Zacks Small-Cap Research

November 24, 2015

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Aethlon Medical (AEMD-NASDAQ)

AEMD: 5 Objectives Hit, New ADAPT Program To Broaden Applications

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	11/11/2014
Current Price (11/24/15)	$7.50
Target Price	**$18.00**

OUTLOOK

AEMD's novel blood filtration device could have utility in the treatment of Hepatitis-C, HIV, sepsis, cancer, pandemic diseases and bioterror applications.
AEMD recently got FDA and IRB approvals to run a human study in HCV which is a major milestone. Enrollment commenced.
DARPA contracts have provided revenue/cash while also providing credibility of the technology and potentially facilitating the quest towards regulatory approval and commercialization.
Mgmt has been very resilient and successful in pursuing high potential opportunities in other areas including Ebola, cancer, Alzheimer's and CTE. First Ebola patient treated with Hemopurifier has recovered, manuscript published. Clinical study in Ebola, other Category A threats could be next. New Aethlon ADAPT initiative could broaden scope of utility for their technology to other diseases.
Maintaining Buy recommendation.

SUMMARY DATA

52-Week High	**$31.50**
52-Week Low	**$6.00**
One-Year Return (%)	**-67.29**
Beta	**2.47**
Average Daily Volume (sh)	**97,587**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$57**
Short Interest Ratio (days)	**1.71**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**16**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-14.7**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med-Hmo**

ZACKS ESTIMATES

Revenue
(in '000 of $)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2014	0.2 A	0.6 A	0.1 A	0.7 A	1.6 A
2015	0.1 A	0.5 A	0.0 A	0.2 A	0.8 A
2016	0.2 A	0.2 A	0.3 E	0.3 E	1.0 E
2017					0.4 E

Earnings per Share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2014	-$0.09 A	-$0.89 A	-$0.56 A	-$1.74 A	-$3.44 A
2015	-$0.80 A	-$0.16 A	-$0.26 A	-$0.13 A	-$1.22 A
2016	-$0.18 A	-$0.16 A	-$0.17 E	-$0.19 E	-$0.70 E
2017					-$0.69 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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Fiscal Q2 2016 Financials, Operational Update
Aethlon reported financial results for their fiscal second quarter 2016 and provided an operational update. Results continue to come in very much inline with our estimates including revenue (a hair lower), OpEx (on the nose) and net income/EPS (inline). On the call management summarized their operational progress, which included meeting all of their five objectives that they outlined on their fiscal Q1 conference call held in August.

In addition to these objectives AEMD has made progress on other fronts, including realizing a breakthrough that should dramatically reduce the production cost of the key affinity agent used in Hemopurifier. And the company now has other new irons in the fire, including what they are calling Aethlon ADAPT which will focus on broadening the applications for their affinity biofiltration technology in other diseases through partnerships.

Q2 revenue was $188k, consisting of $186k of DARPA grants and $2k from the Battelle subcontract, compared to our $201k estimate which consisted of $200k in DARPA revenue and $1k from Battelle. The DARPA revenue relates to the 26th milestone – see our Appendix for the description. In late September AEMD announced that they were awarded year 5 of the DARPA contract which is the final year and will pay up to $581k if all the requisite milestones are met. On the call management noted that they are in process of preparing to bill for the next DARPA milestone of $297k.

Q2 OpEx was $1.3M, inline with our $1.3M estimate. We continue to expect operating expenses to trend higher as a result of increased clinical trial activities related to the U.S. HCV and cancer studies as well as some incremental hiring to support other areas of the business. Net loss and EPS were $1.2M and ($0.16), compared to our $1.3M and ($0.17) estimates. AEMD exited the quarter with $4.2M in cash, down from $5.7M at the end of Q1. Management expects the cash balance to be sufficient to fund for fiscal 2016 (ending 3/31/2016).

Operational Update: *Meets All 5 Objectives, Aethlon ADAPT, Additional Progress…*

On the fiscal first quarter conference call in August management laid out five specific objectives that they planned to accomplish over the following months. They successfully did so and went through each one on the Q2 call, which we have provided an update to below. But in addition to meeting these goals the company also made parallel progress in not only further shoring up their operational capabilities in preparation for increased activities related to both the HCV and cancer applications but also made strides in broadening the scope of potential applications where their technology might be applied.

A recap and update to the five objectives that the company laid out on the Q1 call in August….

- Collect an additional ~$200k under the DAPRA contract which relates to year 4. Hope to be granted year 5 of the contract (which was subsequently awarded). Accomplished with $186k collected in Q2 and DARPA year 5 awarded in September.
- Submission of manuscript of the DETECT (Diagnosing and Evaluating Traumatic Encephalopathy Using Clinical Tests) study. As a reminder, since late last calendar year Aethlon's majority-owned subsidiary Exosome Sciences (ESI) has collaborated with Boston University's CTE Center for the development of a blood-based diagnostic that would be able to identify CTE in living individuals. ESI has used what they learned in how to isolate certain brain-specific biomarkers to evaluate blood samples collected by participants (former NFL players and a control group) enrolled in BU's DETECT study. The study is the first on CTE funded by the NIH. Aethlon submitted the manuscript subsequent to the Q1 call. Management noted on the Q2 call that they think it could be published within the next ~60 days. As an aside, the night before AEMD's earnings call there was a timely 60 Minutes story about BU's CTE study and the blood-based diagnostic that AEMD's Exosome Sciences is helping lead the development of.
- Accelerate cancer study with University of California, Irvine. As a reminder, in mid-April AMED announced that they entered an agreement with UC, Irvine to conduct an investigator-initiated study with various cancer types including breast, colorectal lung, head and neck and others. Targeted enrollment is five patients in each of nine cancer types (45 patients total) including breast adenocarcinoma, colorectal, gastric and gastroesophageal, pancreatic, cholangiocarcinoma, lung, head and neck, melanoma and ovarian adenocarcinoma. The proposed study protocol, *Plasma Exosome Concentration in Cancer Patients Undergoing Treatment"*, will monitor changes in circulating exosome levels and their association with cancer treatment and response to treatment. In May AEMD announced that UC, Irvine Medical Center approved an IRB to commence the study. AEMD noted on the Q2 call that this study has commenced and has now enrolled three patients so far.

- Advance additional collaborations for Hemopurifier in cancer and infectious diseases. As a reminder, Hemopurifier has shown potential utility in HCV, HIV, Ebola, other pandemic diseases, bioterror applications, cancer and other areas. AEMD is clearly focused on deepening and broadening the potential applications that their device may have utility for. In June the company announced an agreement with the India's National Institute of Virology to commence testing of Hemopurifier for treatment of Chikungunya. Management also noted on the Q2 call that they have initiated a research project with the National Center for Biodefense and Infectious Diseases to investigate the use of Hemopurifier in Venezuelan equine encephalitis. AEMD has had a relationship with the National Center for Biodefense and Infectious Diseases for over ten years and this latest announcement appears to be further progress towards working with the center for applications of AEMD's technology in addressing biological threats.
- Initiate the U.S. HCV feasibility study and transition Dr. Stephen Fadem from principal investigator of the study to a medical advisory role within the company. Subsequent to the Q1 call that transition was made and Dr. Ronal Ralph was brought on as the new principal investigator. AEMD expects to hire two sub-principal investigators to help further accelerate the trial schedule. And while progression of the study has been drawn out longer than initially anticipated, AEMD noted on the Q2 call that they expect to have the new study team trained after Thanksgiving and begin new patient enrollment in January.

Aethlon ADAPT

In early November the company announced a new initiative at the IN3 Medical Device 360 Summit Conference in San Francisco called Aethlon ADAPT. ADAPT, is an acronym for the company's technology and stands for Adaptive Dialysis-like Affinity Platform Technology. The Aethlon ADAPT initiative is focused on partnering with organizations in development of other affinity bio-filtration devices to address other diseases, which is a program that will run parallel to AEMD's individual efforts. We view this as a way to de-risk (at least from a financial standpoint) and, potentially accelerate, development of their technology in a broader spectrum of diseases and applications.

AEMD Picks Up Operational Momentum in FY2016

Fiscal 2015 saw several highlights with progress of both the Hemopurifier program as well as with ESI. In addition, management made tremendous progress with shoring up the balance sheet, eliminating almost all debt. AEMD built on their operational momentum over the last several months including a Nasdaq uplisting, $6 million equity raise and further progress with expanding the potential indications for Hemopurifier. AEMD began trading on Nasdaq in mid-July which followed a 1 for 50 reverse split. This should provide for greater investor visibility and, with the stock trading over $5, provide greater access to institutional investors.

The $6 million ($5.6M net) raise was done at $6.30/share and came with 75% warrant coverage ($6.30 strike, five years). As we mentioned in our June 24 investor note, this raise continues to confirm the company's ability to bring on additional capital at reasonable terms and without compromising the balance sheet - which had been an issue in the past. It also should provide a substantial runway for the company to further its development programs. The shares continue to trade higher than the offering price.

AEMD has also been very aggressive in looking for potential new indications for Hemopurifier. As a reminder, HCV had been the only real main focus for the company just a couple of years ago. Since then they have ramped up activities in several other areas, most notably cancer and Ebola, and at the same time made significant progress on the HCV indication. Clinical studies in all of these areas have already been planned, the U.S. HCV study is finally starting to gain traction and the cancer study now has three patients enrolled. Studies in other indications could start in the near-term. And the new Aethlon ADAPT initiative, which is focused on partnering for development of other affinity bio-filtration devices to address other diseases could accelerate broadening the applications for the technology while at the same time de-risking cost of development through partnerships.

In early June management announced an agreement with the National Institute of Virology to commence testing of Hemopurifier for treatment of Chikungunya. Chikungunya is a virus passed from mosquitoes with recent outbreaks in the Americas, Europe and Asia. Records indicate that people in at least 44 countries have had exposure to Chikungunya. Symptoms include fever, sometimes severe, and joint pain which can last from weeks to years. During one outbreak in 2006 over 50% of those infected reported long-term joint pain. As there is no currently known treatment for the virus, Hemopurifier, if deemed effective and safe, could be the eventual standard of care. We expect to hear more about this collaboration and planned studies in the near future.

Operational Update:

U.S. HCV Study: Commencement of the U.S. HCV study, while delayed from initial expectations, finally kicked off with the first patient completing treatment in late February. Subsequent to that AEMD announced that the second and third patient. However, the study all but stalled until recently as a new principal investigator was sought. A new principal investigator has now been brought on and two sub-principal investigators are expected to be hired in the near-term to help to accelerate timelines. AEMD noted on the Q2 call that they expect to have the new study team trained after Thanksgiving and begin new patient enrollment in January.

As a reminder, this is a safety study being conducted at DaVita Medical Center Dialysis in Houston with target enrollment of 10 HCV-infected patients who are already undergoing dialysis. Patients will receive Hemopurifier treatment three times per week for two weeks. This is primarily a safety study but secondary outcomes including quantity of captured viral copies and change in viral load will also be measured. Per the study protocol on clinicaltrials.gov, estimated completion date is December 2015 – although due to delays in getting the study moving, that timeline will not be met and we expect the trial to complete sometime in calendar 2016. Results which were initially expected to be used solely for support of FDA approval to conduct larger pivotal studies in HCV as well as potentially other diseases such as HIV and cancer, may now also include pursuit of clinical studies for other viruses, including Ebola and other category A threats.

Ebola: As we have discussed in recent updates, AEMD appears to be getting closer to realizing Ebola as a viable opportunity for Hemopurifier. As a reminder, in mid-October 2014 AEMD announced that Hemopurifier was being used on an Ebola patient for the first time. Introduction of Hemopurifier was made possible by a special approval from the German Federal Institute for Drugs and Medical Devices. The patient, a Ugandan doctor who contracted the virus in Sierra Leone, was treated at Frankfurt Hospital in Germany. About three weeks later the company announced that the hospital reported that the patient had undetectable levels of Ebola. He was subsequently released from the hospital.

The Chief of Nephrology at the hospital where the patient was treated presented the treatment findings at the American Society of Nephrology (ASN) Annual Meeting on November 14th 2014 during a special session on Ebola. Hemopurifier captured 242 million copies of Ebola. Hemopurifier was introduced 13 days after the patient was diagnosed with Ebola. Prior to Hemopurifier administration, the patient had multiple organ failure, was unconscious and had a viral load of 400k virus copies/ml. Following a 6.5 hour treatment with Hemopurifier viral load was 1k virus copies/ml.

The experience was documented in a manuscript published in the journal Blood Purification in February. The article, titled *Extracorporeal Virus Elimination for the Treatment of Severe Ebola Virus Disease – First Experience with Lectin Affinity Plasmepheris*, was written by the physician that administered the therapy and his colleagues.

Among the highlights, the article notes;

- "Notwithstanding scientific efforts and anecdotal reports of successful interventions, no EBOV [Ebola virus]-specific therapy has proved to be efficient to this point." "An entirely new approach is the extracorporeal elimination of viruses and viral GP [glycoproteins] by lectin affinity plasmapheresis ((LAP)."
- reported "for the first time the successful and safe use of lectin affinity plasmapheresis in a patient with severe Ebola virus disease (EVD)"
- there were no adverse events and Hemopurifier treatment was well tolerated
- viral load just prior to Hemopurifier therapy was 3.78×10^5 and fell to 6.08×10^3 the following day. This represents a 62 times reduction in viral load
- 253 million copies of Ebola virus were captured by Hemopurifier (slightly more than initially calculated)
- Viral load was undetectable and the patient fully recovered six days after Hemopurfier treatment
- the authors note that by reducing the number of circulating viruses via plasmapheresis, the body's natural immune response is freed up to attack and eliminate the remaining virus
- "The data contained in this case study represents a 'proof of concept' for extracorporeal virus removal in EVD." "We consider that LAP is a new option to expand best supportive care toward a virus-targeted therapy for EVD."
- the authors acknowledge that while this case provided definitive evidence that Hemopurifier is able to capture significant Ebola virus copies, that it is not possible to conclude that Hemopurifier treatment alone was the reason for recovery of the patient. However, they also note that this case "provides optimism that LAP is a promising new tool for the treatment of severe Ebola virus infection, and warrants further evaluation as well as technical development."

U.S. HUD Ebola Submission: shortly following the positive outcomes of the first Ebola patient treated with Hemopurifier AEMD filed a Humanitarian Use Device (HUD) submission with the FDA. The April 9th submission seeks eventual designation by FDA for use of Hemopurifier in the treatment of individuals with Ebola in the U.S. The next step, assuming FDA designates Hemopurifier HUD status, will be for AEMD to submit an application seeking Humanitarian Device Exemption.

U.S. Ebola Study: While HDE approval does not typically require the applicant to demonstrate effectiveness through clinical trials, AEMD may pursue a multi-site (up to) 20-patient investigational Ebola study that FDA approved the protocol for in January. Hemopurifier therapy will be administered daily for six to eight hours until Ebola viral load falls below 1k copies/ml. Timetables for commencement of this study have not been offered. And enrollment will likely be a challenge given the dearth of Ebola-infected individuals, particularly those that are treated in the U.S. Despite this, we view the protocol approval, positive outcomes of the first Ebola patient treated with Hemopurifier and the recent HDE submission as very positive steps.

Ebola Canadian Study: More recently, in May 2015, Health Canada approved an Ebola study protocol titled, *The Treatment of Ebola Virus Disease in Humans with the Aethlon Hemopurifier Lectin Affinity Plasmapheresis Device*. The protocol would include up to three patients. Similar to the U.S. study protocol, there are also no timelines for commencement of a study in Canada and recruitment will likely also be challenging, albeit this Canadian study would only enroll up to three patients.

Progress towards CTE, Cancer…

CTE: As a reminder, in March 2014 AEMD announced that ESI has been investigating certain brain-specific biomarkers and whether they can be identified in circulating exosomes. ESI has isolated the brain-specific biomarkers tau, beta-amyloid, glycoprotein A2B5 and S100B in the circulatory system - previously only identified in cerebrospinal fluid. These biomarkers have been shown to be associated with Alzheimer's Disease (beta-amyloid), Chronic Traumatic Encephalopathy (tau) and traumatic brain injury. There is currently no cure for these disorders and identifying their presence is often not possibly until either well into their progression or, in the case of Chronic Traumatic Encephalopathy (CTE), until an autopsy is done. CTE has received significant mainstream media attention of late as it been associated with head injuries of NFL players and been implicated as a cause for severe depression and some resultant suicides.

Then in late September 2014 AEMD announced that they and ESI entered into a collaboration with Boston University's CTE Center in development of a blood-based diagnostic that would be able to identify CTE in living individuals. Development of an accurate test for CTE in living individuals would be a breakthrough for diagnosing the condition and could lead to improvement in care. Noteworthy is that in November 60 Minutes did a story about BU's CTE study and the blood-based diagnostic that AEMD's Exosome Sciences is helping lead the development of.

ESI is using what they learned in how to isolate certain brain-specific biomarkers to evaluate blood samples collected by participants (former NFL players and a control group) enrolled in BU's DETECT (Diagnosing and Evaluating Traumatic Encephalopathy Using Clinical Tests) study. The study is the first on CTE funded by the NIH.

In mid-April investigators presented initial findings of DETECT at the annual Traumatic Brain Injury Conference held in Washington, DC. Results were from 78 former NFL players and 16 controls and showed that the NFL players had significantly higher levels of tausome (tau) in their blood than those of the controls. Tau levels were also correlated to performance on memory tests, with higher tau levels corresponding to poorer test performance. Aethlon recently submitted a manuscript of the results for publication - which management noted they believe could be published by the mid-January 2016 timeframe.

Hemopurifier in Cancer: As we have noted in recent updates, based on preliminary research, Hemopurifier may have utility in the treatment of cancer. A potential application in cancer received arguably additional support in an article titled, "Extracellular Vesicles: Emerging Target for Cancer Therapy" published in the April 2014 issue of the journal, *Trends in Molecular Medicine*. The article, written by researchers at Harvard Medical School, Massachusetts General Hospital and University of Oxford explores evidence that extracellular vesicles (i.e. - exosomes) play a key role in cancer development and progression and suppression of immune response. As such, extracellular vesicles (EVs) have increasingly become targets for anticancer therapy. This coincides with AEMD's cancer research and how Hemopurifier, via the removal of circulating cancer-secreted exosomes, could have utility in the treatment of cancer.

The authors also believe that EVs may also increase the body's resistance to cancer drugs and hinder their effectiveness. They further note that, while early evidence suggests that inhibition of EV biogenesis may have beneficial effects in the treatment of cancer, that a challenge has been to find therapies that can specifically target cancer related EVs without affecting normal cell function. The researchers specifically reference Hemopurifier as a potential therapy to overcome these challenges, noting that with the use of Hemopurifier "it might be possible to specifically capture tumour cell-derived EVs on an antibody-coated matrix during extracorporeal dialysis. For example, in human epidermal growth factor receptor-2 (HER-2) overexpressing breast cancer, where HER-2-expressing EVs have been shown to interfere with therapy and are associated with tumour aggressiveness, anti-HER-2 antibodies could be used to remove HER-2-expressing EVs from circulation with the aim of improving therapeutic outcome. In principal, this approach could be tailored for other tumour types, as long as the tumour cell-derived EVs are enriched for tumour-specific proteins. However, whether the level and duration of EV depletion after ADAPT (i.e. - Hemopurifier) therapy would be sufficient to achieve a clinically relevant outcome remains to be determined."

The authors note that their current understanding of EVs role in cancer development and progression is still in the relatively early stages and is based on data from in vitro experiments. Their acknowledgement of Hemopurifier as potentially having utility in the treatment of cancer is also largely based on the supposition that removal of circulating EVs may be beneficial in interrupting the development and spread of tumors - which is still just a theory at this point. Nonetheless, we think this research does add meaningful credibility to Hemopurifier's potential role in cancer suppression and adds additional support to AEMD's research which indicates the same.

As we had previously noted, we had anticipated that cancer-related studies might be on the horizon. This recently became more of a reality when in mid-April AMED announced that they entered an agreement with the University of California, Irvine to conduct an investigator-initiated study with various cancer types including breast, colorectal lung, head and neck and others. Targeted enrollment will be five patients in each of nine cancer types (45 patients total) including breast adenocarcinoma, colorectal, gastric and gastroesophageal, pancreatic, cholangiocarcinoma, lung, head and neck, melanoma and ovarian adenocarcinoma. The proposed study protocol, *Plasma Exosome Concentration in Cancer Patients Undergoing Treatment"*, will monitor changes in circulating exosome levels and their association with cancer treatment and response to treatment. In May AEMD announced that UC, Irvine Medical Center approved an IRB to commence the study. Then in November AEMD noted that this study has commenced and has now enrolled three patients so far.

Exosome Sciences and Cancer: ESI was formed to be not only a supplement to AEMD's Hemopurifier business but also as a complement to it. Much of ESI's research has focused on diagnostics that could be developed to identify conditions where Hemopurifier treatment may be appropriate. One of those areas, as discussed above is CTE (as well as other brain-specific applications), another is cancer.

ESI recently made its first major foray into advancing its cancer research with the early April announcement of a research collaboration with Thomas Jefferson University (Philadelphia). While few details were provided, the duo will work to develop a "liquid biopsy" to better diagnose and monitor cancers of the head and neck. The research will focus on the role of exosomes and how they may act as a marker to help predict response to therapy, which is a similar endpoint in the recently proposed UC, Irvine investigator-initiated study.

Maintaining Outperform Recommendation

The company continues to make substantive positive progress on several fronts including strengthening the balance sheet and ongoing ability to raise capital, diligence on cash burn and operating expenses, initiating the U.S. studies in HCV and cancer, scoring additional government grants and broadening into what we believe are more commercializable and attractive markets for Hemopurifier.

We note our model still does not incorporate potential revenue contribution from indications outside of HCV, DARPA or Battelle - although with the recent substantive expansion into other indications such as Ebola, cancer and others (including via the Aethlon ADAPT program) as well as directly from ESI, our model is subject to updating based on successful further progress.

Aethlon affected a 1 for 50 reverse stock in mid-April. Current market discount rate, calculated by CAPM is approximately 9%. Based on our DCF model and a 9% discount rate, AEMD is valued at approximately $18/share. We are maintaining our Buy rating.

APPENDIX

Milestones Related to DARPA Year-1 Contract

Milestone 2.2.1.1 – Write requirements definition for the extracorporeal blood purification system and acquire necessary equipment with a milestone payment of $358,284. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We worked on this concept for a number of months beginning with a presentation to DARPA in late 2010. We subsequently filed for IP protection on certain of the key concepts in March 2011 and our management visited selected potential vendors to work out many of the details in the summer of 2011 before we were awarded the contract on September 30, 2011. We ordered the breadboard device from one of our vendors before the milestone payment was made. We designed the breadboard prototype and then presented the design to DARPA in order to achieve the milestone.

Milestone 2.2.1.2 -- Fabricate breadboard prototypes for anticoagulation-free anti-sepsis extracorporeal system (ASEPSYS) device. Fabricate prototype blood tubing sets. Acquire anti-thrombogenic surface modified hollow fiber plasma separators with a milestone payment $183,367. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. The consideration for this milestone covers the cost of having the breadboard prototype developed to our specifications, hiring an engineer to supervise the project, acquiring specially coated cartridges and associated overhead. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter.

Milestone 2.2.2.1 – Begin to develop the ADAPT device to efficiently capture sepsis precursors and acquire important equipment and supplies with a milestone payment of $426,424. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. It was critically important to obtain certain pieces of lab equipment as early as possible after winning the contract in order to measure the binding ability of sepsis precursors. We demonstrated that we were able to capture one of the identified possible sepsis precursors as part of our submission for approval. The consideration was also designed to cover the salaries of new and existing scientists, lab space, materials as well as fringe and corporate overhead.

Milestone 2.2.2.2 - Perform initial screening of the different proposed capture agents by measuring binding affinity and kinetics using surface plasmon resonance (SPR) or biolayer surface interferometry (BLI) with a milestone payment amount of $216,747. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We demonstrated that we were able to capture several of the identified possible sepsis precursors as part of our submission for approval. The consideration was also designed to cover the salaries of new and existing scientists, lab space, materials as well as fringe and corporate overhead. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter. DARPA made the milestone payment in full.

Milestone 2.2.1.3 - Assemble and test breadboard ASEPSYS devices. Evaluate the use of different techniques and approaches to eliminating anticoagulants. The milestone payment amount was $183,367. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. The consideration for this milestone covers the cost of assembling and testing the breadboard prototype that we had developed to our specifications, hiring an engineer to supervise the project, testing specially coated cartridges and associated overhead. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter. DARPA made the milestone payment in full.

Milestone 2.2.2.3 - Perform preliminary quantitative real time PCR to measure viral load, and specific DNA or RNA targets. The milestone payment was $216,747. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We demonstrated that we were able to measure viral load of one or more targets as part of our submission for approval. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter.

Milestone 2.2.1.4 - Obtain all necessary IRB documentation and obtain both institutional and Government approval in accordance with IRB documentation submission guidance prior to conducting human or animal testing. The milestone payment was $183,367. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We obtained all of the required documentation from both institutional and Government authorities. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter.

Milestone M2 – Target capture > 50% in 24 hours for at least one target in blood or blood components. The milestone payment was $216,747. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We demonstrated that we were able to capture > 50% in 24 hours of one of the agreed targets in

blood or blood components. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter.

Milestones Related to DARPA Year-2 Contract

Milestone 2.3.3.1 – Build the ADAPT capture cartridges with the identified affinity agents. Measure the rate of capture of the specific targets from in ex vivo recirculation experiments from cell culture and blood. The milestone payment was $208,781. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We demonstrated that we were able build the ADAPT capture cartridges with the identified affinity agents and to measure the rate of capture of the specific targets from in ex vivo recirculation experiments from cell culture and blood. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter.

Milestone 2.3.2.1 – Demonstrate the effectiveness of the prototype device in vivo in animals preventing platelet activation or clotting in at least a 2 hour blood pumping experiment at 75 mL/min blood flow. The milestone payment amount was $195,581. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. The prototype device was successfully used in vivo in animals preventing platelet activation or clotting in at least a 2 hour blood pumping experiment at 75 mL/min blood flow. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter.

Milestone M4 – Target capture > 50% in 24 hours for at least 5 targets in blood or blood components. The milestone payment was $208,781. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We demonstrated that we were able to capture > 50% in 24 hours for at least 5 of the agreed targets in blood or blood components. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter.

Milestone 2.3.2.2 – Formulate initial design based on work from previous phase. Begin to build and test selected instrument design and tubing sets. The milestone payment amount was $195,581. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We demonstrated that we had begun to build and test selected instrument design and tubing sets. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter.

Milestone 2.3.2.2 – Write and test software and conduct ergonomic research. Begin discussions with the systems integrator. The milestone payment was $195,581. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We obtained wrote and tested software and conducted ergonomic research and began discussions with the systems integrator. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter.

Milestone 2.3.3.2 – Cartridge construction with optimized affinity matrix design for each potential target. Complete the capture agent screening. The milestone payment was $208,781. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We completed the cartridge construction with optimized affinity matrix design for each potential target and completed the capture agent screening. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter.

Milestone M5 – Target capture > 90% in 24 hours for at least three targets in blood or blood components. The milestone payment was $208,781. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We demonstrated that we were able to capture > 90% in 24 hours for at least three of the agreed targets in blood or blood components. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter.

Milestone M3 – Conduct a series of experiments aimed at characterizing the contribution of several alternate fluidic designs and methods of perfusing plasma filters and affinity columns in the performance of affinity plasmapheresis. The milestone payment was $195,576. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We demonstrated that we had conducted the relevant series of experiments. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter.

Milestones Related to DARPA Year-3 Contract

Milestone 2.4.2.1 – Evaluate contribution of manufacturing process variables to binding capacity of affinity resin. The milestone payment was $197,362. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We demonstrated that we had evaluated the contribution of manufacturing process variables to binding capacity of affinity resin. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter.

Milestone 2.4.1.1 – Design and fabricate optimized configuration(s) of hemopurification device(s) that contain(s) a combination of hemofilters, plasma filters and affinity columns. The milestone payment was $186,164. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We demonstrated that we had designed and fabricated optimized configuration of hemopurification devices. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter.

Milestone 2.4.2.3 – Perform biocompatibility tests for the combination ADAPT device to confirm the combination cartridge does not present additional risk. The milestone payment was $78,641. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We demonstrated that we had performed biocompatibility tests for the combination ADAPT device to confirm the combination cartridge does not present additional risk. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter.

Milestone 2.4.2.2 – Determine capacity requirements of affinity resin to multiple simultaneous targets. The milestone payment was $197,362. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We demonstrated that we were able to determine the capacity requirements of affinity resin to multiple simultaneous targets. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter.

Milestone 2.4.2.4 – Finish construction and delivery of 25 experimental cartridges for testing by the system integrator. The milestone payment was $50,000. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We demonstrated that we delivered the 25 cartridges to the systems integrator as part of our submission for approval. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter.

Milestone M9 – Target capture > 90% in 24 hours for at least 3 targets ex vivo in blood or blood components using the optimized cartridge. The milestone payment was $197,361. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We demonstrated that we were able to capture approximately 90% in 24 hours for at least 3f targets ex vivo in blood or blood components using the optimized cartridge. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter.

Milestones Related to DARPA Year-4 Contract

Milestone M11 - Develop a strategic plan for developing an alternate method of producing galanthus nivalis agglutinin by cloning the gene into an alternate vector and identify potential partners for such production. The milestone payment was $186,164. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We demonstrated that we developed a strategic plan for developing an alternate method of producing GNA by cloning the gene into an alternate vector and identified potential partners for such production. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter.

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

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

PROJECTED INCOME STATMENT

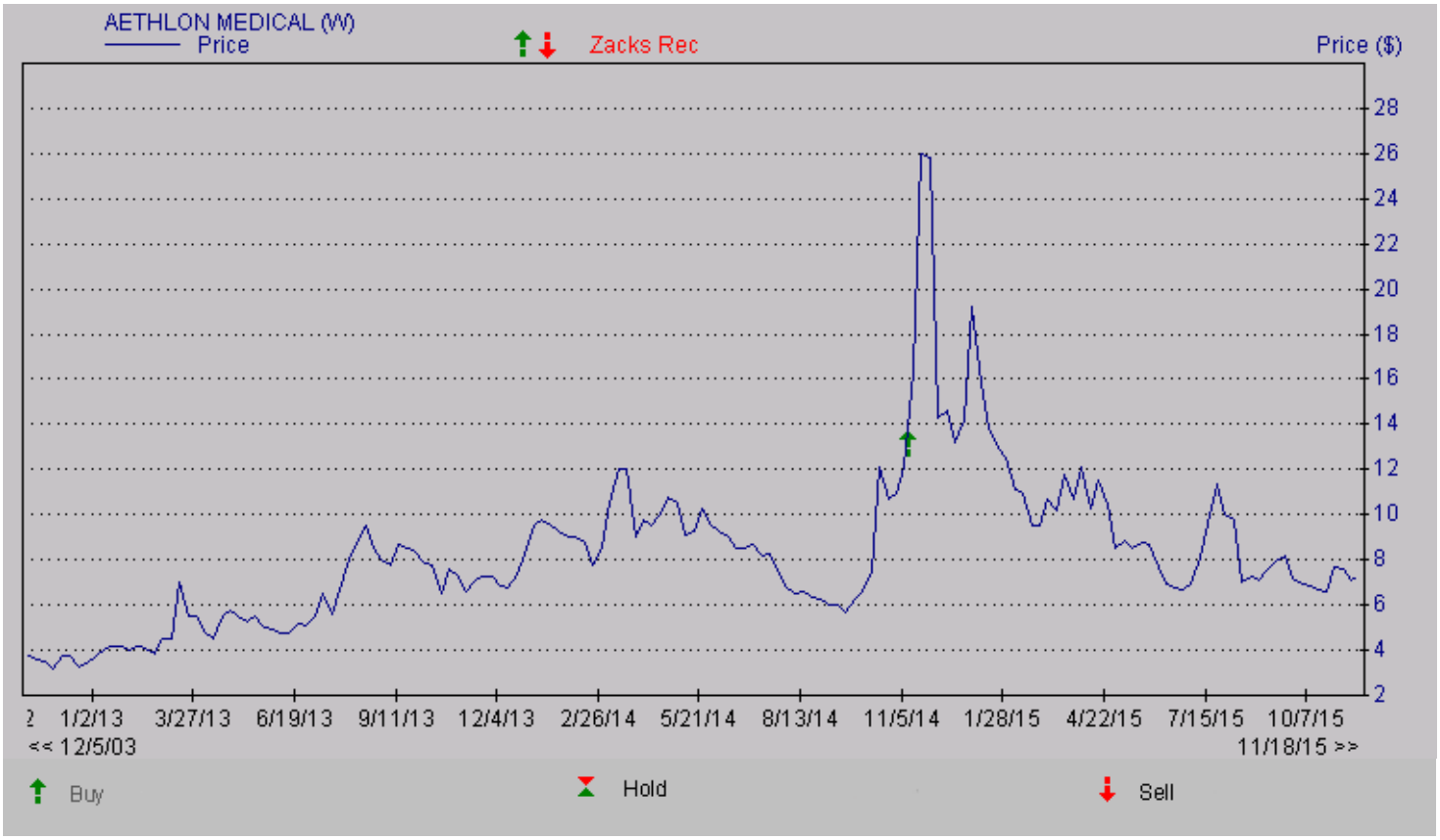
Aethlon Medical, Inc.

	2013 A	2014 A	Q1 A	Q2 A	Q3 A	Q4 A	2015 A	Q1 A	Q2 A	Q3 E	Q4 E	2016 E	2017 E
Revenue	$1,230.0	$1,623.8	$51.3	$479.1	$33.4	$198.6	$762.4	$192.5	$188.4	$332.0	$303.0	$1,015.9	$433.0
YOY Growth	*-9.5%*	*32.0%*	*-73.8%*	*-25.7%*	*-56.2%*	*-71.9%*	*-53.0%*	*275.3%*	*-60.7%*	*893.0%*	*52.6%*	*33.2%*	*-57.4%*
Cost of Goods Sold	$0.0	$0.0					$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Income	$1,230.0	$1,623.8	$51.3	$479.1	$33.4	$198.6	$762.4	$192.5	$188.4	$332.0	$303.0	$1,015.9	$433.0
Gross Margin	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*
SG&A	$3,365.4	$3,170.4	$876.3	$829.9	$906.2	$1,115.3	$3,727.7	$1,100.5	$1,105.1	$1,142.0	$1,221.0	$4,568.5	$4,688.0
%SG&A	*273.6%*	*195.2%*	*1708.3%*	*173.2%*	*2710.6%*	*561.5%*	*488.9%*	*571.7%*	*586.7%*	*344.0%*	*403.0%*	*449.7%*	*1082.7%*
R&D	$1,440.0	$1,509.0	$347.0	$250.4	$214.2	$216.0	$1,027.6	$182.0	$207.7	$362.0	$444.0	$1,195.7	$1,512.0
%R&D	*117.1%*	*92.9%*	*676.5%*	*52.3%*	*640.6%*	*108.8%*	*134.8%*	*94.5%*	*110.3%*	*109.0%*	*146.5%*	*117.7%*	*349.2%*
Impairment	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($3,575.4)	($3,055.6)	($1,172.0)	($601.2)	($1,087.0)	($1,132.7)	($3,992.8)	($1,090.0)	($1,124.4)	($1,172.0)	($1,362.0)	($4,748.3)	($5,767.0)
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	*-467.4%*	*-1331.9%*
Loss on extinguishment of debt	$139.8	$40.3	$2,453.6	$208.9	$222.9	($131.4)	$2,754.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
(Gain)/loss on derivative liability	$44.7	$8,547.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Interest (income), net	$1,107.1	$1,287.2	$78.7	$78.1	$148.7	$146.8	$452.3	$126.7	$127.2	$127.0	$127.0	$507.9	$212.0
Other expense	$25.0	$508.6	$0.0	($143.4)	$143.4	($219.6)	($219.6)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($4,892.0)	($13,438.6)	($3,704.3)	($744.8)	($1,602.0)	($928.4)	($6,979.5)	($1,216.7)	($1,251.6)	($1,299.0)	($1,489.0)	($5,256.3)	($5,979.0)
Taxes (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($4,892.0)	($13,356.9)	($3,655.9)	($704.0)	($1,550.5)	($886.8)	($6,797.2)	($1,183.0)	($1,224.6)	($1,299.0)	($1,489.0)	($5,195.6)	($5,979.0)
Net Margin	-	-	-	-	-	-	*-891.5%*	-	-	-	-	*-511.4%*	*-1380.8%*
EPS	($1.64)	($3.44)	($0.80)	($0.14)	($0.26)	($0.13)	($1.22)	($0.18)	($0.16)	($0.17)	($0.19)	($0.70)	($0.69)
YOY Growth	*1956.5%*	*110.0%*	*834.7%*	*-84.8%*	*-54.3%*	*-92.3%*	*-64.7%*	*-78.1%*				*-42.5%*	*-1.1%*
Diluted Shares O/S	2,984	3,881	4,542	5,187	6,032	6,616	5,594	6,720	7,610	7,614	7,820	7,441	8,655

Brian Marckx, CFA

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