Zacks Small-Cap Research

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# Aethlon Medical (AEMD-OTCBB)

## AEMD: Initiating With Neutral Rating

| | |
|---|---|
| **Current Recommendation** | **Neutral** |
| Prior Recommendation | N/A |
| Date of Last Change | 03/12/2012 |
| Current Price (03/12/12) | $0.09 |
| **Target Price** | **$0.09** |

## OUTLOOK

AEMD's novel blood filtration device could have utility in the treatment of Hepatitis-C, HIV, sepsis, cancer and bioterror applications. Preliminary data from key clinical trial for HCV in India was announced in February. AEMD hopes to use the trial data to support U.S. IDE application for approval to start U.S.-based studies. In Sept 2011 AEMD was awarded U.S. gov't contract related to development of a sepsis treatment device.
Cash / financial position needs attention, which along with a number of material unknowns pose risk.

We are initiating coverage of Aethlon with a Neutral rating.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$0.18** |
| **52-Week Low** | **$0.04** |
| **One-Year Return (%)** | **-41.62** |
| **Beta** | **-1.66** |
| **Average Daily Volume (sh)** | **556,097** |
| **Shares Outstanding (mil)** | **112** |
| **Market Capitalization ($mil)** | **$10** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **2** |
| **Insider Ownership (%)** | **N/A** |
| **Annual Cash Dividend** | **$0.00** |
| **Dividend Yield (%)** | **0.00** |
| **5-Yr. Historical Growth Rates** | |
| **Sales (%)** | **N/A** |
| **Earnings Per Share (%)** | **N/A** |
| **Dividend (%)** | **N/A** |
| **P/E using TTM EPS** | **N/A** |
| **P/E using 2012 Estimate** | **N/A** |
| **P/E using 2013 Estimate** | **N/A** |
| **Zacks Rank** | **N/A** |

| | |
|---|---|
| **Risk Level** | **High,** |
| **Type of Stock** | **N/A** |
| **Industry** | **Med-Hmo** |

## ZACKS ESTIMATES

**Revenue**
(in '000 of $)

| | Q1 (Jun) | Q2 (Sep) | Q3 (Dec) | Q4 (Mar) | Year (Mar) |
|---|---|---|---|---|---|
| 2011 | 0.0 A | 0.0 A | 0.0 A | 0.0 A | 0.0 A |
| 2012 | 0.0 A | 0.0 A | 1.0 A | 0.4 E | 1.4 E |
| 2013 | | | | | 1.3 E |
| 2014 | | | | | 1.3 E |

**Earnings per Share**

| | Q1 (Jun) | Q2 (Sep) | Q3 (Dec) | Q4 (Mar) | Year (Mar) |
|---|---|---|---|---|---|
| 2011 | -$0.05 A | -$0.04 A | -$0.03 A | $0.04 A | -$0.08 A |
| 2012 | -$0.03 A | -$0.00 A | -$0.01 A | -$0.01 E | -$0.05 E |
| 2013 | | | | | -$0.03 E |
| 2014 | | | | | -$0.03 E |

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

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## BUSINESS

Aethlon Medical Inc. (Aethlon) is a medical device company which is engaged in the development of an extracorporeal (i.e. - outside of the body) blood filtration device designed to selectively remove harmful particles from the circulatory system. Using the company's patent protected Adaptive Dialysis-Like Affinity Platform Technology (ADAPT), Aethlon's lead product, the Hemopurifier, is a cylindrical cartridge encased with hollow fibers and affinity (i.e. - binding antibodies) agents which is used in conjunction with existing blood circulatory equipment (such as dialysis and CRRT machines already located in hospitals and clinics) to aid the body's ability to fight disease by removing viruses and other injurious substances from the blood. The cleansed blood is then returned to the bloodstream. Targeted applications are in the treatment of Hepatitis-C (HCV), HIV, sepsis and cancer as well as for the suppression of bioterrorism agents.

Following encouraging results from a small study done in India with dialysis patients, in Q3 2010 Aethlon initiated a study protocol to demonstrate that the Hemopurifier can improve the benefit of standard of care drug therapy in genotype 1 HCV patients. Issues, including problems with patient enrollment, caused delays but after tweaking the trial design based on feedback from the FDA (which may help support an eventual application to initiate U.S.-based trials), this second India-based study has been restarted and is currently ongoing. Aethlon announced preliminary data from three patients in February 2012. The company hopes to use data from the studies to support a soft launch in India as well as to supplement their Investigational Device Exemption application, which is already on file with the FDA. If granted, the IDE will allow Aethlon to begin U.S. (in vivo) clinical studies for HCV and possibly other targeted conditions such as HIV. While HCV is the initial therapeutic focus, Aethlon was given institutional review board approval in December 2011 to begin a small (ex vivo) cancer-related study at the (Santa Monica, CA) Sarcoma Oncology Center.

In October 2011 Aethlon announced that the U.S. government's Defense Advanced Research Projects Agency (DARPA) awarded the company a (up to) $6.8 million contract for the utilization of its ADAPT technology for a blood purification device to reduce the incidence of sepsis. Aethlon billed ~$958k under the milestone-based contract through 12/31/2011 and is eligible to receive up to $1.97 million during the first 12 months of the contract.

As Aethlon had been a development-stage (the company emerged from development-stage to revenue-generating following initial revenue under the DARPA contract) company requiring financing over the years to fund development of the Hemopurifier, typical of early-stage micro-cap companies, Aethlon's balance sheet is light on cash and reflects regular sales of debt and equity. Although the company is in default on much of its $3MM+ in debt, management continues to be successful in raising operating capital and initial receipts from the DARPA contract have (at least temporarily) benefitted the cash balance. Further development of the Hemopurifier will require even more capital, especially in order to pursue FDA approval which will need to come via PMA. U.S. commercial launch for any of these indications, assuming it eventually happens, is likely to be at least a couple of years away - between now and then Aethlon will need to raise a substantial amount of cash, enter into partnering arrangements or score additional valuable contracts/grants in order to maintain operations. Meanwhile, the initial commercial launch in India is expected to happen in the coming year. The company is also currently requesting approval for use of Hemopurifier in compassionate use programs in the U.S. and has initiated discussions with potential clinical partners in Europe for an HCV related program.

## PRODUCTS

The company's flagship product, the Aethlon Hemopurifier, is a single-use cylindrical cartridge containing immobilized lectin affinity agents which surround approximately 2,800 hollow fibers. Lectins are sugar-binding proteins which attach themselves to the glycoprotein structure of healthy cells. Certain viruses envelope themselves with glycoproteins, disguising them from the body's immune system. These viral glycoproteins are also often shed by the virus which can bind to antibodies and suppress the body's immune response. As blood flows through the Hemopurifier, the fibers first separate plasma which contain viruses and other target pathogens which are then trapped by these lectin affinity agents. The device uses immobilized lectins which specifically bind to the unique high mannose structures of viral glycoproteins that are derived from the host, removing the virus and harmful viral glycoproteins from the body while allowing for healthy cells to pass through and back into the circulatory system.

The Hemopurifier is used with existing dialysis, blood pump and continuous renal replacement therapy (CRRT) equipment. Use does not require dialysate - chemicals used in dialysis to pull fluids out of the bloodstream and to replenish the body. As the Hemopurifier discriminately captures harmful agents, it reduces loss of essential blood components and therefore does not require the use of replacement fluids - this is a key differentiation compared to other extracorporeal pathogen clearing technologies which focused on molecule size, thereby removing healthy as well as infected blood components. A patient's entire circulatory system can flow through the Hemopurifier in about 15 minutes. Clinical programs have demonstrated safety of the Hemopurifier in four-hour and six-hour treatment studies. The device is covered by three U.S. and eight international patents.




SOURCE: http://www.acc-tv.com/images/wjla/news/vidcap_hemopurifier0314.jpg




SOURCE: www.aethlonmedical.com

Aethlon is pursuing several applications for their ADAPT technology including for the treatment of Hepatitis-C, HIV, cancer and against bioterrorism agents and pandemic threats. The initial focus is use of the Hemopurifier to improve the drug regimens for HCV. While not a current significant focus for Aethlon, as affinity drug agents are a key component of the device, the company also hopes there will be an opportunity to eventually market the technology to the pharmaceutical industry as a means to get their affinity drug candidates FDA-approved via a (less stringent and less costly) medical device regulatory approval pathway (versus the "new drug application" pathway typical for drugs that enter the body).

## ➢ Hepatitis-C

Hepatitis-C is a viral disease transmitted through the direct contact of infected blood which causes swelling of the liver and is the leading cause of liver transplantation in the U.S. There are approximately three million Americans with chronic HCV and about 36k people contract the virus in the U.S. every year. Worldwide there are about 170 million people with HCV. Symptoms vary from person-to-person with many showing no signs of the disease while others may have acute symptoms such as mild fever, headache, fatigue, nausea and muscle aches. These symptoms usually abate within a few weeks or months after becoming infected. However, the majority of people exposed to the virus develop a chronic infection - if left untreated these chronic carriers of the virus can eventually experience abdominal pain, jaundice, liver failure and even death. The goal of treatment is to remove the virus from the blood and reduce the risk of liver damage. Specifically, the goal is to rapidly reduce viral load, the extent of which is highly correlated with what is considered a clinical cure and improved patient outcomes. In small clinical trials the Hemopurifier, in combination with standard drug therapy, has shown to be able to rapidly reduce viral loads within the first few days of treatment.

Aethlon's expected early-adopter (i.e. - initial) target market for this application are HCV patients with end-stage renal disease. Since these patients are already on dialysis ( ~3 - 4 hours/day, 3 days/week), Hemopurifier therapy would not necessarily substantially increase their treatment burden (Hemopurifier studies to-date have used four-hour or six-hour Hemopurifier treatment regimens). This, combined with the fact that about 50% of non-dialysis HCV patients are well managed with just conventional HCV drug therapy (which is often is contraindicated for patients with end-stage renal disease), makes end-stage renal disease population a more practical initial target

market for the Hemopurifier. According to Aethlon, worldwide there are about 300k HCV patients already on dialysis. There are about 500k Americans with end-stage renal disease and, based on separate studies, roughly 35k - 60k of those have HCV and are on dialysis - this patient population is growing at about 2% per year.

The expanded target market for the HCV application are non-dialysis patients just beginning standard of care drug therapy and or those that have already undergone drug therapy but either failed or relapsed. Roughly 50% of HCV patients fail or relapse from standard therapy, which represents a very sizable market and a tremendous opportunity for novel therapies that can effectively treat this population. While there are several novel drug candidates under development focused on trying to cure this difficult to treat population, clinical trials have shown that rapid and sustained reduction of viral load remains a hurdle that may be difficult to overcome. Adverse side-effects of some HCV drugs can also be an issue, especially when different drugs are dosed together to increase efficacy. If Hemopurifier, which eliminates any risk of drug toxicity, can demonstrate significant efficacy in patients that fail drug therapy, this would be a potentially huge opportunity for Aethlon.

***Standard Treatment……***
The most common form of treatment for HCV are antiviral medications pegylated interferon and ribavarin, although there have also been some promising novel HCV medications that have recently launched which could be even more effective. For genotype-1 patients, the standard duration of treatment with pegylated interferon and ribavarin is 48 weeks, unless rapid virological response is achieved, which can reduce treatment duration to 24 weeks. While pegylated interferon is often used in combination with ribavarin, the evidence is mixed whether pegylated interferon/ribavarin combination is more effective than pegylated interferon alone.

While treatment for HCV has shown to be most effective when administered during the first six months following infection, and especially prior to the disease reaching a chronic state, in most cases the disease usually goes undetected for years which can make it much more difficult to achieve a clinical cure (which contributes to the ~50% of HCV patients failing or relapsing from treatment). For patients where the disease relapses after initial treatment, doctors will typically either order another course of similar treatment or recommend additional medications. Boceprevir and Telaprevir are two relatively new oral HCV drugs, both of which are protease inhibitors (i.e. - they prevent replication of the virus by inhibiting its ability to produce certain proteins) and received FDA approval for the treatment of HCV in the last year. Boceprevir and Telaprevir are both indicated for use in combination with pegylated interferon/ribavarin for total durations ranging from 24 to 48 weeks. Boceprevir (Merck) and Telaprevir (Vertex, Johnson & Johnson) both showed to be significantly more effective when used in combination with pegylated interferon/ribavarin compared to pegylated interferon/ribavarin alone in clinical trials with difficult to treat HCV patients. Specifically, clinical data showed between 66% and 75% (depending on the specific trial) of Boceprivir treated patients had a sustained virologic response (i.e. - clinical cure) compared to approximately 21% to 40% for interferon/ribavarin monotherapy patients after 44 weeks of treatment. Telaprevir trial data showed a sustained virologic response rate after 48 weeks of treatment in 70% of patients (80% of treatment-naïve patients), compared with less than 50% treated with interferon/ribavarin monotherapy.

Interferon-free, all-oral regiments are the new rage as interferon can cause adverse side effects (such as flulike symptoms) and must be injected. There are no interferon-free regiments currently on the market but several in late-stage development - the furthest along is (or at least had been) Gilead's experimental drug candidate, GS-7977, a nucleotide polymerase inhibitor. GS-7977's recent clinical trial data brings into question its efficacy, however. Preliminary clinical study results released in February 2012 showed six out of eight genotype-1 patients which had already failed ribavarin/interferon treatment who were then treated for 12 weeks with GS-7977, in combination with ribavarin, relapsed at the four-week follow-up. Many analysts have been very bullish on GS-7977, with one noting it is "the single most attractive drug in development for HCV." While these results are just preliminary and included only a very small patient population, this was a clear disappointment and a setback for Gilead - especially given Gilead paid almost $11 billion to acquire the candidate with its purchase of Pharmasset in late-2011. The jury is still out on GS-7977, however, as it's possible that longer duration of treatment (i.e. - 24 weeks) or substituting ribavarin with a potent antiviral would show much better efficacy than these preliminary results. Bristol-Myers also has an interferon-free regimen under development, although at a earlier stage of development than GS-7977. Hemopurifier, which eliminates any risk of interferon-related toxicity may, if proven effective, be an alternative to these interferon-free drug regimens.

***Hemopurifier for HCV….***
For HCV, Aethlon is looking to commercialize the Hemopurifier as an adjunct to existing standard of care medication in non-dialysis patients (per the treatment protocol of their most recent clinical study, "Extract-1"). Earlier small studies have shown the device was associated with the reduction of viral load in HCV patients undergoing dialysis. Results of *Reduction of Hepatitis C Virus using Lectin Affinity Plasmapheresis in Dialysis Patients* were published in a 2009 issue of the journal *Blood Purification*. Goal of the study was to test the safety of

the Hemopurifier as well as its ability in clearing HCV from the blood of non-genotype 1 HCV-positive end-stage renal disease patients undergoing dialysis. The India-based study included seven patients, four of which received dialysis three times per week for two weeks and three which received dialysis three times per week for one week. No patients received drug therapy. In the four-patient/two-week cohort, the Hemopurifier cartridge captured approximately 30% of the initial viral body burden on average. In the three-patient/one-week cohort, average viral load decreased by approximately 57% after Hemopurifier treatment. In addition, viral load was 82% lower seven days after treatment. The control cohort (dialysis alone, without Hemopurifier) "also showed a marked transient reduction in HCV viral load" (per the study abstract). The study authors concluded that "The Hemopurifier rapidly cleared HCV from blood treated in vitro. In patients, the combination of the Hemopurifier plus dialysis decreased HCV viral load by 57% in 1 week. Moreover, viral load reduction continued up to 7 days after treatment."

***Extract-1 Study….***

Based on these results, along with unrelated Japan-based studies supporting the use of dual plasmapheresis in HCV therapy and the Japanese Ministry of Health and Welfare approving technology (VRAD system - see below) for a similar application, Aethlon decided to further pursue development of the Hemopurifier in HCV. The company initiated a new India-based study, this time with genotype 1 non-dialysis patients who were initiating HCV drug therapy. The study, titled *Use of the Aethlon Hemopurifier in Treating Chronic HCV Infection in Combination with Standard of Care Drug Therapy (*currently known as "Extract-1") was approved to move forward at The Medicity Institute (India) in August 2010.

The study initially ran into problems getting started as a result of difficulty with enrollment and most recently a change to the protocol which caused significant delays. The enrollment delays related to finding patient candidates that fit the specific enrollment criteria, such as finding genotype 1 HCV patients (previous studies enrolled non-genotype 1 patients) - while approximately 70% of all U.S. cases of HCV are genotype 1, this is not necessarily the case in many parts of India where other genotypes including 2, 3, and 4 can be most prevalent. Genotype 1 is the most difficult to treat compared to other genotypes such as 2 and 3 which can be almost three times more likely to respond to drug therapy. Change in the protocol relates to Aethlon's July 2011 meeting with the FDA to discuss what the agency might be looking for in an eventual Investigational Device Exemption (IDE) application - approval of which will be required to initiate U.S. based studies (Aethlon had previously submitted an IDE application, which is on file with FDA - they now hope to supplement the IDE with additional trial data). The agency inquired about the ability of the Hemopurifier to measure the quantity of HCV virus captured - although this was not slated to be measured in the India trial, Aethlon was able to measure this previously. Based on the FDA's comments, Aethlon decided to include this data point into the study protocol for the Extract-1 study - which, assuming positive results, will be used as additional support for an eventual IDE application for approval for U.S. trials. The fact that genotype 1 patients are being used in this current India-based trial is also an obvious positive for seeking IDE approval.

The goal of the study is to show that the Hemopurifier is able to safely and effectively accelerate viral load depletion of HCV when used during the first three days of standard of care drug therapy (peginterferon/ribavarin). The study expects to enroll up to 30 patients. Blood is pumped with the use of a dialysis machine, although only the Hemopurifier cartridge is used to filter the blood.

Clinical endpoints of Extract-1 include;

- at **day 3**, the change in HCV RNA from baseline (day 3 is the end of the Hemopurifier plus peginterferon/ribavarin treatment)
- at **day 7**, the change in HCV RNA from initial baseline. HCV RNA decrease of more than 2 logs at day seven is called an Immediate Virologic Response (IVR) - large HCV studies have shown that 90% or more patients that reach IVR will achieve Sustained Virologic Response (i.e. - clinical cure). IVR is typically achieved in only about 5% of patients treated with only peginterferon/ribavarin (we note, however, that many people that fail to achieve IVR do achieve SVR. SVR is typically achieved in approximately 40% of HCV patients treated with peginterferon/ribavarin)
- at **day 30**, the change in HCV RNA from initial baseline. Undetectable HCV RNA at day 30 is called a Rapid Virologic Response (RVR) - large HCV studies have shown that over 85% of patients that reach RVR will achieve Sustained Virologic Response (SVR). RVR is typically achieved in only about 10% of patients treated with only peginterferon/ribavarin (again, we note that failure to hit these early response milestones does not necessarily predict eventual failure to achieve clinical cure as SVR is typically achieved in approximately 40% of HCV patients treated with peginterferon/ribavarin)

Aethlon announced preliminary results from the first three patients of Extract-1 on February 1, 2012. The patients received three, six-hour applications of Hemopurifier during the first three days of peginterferon/ribavarin therapy. On day one peginterferon/ribavarin therapy is initiated within one hour of first Hemopurifer therapy completion. Hemopurifier therapy is then administered again once daily for the next two days in combination with peginterferon/ribavarin therapy. The Hemopurifier treatment was well tolerated without any device-related adverse events. Results of each clinical endpoint from these three patients were;

- **Day 3**: Baseline HCV RNA fell: in patient 1 from 5,800,000 IU/ml to 1,840 IU/ml equal to 3.49 logs, in patient 2 from 199,500 IU/ml to 31,550 IU/ml equal to 0.80 logs, and in patient 3 from 1,340,000 IU/ml to 54,900 IU/ml equal to 1.38 logs
- **Day 7**: One of the three patients achieved IVR. Baseline HCV RNA fell: in patient 1 from 5,800,000 IU/ml to 234 IU/ml equal to 4.39 logs, in patient 2 from 199,500 IU/ml to 17,300 IU/ml equal to 1.06 logs, and in patient 3 from 1,340,000 IU/ml to 24,400 IU/ml equal to 1.74 logs
- **Day 30**: Two of the three patients achieved RVR, with the third almost achieving RVR. RVR is typically achieved in only about 10% of HCV patients treated with only peginterferon/ribavarin. Baseline HCV RNA fell: in patient 1 from 5,800,000 IU/ml to undetectable (<15 IU/ml) equal to 5.58 logs, in patient 2 from 199,500 IU/ml to 40 IU/ml (i.e. - virtually undetectable) equal to 3.69 logs, and in patient 3 from 1,340,000 IU/ml to undetectable equal to 4.95 logs

Based on statistics, which show only about 5% and 10% of HCV patients treated with peginterferon/ribavarin alone achieve IVR and RVR, respectively, compared to one in three (33%) achieving IVR and two in three (67%) achieving RVR in this preliminary data, it suggests that Hemopurifier may be having a positive effect on rapidly reducing HCV RNA. We note, however, that based on the tiny sample size the data to-date is not considered statistically significant and caution that it's much too early to draw any conclusions regarding the efficacy of Hemopurifier. The full data set should provide more insight.

Aethlon's press release announcing the preliminary trial data notes that they will now seek permission to open up the study to HCV patients outside of India. Aethlon has previously indicated that once the full data set is available that they will look to have it published. The February 2012 press release also notes that following quantification of the HCV virus captured in the Hemopurifier cartridge, that the company will resubmit their IDE to the FDA seeking approval to initiate U.S. clinical trials. We note that IDE approval is definitely not a certainty but is critical for Aethlon to be able to move their program along in the U.S. It is also not clear how much weight FDA will place on the Extract-1 data and even if the full data set is highly compelling, FDA may not approve their IDE - as such, we await more data from this trial and, following that, will be looking forward to hearing what the FDA thinks.

Following conclusion of the Extract-1 study, Aethlon will also be evaluating their strategy towards further use of the device in that country. Initially this may involve additional small studies at a select number of trial sites in a compassionate use setting - which would hopefully provide a self-funding arrangement for the company to be able to collect additional clinical data. The longer-term commercialization plan in India (and other countries) could involve some form of a partnership and selling through a select number of hospitals. In India, Aethlon already has institutional review board approval at their trial sites, which is sufficient to be able to sell the device on a commercial basis. We note, however, that while the India market could provide a convenient and low-cost way to collect additional clinical data, we think it may offer only limited opportunity from a commercialization and profitability standpoint, especially compared to the U.S. market. However, Aethlon believes that India is a very viable commercial market and views both the large Indian citizenry and medical tourism (Medanta Medicity has a focus on medical tourism) as attractive patient populations for its device in that country.

Aethlon could also seek to bring the device to the European market, which could significantly expand the size of their target markets and offer potentially sizeable additional opportunity. In their January 2012 Biotech Showcase presentation management indicated that they have initiated discussions with potential clinical partners in Europe for an HCV related program.

***VRAD…***

Aethlon cites the VRAD (Virus Removal and Eradication by Double Filtration Plasmapherisis) system, approved and commercialized by Asahi Kasei Kuraray Medical in Japan as evidence that a market exists for Hemopurifier in HCV. In clinical trials VRAD in combination with standard drug therapy achieved a sustained virological response (SVR) rate of 71% in patients that failed standard of care which compared very favorably to the control arm (standard of care only) which achieved a 29% SVR rate. VRAD was administered for ~ 3 hours for three consecutive days. Based on initial clinical data and a different filtration system allowing the capture of key immunosuppressive

proteins, Aethlon believes their Hemopurifier may be able to reduce viral loads even further than VRAD. An important difference between the two devices is that VRAD indiscriminately removes fibrin (used for clotting) from the blood, while Hemopurifier allows for selective capture. As a result, Hemopurifier treatment may be able to be applied more aggressively, thereby optimizing treatment efficacy. We have been unable to find any information relative to the commercial success of VRAD.

## ➢ Cancer

In cancer (as well as HIV) applications the ADAPT technology targets the collection of exosomes, small membranous particles released from cells (normal or diseased) which act as messengers between cells modulating the transport of proteins. Evidence shows that exosomes secreted by some tumor (i.e. - cancer) cells are not only associated with tumor progression through the stimulation of angiogenesis (i.e. - formation of new blood vessels) but also bind to certain cancer fighting drugs, potentially interfering with their therapeutic activity. These tumor secreted exosomes can be found within the lesion itself as well as in the blood.

Aethlon's current focus with cancer is in the treatment of HER2 breast cancer, although their device could also have potential utility with targeting different pathogens and with treating other types of tumors. With HER2, Aethlon's device dually targets the removal of HER2 protein and tumor secreted exosomes. We view Aethlon's cancer program as currently more of a work-in-progress compared to HCV, especially as it relates to confirmation that removing the targeted pathogens (i.e. - exosomes) from the body will indeed reduce disease progression and improve patient outcomes. This is in contrast to HCV, where it's already widely accepted that reduction in viral load increases the chances of a clinical cure.

***HER2 Breast Cancer….***

Human epidermal growth factor receptor-2 (HER2) breast cancer is a very aggressive form of the disease which accounts for approximately 30% of all breast cancers. Typical treatment for HER2 breast cancer involves the use of the monoclonal antibody Herceptin (trastuzumab) which is only effective in cancer where the HER2 receptor is overexpressed. Herceptin can be used alone or in combination with chemotherapy. While Herceptin has shown to significantly extend the lives of HER2 breast cancer patients (five year survival rate is ~ 95%) compared to legacy drugs, there's clearly a market for a product that would provide even greater efficacy (especially with no compromise to safety or patient comfort).

Herceptin works by binding to HER2 receptors on the surface of breast cancer cells, preventing the growth factor from entering and thus stopping the cancer cells from replicating. While Herceptin is considered standard of care for HER2 breast cancer, only about one-third of patients respond to the drug. Even those that do respond typically experience only a limited duration of benefit. Aethlon hypothesizes that their Hemopurifier may be able to increase response to Herceptin through the removal of HER2 protein and tumor secreted exosomes which are binding to the cancer drug and inhibiting its efficacy.

Aethlon has dubbed the HER2 breast cancer ADAPT device as the HER2osome, which is expected to be used as an adjunct to Herceptin and standard of care chemotherapies. It will also be used with common dialysis, blood pump and CRRT equipment.

In order to help fund their HER2 breast cancer program, Aethlon recently submitted an application for funding to the Breast Cancer Research Program (BCRP) provided through the Assistant Secretary of Defense for Health Affairs, Defense Health Program. The BCRP, which has appropriated over $2.5 billion since inception, was set up in the early 1990's to work on eliminating breast cancer. Aethlon's funding proposal is titled, "An Innovative Device Strategy to Eliminate HER2 Breast Cancer Progression." The company was informed that they were not selected but expects to prepare a follow-on submission that includes additional new data.

***Cancer Study….***

In August 2011 Aethlon entered into an agreement with the Sarcoma Oncology Center to study the ability of the Hemopurifier to remove immunosuppressive exosomes from the blood of patients with metastatic non-small cell lung cancer, prostate cancer, melanoma, head and neck cancer, and sarcoma. The study, which is ex vivo (blood samples will be taken from the patients and run through the Hemopurifier but not returned to the patient), is expected to enroll up to 25 patients and, assuming successful results, is expected to provide support for follow-on clinical trials in cancer. As of early December 2011, testing of blood from three patients began. The study is still in its early stages and continues to enroll participants. Aethlon noted in their presentation in early January at the Biotech Showcase conference in San Francisco that they expect these studies to complete during 2012.

## HIV

The application of the Hemopurifier for HIV therapy relates to effectively managing a broad range of HIV strains, including drug-resistant mutant strains. In addition to capturing HIV, the device targets the capture of envelope glycoprotein GP120 as well negative factor (Nef) protein exosomes from the blood. GP120 is a glycoprotein that is essential for virus entry into cells. GP120 was one of the first targets of HIV vaccine research and continues today - although efforts to develop such a vaccine have been hampered by certain properties of GP120 which make it difficult for antibodies to bind to it. Nef proteins are one of the initial and most abundant viral proteins expressed by HIV which have been found to deplete CD4(+) T cells, which play an integral role in immune protection, facilitating progression of the virus to full-blown AIDS. Aethlon hopes to position the Hemopurifier as a second-line treatment for HIV patients that have shown resistance to standard antiviral drug therapy.

In December 2011 Aethlon announced that an ex vivo study at the Morehouse School of Medicine showed the Hemopurifier was able to reduce the presence of Nef exosomes by over 85% in cell culture fluids in less than 24 hours. This follows a single-patient study conducted at the Sigma Life Hospital in India in which an HIV-infected AIDS patient experienced a 92% reduction in HIV viral load following twelve (3x/week for 4 weeks) four-hour dialysis treatments - a Hemopurifier cartridge was included in series with the dialysis cartridge. While the study was not optimized for efficacy, it showed that viral load remained 56% below baseline 14 days following the final treatment. No antiviral drug therapy was administered during the course of the treatment. The patient's CD4 T-cell to lymphocyte levels were also measured and found to increase from 13.5% to 18.1% (<15% is the clinical definition of AIDS).

Aethlon recently noted that the next step with their HIV program may be to see if they can get it used under the FDA's "expanded access" status, either for compassionate or emergency use for patients that have become resistant to HIV drug therapy. Expanded access is when medical devices that have not yet received FDA approval are used on seriously ill patients when no viably better alternatives exist. Compassionate use requires that an IDE already be approved but allows the device to be used outside of the current clinical trials - compassionate use requires the FDA's approval before treatment begins and can be approved for single patients or small groups of patients. Emergency use is typically only applied when the patient is in a very dire state and no better options exist to save their lives. Emergency use, while not requiring an approved IDE, does require that an IDE be filed and IRB approval granted (on a patient-by-patient basis).

## Bioterrorism

In vivo studies conducted by Aethlon and in conjunction with other organizations, including the Centers for Disease Control and Prevention (CDC), have shown the Hemopurifier was able to rapidly clear viral particles and remove glycoproteins in cell cultures fluids. Pre-clinical studies have shown success with the capture of several Category A pathogens including the Ebola virus, Dengue virus, Lassa virus, West Nile virus, Monkeypox virus, H5N1 Avian flu virus and the H1N1 Swine flu virus.

"Category A" is CDC's classification for the most serious pathogens, which they characterize as "high-priority agents (which) include organisms that pose a risk to national security because they can be easily disseminated or transmitted from person to person, result in high mortality rates and have the potential for major public health impact, might cause public panic and social disruption, and require special action for public preparedness." Although the risk of becoming infected with any of these viruses is very remote, especially in the U.S., they can be highly lethal and for some, such as Ebola, there is no current preventative vaccine or cure. Only Ribavarin is effective against Lassa and its two-year shelf-life and indeterminate government stockpiling means demand might quickly outstrip necessary supply in the event of widespread infection. As a result, these viruses could be used as potentially effective bio-weapons. Aethlon hopes to develop the Hemopurifier as an effective therapy against these, as well as other potential bioterrorism agents, the protection from which has become a significant focus of the U.S. government following the 9/11 terrorist attacks.

Aethlon, in collaboration with the United States Army Medical Research Institute for Infectious Diseases (USAMRIID) and other organizations, have worked in the past to validate Hemopurifier for use against Category A threats. Studies have yet to move forward, however - possibly as enrolling for a trial with Ebola infected patients would present serious challenges. As a result, Aethlon's bioterror program is currently in somewhat of a holding pattern.

## Sepsis

In February 2011 the Defense Advanced Research Projects Agency (DARPA) announced that it was soliciting innovative research proposals under a program titled *Dialysis Like Therapeutics* (DLT) to manage sepsis, a potential life-threatening blood infection. Aethlon subsequently submitted a proposal and in early October 2011 was notified that it was one of the recipients of a contract to collaborate in the development of a device that reduces the incidence of sepsis.

DARPA is part of the U.S. Defense Department whose mission is to "maintain the technological superiority of the U.S. military and prevent technological surprise from harming our national security by sponsoring revolutionary, high-payoff research bridging the gap between fundamental discoveries and their military use." Since its creation in 1958 DARPA has been instrumental in the development of a number of high profile products and services including the internet, the Stealth Fighter and M16 assault rifle. Many technologies initially funded by DARPA are not only in widespread use by the military but are also being used in commercial products.

Sepsis, more commonly known as blood poisoning, is a potentially lethal blood infection caused by pathogens. It is one of the major leading causes of deaths in intensive care unit patients. Soldiers injured in combat can be particularly prone to wound infections which can lead to sepsis, which is initially characterized by inflammation throughout the entire body, fever and vomiting. It is an especially dangerous infection as it is not only aggressive, eventually leading to loss of limbs, organ failure and death, it is also difficult to treat. As there currently are no effective methods to remove the toxins from the blood or to consistently and effectively identify the circulating pathogens, sepsis is typically treated with antibiotics that are not necessarily specific to the pathogens. As a result, antibiotic treatment protocol for sepsis often fails, contributing to its ~30% mortality rate.

Per DARPA's 2/8/2011 Broad Agency Announcement describing the funding opportunity for the DLT program;

> "The goal of the DLT program is to develop a portable device that removes "dirty" blood from the body, separates harmful agents, and returns "clean" blood to the body in a manner similar to dialysis treatment of kidney failure. While the device could have an impact across multiple areas of medicine, the target application for this device is sepsis. The envisioned device will persistently interrogate the entire blood volume, providing early identification of the presence of a pathogen. Once the presence of pathogens has been confirmed, the DLT device will provide continuous "label-free" removal of pathogens, toxins and activated patient cells without pathogen identification or use of pathogen-specific binding chemistries. As a final step in the treatment process, the DLT device will enable closed-loop therapy based on continuous, reduced dimensionality modeling of patient health. Predictive modeling in this fashion will allow us to identify sepsis early, learn what we need to remove, and direct the most effective intervention to improve patient health. This cycle of sensing, adjustment, estimation, computation, and manipulation will modulate key health parameters faster than the underlying disease process and drive the patient towards a stable, healthy state.
>
> The envisioned device will be capable of removing at least 90% of unknown pathogens, toxins, and activated cells from a patient in one day. *In vivo* experiments in a clinically relevant animal model will validate the device for use in sepsis. At the completion of the program the device will be ready for transition to military medical commands and industry as well as clinical trials required for regulatory approval."

DARPA awarded Aethlon a contract to help develop a device using their ADAPT technology that reduces the incidence of sepsis by clearing infection-enabling particles from the blood. The proposal also calls for the device to not require the use of anticoagulants (i.e. - anti blood-clotting agents which are typically used with blood flow devices) - which Aethlon will need to incorporate into their system. The contract is milestone-based and will potentially pay Aethlon up to $6.8 million over five years. The current contract is for payments of up to $2.0 million over the first twelve months, full payment of which is contingent on Aethlon hitting all the requisite milestones. Aethlon started work under the contract in October 2011 and through 12/31/2011 had billed $958k ($774k received, $184k in A/R) - see Appendix for description of milestones billed. DARPA has the option of entering into the remainder of the proposed contract for years two through five, which would pay Aethlon up to an additional $4.8

million, annual payments under which would range between $775k and $1.6 million. Specifics (activities, dates, etc.) of the remaining milestones under the $2.0 million contract or on the $4.8 million potential additional portion have not been made public.

Aethlon has indicated in public filings that some of the work under their contract may be subcontracted out. As the award is milestone-based, there is no guarantee on the amount of money that Aethlon will ultimately receive under the award or that contract will not be terminated at any certain point in time. There is also the possibility that Aethlon can apply for additional funding opportunities related to the DARPA DLT program - which could provide an additional revenue stream.

- **Exosome Sciences, Inc.**

Exosome Sciences, Inc. (EIS) was created in 2009 as consequence of Aethlon's research related to the development of Hemopurifier. In order to test the device's effectiveness, Aethlon needed a high-sensitivity tool to measure the presence and changes of exosome levels in the body. EIS, a wholly-owned subsidiary of Aethlon, developed an Enzyme Linked Lectin Specific Assay (ELLSA) that can identify and quantify the presence of exosomes in bodily fluids, including blood, which are present with HIV, tuberculosis and a variety of cancers including ovarian, melanoma, breast, lymphoma, and colorectal.

In October 2011 the company announced availability of the assay. In their January 9, 2012 presentation at the Biotech Showcase conference in San Francisco, Aethlon noted that they received and shipped their first Exosome Sciences-related orders in December 2011 and that the assay is currently under evaluation with research diagnostic organizations. However, while Aethlon's initial plan with Exosome Sciences was to sell the assay themselves to organizations involved in research diagnostics, the company most recently indicated that it may make more sense to shop the entire business. As such the company may look to sell the business outright. In either case, we do not expect Exosome Sciences will be a significant contributor to Aethlon's future.

***Exosome Related Product Sale….***

Aethlon noted in their Q3 2011 10-Q that subsequent to 12/31/2011 they recorded the first commercial sale of one of their diagnostic products (for $1.4k) - we do not expect any material contribution from any possible future sales of this product, however. Aethlon did not disclose exactly what the product was, (presumably it's related to the Exosome Sciences business), who the customers was, or what application the customer intended to use the product for only noting in the 10-Q that, *"Subsequent to December 31, 2011, we recorded the first commercial shipment of one of our products to a life sciences company for diagnostics use. In January 2012, we shipped a diagnostic product that isolated exosomes from blood serum to a life sciences company and invoiced them for $1,432. We received payment in full under that invoice in February 2012. This represents our first commercial sale, which will be recorded in the March 2012 quarter."*

## FINANCIAL POSITION

As of their most recent reporting period (fiscal Q3 2012 ending 12/31/11) the company had $355k in cash - pro forma for the February sale of OID convertibles, cash balance would be approximately $800k at 12/31/2011. Aethlon is in default on all (or at least the majority) of their debt obligations but continues to be successful in raising piecemeal capital to finance operations. It's currently unclear what the state is of any discussions with creditors of the past due debt. Cash burn was $65k and $1,102k in the three and nine months ending 12/31/11 - the most recent three month period benefitted from $775k received under the DARPA contract. Excluding changes in working capital, cash used in operations was $225k and $1,657k for these same periods. About $1.2 million (~$180k of which has already been billed) more could be received over the next ~ 6 - 9 months from DARPA if all requisite milestones are hit - this, however, may still not cover ongoing cash expenses.

Aethlon has been funding operations through the regular issuance of debt and equity. The most recent of which came in February 2012 with the sale of $525k in 5% original issue discount convertible bonds. Further development of the Hemopurifier will require even more capital, especially in order to pursue FDA approval which will need to come via PMA. U.S. commercial launch for any of these indications, assuming it eventually happens, is likely to be at least a couple of years away - between now and then Aethlon will need to raise a substantial amount

of cash, enter into partnering arrangements or score additional valuable contracts/grants in order to maintain operations.

**Debt**

As of 12/31/2011 Aethlon had $585k outstanding in notes payable, in addition to $3.3 million outstanding in convertible notes, the majority of which are in default. Other current liabilities total $1.0 million, with $734k in accrued interest, $240k in accrued legal fees, and $48k in deferred rent and other expenses. The company's also carrying $618k in accounts payable, which has crept up from $411k at 9/30/2011 and $308k at 3/31/2011.

In a 2/28/2012 8-K filing Aethlon announced that on 2/16/12 and 2/24/12 they entered into a definitive agreement with certain investors whereby Aethlon will sell $525k in original issue discount (OID) convertible bonds. The bonds accrue annual interest at 20%, mature on April 20, 2012 (i.e. - 2 months after issuance), and are convertible at any time at the option of the holder at $0.079. The purchasers also received five-year warrants to purchase 3.37 million shares of common stock at $0.11/share.

## RECOMMENDATION

Our current financial model through fiscal 2014 (March 2014) assumes AEMD continues to hit milestones related to the DARPA sepsis contract, DARPA picks up the option to fund the contract for years 2 through 5 (which would pay Aethlon an additional $4.8 million) and (for simplicity purposes given the current lack of foresight relative to timing, aggregate amount or probability of future payments under this contract) assumes equal annual payments of approximately $1.3 million. We currently do not model revenue from any other source through fiscal 2014 as we believe any sales in India may be immaterial and the high level of uncertainty relative to timing and probability of eventual commercialization in the U.S. and/or Europe. A favorable decision by the FDA on the IDE application to begin U.S. studies along with more clarity relative to the U.S. clinical and regulatory approval pathway could provide some upside to our current financial estimates (as well our recommendation and per share price target), which could include revenue from commercial product sales prior to fiscal 2014 year-end.

Our model also assumes that Aethlon successfully raises additional financing in the near term (and continues to do so) and remains a going concern - we note, however, that we have no insight into timing or likelihood of continued financing.

Given the number and degree of uncertainties (as we detail below under "Risks") and the company's current financial state, calculating a reasonable value for Aethlon with any degree of comfort is probably not possible. As of the date of this report, the stock is trading at about $0.09, implying an equity value of around $10 million and (if all the debt was performing) an enterprise value (i.e. - par take-out value) of about $13 million. While an argument could be made for or against this implied value being rich or cheap, we feel it is irresponsible to assign an arbitrary valuation and price target on the company (different from where the market currently values it at) with virtually nothing to support them. Until there is more clarity on some of the major unknowns and risks, we are "punting" on calculating a value for the company. As such, our current price target mirrors the current market price of the stock and reflects our Neutral recommendation.

We also note, however, that in a buy-out scenario, an acquirer may be willing to pay well more than $13 million. Although we have no reason to believe that any potential acquirers are kicking the tires on Aethlon, it's not impracticable that HCV drug manufacturers (such as GILD, MRK, BMY, VRTX, etc.) could, for example, view the Hemopurifier as somewhat of a threat and in order to mitigate any risk to market share, might move to acquire Aethlon. With mountains of cash, even paying a healthy price premium for Aethlon would be a relatively immaterial transaction for any of these drug companies.

## RISKS

Despite the Hemopurifier demonstrating an ability to meaningfully reduce HCV and HIV viral loads in small clinical trials to-date (as well as some potential in cancer, bioterror and sepsis applications) and the possibility that one day it may act as an adjunct to standard of care in clinical practice, Aethlon faces a number of significant unknowns and challenges, many of which could seriously hurt or altogether derail the company's chances of success. Answers to some of these questions will need to be come on an ongoing basis (i.e. - financing) while others, assuming the company successfully clears near and intermediate-term hurdles, may not be known for years to come.

The major challenges, risks and unknowns that investors should consider are;

- **Cash / Debt Default:** At the most recent reporting period (12/31/2011) Aethlon had little cash and was in default on much of its $3+ million worth of debt. While milestone payments from the DARPA contract may provide a small window worth of breathing room, if Aethlon can't convert or renegotiate the defaulted debt and raise more cash, they may not be able to remain a going concern and the equity would become worthless.

- **U.S. Approval:** At this time there's no way to comfortably judge the chances that FDA approves an IDE - if Aethlon can not initiate clinical testing in the U.S., they'll never commercially launch in the U.S. Lack of access to the U.S. market could present a major difficulty for Aethlon. While enhanced access, if permitted, would allow the Hemopurifier to be used with patients in the U.S., we do not believe it will generate any meaningful revenue.

- **Time / Cost to Commercialization:** Assuming the IDE is approved, Aethlon will need to run safety and efficacy clinical trials in the U.S. to support a PMA application to gain FDA approval. The best-case scenario is FDA gives the green-light for trials to commence, a small (i.e. 10-patient) study is deemed sufficient to prove the device is safe which is conducted and completed by year end-2012, and a pivotal efficacy study is completed in 2013. However, this is the best-case scenario and given that the PMA regulatory process can be a long, drawn out affair, the final decision on FDA approval could be several years away. We note that a U.S. efficacy study would likely be larger and costlier (costing many millions of dollars) than the IRB-approved studies in India.

- **Market Size:** While there are ~ 3 million Americans with HCV, Aethlon's initial target market is only a fraction of this. Approximately 50% of HCV patients are already well managed with existing drug therapy and may have little reason to endure the treatment regimen (or associated risks of dialysis-like treatment such as bleeding and infection) required with Hemopurifier. As such, most of these patients fall outside of Hemopurifier's target market. Aethlon's expected initial U.S. target market is end-stage renal disease patients, the size of which is estimated to be about 50k and growing at about 2% annually - which may still represent a huge opportunity - although this is dependent on a number factors including the rate of market penetration and Hemopurifier's eventual selling price and margins - all of which are complete unknowns. The expanded market, including those patients that failed or relapsed from standard drug therapy but are not on dialysis would meaningfully expand Aethlon's target patient population, although penetration in this market would likely be much lower. Approval and launch in Europe would also expand the target market, although, similar to U.S. commercialization, we do not believe that this will be a near-term event (Aethlon has recently noted, however, that a European clinical program is in the works and that they are in discussions with potential clinical partners in Europe for an HCV related program).

- **U.S. Reimbursement:** Reimbursement in the U.S. may or may not be an issue - although it is something to keep in mind. There is no specific CMS reimbursement currently in place for Hemopurifier treatment, although Aethlon notes that Hemopurifier treatment might be reimbursed under an existing CPT code covering therapeutic apheresis with extracorporeal immunoadsorption and plasma reinfusion. The CPT code, 36516, reimburses $1,500 - $2,500 per treatment. It is also possible that if and when Hemopurifier receives FDA approval, that new codes are assigned with even higher reimbursement amounts - although certainly no guarantees. Reimbursement would be critical for there to be any significant demand for the product in this country. The level of reimbursement will also directly affect the selling price and Aethlon's margins.

## MANAGEMENT

### James A. Joyce

***Chairman and Chief Executive Officer***

Mr. Joyce is the founder, Chairman and Chief Executive Officer of Aethlon Medical. Under his leadership, Aethlon has transformed the concept of a selective therapeutic filtration device (The Aethlon Hemopurifier®) into the reality of treating both HIV and hepatitis C patients in a clinical setting. Follow-on research has further validated the ability of the Hemopurifier® to capture a broad-spectrum of bioterror and pandemic threats as well as immunosuppressive cancer exosomes. Mr. Joyce has originated numerous collaborative relationships with government and non-government research organizations, has authored supporting publications and reports, and raised capital resources to support the mission of Aethlon Medical. He has represented the Company on CNN, NBC, ABC, and other media outlets and has testified before Congress on issues related to Project BioShield legislation and the deployment of the Aethlon Hemopurifier® as a countermeasure against biological weapons. His efforts on Capital Hill were instrumental in expanding the definition of treatment countermeasure in Project BioShield legislation to include medical devices. In May 2011, the Company introduced the Aethlon ADAPT™ system to advance Mr. Joyce's vision of an expansive device platform that converges affinity drug agents with plasma membrane technology to create new candidate therapies against life-threatening disease conditions. From February 1993 until founding Aethlon Medical, Mr. Joyce was Chief Executive Officer of James Joyce & Associates. Previously he was founder and Chief Executive Officer of Mission Labs, Inc., was a principal at London Zurich Securities, Inc., and was a member of the Denver Broncos Football Club of the National Football League. Mr. Joyce is a graduate of the University of Maryland.

### Rodney S. Kenley

***President***

Mr. Kenley has 33 years of experience in healthcare, most of which have been spent in the extracorporeal blood purification arena. Mr. Kenley held several positions at Baxter Healthcare (Travenol) from 1977 through 1990 including International Marketing Manager, Business Unit Manager for Peritoneal and Hemodialysis products, Manager of New Business Development, Director of Worldwide Product Planning, Director of Advanced Product Development, and VP of Electronic Drug Infusion. During this tenure he conceived of and managed the launch of several new products that have been highly commercially successful including the HomeChoice peritoneal dialysis cycler.

Mr. Kenley founded Aksys Ltd. in January 1991 to develop and commercialize his concept of a daily home hemodialysis system which was commercially launched in 2002 as the PHD system. In 2004, Mr. Kenley initiated the development of a second-generation home hemodialysis system in partnership with DEKA Research & Development Corporation in Manchester, New Hampshire. In 2007, the assets of Aksys Ltd. were acquired by DEKA, where Mr. Kenley was employed prior to joining Aethlon.

Mr. Kenley is the recipient of over 30 patents and has been a frequent presenter at international symposia regarding the provision of dialysis, the design of dialysis equipment, designing medical equipment according to FDA guidelines as well as lecturing at the Kellogg School of Management at Northwestern University and at other business schools in the area of entrepreneurship.

Mr. Kenley received his Bachelor of Arts degree in Biology and Chemistry from Wabash College, a Masters of Science degree in Molecular Biology from Northwestern University and a Masters of Management from the Kellogg School of Management, also at Northwestern University.

### James B. Frakes

***Chief Financial Officer***

Mr. Frakes joined Aethlon Medical in January 2008 and brought 16 consecutive years of financial responsibility for publicly traded companies, as well as, specific knowledge and experience in equity and debt transactions, acquisitions, public reporting and Sarbanes-Oxley section 404 internal control requirements. He previously served as the CFO for Left Behind Games Inc., a

start-up video game company. Prior to 2006, he served as CFO of NTN Buzztime, Inc., an interactive entertainment company with $40 million in sales, where he played a key role in acquisitions that doubled the company's revenue.
Mr. Frakes received an MBA from the University of Southern California, and completed his BA with Honors at Stanford University.

**Richard H. Tullis, Ph.D.**
***Senior Vice President, Chief Science Officer***
Dr. Tullis has extensive biotechnology management and research experience, and is the founder of Syngen Research, a wholly-owned subsidiary of Aethlon Medical, Inc. Dr. Tullis became a Vice President and Director of Aethlon Medical, Inc. in January of 2000, and succeeded Dr. Clara M. Ambrus as Chief Scientific Officer in June of 2001. Previously, Dr. Tullis co-founded Molecular Biosystems, Inc., a former NYSE company. At Molecular Biosystems, Dr. Tullis was Director of Research and Development, Director of Oligonucleotide Hybridization, Senior Research Scientist and Member of the Board of Directors. In research, Dr. Tullis developed and patented the first application of oligonucleotides to antisense antibiotics and developed new methods for the chemical synthesis of DNA via methoxy-phosphorochloridites. Dr. Tullis also co-developed the first applications of covalently coupled DNA-enzyme conjugates using synthetic oligonucleotides during his tenure at Molecular Biosystems. In 1985, Dr. Tullis founded, and served as President and CEO of Synthetic Genetics, Inc., a pioneer in custom DNA synthesis, which was sold to Molecular Biology Resources in 1991. Dr. Tullis also served as interim-CEO of Genetic Vectors, Inc., which completed its IPO under his management, and was co-founder of DNA Sciences, Inc., a company that was eventually acquired by Genetic Vectors. Dr Tullis received his Ph.D. in Biochemistry and Cell Biology from the University of California at San Diego, and has done extensive post-doctoral work at UCSD, USC, and The Scripps Research Institute.

# APPENDIX

## *Milestones Related to DARPA 1-Year, $2.0MM Contract* (AEMD 10-Q for period ending 12/31/11)

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.

# PROJECTED INCOME STATMENT

Aethlon Medical, Inc.

| | 2011 A | Q1A | Q2A | Q3A | Q4E | 2012 E | 2013 E | 2014 E |
|---|---|---|---|---|---|---|---|---|
| Revenue | $0.0 | $0.0 | $0.0 | $958.1 | $401.4 | $1,359.5 | $1,300.0 | $1,300.0 |
| *YOY Growth* | - | - | - | - | - | - | - | *0.0%* |
| Cost of Goods Sold | $0.0 | $0.0 | $0.0 | $0.0 | $0.1 | $0.1 | $25.0 | $25.0 |
| Gross Income | $0.0 | $0.0 | $0.0 | $958.1 | $401.3 | $1,359.4 | $1,275.0 | $1,275.0 |
| *Gross Margin* | - | - | - | *100.0%* | *71.5%* | *100.0%* | *98.1%* | *98.1%* |
| SG&A | $4,117.1 | $831.4 | $764.4 | $763.0 | $656.0 | $3,014.8 | $3,141.0 | $3,218.0 |
| *% SG&A* | - | - | - | - | - | - | - | - |
| R&D | $440.0 | $201.0 | $118.6 | $536.1 | $455.0 | $1,310.7 | $1,887.0 | $2,350.0 |
| *% R&D* | - | - | - | - | - | - | - | - |
| Impairment | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| Operating Income | ($4,557.1) | ($1,032.5) | ($883.0) | ($341.0) | ($709.7) | ($2,966.1) | ($3,753.0) | ($4,293.0) |
| *Operating Margin* | - | - | - | - | - | - | - | - |
| Loss on extinguishment of debt | $3,306.3 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| (Gain)/loss on derivative liability | ($6,079.8) | ($491.8) | ($1,029.7) | ($74.9) | $0.0 | ($1,596.4) | $0.0 | $0.0 |
| Interest (income), net | $3,927.7 | $1,685.1 | $600.2 | $308.3 | $840.0 | $3,433.6 | $900.0 | $1,250.0 |
| Other expense | $0.0 | $360.2 | $0.0 | $0.0 | $0.0 | $360.2 | $0.0 | $0.0 |
| Pre-Tax Income | ($5,711.4) | ($2,585.9) | ($453.5) | ($574.3) | ($1,549.7) | ($5,163.4) | ($4,653.0) | ($5,543.0) |
| Taxes (benefit) | $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%* |
| Net Income | ($5,711.4) | ($2,585.9) | ($453.5) | ($574.3) | ($1,549.7) | ($5,163.4) | ($4,653.0) | ($5,543.0) |
| *Net Margin* | - | - | - | - | - | - | - | - |
| EPS | ($0.08) | ($0.03) | ($0.00) | ($0.01) | ($0.01) | ($0.05) | ($0.03) | ($0.03) |
| *YOY Growth* | - | - | - | - | - | - | - | - |
| Diluted Shares O/S | 69,611 | 87,842 | 99,703 | 107,061 | 111,450 | 101,514 | 150,000 | 200,000 |

*Brian Marckx, CFA*

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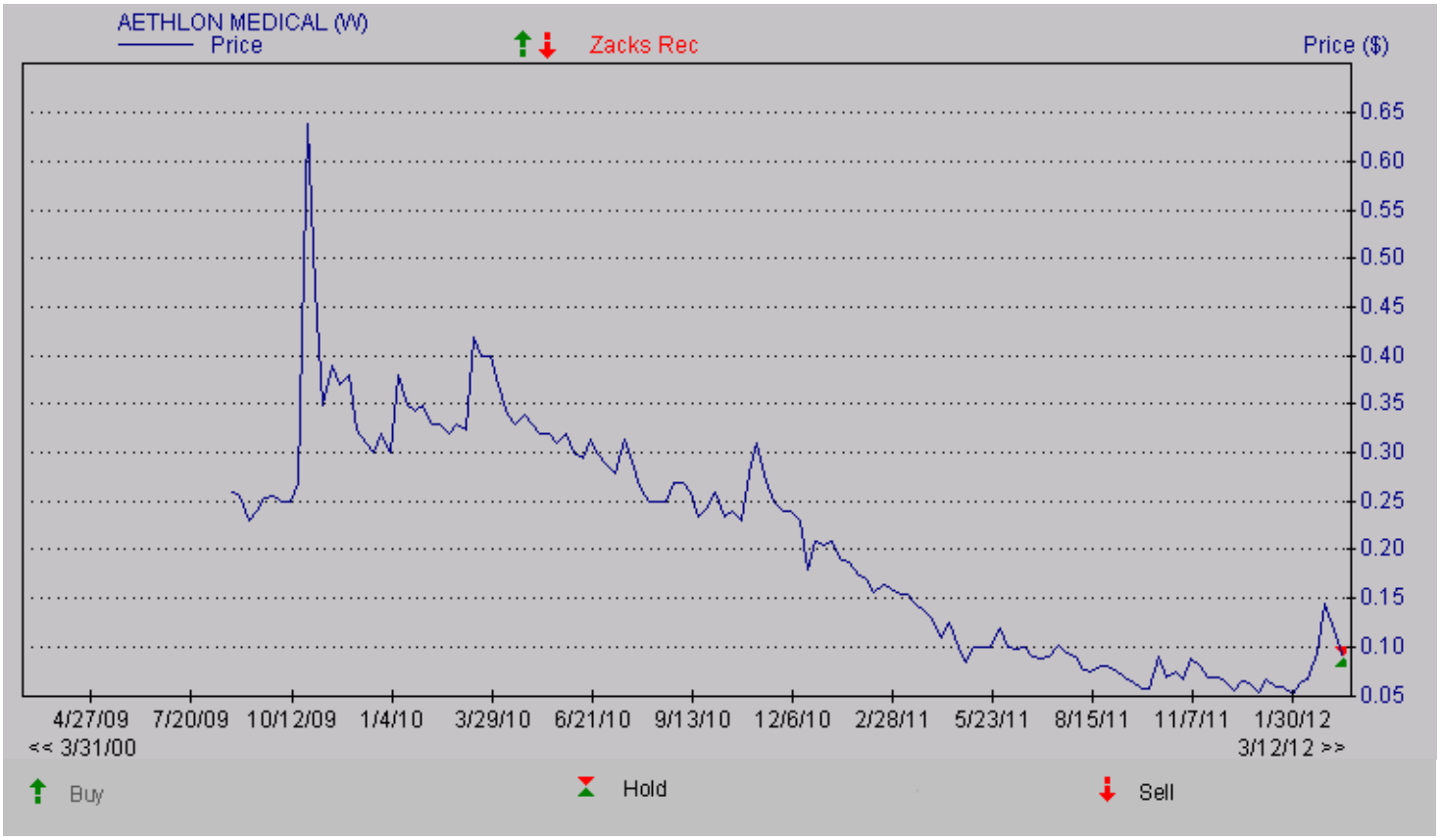
## HISTORICAL ZACKS RECOMMENDATIONS

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