer part number, or wholesaler number); item description; and any readily available information about mitigation actions undertaken or recommended.

   ii. Within 10 business days of submitting the information in paragraph (d)(2)(i) of this clause: any further available information about mitigation actions undertaken or recommended. In addition, the Contractor shall describe the efforts it undertook to prevent use or submission of covered telecommunications equipment or services, and any additional efforts that will be incorporated to prevent future use or submission of covered telecommunications equipment or services.

e. Subcontracts. The Contractor shall insert the substance of this clause, including this paragraph (e), in all subcontracts and other contractual instruments, including subcontracts for the acquisition of commercial items.

(End of clause)

3. FAR Clause 52.244-6, **Subcontracts for Commercial Items.** (AUG 2019)

a. Definitions. As used in this clause-

"Commercial item and commercially available off- the- shelf item" have the meanings contained Federal Acquisition Regulation 2.101, Definitions.

"Subcontract" includes a transfer of commercial items between divisions, subsidiaries, or affiliates of the Contractor or subcontractor at any tier.

b.To the maximum extent practicable, the Contractor shall incorporate, and require its subcontractors at all tiers to incorporate, commercial items or nondevelopmental items as components of items to be supplied under this contract.

c. (1) The Contractor shall insert the following clauses in subcontracts for commercial items:

   i. 52.203-13, Contractor Code of Business Ethics and Conduct (Oct 2015) (41 U.S.C. 3509), if the subcontract exceeds $5.5 million and has a performance period of more than 120 days. In altering this clause to identify the appropriate parties, all disclosures of

violation of the civil False Claims Act or of Federal criminal law shall be directed to the agency Office of the Inspector General, with a copy to the Contracting Officer.

ii. 52.203-15, Whistleblower Protections Under the American Recovery and Reinvestment Act of 2009 (Jun 2010) (Section 1553 of Pub. L. 111- 5), if the subcontract is funded under the Recovery Act.

iii. 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017).

iv. 52.204-21, Basic Safeguarding of Covered Contractor Information Systems (JUN 2016) other than subcontracts for commercially available off-the-shelf items, if flow down is required in accordance with paragraph (c) of FAR clause 52.204-21.

v. 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (JUL 2018) (Section 1634 of Pub. L. 115-91).

vi. 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG2019) (Section 889(a)(1)(A) of Pub. L. 115-232).

vii. 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)), if the subcontract offers further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds $700,000 ($1.5 million for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

viii. 52.222-21, Prohibition of Segregated Facilities (Apr 2015).

ix. 52.222-26, Equal Opportunity (Sep 2016) (E.O. 11246).

x. 52.222-35, Equal Opportunity for Veterans (Oct 2015) (38 U.S.C. 4212(a));

xi. 52.222-36, Equal Opportunity for Workers with Disabilities (Jul 2014) (29 U.S.C. 793).

xii. 52.222-37, Employments Reports on Veterans (Feb 2016) (38 U.S.C. 4212).

xiii. 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496), if flow down is required in accordance with paragraph (f) of FAR clause 52.222-40.

xiv. (A) 52.222-50, Combating Trafficking in Persons (Jan 2019) (2 2 U.S.C. chapter 78 and E.O. 13627). (B) Alternate I (Mar 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).

xv. 52.222-55, Minimum Wages under Executive Order 13658 (Dec 2015), if flowdown is required in accordance with paragraph (k) of FAR clause 52.222-55.

xvi. 52.222-62, Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706), if flow down is required in accordance with paragraph (m) of FAR clause 52.222-62.

xvii. (A) 52.224-3, PrivacyTraining (JAN 2017)(5 U.S.C. 552a) if flow down is required in accordance with 52.224-3(f) (B) Alternate I (JAN 2017) of 52.224-3, if flow down is required in accordance with 52.224-3(f) and the agency specifies that only its agency- provided training is acceptable.

xviii. 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).

xix. 52.232-40, Providing Accelerated Payments to Small Business Subcontractors (Dec 2013), if flow down is required in accordance with paragraph (c) of FAR clause 52.232-40.

xx. 52.247-64 clause FAR of) d (paragraph with accordance in required is down flow if), 2631. U.S.C 10 and 1241. App. U.S.C 46) (2006 Feb (Vessels Commercial Flag.- U.S Owned Privately for Preference, 52.247-64

(2) While not required, the Contractor may flow down to subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

d. The Contractor shall include the terms of this clause, including this paragraph (d), in subcontracts awarded under this contract.

(End of Clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Statement of Work

Statement of Work, dated August 28, 2019, 5 pages.

2. Invoice Instructions for NIH Fixed-Price Contracts, NIH(RC)-2

Invoice Instructions for NIH Fixed-Price Contracts, NIH(RC)-2, (8/12), 3 pages.

3. Safety and Health

Safety and Health, HHSAR Clause 352.223-70, (12/15), 2 pages.

4. Disclosure of Lobbying Activities, SF-LLL

Disclosure of Lobbying Activities, SF-LLL, dated 7/97, 2 pages.

5.NIH Small Business Innovative Research (SBIR) Program Funding Agreement Certification

NIH Small Business Innovative Research (SBIR) Program Funding Agreement Certification, 3 pages, located at: http://grants.nih.gov/grants/funding/sbir_forms/SBIR%20Funding%20Agreement%20Certification.pdf.

6. NIH Small Business Innovation Research (SBIR) Program Life Cycle Certification

NIH Small Business Innovative Research (SBIR) Program Life Cycle Certification, 3 pages, located at: http://grants.nih.gov/grants/funding/sbir_forms/SBIR%20Life%20Cycle%20Certification.pdf.

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS AND CERTIFICATIONS

The following documents are incorporated by reference in this contract:

1. FAR Clause 52.204-19 **Incorporation by Reference of Representations and Certifications** (December 2014).

   The Contractor's representations and certifications, including those completed electronically via the System for Award Management (SAM), are incorporated by reference into the contract.

   (End of clause)

2. NIH Representations & Certifications, dated 11/21/2018

3. Animal Welfare Assurance Number A8611-03.

END of the SCHEDULE

(CONTRACT)

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, Timothy C. Rodell, MD 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 1, 2019

/s/ TIMOTHY C. RODELL, MD
TIMOTHY RODELL
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 1, 2019

/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, 2019 as filed with the Securities and Exchange Commission on the date hereof, I, Timothy C. Rodell, MD, 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 1, 2019

/s/ TIMOTHY C. RODELL, MD
Timothy C. Rodell, MD
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, 2019 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 1, 2019

/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.