Zacks Small-Cap Research

June 3, 2013

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Aethlon Medical (AEMD-OTCBB)

AEMD: FDA Answer On IDE Should Be Forthcoming

Current Recommendation	**Neutral**
Prior Recommendation	N/A
Date of Last Change	03/12/2012
Current Price (06/03/13)	$0.10
Target Price	**$0.11**

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 and additional data in April and July. AEMD recently submitted to FDA to initiate small U.S. trial. Compassionate use recently commenced in India. In Sept 2011 AEMD was awarded U.S. DARPA gov't contract related to development of a sepsis treatment device. AEMD completed the initial $2.0MM portion and was just awarded a follow-on option worth up to another $1.6MM. An additional $3.2MM could be awarded in the following years. DARPA contracts provide near-term revenue/cash while also providing credibility of the technology and potentially facilitating the quest towards regulatory approval and commercialization.
Cash / financial position along with a number of material unknowns pose risk. However, recent financing demonstrates ongoing investor interest.

SUMMARY DATA

52-Week High	**$0.15**
52-Week Low	**$0.06**
One-Year Return (%)	**8.09**
Beta	**0.64**
Average Daily Volume (sh)	**312,887**
Shares Outstanding (mil)	**164**
Market Capitalization ($mil)	**$16**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**9**
Insider Ownership (%)	**16**
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 2013 Estimate	**N/A**
P/E using 2014 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 A	1.4 A
2013	0.2 A	0.4 A	0.2 A	0.4 E	1.2 E
2014					1.4 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	-$0.04 A	-$0.08 A
2013	-$0.01 A	-$0.01 A	$0.00 A	-$0.01 E	-$0.02 E
2014					-$0.03 E

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

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WHAT'S NEW….

Hemopurifier Status Update

AEMD appears to be close to getting an answer from FDA on their application for Investigational Device Exemption (IDE). As a reminder, in early January 2013 AEMD announced that they submitted an IDE to the FDA seeking approval to commence a 10-patient safety and effectiveness feasibility study of Hemopurifier. Included in the submission was data from the recent and ongoing studies at hospitals in India as well as HCV capture data, the latter which that the FDA had requested at a pre-IDE meeting in 2011. Then in late-March, following response from FDA which included comments and study design considerations, AEMD resubmitted the IDE.

FDA has since communicated that they are withholding clearance of the IDE until AEMD addresses the agency's safety concern, namely that the company detail their training and monitoring procedures for heparinization - the anticoagulant used during dialysis and with the Hemopurifier. AEMD noted in early May that they were gathering the requested information and expected to have it submitted to FDA in the coming week (i.e. - by mid-May). This will hopefully be the final step and initiation of the U.S. study will be forthcoming.

The proposed trial, which we expect would begin shortly following an approval by FDA of the IDE, would enroll 10 end stage renal disease patients infected with HCV and be conducted by the Renal Research Institute, a partnership between Fresenius Medical Care (FMS), a leader in dialysis products and services, and Beth Israel Medical Center in NYC.

Cancer / Infectious Disease Presentation

Dr. Annette Marleau, AEMD's Director of Tumor Immunology, made a poster presentation titled, "Extracorporeal Exosome Removal: A Therapeutic Strategy to Address an Evolutionary Survival Mechanism Shared by Cancer and Infectious Viral Pathogens" in April at the 2013 International Society of Extracellular Vesicles conference in Boston.

The presentation addressed cancer-secreted exosomes and the role these exosomes play in cancer progression. Aethlon's Hemopurifier directly targets exosomes in infectious diseases and is also being investigated to target cancer-secreted exosomes, something that current cancer drugs fail to sufficiently address. Pre-clinical studies with the Hemopurifier have shown that it can capture exosomes of various cancers including breast, melanoma, ovarian and colorectal.

While cancer currently remains somewhat of a back-burner application for AEMD, the company has been fairly active in pursuing additional research into the role Hemopurifier could play in cancer therapy. Aethlon's focus with cancer had until recently been mostly in the treatment of HER2 breast cancer, although they are also seriously looking at other cancers including melanoma, ovarian, colorectal and lymphoma as they believe their device could also have potential utility with targeting different pathogens and with treating other types of tumors. In particular and based on recent research, melanoma may hold promise for treatment with the Hemopurifier which Aethlon may also pursue in the near future. Furthering AEMD's quest towards application of Hemopurifier in treatment of cancers, in October 2012 the company announced that a U.S. patent was issued to them entitled "Extracorporeal Removal of Microvesicular Particles" which gives AEMD the exclusive right to remove immune suppressive microvesicular particles, which include but are not limited to exosomes from the circulation of treated patients.

Relative to melanoma Aethlon noted in a press release in June 2012 that based on findings from a study led by Cornell University and published in the (online version) journal *Nature*, that the company may pursue a melanoma treatment study that has been proposed by a (unnamed) U.S. cancer research institute.

The Cornell study found that exosomes released by melanoma cancer cells facilitated the spread of the disease throughout the body and to other organs and bones. There was also a predictive relationship between exosome levels and severity of cancer with late-stage (IV) patients presenting with much greater exosomes levels compared to earlier stage patients. This indicates that removal of exosomes from circulation could reduce progression of the deleterious effects of melanoma to other parts of the body and potentially improve patient outcomes. Aethlon has previously demonstrated in pre-clinical testing that their Hemopurifier can capture exosomes from patients with late stage melanoma.

Melanoma, the incidence of which is growing rapidly, is the most deadly form of skin cancer, accounting for approximately 4% of all skin cancer cases. Melanoma can be lethal, especially if it penetrates the lowest skin layer and enters the lymph system. Statistics show that five-year survivability is as high as 97% if melanoma if diagnosed and treated at its earliest stage (IA) but this drops precipitously as the disease progresses. As such, a device that

could effectively treat these late-stage melanoma patients would have massive appeal, not just in the U.S. but worldwide.

As a melanoma study is still in the early proposal stage and Aethlon remains focused on the near-term opportunities with HCV and the DARPA contract, management does not currently have a timeline when a melanoma or other cancer study may commence. This proposed melanoma study could potentially speed Aethlon's cancer program along, although still likely to be more of a back-burner application as Aethlon pursues their near-term endeavors. Nonetheless, we view this as a positive development, potentially offering another opportunity for Aethlon and their Hemopurifier.

In September 2012 AEMD made a presentation at the MD Anderson Cancer Center in Houston entitled, "The extracorporeal removal of tumor-secreted exosomes: An adjunct strategy to reverse immune suppression and inhibit metastases in melanoma". The presentation focused on the potential of the Hemopurifier to be combined with chemo and immunotherapies as a strategy to improve melanoma treatment outcomes.

Battelle Subcontract

In mid-April AEMD announced that they have been selected as a subcontractor by Battelle Memorial Institute under Battelle's $22.8 million systems integrator contract with DARPA related to the sepsis DLT program. The systems integrator is responsible for integrating the various component technologies developed under the DLT program by the various participating organizations, including AEMD. The contract will pay AEMD on a cost (time and materials) plus margin basis so the total that AEMD will eventually bill will not be known until their work is completed. AEMD noted that they began work on this subcontract in early April. Meanwhile, AEMD continues to work on their DARPA contract and has so far completed eleven milestones.

AEMD's Bioterror Program Potentially Revitalized

Another somewhat back-burner application for AEMD's technology has been bioterrorism. Earlier 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 (i.e. most serious) pathogens including the Ebola virus, Dengue virus, Lassa virus, West Nile virus, Monkeypox virus, H5N1 Avian flu virus and the H1N1 Swine flu virus.

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 had been in somewhat of a holding pattern.

AEMD's bioterror program could potentially be revitalized, however, and sparked by renewed federal funding for bioterror countermeasures (including medical countermeasures) through the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) of 2013. The CBO estimates that $11 billion will be spent on PAHPRA from 2014 to 2018. Included in the scope of the program is countermeasures against the new strains of bird flu. Given Hemopurifier's success in pre-clinical studies in capturing the H5N1 Avian flu virus and the H1N1 Swine flu virus, AEMD may be in a solid position to pursue any grant funding targeting the new strains of bird flu.

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 large 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 and followed in April 2012 and again in July 2012 with additional data. Shortly after the latest data was released, AEMD announced they received IRB approval to open up treatment for compassionate use (at the hospital in India where the trial is ongoing). Compassionate use is now underway under this program. The company also hopes to use data from the studies to support a soft launch in India. This data was also used as support for an IDE submitted to the FDA in January 2013 seeking approval to commence a 10-patient safety and effectiveness feasibility study of Hemopurifier. 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 invoiced the final $400k under the $1.97 million initial 12-month award during fiscal Q2 2013. In August 2012 AEMD announced that DARPA had awarded year 2 of the contract which encompasses another eight milestones and will pay up to $1.6 million if all milestones are met. In October 2012 AEMD invoiced $209k related to work under the first milestone and subsequent to 12/31/2012 invoiced for the second milestone (worth $196k).

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 ~$2.8MM 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, compassionate use and commercialization in India should provide additional data points, increase the patient experience and potentially incremental financial contribution. 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 regimens are the new rage as interferon can cause adverse side effects (such as flulike symptoms) and must be injected. There are no interferon-free regimens 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 brought 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 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) would show much better efficacy than these preliminary results. Subsequent to these study results, Gilead announced other data from treatment-naïve patients that showed 88% (22/25) of patients who completed 12 weeks of treatment with GS-7977 had undetectable HCV four weeks after treatment.

It also appears, based on even more recent study data, that GS-7977 could be very effective when dosed with a potent antiviral. In April 2012 Gilead and Bristol-Myers (BMY) announced results of a 24-week study that showed all 88 patients (including 44 with genotype 1) had undetectable virus after four weeks of treatment with a combination of GS-7977 and BMY's experimental daclatasvir. Interferon was not included in the regimen. While this latest data offers more support for GS-7977, it's important to note that ideally any interferon-free regimen would not have to be dosed with another antiviral.

There are also other interferon-free regimens 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've since supplemented it with additional data and are now waiting to hear back from FDA). 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. The fact that genotype 1 patients are being used in this current India-based trial is also an obvious positive for seeking IDE approval.

AEMD appears to be close to getting an answer from FDA on their application for Investigational Device Exemption (IDE). As a reminder, In early January 2013 AEMD announced that they submitted an IDE to the FDA seeking approval to commence a 10-patient safety and effectiveness feasibility study of Hemopurifier. Included in the submission was data from the recent and ongoing studies at hospitals in India as well as HCV capture data, the latter which that the FDA had requested at a pre-IDE meeting in 2011. Then in late-March, following response from FDA which included comments and study design considerations, AEMD resubmitted the IDE.

FDA has since communicated that they are withholding clearance of the IDE until AEMD addresses the agency's safety concern, namely that the company detail their training and monitoring procedures for heparinization - the anticoagulant used during dialysis and with the Hemopurifier. AEMD noted in early May 2013 that they were gathering the requested information and expected to have it submitted to FDA in the coming week (i.e. - by mid-May). This will hopefully be the final step and initiation of the U.S. study will be forthcoming.

The goal of the Extract-1 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

In July 2012 AEMD announced that ten patients (six of which were infected with genotype-1 HCV) have now been treated, the two most recent of which achieved IVR. Aggregate results of all ten patients on the three efficacy endpoints was not offered although Aethlon does note that four of the six (67%) genotype-1 patients have achieved RVR (undetectable viral load at 30 days).

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 has previously indicated that once the full data set is available that they will look to have it published.

In a press release on 4/24/2012 Aethlon announced preliminary data related to the capture of HCV virus in the Hemopurifier cartridge. The press release notes that data from three cartridges has been analyzed for amount of HCV virus captured after a single six-hour treatment. Also noted was that two of the three cartridges were cracked prior to being evaluated. The cartridge that remained fully intact showed virus capture of 3 billion copies of HVC. The two cracked cartridges, in which the integrity of the virus capture data may have been compromised, showed capture of 145 million and 353 million copies of HCV. While we note that its difficult to judge the clinical significance of this data, it does clearly show that the Hemopurifier is capturing the HCV virus.

AEMD has also been looking to open up treatment outside of the Extract-1 study for compassionate use and shortly following the 10-patient announcement, Aethlon announced that Medicity's Institutional Review Board agreed to allow compassionate use treatment to patients that have failed or relapsed on standard HCV drug therapy. The compassionate use program is separate from the clinical study and Extract-1 is still ongoing. AEMD believes the compassionate use program could draw patients from not only India but other countries including the United States and in Europe. In October 2012 AEMD announced the compassionate use protocol and patient inclusion/exclusion criteria and in December announced treatment pricing ($7,235 for 3-day treatment, $2,295 each add'l day) as well as that the compassionate use program was expanded to include individuals that experience a viral breakthrough during standard of care drug therapy. This program should provide AEMD with another revenue stream (albeit likely minimal, particularly at the outset) and potentially more importantly, will increase the overall patient experience and treatment volume which could bode well for increasing awareness of Hemopurifier therapy and further bolster credibility of the technology. We have since begun to model a small amount of revenue related to this compassionate use program.

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 focus with cancer had until recently been mostly in the treatment of HER2 breast cancer, although they are also seriously looking at other cancers including melanoma, ovarian, colorectal and lymphoma as they believe their device could also have potential utility with targeting different pathogens and with treating other types of tumors. In particular and based on recent research, melanoma may hold promise for treatment with the Hemopurifier which Aethlon may also pursue in the near future. Furthering AEMD's quest towards application of Hemopurifier in treatment of cancers, in October 2012 the company announced that a U.S. patent was issued to them entitled "Extracorporeal Removal of Microvesicular Particles" which gives AEMD the exclusive right to remove immune suppressive microvesicular particles, which include but are not limited to exosomes from the circulation of treated patients.

Relative to melanoma in September 2012 AEMD made a presentation at the MD Anderson Cancer Center in Houston entitled, "The extracorporeal removal of tumor-secreted exosomes: An adjunct strategy to reverse immune suppression and inhibit metastases in melanoma". The presentation focused on the potential of the Hemopurifier to be combined with chemo and immunotherapies as a strategy to improve melanoma treatment outcomes.

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. Nonetheless, cancer treatment could be a viable application and clearly represents a humongous potential market.

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.

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.

Cornell Study Shows Promise in Melanoma….
Aethlon noted in a press release in June 2012 that based on findings from a study led by Cornell University and published in the (online version) journal *Nature*, that the company may pursue a melanoma treatment study that has been proposed by a (unnamed) U.S. cancer research institute.

The Cornell study found that exosomes released by melanoma cancer cells facilitated the spread of the disease throughout the body and to other organs and bones. There was also a predictive relationship between exosome levels and severity of cancer with late-stage (IV) patients presenting with much greater exosomes levels compared to earlier stage patients. This indicates that removal of exosomes from circulation could reduce progression of the

deleterious effects of melanoma to other parts of the body and potentially improve patient outcomes. Aethlon has previously demonstrated in pre-clinical testing that their Hemopurifier can capture exosomes from patients with late-stage melanoma.

Melanoma, the incidence of which is growing rapidly, is the most deadly form of skin cancer, accounting for approximately 4% of all skin cancer cases. Melanoma can be lethal, especially if it penetrates the lowest skin layer and enters the lymph system. Statistics show that five-year survivability is as high as 97% if melanoma if diagnosed and treated at its earliest stage (IA) but this drops precipitously as the disease progresses. As such, a device that could effectively treat these late-stage melanoma patients would have massive appeal, not just in the U.S. but worldwide.

As a melanoma study is still in the early proposal stage and Aethlon remains focused on the near-term opportunities with HCV and the DARPA contract, management does not currently have a timeline when a melanoma study may commence. This proposed melanoma study could potentially speed Aethlon's cancer program along, although still likely to be more of a back-burner application as Aethlon pursues their near-term endeavors. Nonetheless, we view this as a positive development, potentially offering another opportunity for Aethlon and their Hemopurifier.

- **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**

Another somewhat back-burner application for AEMD's technology has been bioterrorism. Earlier 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 (i.e. most serious) pathogens including the Ebola virus, Dengue virus, Lassa virus, West Nile virus, Monkeypox virus, H5N1 Avian flu virus and the H1N1 Swine flu virus.

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 had been in somewhat of a holding pattern.

AEMD's bioterror program could potentially be revitalized, however, and sparked by renewed federal funding for bioterror countermeasures (including medical countermeasures) through the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) of 2013. The CBO estimates that $11 billion will be spent on PAHPRA from 2014 to 2018. Included in the scope of the program is countermeasures against the new strains of bird flu. Given Hemopurifier's success in pre-clinical studies in capturing the H5N1 Avian flu virus and the H1N1 Swine flu virus, AEMD may be in a solid position to pursue any grant funding targeting the new strains of bird flu.

➢ 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 initial contract was for $2.0 million over the first twelve months (representing eight performance and payment milestones), full payment of which was contingent on Aethlon hitting all the requisite milestones. Aethlon started work under the contract in October 2011 and billed the final $400k (representing the final 3 milestones) of the $2.0 million contract during fiscal Q2 2013 (ending 9/30/2012). See Appendix for description of the completed DARPA milestones. In August DARPA picked up the second year option of the contract which encompasses another 8 milestones and will pay AEMD an additional (up to) $1.6 million over 12 months. In fiscal Q3 (ending 12/31/2012) AEMD booked $209k representing work under the first milestone and subsequent to Q3 billed for the second milestone (worth $196k). DARPA also the option of entering into the remainder of the proposed contract for years three through five, which would pay Aethlon up to an additional $3.2 million, annual payments under which would range between $775k and $1.6 million. Specifics (activities, dates, etc.) of the remaining milestones under the current $1.6 million contract or on the $3.2 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. One such opportunity came in April 2013 when AEMD announced that they have been selected as a subcontractor by Battelle Memorial Institute under Battelle's $22.8 million systems integrator contract with DARPA related to the sepsis DLT program. The systems integrator is responsible for integrating the various component technologies developed under the DLT program by the various participating organizations. The contract will pay AEMD on a cost (time and materials) plus margin basis so the total that AEMD will eventually bill will not be known until their work is completed. AEMD noted that they began work on this subcontract in early April.

➢ 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….

In Q4 2012 (ending 3/31/2012) Aethlon 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 Q3 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

Aethlon exited fiscal Q3 (12/31/2012) with $108k in cash and equivalents, compared to $272k at the end of the prior quarter (9/30/2012). Cash used in operations was $662k in Q3 ($1.6MM in 9 months ending 12/31/2012), compared to $595k used in Q2 and $1.84 million in fiscal 2012.

Q3 ending cash balance benefitted from Aethlon raising approximately $498k from the sale of 7.87 million common shares in the separate transactions during the quarter. AEMD sold another $205k (3.2MM shares @ $0.064) worth of restricted shares subsequent to Q3 quarter.

Despite being in default on the majority of their debt obligations (although they have recently successfully converted some debt to common stock), Aethlon continues to be successful in raising piecemeal capital to finance operations. We think this speaks positively to the ongoing investor interest in the company and faith in the potential for the Hemopurifier. And while the additional recent financing and revenue from the year-2 DARPA contract should provide some breathing room, as we've noted in the past Aethlon will need to raise a substantial amount of cash, enter into partnering arrangements or score additional valuable contracts/grants (which could include the potentially valuable DARPA systems integrator contract) in order to maintain operations for the longer-term.

Debt
As of 12/31/2012 Aethlon had $370k outstanding in notes payable, in addition to $2.4 million outstanding in convertible notes, the majority of which are in default. Other current liabilities total $1.2 million, with $942k in accrued interest, $180k in accrued legal fees, and $106k in deferred rent and other expenses. The company's also carrying $6546k in accounts payable.

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 3 through 5 (which would pay Aethlon an additional $3.2 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. Aside from a very small contribution from estimated (essentially a guess at this point) revenue related to compassionate use in India and the Battelle subcontract, we currently do not model revenue from any other source other than DARPA through fiscal 2014 given 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. The stock has traded near $0.11, implying an equity value of around $17 million and (if all the debt was performing) an enterprise value (i.e. - par take-out value) of about $20 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 price target mirrors the recent 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 $20 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 (12/31/2012) Aethlon had little cash and was in default on much of its ~$2.8 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 sometime in calendar 2013, and a pivotal efficacy study is completed in 2013 or 2014. 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

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.

PROJECTED INCOME STATMENT

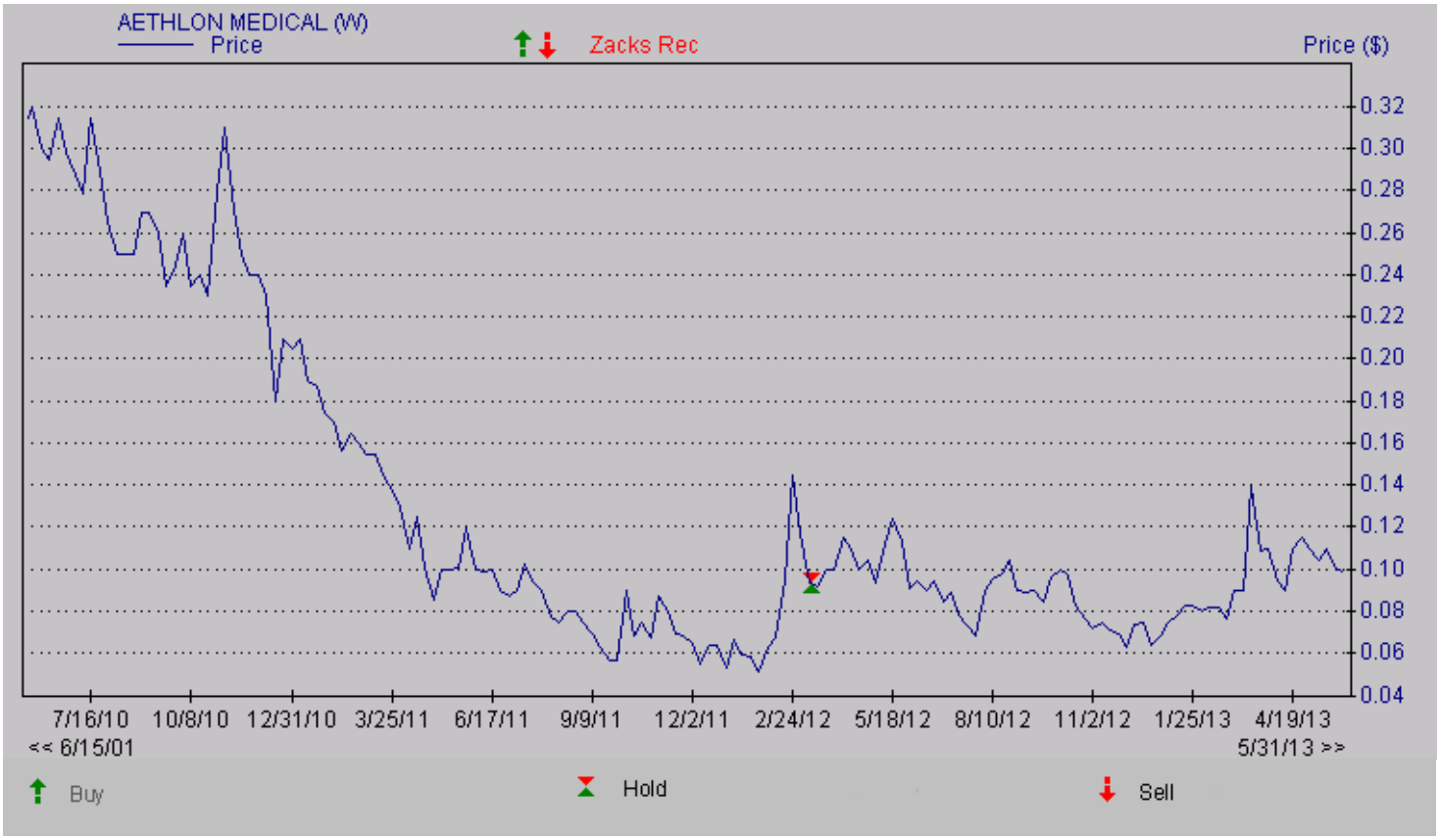
Aethlon Medical, Inc.

	2011 A	Q1A	Q2A	Q3A	Q4A	2012 A	Q1 A	Q2 A	Q3 A	Q4 E	2013 E	2014 E
Revenue	$0.0	$0.0	$0.0	$958.1	$401.5	$1,359.6	$216.7	$400.1	$208.8	$380.0	$1,205.6	$1,440.0
YOY Growth	-	-	-	-	-	-	-		*-78.2%*	*-5.4%*	*-11.3%*	*19.4%*
Cost of Goods Sold	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$12.0	$12.0	$40.0
Gross Income	$0.0	$0.0	$0.0	$958.1	$401.5	$1,359.6	$216.7	$400.1	$208.8	$368.0	$1,193.6	$1,400.0
Gross Margin	-	-	-	*100.0%*	*71.5%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*96.8%*	*99.0%*	*97.2%*
SG&A	$4,117.1	$831.4	$764.4	$763.0	$1,026.2	$3,385.0	$915.7	$839.8	$774.4	$696.0	$3,225.9	$3,398.0
% SG&A	-	-	-	*79.6%*	*255.6%*	*249.0%*	*422.5%*	*209.9%*	*370.9%*	*183.2%*	*267.6%*	*236.0%*
R&D	$440.0	$201.0	$118.6	$536.1	$233.3	$1,089.0	$291.9	$360.1	$371.2	$466.0	$1,489.2	$2,350.0
% R&D	-	-	-	*56.0%*	*58.1%*	*80.1%*	*134.7%*	*90.0%*	*177.8%*	*122.6%*	*123.5%*	*163.2%*
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
Operating Income	($4,557.1)	($1,032.5)	($883.0)	($341.0)	($857.9)	($3,114.3)	($990.8)	($799.8)	($936.8)	($794.0)	($3,521.4)	($4,348.0)
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-
Loss on extinguishment of debt	$3,306.3	$0.0	$0.0	$0.0	$77.3	$77.3	$0.0	$71.1	$26.7	$60.0	$157.8	$120.0
(Gain)/ loss on derivative liability	($6,079.8)	($491.8)	($1,029.7)	($74.9)	$2,363.3	$766.9	($687.6)	$326.1	($1,384.3)	$0.0	($1,745.7)	$0.0
Interest (income), net	$3,927.7	$1,685.1	$600.2	$308.3	$1,199.1	$3,792.7	$688.6	$224.3	$106.8	$147.0	$1,166.7	$1,250.0
Other expense	$0.0	$360.2	$0.0	$0.0	$0.0	$360.2	$25.0	$0.0	$0.0	$0.0	$25.0	$0.0
Pre-Tax Income	($5,711.4)	($2,585.9)	($453.5)	($574.3)	($4,497.6)	($8,111.4)	($1,016.8)	($1,421.3)	$313.9	($1,001.0)	($3,125.2)	($5,718.0)
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
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%*
Net Income	($5,711.4)	($2,585.9)	($453.5)	($574.3)	($4,497.6)	($8,111.4)	($1,016.8)	($1,421.3)	$313.9	($1,001.0)	($3,125.2)	($5,718.0)
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-
EPS	($0.08)	($0.03)	($0.00)	($0.01)	($0.04)	($0.08)	($0.01)	($0.01)	$0.00	($0.01)	($0.02)	($0.03)
YOY Growth	-	-	-	-	-	-	*-72.7%*		*-136.9%*	*-85.9%*	*-74.2%*	*31.5%*
Diluted Shares O/ S	69,611	87,842	99,703	107,061	112,458	101,766	126,316	144,701	158,759	177,000	151,694	211,000

Brian Marckx, CFA

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HISTORICAL ZACKS RECOMMENDATIONS



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