AETHLON MEDICAL INC
Form 10-K
June 29, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(MARK ONE)

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended March 31, 2016

OR

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

For the transition period from _____ to _____

COMMISSION FILE NUMBER 001-37487

AETHLON MEDICAL, INC.

(Exact name of registrant as specified in its charter)

NEVADA	13-3632859
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

9635 Granite Ridge Drive, Suite 100	
San Diego, California	92123
(Address of principal executive office)	(Zip Code)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (858) 459-7800

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE EXCHANGE ACT:

TITLE OF EACH CLASS	NAME OF EACH EXCHANGE ON WHICH REGISTERED
COMMON STOCK, $.001 PAR VALUE	THE NASDAQ STOCK MARKET LLC

SECURITIES REGISTERED UNDER SECTION 12(g) OF THE EXCHANGE ACT:

NONE

(TITLE OF CLASS)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [_] No [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes [_] No [X]

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

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

Large accelerated filer [_] Accelerated filer [_]
Non accelerated filer [_] Smaller reporting company [X]
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes [_] No [X]

The aggregate market value of the common stock held by non-affiliates of the registrant as of September 30, 2015 was approximately $49 million, computed by reference to the closing sale price of the common stock of $7.16 per share on the Nasdaq Capital Market on September 30, 2015. Shares of common stock held by each executive officer and director and by each person who owns 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. The determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of the common stock of the registrant outstanding as of June 29, 2016 was 7,622,393.

Explanatory Note: On April 14, 2015, the registrant completed a 1-for-50 reverse stock split. Accordingly, the registrant’s authorized common stock was reduced from 500,000,000 shares to 10,000,000 shares, and each 50 shares of outstanding common stock held by stockholders were combined into one share of common stock. This Form 10-K reflects, and the accompanying consolidated financial statements and accompanying notes have been retroactively revised to reflect, such reverse stock split as if it had occurred on April 1, 2014. All shares and per share amounts have been revised accordingly.

TABLE OF CONTENTS

PART I

ITEM 1. DESCRIPTION OF BUSINESS

Overview and Corporate History

We are a leading developer of immunotherapeutic technologies to combat infectious disease and cancer. To augment the body's natural immune defenses, the Aethlon Hemopurifier® eliminates life-threatening disease targets that are often shielded from the immune system and not well addressed by traditional drug therapies. The technology captures circulating viruses, bacterial toxins and cancer promoting exosomes through affinity attachment to a unique structure that cloaks these targets from immune detection. At present, the Hemopurifier® is being advanced under an FDA approved clinical study. Aethlon is also the majority owner of Exosome Sciences, Inc., or Exosome, a company focused on the discovery of exosomal biomarkers to diagnose and monitor life-threatening diseases. In addition, we operate under a Department of Defense contract through the Defense Advanced Research Projects Agency, or DARPA, related to the development of a sepsis treatment device. We also operate under a second Department of Defense contract as a subcontractor.

Aethlon Medical was formed on March 10, 1999. Our executive offices are located at 9635 Granite Ridge Drive, Suite 100, San Diego, California 92123. Our telephone number is (858) 459-7800. All references to “us” or “we” are references to Aethlon Medical, Inc., combined with its majority-owned subsidiary, Exosome Sciences, Inc.

Target Market and Strategy

Our primary therapeutic business segment is divided into two areas. First, we are advancing our lead product, the Aethlon Hemopurifier, which targets the removal of circulating viruses and shed glycoproteins to treat infectious viral pathogens. In oncology indications, the Hemopurifier targets the removal of circulating exosomes, which are released to promote cancer progression and to seed the spread of metastasis.

The second focus is government contracting. We operate under two Department of Defense contracts related to a program entitled “Dialysis-Like Therapeutics.” One is a contract with DARPA, and the other is a subcontract with Battelle Memorial Institute.. Under these contracts, our tasks include the development of a dialysis-like device to prevent sepsis, a fatal bloodstream infection that is often the cause of death in combat-injured soldiers. Specific to the Hemopurifier, the program has focused on validating the capture of viral pathogens and bacterial toxins.

The third facet of our business is conducted through Exosome, which is our diagnostic business segment and is developing exosome-based products to diagnose and monitor life-threatening disease conditions.

We initially developed the Hemopurifier as a broad-spectrum countermeasure to address the many infectious viral pathogens that are not addressed with antiviral drugs. We also envision our technology serving as an adjunct therapy to improve the benefit of infectious disease and cancer therapy regimens marketed by pharmaceutical organizations. For example, a clinical trial protocol administered at the Medanta Medicity Institute in India was designed to treat Hepatitis C patients as they began their standard of care drug regimen as a means to reduce the time it normally takes for the virus to become undetectable in the patient's blood. At completion of the Medanta Medicity study, we reported that patients who received the Hemopurifier therapy protocol had higher rapid virologic response and sustained virologic response rates as compared to what would normally be expected for Hepatitis C virus infected individuals who receive standard of care interferon-ribavirin drug therapy alone.

Our Lead Device: The Aethlon Hemopurifier

The Aethlon Hemopurifier is a device that selectively targets the rapid elimination of circulating viruses and tumor-secreted exosomes that promote cancer progression. More specifically, the Hemopurifier addresses antiviral drug-resistance in Hepatitis C virus and Human Immunodeficiency Virus-infected individuals; serves as a countermeasure against viral pathogens not addressed by drug or vaccine therapies; and, we believe, represents the first therapeutic strategy to address cancer promoting exosomes. In clinical studies conducted in India, safety and efficacy observations of Hemopurifier therapy have been observed in both Hepatitis C virus and Human Immunodeficiency Virus-infected individuals. We are currently conducting the first U.S. Food and Drug Administration, or FDA, approved studies of Hemopurifier therapy in the U.S.

The Scientific Mechanism of the Hemopurifier

The Hemopurifier is an extracorporeal (situated or occurring outside the body) device designed for the single-use removal of viruses, viral toxins, and deleterious exosomes from the circulatory system of treated patients. Delivery of Hemopurifier therapy can occur through the established infrastructure of continuous renal replacement therapy and dialysis instruments routinely found in hospitals and clinics worldwide. Most extracorporeal techniques, including dialysis and plasmapheresis, are designed to solely remove circulating particles by molecule size, which results in the elimination of disease targets as well as blood components required for health.

1

However, the Hemopurifier is an interactive technology that incorporates a lectin affinity agent that binds to a unique high mannose signature that is abundant on the surface of tumor-derived exosomes and glycoproteins that reside on the outer membrane of infectious viruses. The Hemopurifier is designed to provide a broad-spectrum mechanism to reduce the presence of certain cancer and infectious disease related particles. To date, clinical treatment protocols have administered Hemopurifier therapy for periods lasting from three to six and one half hours in duration.

The Hemopurifier - Antiviral Drug-Resistance; Planned U.S. Clinical Trials

The Hemopurifier provides a novel methodology to target mutant viral strains that trigger antiviral drug resistance in both Human Immunodeficiency Virus and Hepatitis C virus infections. In Hepatitis C virus care, we believe the Hemopurifier is positioned to address drug resistance associated with emerging all-antiviral therapies and also to accelerate Hepatitis C virus depletion at the outset of peginterferon+ribavirin therapy.

Based on previous studies we conducted in India, safety and efficacy observations of Hemopurifier therapy have been observed in both disease conditions. As a result of these outcomes, we have initiated the first FDA-approved feasibility study of Hemopurifier therapy in the U.S. The feasibility study is being conducted on Hepatitis C virus-infected patients at DaVita MedCenter Dialysis in Houston, Texas. The principal investigator for the study is Dr. Ronald Ralph, who replaced Dr. Stephen Z. Fadem as principal investigator in late 2015.

Successful completion of this study will permit us to initiate further stage studies that are required for market clearance to treat Hepatitis C virus and other viral pathogens in the U.S. Our feasibility study protocol calls for the enrollment of ten Hepatitis C virus-infected end stage renal disease patients who have not received any pharmaceutical therapy for their Hepatitis C virus infection for at least 30 days. The protocol will consist of a control phase of three consecutive standard dialysis treatments during week one followed by the inclusion of our Hemopurifier during a total of six dialysis sessions conducted during weeks two and three. The rate of adverse events observed during the Hemopurifier therapy phase will be compared to the rate experienced during the control phase. Per-treatment changes of viral load will be observed through quantitative polymerase chain reaction analysis. Additionally, we plan to measure the number of viral copies of Hepatitis C virus captured within the Hemopurifier during each treatment session.

On February 14, 2014, we entered into an agreement with Total Renal Research, Inc. (dba DaVita Clinical Research). Pursuant to the agreement, Da Vita Clinical Research is conducting site management administrative services for a study. The agreement with DaVita Clinical Research requires us to pay certain expenses related to the study protocol projected to be less than $200,000, including certain start-up and close-out costs, patient compensation and project management fees. Additional activities and completion of this clinical trial will require us to pay additional costs estimated to be $650,000. We will also be responsible for the fees for any third-party consulting physicians, including Dr. Ralph, utilized in connection with the study and other pass-through expenses if incurred. The work order under

this agreement was effective as of May 16, 2014 and will continue in effect until completion of the services being provided by DaVita Clinical Research.

The Hemopurifier - Antiviral Studies in India

Previously, we conducted Hepatitis C virus treatment studies at the Apollo Hospital, Fortis Hospital, and most recently the Medanta Medicity Institute in India.

In the Medanta Medicity Institute study, twelve Hepatitis C virus-infected individuals were enrolled to receive three six-hour Hemopurifier treatments during the first three days of a 48-week peginterferon+ribavirin treatment regimen. The study was conducted under the leadership of Dr. Vijay Kher at the Medanta Medicity Institute, a multi-specialty medical institute established to be a premier center for medical tourism in India. Dr. Kher's staff reported that Hemopurifier therapy was well tolerated and without device-related adverse events in the twelve treated patients.

Of these twelve patients, ten completed the Hemopurifier-peginterferon+ribavirin treatment protocol, including eight genotype-1 patients and two genotype-3 patients. Eight of the ten patients achieved a sustained virologic response, which is the clinical definition of treatment cure and is defined as undetectable Hepatitis C virus in the blood 24 weeks after the completion of the 48-week peginterferon+ribavirin drug regimen. Both genotype-3 patients achieved a sustained virologic response, while six of the eight genotype-1 patients achieved a sustained virologic response.

Of the ten patients who completed the full treatment protocol, five also achieved a rapid virologic response, defined as undetectable Hepatitis C virus in the blood at day 30 of therapy. Rapid virologic response represents the clinical endpoint that best predicts sustained virologic response cure rates resulting from peginterferon+ribavirin therapy. As a point of reference, the landmark Individualized Dosing Efficacy vs Flat Dosing to Assess Optimal Pegylated Interferon Therapy study of 3,070 Hepatitis C virus genotype-1 patients documented that 10.35% (n=318/3070) of peginterferon+ribavirin-treated patients achieved a rapid virologic response. Patients who achieved a rapid virologic response had sustained virologic response rates of 86.2% (n=274/318) versus sustained virologic response rates of 32.5% (n=897/2752) in non-rapid virologic response patients. Two of the genotype-1 patients who achieved a rapid virologic response also achieved an immediate virologic response, defined as undetectable Hepatitis C virus in the blood seven days after initiation of Hemopurifier-peginterferon+ribavirin treatment protocol. The earliest measured report of undetectable Hepatitis C virus in blood in the Individualized Dosing Efficacy vs Flat Dosing to Assess Optimal Pegylated Interferon Therapy study was on day 14 of the study.

Data from two patients was not included in the reported Hemopurifier-peginterferon+ribavirin dataset. One of these patients was a genotype-5 patient who discontinued peginterferon+ribavirin therapy at day 180, yet still achieved a sustained virologic response. The second patient was a genotype-3 patient who also achieved a sustained virologic response, yet was unable to tolerate peginterferon+ribavirin therapy and discontinued therapy at day 90. Overall, ten of the twelve patients who enrolled in the study achieved a sustained virologic response and seven of the twelve patients achieved a rapid virologic response.

Hemopurifier - Human Immunodeficiency Virus; Single Proof Study

In addition to treating Hepatitis C virus-infected individuals, we have conducted a single proof-of-principle treatment study related to the treatment of Human Immunodeficiency Virus. In the study, Hemopurifier therapy reduced viral load by 93% in a Human Immunodeficiency Virus-Acquired Immunodeficiency Syndrome-infected individual without the administration of antiviral drug therapy. The study protocol provided for 12 Hemopurifier treatments, each four hours in duration, which were administered over the course of one month.

Researchers at the Morehouse School of Medicine have since discovered that the Hemopurifier is able to capture exosomes that transport negative regulatory factor protein, which is reported to suppress the immune response in Human Immunodeficiency Virus-infected individuals.

The Hemopurifier - Viral Pathogens Not Addressed by Drug Therapies

The protocol design of our forthcoming FDA-approved study was originally designed as a human safety challenge and model for addressing drug and vaccine resistant bioterror and emerging pandemic threats. *In vitro* studies conducted by leading government and non-government researchers have demonstrated that the Hemopurifier is able to capture a broad spectrum of some of the world's deadliest viral pathogens. These include: Dengue hemorrhagic fever, Ebola hemorrhagic fever, Lassa hemorrhagic fever, H5N1 avian influenza, H1N1 swine flu virus, the reconstructed 1918 influenza virus, West Nile virus and Vaccinia and Monkeypox, which serve as models for human smallpox infection. Human efficacy studies are not permissible against high-threat bioterror and pandemic threats.

The following table lists some of the key viral pathogens captured during *in vitro* studies and the name of the research institute that ran the study.

Virus Type	**Collaborator**

Ebola Virus	United States Army Medical Research Institute of Infectious Diseases/Centers for Disease Control
Dengue Fever	National Institute of Virology/World Health Organization
Lassa Hemorrhagic Fever	Southwest Foundation for Biomedical Research
West Nile Virus	Battelle
H5N1 Avian Flu	Battelle
1918-r Spanish Flu	Battelle
2009 H1N1 Swine Flu	Battelle

The Hemopurifier - Candidate to Treat Cancer

In “Extracellular Vesicles: Emerging Targets for Cancer Therapy,” a review article sponsored by the National Cancer Institute and published in the July 2014 issue of *Trends in Molecular Medicine*, we were the sole organization referenced to have a therapeutic candidate to address tumor-secreted exosomes, which have been discovered to suppress the immune system of cancer patients, seed the creation and spread of metastasis, promote angiogenesis, trigger resistance to chemotherapy, and transport primary cancer therapeutic targets of the biopharmaceutical industry. To date, we have received an issued patent that protects the use of our Hemopurifier to remove immunosuppressive extracellular vesicles or exosomes from the blood of cancer patients. Through internal research and external research collaborations, we have demonstrated that the affinity lectin immobilized in our Hemopurifier is able to bind exosomes underlying a broad spectrum of disease indications including cancer.

We believe that Hemopurifier therapy could play a role in the emerging immuno-oncology industry as an adjunct that can combine with established and emerging cancer therapies without adding drug toxicity. More specifically, we believe that a mechanism to inhibit exosome immune suppression should be clinically tested in combination with drugs designed to stimulate the immune response.

On April 9, 2015, we entered into an investigator-initiated clinical trial agreement with the University of California, Irvine, or UCI, pursuant to which UCI will conduct a five-year clinical study protocol entitled “Plasma Exosome Concentration in Cancer Patients Undergoing Treatment.” The protocol will seek to enroll five individuals in each of nine defined tumor types for a total study population of up to 45 subjects. The tumor types include the following forms of cancer: breast adenocarcinoma, colorectal, gastric and gastroesophageal, pancreatic, cholangiocarcinoma, lung, head and neck, melanoma and ovarian adenocarcinoma. The principal investigator of the study is Edward Nelson, M.D. The budget for the protocol provides for (i) $19,032 in startup charges; (ii) $8,039 in protocol-related variable pass-through charges; and (iii) per subject visit charges of $3,359 per subject, for a total subject visit charge of $151,155 for 45 subjects. We will bear these costs. UCI may disseminate the results of the clinical trial through presentation and publication but may not disclose any of our confidential information.

Exosome Sciences, Inc. - Diagnostic Candidates

Through our majority-owned subsidiary Exosome, which is our diagnostic product-oriented business segment, we are developing exosome-based product candidates to diagnose and monitor neurological disorders and cancer. Since it began operations in 2013, Exosome researchers have disclosed that they have isolated brain-specific biomarkers associated with Alzheimer's Disease and Chronic Traumatic Encephalopathy. Specific to Chronic Traumatic Encephalopathy, Exosome is participating in a research collaboration with The Boston University CTE Center to study the correlation of a biomarker known as tausome with Chronic Traumatic Encephalopathy. The initial results from that research collaboration were published in an article entitled “Preliminary Study of Plasma Exosomal Tau as a Potential Biomarker for Chronic Traumatic Encephalopathy” in the *Journal of Alzheimer's Disease* on April 12, 2016.

Exosome researchers have demonstrated the ability to identify, quantify, and characterize circulating Glioblastoma multiforme exosomes, which hold promise as a disease biomarker to identify the early detection of this aggressive form of cancer and monitor response to therapy. We believe that the discovery of circulating glioblastoma multiforme exosomes may offer a potential new paradigm in glioblastoma multiforme exosomes clinical management through a platform technology to predict tumor regression or progression.

U.S. Government Contract with the Defense Advanced Research Projects Agency

On September 30, 2011, we entered into a $6.8 million multi-year contract with the Defense Advanced Research Projects Agency, or DARPA, part of the Department of Defense, resulting from our response to a program entitled “Dialysis-Like Therapeutics.” Under this contract, our tasks include the development of a dialysis-like device to prevent sepsis, a fatal bloodstream infection that is often the cause of death in combat-injured soldiers.

The initial award from DARPA was a fixed-price contract with potential total payments to us of $6,794,389 over the course of five years. As noted below, such contract was subsequently reduced by $858,469. Fixed price contracts require the achievement of multiple, incremental milestones to receive the full award during each year of the contract. Under the terms of the contract, we are required to perform certain incremental work towards the achievement of specific milestones against which we will invoice the government for fixed payment amounts.

Originally, only the base year (year one of the contract) was effective for the parties, however, DARPA subsequently exercised the option on the remaining four years of the contract. The milestones are comprised of planning, engineering and clinical targets, the achievement of which in some cases will require the participation and contribution of third party participants under the contract. We cannot assure you that we alone, or with third party participants, will meet such milestones to the satisfaction of the government and in compliance with the terms of the contract or that we will be paid the full amount of the contract revenues during any year of the remaining contract term. We commenced work under the contract in October 2011.

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

The DARPA contract requires us to perform certain scientific research and development activities geared toward the achievement of specific milestones set forth in the contract. During the fiscal years ended March 31, 2016 and March 31, 2015, we recognized revenue of $863,011 and $630,887, respectively, under the DARPA contract. Based on the DARPA contract, as now in force, we may achieve up to an additional $387,438 in revenue under the DARPA contract during the fiscal year ending March 31, 2017.

Subcontract with Battelle Memorial Institute

We entered into a subcontract agreement with Battelle in March 2013. Battelle was chosen by DARPA to be the prime contractor on the systems integration portion of the DARPA contract, and we are one of several subcontractors on that systems integration project. We began generating revenues under the subcontract in the three months ended September 30, 2013. During the fiscal years ended March 31, 2016 and March 31, 2015, we recognized revenue of $23,561 and $131,530, respectively, under the Battelle subcontract. Our expected future revenue from the subcontract will be at the discretion of Battelle. The Battelle subcontract is our first cost-reimbursable contract.

Our revenue under this contract is a function of cost reimbursement plus an overhead mark-up for hours devoted to the project by specific employees (with specific hourly rates for those employees), for travel expenses related to the project, for any equipment purchased for the project and for the cost of any consultants hired by us to perform work on the project. Each payment will require approval by the program manager at Battelle.

Research and Development Costs

A substantial portion of our operating budget is used for research and development activities. The cost of research and development, all of which has been charged to operations, amounted to approximately $782,000 and $1,028,000 in the fiscal years ended March 31, 2016 and 2015, respectively.

Intellectual Property

We currently own or have license rights to a number of U.S. and foreign patents and patent applications and endeavor to continually improve our intellectual property position. We consider the protection of our technology, whether owned or licensed, to the exclusion of use by others, to be vital to our business. While we intend to focus primarily on patented or patentable technology, we may also rely on trade secrets, unpatented property, know-how, regulatory exclusivity, patent extensions and continuing technological innovation to develop our competitive position. We also own certain trademarks.

Patents

We have been exclusively assigned all rights and title to and interest in an invention and related worldwide patent rights for a method to treat cancer under an assignment agreement with the London Health Science Center Research, Inc. The invention provides for the "Depression of anticancer immunity through extracorporeal removal of microvesicular particles" (including exosomes) for which the U.S. Patent and Trademark Office issued a patent in 2012 (patent #8,288,172) and for which we have filed additional patent applications domestically and abroad (patent applications #US13/623662, #US14/180093, #US14/185033, #EP7,752,778.6, #HK9,104,740.6, #IN8139/DELNP/2008 and #CA2644855). Please see the tables below for more information regarding these patents and patent applications.

The agreement provides for an upfront payment of 800 shares of unregistered common stock and a 2% royalty on any future net sales. We are also responsible for paying certain patent application and filing costs. Under the assignment agreement, the London Health Science Center Research, Inc. sold and assigned all of its rights, title and interest in the worldwide patents to us.

The following table lists all of our issued patents and patent applications, including their ownership status:

Patents Issued in the United States

PATENT #	PATENT NAME	ISSUANCE DATE	OWNED OR LICENSED	EXPIRATION DATE
9,364,601	Extracorporeal removal of microvesicular particles	6/14/16	Owned	10/2/29
8,288,172	Extracorporeal removal of microvesicular particles (exosomes) (method patent)	10/16/12	Owned	3/30/29
7,226,429	Method for removal of viruses from blood by lectin affinity hemodialysis	6/5/07	Owned	1/20/25
6,528,057	Method for removal of HIV and other viruses from blood	3/4/03	Licensed	8/30/19

Patent Applications in the United States

APPLICATION #	APPLICATION NAME	FILING DATE	OWNED OR LICENSED
14/490,418	Method for removal of viruses from blood by lectin affinity hemodialysis	9/18/14	Owned
14/856361	Device and method for purifying virally infected blood	9/16/15	Owned
14/790684	Affinity capture of circulating biomarkers	7/02/15	Owned
13/808561	Methods and compositions for quantifying exosomes	8/14/13	Owned
14/180093	Extracorporeal removal of microvesicular particles	2/13/14	Owned
14/185033	Extracorporeal removal of microvesicular particles	2/20/14	Owned
62/258340	Plasma exosomal tau as a biomarker for chronic traumatic encephalopathy	11/20/15	Owned
62/352358	Exosomal Tau as a Biomarker for Brain Disorders	6/20/16	Owned

Foreign Patents

PATENT #	PATENT NAME	ISSUANCE DATE	OWNED OR LICENSED	EXPIRATION DATE
2,353,399	Method for removal of viruses from blood by lectin affinity hemodialysis (Russia)	4/27/09	Owned	1/20/24
770,344	Method for removal of HIV and other viruses from blood (Australia)	6/3/04	Licensed	8/30/19
DE69929986	Method for removal of HIV and other viruses from blood (Germany)	2/22/06	Licensed	8/30/19
1,109,564	Method for removal of HIV and other viruses from blood (France)	2/22/06	Licensed	8/30/19
1,109,564	Method for removal of HIV and other viruses from blood (Great Britain)	2/22/06	Licensed	8/30/19
1,109,564	Method for removal of HIV and other viruses from blood (Italy)	2/22/06	Licensed	8/30/19
2342203	Method for removal of HIV and other viruses from blood (Canada)	3/1/11	Licensed	8/30/19
1624785	Method for removal of viruses from blood by lectin affinity hemodialysis (Belgium)	7/17/13	Owned	1/20/24
1624785	Method for removal of viruses from blood by lectin affinity hemodialysis (Ireland)	7/17/13	Owned	1/20/24
1624785	Method for removal of viruses from blood by lectin affinity hemodialysis (Italy)	7/17/13	Owned	1/20/24
1624785	Method for removal of viruses from blood by lectin affinity hemodialysis (Great Britain)	7/17/13	Owned	1/20/24
1624785	Method for removal of viruses from blood by lectin affinity hemodialysis (France)	7/17/13	Owned	1/20/24
1624785		7/17/13	Owned	1/20/24

	Method for removal of viruses from blood by lectin affinity hemodialysis (Germany)			
2,516,403	Method for removal of viruses from blood by lectin affinity hemodialysis (Canada)	8/12/14	Owned	1/20/24

Foreign Patent Applications

APPLICATION #	APPLICATION NAME	FILING DATE	OWNED OR LICENSED
EP20070752778	Extracorporeal removal of microvesicular particles (exosomes) (Europe)	3/9/07	Owned
9,104,740.6	Extracorporeal removal of microvesicular particles (exosomes) (Hong Kong)	3/9/07	Owned
8139/DELNP/2008	Extracorporeal removal of microvesicular particles (exosomes) (India)	3/9/07	Owned
2644855	Extracorporeal removal of microvesicular particles (Canada)	3/9/07	Owned
EP20110804372	Methods and compositions for quantifying exosomes (Europe)	7/7/11	Owned

International Patent Applications

APPLICATION #	APPLICATION NAME	FILING DATE	OWNED OR LICENSED
PCT/US2016/028482	Methods for delivering regional citrate anticoagulation during extracorporeal blood treatments	4/20/16	Owned
PCT/US2015/017800	Brain specific exosome based diagnostics and extracorporeal therapies	2/26/15	Owned

We expect that our ability to enforce our patents and proprietary rights in many countries will be adversely impacted due to possible changes in law, our lack of familiarity with foreign law, or our lack of professional resources in jurisdictions outside the U.S. We cannot guarantee that any patents issued or licensed to us, including within the U.S., will provide us with competitive advantages or will not be challenged by others, or will not expire prior to our successful commercialization of our products. Furthermore, we cannot be certain that others will not independently develop similar products or will not design around patents issued or licensed to us. We cannot guarantee that patents that are issued will not be challenged, invalidated or infringed upon or designed around by others, or that the claims contained in such patents will not infringe the patent claims of others, or provide us with significant protection against competitive products, or otherwise be commercially valuable. We may need to acquire licenses under patents belonging to others for technology potentially useful or necessary to us. If any such licenses are required, we cannot be certain that they will be available on terms acceptable to us, if at all. To the extent that we are unable to obtain patent protection for our products or technology, our business may be materially adversely affected by competitors who develop substantially equivalent technology.

Trademarks

We have obtained trademark registrations in the U.S. for Hemopurifier, Aethlon Medical, Inc., and the Exosome Sciences Logo and obtained a trademark registration in India for Hemopurifier. Exosome Sciences, Inc. has applied for the Tausome trademark in the U.S., which application is currently pending. We also have common law trademark rights in Aethlon ADAPT™ and ELLSA™.

Licensing and Assignment Agreements

Effective January 1, 2000, we entered into an agreement with a related party under which an invention and related patent rights for a method of removing Human Immunodeficiency and other viruses from the blood using the Hemopurifier were assigned to us by the inventors in exchange for an 8.75% royalty to be paid on future net sales of the patented product or process and shares of our common stock. On March 4, 2003, the related patent (patent #6,528,057) was issued and we issued 3,922 shares of unregistered common stock to that related party. The license runs for the life of the patent, which expires in August 2019.

On November 7, 2006, we entered into an exclusive assignment agreement with the London Health Science Center Research, Inc. under which an invention and related patent rights for a method to treat cancer were assigned to us. The invention provides for the "Extracorporeal removal of microvesicular particles" for which the U.S. Patent and Trademark Office allowed a patent (patent #8,288,172) in the U.S. as of October 2012. The agreement provides for an upfront payment of 800 shares of unregistered common stock and a 2% royalty on any future net sales. We are also responsible for paying certain patent application and filing costs. Under the assignment agreement, we own the patents outright for the life of the patent, which expires in March 2029. Under certain circumstances, ownership of the patents

may revert back to the London Health Science Center Research, Inc. if there is an uncured substantial breach of the assignment agreement.

Industry

The industry for treating infectious disease and cancer is extremely competitive, and companies developing new treatment procedures face significant capital and regulatory challenges. Additionally, as the Hemopurifier is a new device, we have the additional challenge of establishing medical industry support, which will be driven by treatment data resulting from clinical studies of each disease condition that we pursue. The industry includes pharmaceutical companies and medical device companies competing to treat illnesses on a worldwide basis.

Competition

We are advancing our Hemopurifier as a treatment strategy to enhance and prolong current drug therapies by removing the viral strains that cause drug resistance. We are also advancing the Hemopurifier as a tool for cancer treatment in conjunction with existing, and to be developed, cancer therapies. The Hemopurifier also may prolong life for infected patients who have become drug resistant or have been infected with a viral pathogen for which there is no drug or vaccine therapy. We believe our Hemopurifier augments the benefit of drug therapies and should not be considered a competitor to such treatments. However, if the industry considered the Hemopurifier to be a potential replacement for drug therapy, or a device that limited the need or volume of existing drug therapies, then the marketplace for the Hemopurifier would be extremely competitive. We believe our Hemopurifier is the sole therapeutic device able to selectively remove viruses and immunosuppressive proteins from circulation. However, we are aware that Asahi Kasei Kurary Medical based in Japan has created a double filtration plasmapheresis system that indiscriminately removes particles from blood in a certain molecule range that includes Hepatitis C virus. Asahi Kasei Kurary Medical is now marketing this device in Japan as an adjunct therapy for Hepatitis C virus. We may also face competition from producers of antiviral drugs and vaccines.

Government Regulation of Medical Devices

The Hemopurifier is subject to regulation by numerous regulatory bodies, primarily the FDA, and comparable international regulatory agencies. These agencies require manufacturers of medical devices to comply with applicable laws and regulations governing the development, testing, manufacturing, labeling, marketing, storage, distribution, advertising and promotion, and post-marketing surveillance reporting of medical devices. Devices are generally subject to varying levels of regulatory control, the most comprehensive of which requires that a clinical evaluation program be conducted before a device receives approval for commercial distribution. Failure to obtain approval or clearance to market our product and products under development and to meet the ongoing requirements of these regulatory authorities could prevent us from commercializing the Hemopurifier and future products in the U.S. and elsewhere.

Hemopurifier Investigational Device Exemption and Supplement

In 2013, the FDA approved our investigational device exemption to initiate human clinical studies in the U.S. as a feasibility study. We were required to reach agreement with the internal review board of DaVita MedCenter Dialysis prior to beginning our U.S. clinical trial. We are also required to obtain patients' informed consent that complies with both FDA requirements and state and federal privacy regulations. We, the FDA or the internal review board at each site at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the benefits. Even if a trial is completed, the results of clinical testing may not demonstrate the safety and efficacy of the device, may be equivocal or may otherwise not be sufficient to obtain approval of the product. The investigational device exemption is part of the FDA’s clearance process. This process is discussed in detail in the “Pre-Marketing Regulations in the U.S.” section below.

In December 2014, the FDA approved our request for a supplement to our investigational device exemption to establish a protocol to clinically investigate the use of the Hemopurifier for the treatment of Ebola-infected patients in the U.S. Under the supplement, we may treat up to 20 Ebola-infected persons, at no more than 10 institutions in the U.S., using the supplement protocol; however, this is not a clinical trial. We must clearly distinguish data collected in the supplement protocol from data collected in our chronic Hepatitis C virus clinical trial (discussed above). Prior to treating Ebola-infected patients, we must comply with specified patient protection procedures established by the applicable institution including its institutional review board. Also, we must report any unanticipated adverse events resulting from the supplement protocol to the FDA within 10 working days. Even if the protocol is established, and patients are treated, the results of such treatments may not demonstrate the safety and efficacy of the device. In addition, we cannot assure you that any Ebola-infected individuals will be treated under this protocol.

Pre-Marketing Regulations in the U.S.

Unless an exemption applies, each medical device distributed commercially in the U.S. requires either prior 510(k) clearance or premarket approval, or PMA, from the FDA. The FDA classifies medical devices into one of three classes. Class I devices are subject to only general controls, such as establishment registration and device listing, labeling, medical device reporting, and prohibitions against adulteration and misbranding. Class II medical devices generally require prior 510(k) clearance before they may be commercially marketed in the U.S. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a predicate device, are placed in Class III, generally requiring submission of a PMA supported by clinical trial data. Our Hemopurifier is a Class III product, and we believe that products utilizing our Aethlon ADAPT™ system will be considered to be Class III products and thus will require submission and approval of a PMA. In the future, we may develop new products that are considered to be Class II and require the clearance of a 510(k).

510(k) Clearance Pathway

To obtain 510(k) clearance, a premarket notification must be submitted to FDA demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of premarket approval applications. FDA’s 510(k) clearance pathway usually takes from three to twelve months, but it can take significantly longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, require premarket approval. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k), or a premarket approval, but the FDA can review any such decision and can disagree with a manufacturer’s determination. If the FDA disagrees with a manufacturer’s determination, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or premarket approval is obtained. If the FDA requires a 510(k) holder to seek 510(k) clearance or premarket approval for any modifications to a previously cleared product, the 510(k) holder also may be required to cease marketing or recall the modified device until this clearance or approval is obtained.

Premarket Approval Pathway

A PMA must be supported by extensive data, including but not limited to data obtained from technical, preclinical and clinical studies and relating to manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device.

After a PMA submission is sufficiently complete, the FDA will accept the application and begin an in-depth review, which generally takes between one and three years, but may take significantly longer. During this review period, the FDA will typically request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with Quality System Regulation, or QSR. New PMA applications or PMA supplements are required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. PMA supplements often require submission of the same type of information as a PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application and may not require as extensive clinical data or the convening of an advisory panel.

Clinical Trials

Clinical trials are almost always required to support a PMA. To perform a clinical trial in the U.S. for a significant risk device, FDA requires the device sponsor to file an Investigational Device Exemption, or IDE, application with the FDA and obtain IDE approval prior to commencing the human clinical trial. An IDE amendment or supplement must also be submitted before initiating a significant change to the clinical protocol or device under an existing IDE. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, and any available data on human clinical experience, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound.

The IDE must be approved in advance by the FDA for a specific number of patients. Clinical trials conducted in the U.S. for significant risk devices may begin once the IDE application is approved by the FDA and the appropriate institutional review boards, or IRBs, overseeing the welfare of the research subjects and responsible for that particular clinical trial. Under its regulations, the FDA responds to an IDE or an IDE amendment within 30 days. The FDA may approve the IDE or amendment, grant an approval with certain conditions, or identify deficiencies and request additional information. It is common for the FDA to require additional information before approving an IDE or amendment for a new trial, and thus final FDA approval on a submission may require more than the initial 30 days. The FDA may also require that a small-scale feasibility study be conducted before a pivotal trial may commence. In a

feasibility trial, the FDA limits the number of patients, sites and investigators that may participate. Feasibility trials are typically structured to obtain information on safety and to help determine how large a pivotal trial should be to obtain statistically significant results.

Clinical trials are subject to extensive recordkeeping and reporting requirements. Our clinical trials must be conducted under the oversight of an IRB for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices. We are also required to obtain the patients' informed consent in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. We, the FDA or the IRB may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and effectiveness of the device or may otherwise not be sufficient to obtain FDA approval to market the product in the U.S.

Post-Marketing Regulations in the U.S.

Should our Hemopurifier device be cleared for market use in the U.S. by the FDA, numerous regulatory requirements continue to apply. These include:

- the FDA's Quality System Regulation which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for un-cleared, unapproved or off-label uses;
- clearance or approval of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use;
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action; and
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

The regulations also require that we report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury.

We will also be required to register with FDA as a medical device manufacturer within 30 days of commercial distribution of our products and must obtain all necessary state permits or licenses to operate our business. As a manufacturer, we are subject to announced and unannounced inspections by FDA to determine our compliance with quality system regulation and other regulations, and these inspections may include the manufacturing facilities of our suppliers. Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or state authorities, which may include any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;

- customer notifications for repair, replacement, refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for premarket approval of new products or modified products;
- operating restrictions;
- withdrawing PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Compliance with U.S. Health Care Laws

Should our Hemopurifier device be cleared for market use in the U.S. by the FDA, we must comply with various U.S. federal and state laws, rules and regulations pertaining to healthcare fraud and abuse, including anti-kickback regulations, as well as other healthcare laws in connection with the commercialization of our products. Fraud and abuse laws are interpreted broadly and enforced aggressively by various state and federal agencies, including the U.S. Department of Justice, the U.S. Office of Inspector General for the Department of Health and Human Services and various state agencies.

The U.S. federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, as amended, prohibits persons, including a medical device manufacturer (or a party acting on its behalf), from knowingly or willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for a service or product or the purchasing, ordering, arranging for, or recommending the ordering of, any service or product for which payment may be made by Medicare, Medicaid or any other federal healthcare program. This statute has been interpreted to apply to arrangements between medical device manufacturers on one hand and healthcare providers on the other. The term "remuneration" is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, such as cash payments, gifts or gift certificates, discounts, waiver of payments, credit arrangements, ownership interests, the furnishing of services, supplies or equipment, and the provision of anything at less than its fair market value. Courts have broadly interpreted the scope of the law, holding that it may be violated if merely one purpose of an arrangement is to induce referrals, irrespective of the existence of other legitimate purposes. The Anti-Kickback Statute prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain business arrangements from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from federal Anti-Kickback Statute liability. The reach of the Anti-Kickback Statute was broadened by the recently enacted Patient Protection and Affordable Care Act of 2010 and the Health Care and Education Affordability Reconciliation Act of 2010, collectively, the Affordable Care Act or ACA, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (discussed below) or the civil monetary penalties statute, which imposes fines against any person who is determined to have presented or caused to be presented claims to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. In addition to the federal Anti-Kickback Statute, many states have their own anti-kickback laws. Often, these laws closely follow the language of the federal law, although they do not always have the same scope, exceptions, safe harbors or sanctions. In some states, these anti-kickback laws apply not only to payments made by government healthcare programs but also to payments made by other third-party payors, including commercial insurance companies.

We may also be subject to various federal and state marketing laws, such as the federal Physician Payments Sunshine Act, which generally require certain types of expenditures in the U.S. and the particular states to be tracked and reported. The federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, requires certain pharmaceutical and medical device manufacturers to engage in extensive tracking of payments or transfers of value to physicians and teaching hospitals, maintenance of a payments database, and public reporting of the payment data. Device manufacturers with products for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program are required to track and report such payments. Moreover, several states have enacted legislation requiring pharmaceutical and medical device companies to establish marketing compliance programs or even prohibit providing meals to prescribers or other marketing related activities. Compliance with such requirements may require investment in infrastructure to ensure that tracking and reporting is performed properly. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated.

International Regulation

International development and sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ. For example, the primary regulatory authority with respect to medical devices in Europe is that of the European Union. The unification of these countries into a common market has resulted in the unification of laws, standards and procedures across these countries, which may expedite the introduction of medical devices like those we are offering and developing.

The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of relevant directives will be entitled to bear CE Conformity Marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the European Union. Actual implementation of these directives, however, may vary on a country-by-country basis.

To date, we have not begun any process to obtain the CE Mark and have no immediate plans to test or commercialize the Hemopurifier in any European Union countries.

Manufacturing

Manufacturing of our Hemopurifier occurs in collaboration with a contract manufacturer based in San Diego, California that is compliant with the Good Manufacturing Practice regulations promulgated by the FDA. Our contract manufacturer is registered with the FDA. We also have received an export license from the FDA that allows the export our Hemopurifier for commercial purposes to India. To date, our manufacture of the Hemopurifier has been limited to quantities necessary to support our clinical studies.

Sources and Suppliers

We are not dependent on any specific vendors for the materials used in our Hemopurifier. The key raw materials in the Hemopurifier include the affinity lectin Galanthus nivalis agglutinin, pharmaceutical grade diatomaceous earth, plasmapheresis cartridges and certain chemical binding agents. The affinity lectin is available from several life science supply companies in the U.S. Diatomaceous earth is available from several life science supply companies in the U.S. To date, we have purchased plasmapheresis cartridges from one vendor in Europe however similar cartridges are commercially available from vendors on a worldwide basis should that European vendor cease to be available for any reason, including prohibitive pricing. The chemical binding agents are available from a number of life science supply companies on a worldwide basis. We typically purchase our raw materials on purchase order basis. Therefore, we remain subject to risks of supply shortages and price increases that potentially could materially adversely affect our financial condition and operating results if and when we begin large scale manufacture of the Hemopurifier.

The key raw materials used by Exosome Sciences, Inc. in its research are blood samples supplied by research partners and a number of chemical and lab products commercially available from vendors on a worldwide basis. Exosome Sciences, Inc. is not dependent on any specific vendors for the materials used in its research activities.

Sales and Marketing

We do not currently have any sales and marketing capability. With respect to commercialization efforts in the future, we intend to build or contract for distribution, sales and marketing capabilities for any product candidate that is approved. From time to time, we have had and are having strategic discussions with potential collaboration partners for our product candidates, although no assurance can be given that we will be able to enter into one or more collaboration agreements for our product candidates on acceptable terms, if at all.

Product Liability

The risk of product liability claims, product recalls and associated adverse publicity is inherent in the testing, manufacturing, marketing and sale of medical products. We have limited clinical trial liability insurance coverage. We cannot assure you that future insurance coverage will be adequate or available. We may not be able to secure product liability insurance coverage on acceptable terms or at reasonable costs when needed. Any liability for mandatory damages could exceed the amount of our coverage. A successful product liability claim against us could require us to pay a substantial monetary award. Moreover, a product recall could generate substantial negative publicity about our products and business and inhibit or prevent commercialization of other future product candidates.

Employees

We have five full-time employees consisting of our Chief Executive Officer, our President, our Chief Financial Officer, a research scientist and an executive assistant. We utilize, whenever appropriate, consultants in order to conserve cash and resources.

We believe our employee relations are good. None of our employees are represented by a labor union or are subject to collective-bargaining agreements.

ITEM 1A. RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully consider the risks described below as well as the other information in this Annual Report before deciding to invest in or maintain your investment in our company. The risks described below are not intended to be an all-inclusive list of all of the potential risks relating to an investment in our securities. Any of the risk factors described below could significantly and adversely affect our business, prospects, financial condition and results of operations. Additional risks and uncertainties not currently known or that are currently considered to be immaterial may also materially and adversely affect our business. As a result, the trading price or value of our securities could be materially adversely affected and you may lose all or part of your investment.

Risks Relating to Our Financial Position and Need for Additional Capital

We have incurred significant losses and expect to continue to incur losses for the foreseeable future.

We have never been profitable. We have generated revenues during the fiscal years ended March 31, 2016 and March 31, 2015, in the amounts of $886,572, and $762,417, respectively, primarily from our contract with the Defense Advanced Research Projects Agency, or DARPA. However, our revenues continue to be insufficient to cover our cost of operations. Future profitability, if any, will require the successful commercialization of our Hemopurifier technology, other products that may emerge from our Aethlon ADAPT platform or from additional government contract or grant income. We cannot assure you when or if we will be able to successfully commercialize one or more of our products, or if commercialization is successful, whether we will ever be profitable.

12

We have received an explanatory paragraph from our auditors regarding our ability to continue as a going concern.

Our independent registered public accounting firm noted in their report accompanying our financial statements for our fiscal year ended March 31, 2016 that we have a significant accumulated deficit and that a significant amount of additional capital will be necessary to advance the development of our products to the point at which we may become commercially viable. Our independent registered public accounting firm stated that those conditions raised substantial doubt about our ability to continue as a going concern. Note 1 to our financial statements for the year ended March 31, 2016 describes management's plans to address these matters. We cannot assure you that our business plans will be successful in addressing these issues. This explanatory paragraph about our ability to continue as a going concern could affect our ability to obtain additional financing at favorable terms, if at all, as it may cause investors to lose faith in our long-term prospects. If we cannot successfully continue as a going concern, our shareholders may lose their entire investment.

We will require additional financing to sustain our operations, and without it, we will not be able to continue operations.

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

We will need to raise additional funds through debt or equity financings in the future to achieve our business objectives and to satisfy our cash obligations, which would dilute the ownership of our existing stockholders.

We will need to raise additional funds through debt or equity financings in order to complete our ultimate business objectives, including funding working capital to support development and regulatory clearance of our products. We also may choose to raise additional funds in debt or equity financings if they are available to us on reasonable terms to increase our working capital and to strengthen our financial position. Any sales of additional equity or convertible debt securities would result in dilution of the equity interests of our existing stockholders, which could be substantial. Also, new investors may require that we and certain of our stockholders enter into voting arrangements that give them

additional voting control or representation on our Board of Directors.

Risks Related to Our Business Operations

We face intense competition in the medical device industry.

We compete with numerous U.S. and foreign companies in the medical device industry, and many of our competitors have greater financial, personnel and research and development resources than we do. Our competitors are developing vaccine candidates, which could compete with the Hemopurifier medical device candidates we are developing. Our commercial opportunities will be reduced or eliminated if our competitors develop and market products for any of the diseases we target that:

- are more effective;
- have fewer or less severe adverse side effects;
- are better tolerated;
- are more adaptable to various modes of dosing;
- are easier to administer; or
- are less expensive than the products or product candidates we are developing.

Even if we are successful in developing the Hemopurifier and other Aethlon ADAPT based-products, and obtain FDA and other regulatory approvals necessary for commercializing them, our products may not compete effectively with other successful products. Researchers are continually learning more about diseases, which may lead to new technologies for treatment. Our competitors may succeed in developing and marketing products that are either more effective than those that we may develop, alone or with our collaborators, or that are marketed before any products we develop are marketed. Our competitors include fully integrated pharmaceutical companies and biotechnology companies as well as universities and public and private research institutions. Many of the organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, greater experience in product development and in obtaining regulatory approvals, and greater marketing capabilities than we do. If our competitors develop more effective pharmaceutical treatments for infectious disease or cancer, or bring those treatments to market before we can commercialize the Hemopurifier for such uses, we may be unable to obtain any market traction for our products, or the diseases we seek to treat may be substantially addressed by competing treatments. If we are unable to successfully compete against larger companies in the pharmaceutical industry, we may never generate significant revenue or be profitable.

We have limited experience in identifying and working with large scale contracts with medical device manufacturers; manufacture of our devices must comply with good manufacturing practices in the U.S.

To achieve the levels of production necessary to commercialize our Hemopurifier and other future Aethlon ADAPT-based products, we will need to secure large scale manufacturing agreements with contract manufacturers which comply with good manufacturing practice standards and other standards prescribed by various federal, state and local regulatory agencies in the U.S. and any other country of use. We have limited experience coordinating and overseeing the manufacture of medical device products on a large scale. We cannot assure you that manufacturing and control problems will not arise as we attempt to commercialize our products or that such manufacturing can be completed in a timely manner or at a commercially reasonable cost. In addition, we cannot assure you that we will be able to adequately finance the manufacture and distribution of our products on terms acceptable to us, if at all. If we cannot successfully oversee and finance the manufacture of our products when they have obtained regulatory clearances, we may never generate revenue from product sales and we may never be profitable.

Our Aethlon ADAPT technology may become obsolete.

Our Aethlon ADAPT products may be made unmarketable by new scientific or technological developments where new treatment modalities are introduced that are more efficacious and/or more economical than our Aethlon ADAPT products. The homeland security industry is growing rapidly with many competitors that are trying to develop products or vaccines to protect against infectious disease. Any one of our competitors could develop a more effective product which would render our technology obsolete. Further, our ability to achieve significant and sustained penetration of our key target markets will depend upon our success in developing or acquiring technologies developed by other companies, either independently, through joint ventures or through acquisitions. If we fail to develop or acquire, and manufacture and sell, products that satisfy our customers' demands, or we fail to respond effectively to new product announcements by our competitors by quickly introducing competitive products, then market acceptance of our products could be reduced and our business could be adversely affected. We cannot assure you that our products will remain competitive with products based on new technologies.

Our use of hazardous materials, chemicals and viruses exposes us to potential liabilities for which we may not have adequate insurance.

Our research and development involves the controlled use of hazardous materials, chemicals and viruses. The primary hazardous materials include chemicals needed to construct the Hemopurifier cartridges and the infected plasma samples used in preclinical testing of the Hemopurifier. All other chemicals are fully inventoried and reported to the appropriate authorities, such as the fire department, who inspect the facility on a regular basis. We are subject to federal, state, local and foreign laws governing the use, manufacture, storage, handling and disposal of such materials. Although we believe that our safety procedures for the use, manufacture, storage, handling and disposal of such

materials comply with the standards prescribed by federal, state, local and foreign regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. We have had no incidents or problems involving hazardous chemicals or biological samples. In the event of such an accident, we could be held liable for significant damages or fines.

We currently carry a limited amount of insurance to protect us from damages arising from hazardous materials. Our product liability policy has a $3,000,000 limit of liability that would cover certain releases of hazardous substances away from our facilities. For our facilities, our property policy provides $25,000 in coverage for contaminant clean-up or removal and $50,000 in coverage for damages to the premises resulting from contamination. Should we violate any regulations concerning the handling or use of hazardous materials, or should any injuries or death result from our use or handling of hazardous materials, we could be the subject of substantial lawsuits by governmental agencies or individuals. We may not have adequate insurance to cover all or any of such claims, if any. If we were responsible to pay significant damages for violations or injuries, if any, we might be forced to cease operations since such payments could deplete our available resources.

Our success is dependent in part on a few key executive officers.

Our success depends to a critical extent on the continued services of our Chief Executive Officer, James A. Joyce, and our President, Rodney S. Kenley. If one or both of these key executive officers were to leave us, we would be forced to expend significant time and money in the pursuit of a replacement, which would result in both a delay in the implementation of our business plan and the diversion of limited working capital. The unique knowledge and expertise of these individuals would be difficult to replace within the biotechnology field. We can give you no assurances that we can find satisfactory replacements for these key executive officers at all, or on terms that are not unduly expensive or burdensome to us. Although Mr. Joyce has signed an employment agreement providing for his continued service to us, that agreement will not preclude him from leaving us should we be unable to compete with offers for employment he may receive from other companies. We do not currently carry key man life insurance policies on any of our key executive officers which would assist us in recouping our costs in the event of the loss of those officers. If any of our key officers were to leave us, it could make it impossible, if not cause substantial delays and costs, to implement our long term business objectives and growth.

Our inability to attract and retain qualified personnel could impede our ability to achieve our business objectives.

We have five full-time employees consisting of our Chief Executive Officer, our President, our Chief Financial Officer, a research scientist and an executive assistant. We utilize, whenever appropriate, consultants in order to conserve cash and resources.

Although we believe that these employees and consultants will be able to handle most of our additional administrative, research and development and business development in the near term, we will nevertheless be required over the longer-term to hire highly skilled managerial, scientific and administrative personnel to fully implement our business plan and growth strategies, including to mitigate the material weakness in our internal control over financial reporting described above. Due to the specialized scientific nature of our business, we are highly dependent upon our ability to attract and retain qualified scientific, technical and managerial personnel. Competition for these individuals, especially in San Diego, California, where many biotechnology companies are located, is intense and we may not be able to attract, assimilate or retain additional highly qualified personnel in the future. We cannot assure you that we will be able to engage the services of such qualified personnel at competitive prices or at all, particularly given the risks of employment attributable to our limited financial resources and lack of an established track record. Also, if we are required to attract personnel from other parts of the U.S. or abroad, we may have significant difficulty doing so due to the high cost of living in the Southern California area and due to the costs incurred with transferring personnel to the area. If we cannot attract and retain qualified staff and executives, we will be unable to develop our products and achieve regulatory clearance, and our business could fail.

We plan to grow rapidly which will strain our resources; our inability to manage our growth could delay or derail implementation of our business objectives.

We will need to significantly expand our operations to implement our longer-term business plan and growth strategies. We will also be required to manage multiple relationships with various strategic partners, technology licensors, customers, manufacturers and suppliers, consultants and other third parties. This expansion and these expanded relationships will require us to significantly improve or replace our existing managerial, operational and financial systems, procedures and controls; to improve the coordination between our various corporate functions; and to manage, train, motivate and maintain a growing employee base. The time and costs to effectuate these steps may place a significant strain on our management personnel, systems and resources, particularly given the limited amount of financial resources and skilled employees that may be available at the time. We cannot assure you that we will institute, in a timely manner or at all, the improvements to our managerial, operational and financial systems, procedures and controls necessary to support our anticipated increased levels of operations and to coordinate our various corporate functions, or that we will be able to properly manage, train, motivate and retain our anticipated increased employee base. If we cannot manage our growth initiatives, we will be unable to commercialize our products on a large scale in a timely manner, if at all, and our business could fail.

As a public company with limited financial resources undertaking the launch of new medical technologies, we may have difficulty attracting and retaining executive management and directors.

The directors and management of publicly traded corporations are increasingly concerned with the extent of their personal exposure to lawsuits and stockholder claims, as well as governmental and creditor claims which may be made against them, particularly in view of recent changes in securities laws imposing additional duties, obligations and liabilities on management and directors. Due to these perceived risks, directors and management are also becoming increasingly concerned with the availability of directors' and officers' liability insurance to pay on a timely basis the costs incurred in defending such claims. While we currently carry directors' and officers' liability insurance, such insurance is expensive and difficult to obtain. If we are unable to continue or provide directors' and officers' liability insurance at affordable rates or at all, it may become increasingly more difficult to attract and retain qualified outside directors to serve on our Board of Directors. We may lose potential independent board members and management candidates to other companies in the biotechnology field that have greater directors' and officers' liability insurance to insure them from liability or to biotechnology companies that have revenues or have received greater funding to date which can offer greater compensation packages. The fees of directors are also rising in response to their increased duties, obligations and liabilities. In addition, our products could potentially be harmful to users, and we are exposed to claims of product liability including for injury or death. We have limited insurance and may not be able to afford robust coverage even as our products are introduced into the market. As a company with limited resources and potential exposures to management, we will have a more difficult time attracting and retaining management and outside independent directors than a more established public or private company due to these enhanced duties, obligations and potential liabilities.

If we fail to comply with extensive regulations of U.S. and foreign regulatory agencies, the commercialization of our products could be delayed or prevented entirely.

Our Hemopurifier products are subject to extensive government regulations related to development, testing, manufacturing and commercialization in the U.S. and other countries. The determination of when and whether a product is ready for large-scale purchase and potential use will be made by the U.S. Government through consultation with a number of governmental agencies, including the FDA, the National Institutes of Health, the Centers for Disease Control and Prevention and the Department of Homeland Security. Our product candidates are in the pre-clinical and clinical stages of development and have not received required regulatory approval from the FDA, or any foreign regulatory agencies, to be commercially marketed and sold. The process of obtaining and complying with FDA and other governmental regulatory approvals and regulations in the U.S. and in foreign countries is costly, time consuming, uncertain and subject to unanticipated delays. Obtaining such regulatory approvals, if any, can take several years. Despite the time and expense exerted, regulatory approval is never guaranteed. We also are subject to the following risks and obligations, among others:

- the FDA may refuse to approve an application if they believe that applicable regulatory criteria are not satisfied;
- the FDA may require additional testing for safety and effectiveness;
- the FDA may interpret data from pre-clinical testing and clinical trials in different ways than we interpret them;
- if regulatory approval of a product is granted, the approval may be limited to specific indications or limited with respect to its distribution; and
- the FDA may change their approval policies and/or adopt new regulations.

Failure to comply with these or other regulatory requirements of the FDA may subject us to administrative or judicially imposed sanctions, including:

- warning letters;
- civil penalties;
- criminal penalties;
- injunctions;
- product seizure or detention;
- product recalls; and

· total or partial suspension of productions.

Delays in successfully completing our planned clinical trials could jeopardize our ability to obtain regulatory approval.

Our business prospects will depend on our ability to complete studies, clinical trials, obtain satisfactory results, obtain required regulatory approvals and successfully commercialize our Hemopurifier product candidates. Completion of our clinical trials, announcement of results of the trials and our ability to obtain regulatory approvals could be delayed for a variety of reasons, including:

· serious adverse events related to our medical device candidates;

· unsatisfactory results of any clinical trial;

· the failure of our principal third-party investigators to perform our clinical trials on our anticipated schedules; and

· different interpretations of our pre-clinical and clinical data, which could initially lead to inconclusive results.

Our development costs will increase if we have material delays in any clinical trial or if we need to perform more or larger clinical trials than planned. If the delays are significant, or if any of our product candidates do not prove to be safe or effective or do not receive required regulatory approvals, our financial results and the commercial prospects for our product candidates will be harmed. Furthermore, our inability to complete our clinical trials in a timely manner could jeopardize our ability to obtain regulatory approval.

If we or our suppliers fail to comply with ongoing FDA or foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our third-party suppliers may be required to comply with the FDA's Quality System Regulation, or QSR. These FDA regulations cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. If we, or our manufacturers, fail to adhere to QSR requirements in the U.S., this could delay production of our products and lead to fines, difficulties in obtaining regulatory clearances, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition or results of operations.

In addition, the FDA assesses compliance with the QSR through periodic announced and unannounced inspections of manufacturing and other facilities. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products;
- withdrawing 510(k) clearances or premarket approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Any of these sanctions could have a material adverse effect on our reputation, business, results of operations and financial condition. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

If our products, or malfunction of our products, cause or contribute to a death or a serious injury, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report these events to the FDA within the required timeframes, or at all, FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

Our products may in the future be subject to product recalls. A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, including a third-country authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In this case, the FDA, the authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. A government-mandated or voluntary recall by us or one of our international distributors could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be subject to liability claims, be required to bear other costs, or take other actions that may have a negative impact on our future sales and our ability to generate profits. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA or another third-country competent authority. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA or another third-country competent authority. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were.

We are also required to follow detailed recordkeeping requirements for all firm-initiated medical device corrections and removals. In addition, in December of 2012, the FDA issued a draft guidance intended to assist the FDA and industry in distinguishing medical device recalls from product enhancements. Per the guidance, if any change or group of changes to a device addresses a violation of the Federal Food, Drug, and Cosmetic Act, that change would generally constitute a medical device recall and require submission of a recall report to the FDA.

We outsource almost all of our operational and development activities, and if any party to which we have outsourced certain essential functions fails to perform its obligations under agreements with us, the development and commercialization of our lead product candidate and any future product candidates that we may develop could be delayed or terminated.

We generally rely on third-party consultants or other vendors to manage and implement the day-to-day conduct of our operations, including conducting clinical trials and manufacturing our current product candidates and any future product candidates that we may develop. Accordingly, we are and will continue to be dependent on the timeliness and effectiveness of their efforts. Our dependence on third parties includes key suppliers and third party service providers supporting the development, manufacture and regulatory approval of our products as well as support for our information technology systems and other infrastructure. While our management team oversees these vendors, failure of any of these third parties to meet their contractual, regulatory and other obligations or the development of factors that materially disrupt the performance of these third parties could have a material adverse effect on our business. For example, all of the key oversight responsibilities for the development and manufacture of our lead product candidate are conducted by our management team but all activities are the responsibility of third party vendors.

If a clinical research organization that we utilize is unable to allocate sufficient qualified personnel to our studies in a timely manner or if the work performed by it does not fully satisfy the requirements of the FDA or other regulatory agencies, we may encounter substantial delays and increased costs in completing our development efforts. Any manufacturer that we select may encounter difficulties in the manufacture of new products in commercial quantities, including problems involving product yields, product stability or shelf life, quality control, adequacy of control procedures and policies, compliance with FDA regulations and the need for further FDA approval of any new manufacturing processes and facilities. If any of these occur, the development and commercialization of our product candidates could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue such development and commercialization on our own. If we rely on only one source for the manufacture of the clinical or commercial supplies of any of our product candidates or products, any production problems or supply constraints with that manufacturer could adversely impact the development or commercialization of that product candidate or product.

If we or our contractors or service providers fail to comply with regulatory laws and regulations, we or they could be subject to regulatory actions, which could affect our ability to develop, market and sell our product candidates and any other or future product candidates that we may develop and may harm our reputation.

If we or our manufacturers or other third party contractors fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to regulatory actions, which could affect our ability to develop, market and sell our current product candidates or any future product candidates under development successfully and could harm our reputation and lead to reduced or non-acceptance of our proposed product candidates by the market. Even technical recommendations or evidence by the FDA through letters, site visits, and overall recommendations to academia or biotechnology companies may make the manufacturing of a clinical product extremely labor intensive or expensive, making the product candidate no longer viable to manufacture in a cost efficient manner. The mode of administration may make the product candidate not commercially viable. The required testing of the product candidate may make that candidate no longer commercially viable. The conduct of clinical trials may be critiqued by the FDA, or a clinical trial site's Institutional Review Board or Institutional Biosafety Committee, which may delay or make impossible clinical testing of a product candidate. The Institutional Review Board for a clinical trial may stop a trial or deem a product candidate unsafe to continue testing. This may have a material adverse effect on the value of the product candidate and our business prospects.

We will need to outsource and rely on third parties for the clinical development and manufacture, sales and marketing of our current product candidates or any future product candidates that we may develop, and our future success will be dependent on the timeliness and effectiveness of the efforts of these third parties.

We do not have the required financial and human resources to carry out on our own all the pre-clinical and clinical development for our current product candidates or any other or future product candidates that we may develop, and do not have the capability and resources to manufacture, market or sell our current product candidates or any future product candidates that we may develop. Our business model calls for the partial or full outsourcing of the clinical and other development and manufacturing, sales and marketing of our product candidates in order to reduce our capital and infrastructure costs as a means of potentially improving our financial position. Our success will depend on the performance of these outsourced providers. If such providers fail to perform adequately, our development of product candidates may be delayed and any delay in the development of our product candidates would have a material and adverse effect on our business prospects.

We are and will be exposed to product liability risks, and clinical and preclinical liability risks, which could place a substantial financial burden upon us should we be sued.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of medical devices. We cannot be sure that claims will not be asserted against us. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

We cannot give assurances that we will be able to continue to obtain or maintain adequate product liability insurance on acceptable terms, if at all, or that such insurance will provide adequate coverage against potential liabilities. Claims or losses in excess of any product liability insurance coverage that we may obtain could have a material adverse effect on our business, financial condition and results of operations.

Our Hemopurifier products may be used in connection with medical procedures in which it is important that those products function with precision and accuracy. If our products do not function as designed, or are designed improperly, we may be forced by regulatory agencies to withdraw such products from the market. In addition, if medical personnel or their patients suffer injury as a result of any failure of our products to function as designed, or our products are designed inappropriately, we may be subject to lawsuits seeking significant compensatory and punitive damages. The risk of product liability claims, product recalls and associated adverse publicity is inherent in the testing, manufacturing, marketing and sale of medical products. We have recently obtained general clinical trial liability insurance coverage. We cannot give assurances that our insurance coverage will to be adequate or available. We may not be able to secure product liability insurance coverage on acceptable terms or at reasonable costs when needed. Any product recall or lawsuit seeking significant monetary damages may have a material effect on our

business and financial condition. Any liability for mandatory damages could exceed the amount of our coverage. Moreover, a product recall could generate substantial negative publicity about our products and business and inhibit or prevent commercialization of other future product candidates.

We have not received, and may never receive, approval from the FDA to market a medical device in the United States.

Before a new medical device can be marketed in the U.S., it must first receive either premarket approval, or a PMA, or 510(k) clearance from the FDA, unless an exemption exists. A PMA submission, which is a higher standard than a 501(k) clearance, is used to demonstrate to the FDA that a new or modified device is safe and effective. The 510(k) is used to demonstrate that a device is "substantially equivalent" to a predicate device (one that has been cleared by the FDA). We expect that any product we seek regulatory approval for will require a PMA. The FDA approval process involves, among other things, successfully completing clinical trials and filing for and obtaining a PMA. The PMA process requires us to prove the safety and effectiveness of our products to the FDA's satisfaction. This process, which includes preclinical studies and clinical trials, can take many years and requires the expenditure of substantial resources and may include post-marketing surveillance to establish the safety and efficacy of the product. Notwithstanding the effort and expense incurred, the process may never result in the FDA granting a PMA. Data obtained from preclinical studies and clinical trials are subject to varying interpretations that could delay, limit or prevent regulatory approval. Delays or rejections may also be encountered based upon changes in governmental policies for medical devices during the period of product development. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- our inability to demonstrate safety or effectiveness to the FDA's satisfaction;
- insufficient data from our preclinical studies and clinical trials to support approval;
- failure of the facilities of our third-party manufacturer or suppliers to meet applicable requirements;
- inadequate compliance with preclinical, clinical or other regulations;
- our failure to meet the FDA's statistical requirements for approval; and
- changes in the FDA's approval policies, or the adoption of new regulations that require additional data or additional clinical studies.

Modifications to products that are approved through a PMA application generally need FDA approval. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). The FDA's 510(k) clearance process usually takes from three to 12 months, but may last longer. The process of obtaining a PMA is much costlier and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA until an approval is obtained. Any of our products considered to be a class III device, which are considered to pose the greatest risk and the approval of which is governed by the strictest guidelines, will require the submission and approval of a PMA in order for us to market it in the U.S. We also may design new products in the future that could require the clearance of a 510(k).

Although we have received approval to proceed with clinical trials in the U.S. under the investigational device exemption, we cannot assure you that the current approval from the FDA to proceed will not be revoked, that the study will be successful, or that the FDA PMA approval will eventually be obtained and not revoked. Even if we obtain approval, the FDA or other regulatory authorities may require expensive or burdensome post-market testing or controls. Any delay in, or failure to receive or maintain, clearance or approval for our future products could prevent us from generating revenue from these products or achieving profitability. Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could dissuade some physicians from using our products and adversely affect our reputation and the perceived safety and efficacy of our products.

The approval requirements for medical products used to fight bioterrorism are still evolving, and we cannot be certain any products we develop for such uses would meet these requirements.

We are advancing product candidates under governmental policies that regulate the development and commercialization of medical treatment countermeasures against bioterror and pandemic threats. While we intend to pursue FDA market clearance to treat infectious bioterror and pandemic threats, it is often not feasible to conduct human studies against these deadly high threat pathogens. Thus, we may not be able to demonstrate the effectiveness of our treatment countermeasures through controlled human efficacy studies. Additionally, a change in government policies could impair our ability to obtain regulatory approval and there is no assurance that the FDA will approve any of our product candidates.

The Hemopurifier was used to treat one patient suffering from Ebola, and we have received a supplement to our investigational device exemption to establish protocols to treat Ebola patients in the U.S.; however, you should not construe these events as demonstrating that the device is effective in treating Ebola.

In October 2014, physicians at the Frankfurt University Hospital in Frankfurt, Germany administered Hemopurifier therapy in a 6.5-hour treatment session to a patient infected with Ebola. This treatment was made on an emergency basis. The patient was administered Hemopurifier therapy through special approval from The Federal Institute for

Drugs and Medical Devices (Bundesinstitut fur Arzneimittel und Medizinprodukte, BfArM), an independent federal higher authority within the portfolio of the Federal Ministry of Health of Germany. While we believe the results of the treatment of the Ebola patient in Germany to be positive with respect to the usage of the Hemopurifier to combat Ebola, no medical organization or regulatory organization, inside or outside the U.S., has cleared the use of the device for Ebola treatment on a commercial basis.

In addition, although the FDA approved a supplement to our investigational device exemption to establish a protocol for the treatment of Ebola patients in the U.S., this approval is very limited and the results of such protocol and potential treatments, if any, cannot be predicted. The usefulness of the Hemopurifier in treating Ebola is still unproven in any clinical or regulatory process in the U.S. or elsewhere. Even if we enroll patients in the Ebola protocol, the results of such treatments may not demonstrate the safety and efficacy of the device, may be equivocal or may otherwise not be sufficient to obtain approval of the Hemopurifier for any uses associated with Ebola. In addition, the approval of the supplement to our investigational device exemption does not in any way ensure clearance or approval of the Hemopurifier device for any purpose. In April 2015, we submitted a Humanitarian Use Devise submission to the FDA to support market clearance of the Hemopurifier as a treatment for Ebola virus. If the application is designated by the FDA, we then may submit a Humanitarian Device Exemption marketing application to the Center for Devices and Radiological Health for marketing review. We cannot assure you that the Hemopurifier will be proven to be useful in the treatment of Ebola or that it will ever be approved by U.S. or foreign regulatory agencies for such use, or if approved, successfully commercialized by us for such use. We may never commercialize the Hemopurifier specifically for use in treating Ebola.

The results of our clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects.

Any research and development, pre-clinical testing and clinical trial activities involving any products that we are or may develop will be subject to extensive regulation and review by numerous governmental authorities both in the U.S. and abroad. In the future we may conduct clinical trials to support approval of new products. Clinical studies must be conducted in compliance with FDA regulations or the FDA may take enforcement action. The data collected from these clinical studies may ultimately be used to support market clearance for these products. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate’s profile.

20

U.S. legislative or FDA regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to manufacture, market and distribute our products after approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

Should our products be approved for commercialization, lack of third-party coverage and reimbursement for our devices could delay or limit their adoption.

In both the U.S. and international markets, the use of medical devices is dependent in part on the availability of reimbursement from third-party payors, such as government and private insurance plans. Healthcare providers that use medical devices generally rely on third-party payors to pay for all or part of the costs and fees associated with the medical procedures being performed or to compensate them for their patient care services. Should our products be approved for commercialization by the FDA, we cannot assure you that our future products will be considered cost-effective, that reimbursement will be available in other sites or in other countries, including the U.S., if approved, or that reimbursement will be sufficient to allow sales of our future products on a profitable basis. The coverage decisions of third-party payors will be significantly influenced by the assessment of our future products by health technology assessment bodies. Such assessments are outside our control and t we cannot assure you that such evaluations will be conducted or that they will have a favorable outcome.

If approved for use in the U.S., we expect that any products that we develop will be purchased primarily by medical institutions, which will in turn bill various third-party payors for the health care services provided to patients at their facility. Payors may include the Centers for Medicare & Medicaid Services, or CMS, which administers the Medicare program and works in partnership with state governments to administer Medicaid, other government programs and private insurance plans. The process involved in applying for coverage and incremental reimbursement from CMS is lengthy and expensive. Further, Medicare coverage is based on our ability to demonstrate the treatment is “reasonable and necessary” for Medicare beneficiaries. Even if products utilizing our Aethlon ADAPT™ system receive FDA and other regulatory clearance or approval, they may not be granted coverage and reimbursement by any payor, including by CMS. For some governmental programs, such as Medicaid, coverage and reimbursement differ from state to state and some state Medicaid programs may not pay adequate amounts for the procedure necessary to utilize products utilizing our Aethlon ADAPT™ system, or any payment at all. Moreover, many private payors use coverage decisions and payment amounts determined by CMS as guidelines in setting their coverage and reimbursement policies and

amounts. If CMS or other agencies limit coverage or decrease or limit reimbursement payments for doctors and hospitals, this may affect coverage and reimbursement determinations by many private payors.

Should our products be approved for commercialization, adverse changes in reimbursement policies and procedures by payors may impact our ability to market and sell our products.

Healthcare costs have risen significantly over the past decade, and there have been and continue to be proposals by legislators, regulators and third-party payors to decrease costs. Third-party payors are increasingly challenging the prices charged for medical products and services and instituting cost containment measures to control or significantly influence the purchase of medical products and services.

For example, in the U.S., the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, PPACA, among other things, reduced and/or limited Medicare reimbursement to certain providers. The Budget Control Act of 2011, as amended by subsequent legislation, further reduces Medicare's payments to providers by 2 percent through fiscal year 2024. These reductions may reduce providers' revenues or profits, which could affect their ability to purchase new technologies. Furthermore, the healthcare industry in the U.S. has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with service providers. Legislation could be adopted in the future that limits payments for our products from governmental payors. In addition, commercial payors such as insurance companies, could adopt similar policies that limit reimbursement for medical device manufacturers' products. Therefore, we cannot be certain that our product or the procedures or patient care performed using our product will be reimbursed at a cost-effective level. We face similar risks relating to adverse changes in reimbursement procedures and policies in other countries where we may market our products. Reimbursement and healthcare payment systems vary significantly among international markets. Our inability to obtain international reimbursement approval, or any adverse changes in the reimbursement policies of foreign payors, could negatively affect our ability to sell our products and have a material adverse effect on our business and financial condition.

Should our products be approved for commercialization, our financial performance may be adversely affected by medical device tax provisions in the healthcare reform laws.

PPACA currently imposes, among other things, an excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the U.S. Under these provisions, the Congressional Research Service predicts that the total cost to the medical device industry may be up to $20 billion over the next decade. The Internal Revenue Service issued final regulations implementing the tax in December 2012, which requires, among other things, bi-monthly payments and quarterly reporting.

The Consolidated Appropriations Act, 2016 (Pub. L. 114-113), signed into law on Dec. 18, 2015, includes a two-year moratorium on the medical device excise tax imposed by Internal Revenue Code section 4191. Thus, the medical device excise tax does not apply to the sale of a taxable medical device by the manufacturer, producer, or importer of the device during the period beginning on January 1, 2016, and ending on December 31, 2017.

Once we market products, we will be subject to this or any future excise tax on our sales of certain medical devices in the U.S. We anticipate that primarily all of our sales, once commenced, of medical devices in the U.S. will be subject to this 2.3% excise tax following December 31, 2017.

Risks Related to Our Intellectual Property and Related Litigation

We rely upon licenses and patent rights from third parties which are subject to termination or expiration.

We rely upon third party licenses and ownership rights assigned from third parties for the development of specific uses for our Hemopurifier devices. For example, we are researching, developing and testing cancer-related applications for our devices under patents assigned from the London Health Science Center Research, Inc. Should any of our licenses be prematurely terminated for any reason, or if the patents and intellectual property assigned to us or owned by such entities that we have licensed should be challenged or defeated by third parties, our research efforts could be materially and adversely affected. We cannot assure you that any of our licenses or patents assigned to us will continue in force for as long as we require for our research, development and testing of cancer treatments. We cannot assure you that, should our licenses terminate, should the underlying patents and intellectual property be challenged or defeated, or should patents and intellectual property assigned to us be challenged or defeated, suitable replacements can be obtained or developed on terms acceptable to us, if at all. There is also the related risk that we may not be able to make the required payments under any patent license or assignment agreement, in which case we may lose to ability to use one or more of the licensed or assigned patents.

We could become subject to intellectual property litigation that could be costly, result in the diversion of management's time and efforts, require us to pay damages, prevent us from selling our commercially available products and/or reduce the margins we may realize from our products.

The medical devices industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights. Whether a product infringes a patent involves complex legal and factual issues, and the determination is often uncertain. There may be existing patents of which we are unaware that our products under development may inadvertently infringe. The likelihood that patent infringement claims may be brought against us increases as the number of participants in the infectious market increases and as we achieve more visibility in the market place and introduce products to market.

Any infringement claim against us, even if without merit, may cause us to incur substantial costs, and would place a significant strain on our financial resources, divert the attention of management from our core business, and harm our reputation. In some cases, litigation may be threatened or brought by a patent holding company or other adverse patent owner who has no relevant product revenues and against whom our patents may provide little or no deterrence. If we were found to infringe any patents, we could be required to pay substantial damages, including triple damages if an infringement is found to be willful. We also could be required to pay royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. We may not be able to obtain a license enabling us to sell our products on reasonable terms, or at all, and we cannot assure you that we would be able to redesign our products in a way that would not infringe those patents. If we fail to obtain any required licenses or make any necessary changes to our technologies or the products that incorporate them, we may be unable to commercialize one or more of our products or may have to withdraw products from the market, all of which would have a material adverse effect on our business, financial condition and results of operations.

If the combination of patents, trade secrets and contractual provisions upon which we rely to protect our intellectual property is inadequate, our ability to commercialize our products successfully will be harmed.

Our success depends significantly on our ability to protect our proprietary rights to the technologies incorporated in our products. We currently have four issued U.S. patents and eight pending U.S. patent applications. We also have fourteen issued foreign patents and have applied for five additional foreign patents and for seven international patents. Our issued patents begin to expire in 2019, with the last of these patents expiring in 2029, although terminal disclaimers, patent term extension or patent term adjustment can shorten or lengthen the patent term. We rely on a combination of patent protection, trade secret laws and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these may not adequately protect our rights or permit us to gain or keep any competitive advantage.

The issuance of a patent is not conclusive as to its scope, validity or enforceability. The scope, validity or enforceability of our issued patents can be challenged in litigation or proceedings before the U.S. Patent and Trademark Office or foreign patent offices where our applications are pending. The U.S. Patent and Trademark Office or foreign offices may deny or require significant narrowing of claims in our pending patent applications. Patents issued as a result of the pending patent applications, if any, may not provide us with significant commercial protection or be issued in a form that is advantageous to us. Proceedings before the U.S. Patent and Trademark Office or foreign offices could result in adverse decisions as to the priority of our inventions and the narrowing or invalidation of claims in issued patents. The laws of some foreign countries may not protect our intellectual property rights to the same extent as the laws of the U.S., if at all. Some of our patents may expire before we receive FDA approval to market our products in the U.S. or we receive approval to market our products in a foreign country. Although we believe that certain patent applications and/or other patents issued more recently will help protect the proprietary nature of the Hemopurifier treatment technology, we cannot assure you that this protection will be sufficient to protect us during the development of that technology.

Our competitors may successfully challenge and invalidate or render unenforceable our issued patents, including any patents that may issue in the future, which could prevent or limit our ability to market our products and could limit our ability to stop competitors from marketing products that are substantially equivalent to ours. In addition, competitors may be able to design around our patents or develop products that provide outcomes that are comparable to our products but that are not covered by our patents.

We have also entered into confidentiality and assignment of intellectual property agreements with all of our employees, consultants and advisors directly involved in the development of our technology as one of the ways we seek to protect our intellectual property and other proprietary technology. However, these agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements.

In the event a competitor infringes upon any of our patents or other intellectual property rights, enforcing our rights may be difficult, time consuming and expensive, and would divert management's attention from managing our business. We cannot assure you that we will be successful on the merits in any enforcement effort. In addition, we may not have sufficient resources to litigate, enforce or defend our intellectual property rights.

We may rely on licenses for new technology, which may affect our continued operations with respect thereto.

As we develop our technology, we may need to license additional technologies to optimize the performance of our products. We may not be able to license these technologies on commercially reasonable terms or at all. In addition, we may fail to successfully integrate any licensed technology into our proposed products. Our inability to obtain any necessary licenses could delay our product development and testing until alternative technologies can be identified, licensed and integrated. The inability to obtain any necessary third-party licenses could cause us to abandon a particular development path, which could seriously harm our business, financial position and results of our operations.

New technology may lead to our competitors developing superior products which would reduce demand for our products.

Research into technologies similar to ours is proceeding at a rapid pace, and many private and public companies and research institutions are actively engaged in the development of products similar to ours. These new technologies may, if successfully developed, offer significant performance or price advantages when compared with our technologies. There is no assurance that our existing patents or our pending and proposed patent applications will offer meaningful protection if a competitor develops a novel product based on a new technology.

If we are unable to protect our proprietary technology and preserve our trade secrets, we will increase our vulnerability to competitors which could materially adversely impact our ability to remain in business.

Our ability to successfully commercialize our products will depend on our ability to protect those products and our technology with domestic and foreign patents. We will also need to continue to preserve our trade secrets. The issuance of a patent is not conclusive as to its validity or as to the enforceable scope of the claims of the patent. The patent positions of technology companies, including us, are uncertain and involve complex legal and factual issues. We cannot assure you that our patents will prevent other companies from developing similar products or products which produce benefits substantially the same as our products, or that other companies will not be issued patents that may prevent the sale of our products or require us to pay significant licensing fees in order to market our products.

From time to time, we may need to obtain licenses to patents and other proprietary rights held by third parties in order to develop, manufacture and market our products. If we are unable to timely obtain these licenses on commercially reasonable terms, our ability to commercially exploit such products may be inhibited or prevented. Additionally, we cannot assure investors that any of our products or technology will be patentable or that any future patents we obtain will give us an exclusive position in the subject matter claimed by those patents. Furthermore, we cannot assure investors that our pending patent applications will result in issued patents, that patent protection will be secured for any particular technology, or that our issued patents will be valid or enforceable or provide us with meaningful protection.

If we are required to engage in expensive and lengthy litigation to enforce our intellectual property rights, such litigation could be very costly and the results of such litigation may not be satisfactory.

Although we have entered into invention assignment agreements with our employees and with certain advisors, and we routinely enter into confidentiality agreements with our contract partners, if those employees, advisors or contract partners develop inventions or processes independently that may relate to products or technology under development by us, disputes may arise about the ownership of those inventions or processes. Time-consuming and costly litigation could be necessary to enforce and determine the scope of our rights under these agreements. In addition, we may be required to commence litigation to enforce such agreements if they are violated, and it is certainly possible that we will not have adequate remedies for breaches of our confidentiality agreements as monetary damages may not be sufficient to compensate us. In addition, we may be unable to fund the costs of such litigation to a satisfactory conclusion, which could leave us without recourse to enforce contracts that protect our intellectual property rights.

Other companies may claim that our technology infringes on their intellectual property or proprietary rights and commence legal proceedings against us which could be time-consuming and expensive and could result in our being prohibited from developing, marketing, selling or distributing our products.

Because of the complex and difficult legal and factual questions that relate to patent positions in our industry, we cannot assure you that our products or technology will not be found to infringe upon the intellectual property or proprietary rights of others. Third parties may claim that our products or technology infringe on their patents, copyrights, trademarks or other proprietary rights and demand that we cease development or marketing of those products or technology or pay license fees. We may not be able to avoid costly patent infringement litigation, which will divert the attention of management away from the development of new products and the operation of our business. We cannot assure investors that we would prevail in any such litigation. If we are found to have infringed on a third party's intellectual property rights, we may be liable for money damages, encounter significant delays in bringing products to market or be precluded from manufacturing particular products or using particular technology.

Other parties may challenge certain of our foreign patent applications. If such parties are successful in opposing our foreign patent applications, we may not gain the protection afforded by those patent applications in particular jurisdictions and may face additional proceedings with respect to similar patents in other jurisdictions, as well as related patents. The loss of patent protection in one jurisdiction may influence our ability to maintain patent protection for the same technology in other jurisdictions.

Risks Related to U.S. Government Contracts

Our revenues are almost entirely derived from one U.S. Government contract.

We have derived and expect for the near future to continue to derive substantially all of our revenue under our DARPA contract. If we are unable to meet any of the remaining DARPA contract milestones to the satisfaction of DARPA, if at all, we may not earn future payments under the contract. Any reduction in our revenues, or the termination of the DARPA contract for any reason, could have a material and adverse effect on our business and operations. In addition, DARPA has the right to unilaterally cancel the contract at any time. Upon the completion of the DARPA contract there can be no assurance we will develop other sources of revenue in the short term.

We may not obtain additional U.S. Government contracts to further develop our technology.

We can give no assurances that we will be successful in obtaining additional government grants or contracts. The process of obtaining government contracts is lengthy with the uncertainty that we will be successful in obtaining announced grants or contracts for therapeutics as a medical device technology. Accordingly, we cannot be certain that we will be awarded any additional U.S. Government grants or contracts utilizing our Hemopurifier platform technology.

U.S. Government agencies have special contracting requirements including a right to audit us which create additional risks; ***a negative audit would be detrimental to us.***

Our business plan to utilize the Aethlon ADAPT system is likely to involve contracts with the U.S. Government. Such contracts typically contain unfavorable termination provisions and are subject to audit and modification by the government at its sole discretion, which subjects us to additional risks. These risks include the ability of the U.S. Government to unilaterally:

- suspend or prevent us for a period of time from receiving new contracts or extending existing contracts based on violations or suspected violations of laws or regulations;
- audit and object to our contract-related costs and fees, including allocated indirect costs;
- control and potentially prohibit the export of our products; and
- change certain terms and conditions in our contracts.

As a U.S. Government contractor, we are required to comply with applicable laws, regulations and standards relating to our accounting practices and would be subject to periodic audits and reviews. As part of any such audit or review, the U.S. Government may review the adequacy of, and our compliance with, our internal control systems and policies, including those relating to our purchasing, property, estimating, compensation and management information systems. Based on the results of its audits, the U.S. Government may adjust our contract-related costs and fees, including allocated indirect costs. In addition, if an audit or review uncovers any improper or illegal activity, we would possibly be subject to civil and criminal penalties and administrative sanctions, including termination of our contracts, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. Government. We could also suffer serious harm to our reputation if allegations of impropriety were made against us. Although we have not had any government audits and reviews to date, future audits and reviews could cause adverse effects. In addition, under U.S. Government purchasing regulations, some of our costs, including most financing costs, amortization of intangible assets, portions of our research and development costs, and some marketing expenses, would possibly not be reimbursable or allowed under such contracts. Further, as a U.S. Government contractor, we

would be subject to an increased risk of investigations, criminal prosecution, civil fraud, whistleblower lawsuits and other legal actions and liabilities to which purely private sector companies are not.

Our DARPA Contract is a fixed price contract, which may not adequately cover our costs in performance should those costs increase.

Our contract with DARPA is on a firm fixed price basis, which means that we are required to deliver our products at a fixed price regardless of the actual costs we incur and to absorb any costs in excess of the fixed price. If we have not accurately estimated the costs of expenses to perform the contract, we may not have positive revenue and we may incur losses to cover our costs. We expect that our future contracts, if any, with the U.S. Government also may be fixed price contracts. Estimating costs that are related to performance in accordance with contract specifications is difficult, particularly where the period of performance is over several years. Our failure to anticipate technical problems, estimate costs accurately or control costs during performance of a fixed price contract could reduce the profitability of a fixed price contract or cause a loss, which could in turn harm our operating results.

As a U.S. Government contractor, we are subject to a number of procurement rules and regulations.

Government contractors must comply with specific procurement regulations and other requirements. These requirements, although customary in government contracts, impact our performance and compliance costs. In addition, current U.S. Government budgetary constraints could lead to changes in the procurement environment, including the Department of Defense's recent initiative focused on efficiencies, affordability and cost growth and other changes to its procurement practices. If and to the extent such changes occur, they could impact our results of operations and liquidity, and could affect whether and, if so, how we pursue certain opportunities and the terms under which we are able to do so.

In addition, failure to comply with these regulations and requirements could result in reductions of the value of contracts, contract modifications or termination, and the assessment of penalties and fines, which could negatively impact our results of operations and financial condition. Our failure to comply with these regulations and requirements could also lead to suspension or debarment, for cause, from government contracting or subcontracting for a period of time. Among the causes for debarment are violations of various statutes, including those related to procurement integrity, export control, government security regulations, employment practices, protection of the environment, accuracy of records and the recording of costs, and foreign corruption. The termination of our government contract as a result of any of these acts could have a negative impact on our results of operations and financial condition and could have a negative impact on our reputation and ability to procure other government contracts in the future.

In fulfilling our U.S. Government contract we depend on a predictable supply of raw materials and components.

We are dependent upon the delivery by suppliers of materials and the assembly by subcontractors of major components and subsystems used in our products in a timely and satisfactory manner and in full compliance with applicable terms and conditions. Some products require relatively scarce raw materials. We are generally subject to specific procurement requirements, which may, in effect, limit the suppliers and subcontractors we may utilize. In some instances, we are dependent on sole-source suppliers. If any of these suppliers or subcontractors fails to meet our needs, we may not have readily available alternatives. In addition, some of our suppliers or subcontractors may be impacted by the recent global financial crisis, which could impair their ability to meet their obligations to us. If we experience a material supplier or subcontractor problem, our ability to satisfactorily and timely complete our clinical trial or delivery obligations could be negatively impacted which could result in reduced sales, termination of contracts and damage to our reputation and relationships with clinical trial providers and if applicable, the U.S. Government. We could also incur additional costs in addressing such a problem. Any of these events could have a negative impact on our results of operations and financial condition.

Risks Relating to Our Common Stock and Our Corporate Governance

Historically we have not paid dividends on our common stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have never paid cash dividends on our common stock. We intend to retain our future earnings, if any, to fund operational and capital expenditure needs of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Furthermore, future financing instruments may do the same. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our common stockholders in the foreseeable future.

Our stock price is speculative, and there is a risk of litigation.

The trading price of our common stock has in the past and may in the future be subject to wide fluctuations in response to factors such as the following:

- revenue or results of operations in any quarter failing to meet the expectations, published or otherwise, of the investment community;
- reduced investor confidence in equity markets, due in part to corporate collapses in recent years;

- speculation in the press or analyst community;
- wide fluctuations in stock prices, particularly with respect to the stock prices for other medical device companies;
- announcements of technological innovations by us or our competitors;
- new products or the acquisition of significant customers by us or our competitors;
- changes in interest rates;
- changes in investors' beliefs as to the appropriate price-earnings ratios for us and our competitors;
- changes in recommendations or financial estimates by securities analysts who track our common stock or the stock of other medical device companies;
- changes in management;
- sales of common stock by directors and executive officers;
- rumors or dissemination of false or misleading information, particularly through Internet chat rooms, instant messaging, and other rapid-dissemination methods;
- conditions and trends in the medical device industry generally;
- the announcement of acquisitions or other significant transactions by us or our competitors;
- adoption of new accounting standards affecting our industry;
- general market conditions;
- domestic or international terrorism and other factors; and
- the other factors described in this section.

Fluctuations in the price of our common stock may expose us to the risk of securities class action lawsuits. Although no such lawsuits are currently pending against us and we are not aware that any such lawsuit is threatened to be filed in the future, there is no assurance that we will not be sued based on fluctuations in the price of our common stock. Defending against such suits could result in substantial cost and divert management's attention and resources. In addition, any settlement or adverse determination of such lawsuits could subject us to significant liability.

If at any time our common stock is subject to the Securities and Exchange Commission's penny stock rules, broker-dealers may experience difficulty in completing customer transactions and trading activity in our securities may be adversely affected.

If at any time our common stock is not listed on a national securities exchange or we have net tangible assets of $5,000,000 or less and our common stock has a market price per share of less than $5.00, transactions in our common stock will be subject to the Securities and Exchange Commission's, or SEC's, "penny stock" rules. If our common stock is subject to the "penny stock" rules promulgated under the Exchange Act, broker-dealers may find it difficult to effectuate customer transactions and trading activity in our securities may be adversely affected. For any transaction involving a penny stock, unless exempt, the rules require:

- that a broker or dealer approve a person's account for transactions in penny stocks; and
- the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must:

- obtain financial information and investment experience objectives of the person; and
- make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the Securities and Exchange Commission relating to the penny stock market, which, in highlight form:

- sets forth the basis on which the broker or dealer made the suitability determination; and

· that the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Generally, brokers may be less willing to execute transactions in securities subject to the “penny stock” rules. This may make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

Our common stock has had an unpredictable trading volume which means you may not be able to sell our shares at or near trading prices or at all.

Trading in our common shares historically has been volatile and often has been thin, meaning that the number of persons interested in purchasing our common shares at or near trading prices at any given time may be relatively small or non-existent. This situation is attributable to a number of factors, including the fact that we are a small company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give you any assurance that a broader or more active public trading market for our common shares will develop or be sustained, or that current trading levels will be sustained.

The market price for our common stock is volatile; you may not be able to sell our common stock at or above the price you have paid for them, which may result in losses to you.

The market for our common shares is characterized by significant price volatility when compared to seasoned issuers, and we expect that our share price will continue to be more volatile than a seasoned issuer for the indefinite future. In fact, during the 52-week period ended March 31, 2016, the high and low closing sale prices of a share of our common stock were $14.00 and $4.34, respectively. The volatility in our share price is attributable to a number of factors. First, as noted above, trading in our common shares often has been thin. As a consequence of this lack of liquidity, the trading of relatively small quantities of shares by our stockholders may disproportionately influence the price of those shares in either direction. The price for our shares could, for example, decline precipitously in the event that a large number of our common shares are sold on the market without commensurate demand, as compared to a seasoned issuer which could better absorb those sales without adverse impact on its share price. Secondly, we are a speculative investment due to our limited operating history, limited amount of revenue, lack of profit to date, and the uncertainty of future market acceptance for our potential products. As a consequence of this enhanced risk, more risk-adverse investors may, under the fear of losing all or most of their investment in the event of negative news or lack of progress, be more inclined to sell their shares on the market more quickly and at greater discounts than would be the case with the stock of a seasoned issuer. The following factors may add to the volatility in the price of our common shares: actual or anticipated variations in our quarterly or annual operating results; acceptance of our proprietary technology as a viable method of augmenting the immune response of clearing viruses and toxins from human blood; government regulations, announcements of significant acquisitions, strategic partnerships or joint ventures; our capital commitments and additions or departures of our key personnel. Many of these factors are beyond our control and may decrease the market price of our common shares regardless of our operating performance. We cannot make any predictions or projections as to what the prevailing market price for our common shares will be at any time, including as to whether our common shares will sustain their current market prices, or as to what effect the sale of shares or the availability of common shares for sale at any time will have on the prevailing market price.

We cannot assure you that we will be able to comply with the continued listing standards of the NASDAQ Capital Market.

We cannot assure you that we will be able to comply with the listing standards that we are required to meet in order to maintain a listing of our common stock on the NASDAQ Capital Market. Our failure to meet those requirements may result in our common stock being delisted from the NASDAQ Capital Market.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as “covered securities.” Because our common stock is listed on the NASDAQ Capital Market, we believe such securities will be covered securities. Although the states would be preempted from regulating the sale of our securities, in that event, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. Further, our common stock is no longer listed on the NASDAQ Capital Market, our securities would not be covered securities and we would be subject to regulation in each state in which we offer our securities.

The Depository Trust Company imposed restrictions upon electronic trading of our common stock, which negatively affected liquidity of the stock and our ability to raise capital.

In September 2011, The Depository Trust Company placed a "chill" on the electronic clearing of trades in our shares which led to some brokerage firms being unwilling to accept certificates and/or electronic deposits of our stock. We have since been successful in lifting the restrictions and our shares now clear electronically making more brokers willing to trade in our common stock. We cannot assure you that The Depository Trust Company will not again place a chill on our common stock. A chill, if placed on our common stock, would affect the liquidity of our shares which may make it difficult to purchase or sell shares in the open market. It may also have an adverse effect on our ability to raise capital since investors may be unable to resell shares into the market. Our inability to raise capital on terms acceptable to us, if at all, could have a material and adverse effect on our business and operations.

Our directors and officers own or control approximately 10% of our outstanding common shares which may limit your ability to propose new management or influence the overall direction of the business; this concentration of control may also discourage potential takeovers that could otherwise provide a premium to you.

As of June 28, 2016, our officers and directors beneficially own or control approximately 10% of our outstanding common shares (assuming the exercise of all outstanding options and warrants held by our officers and directors). These persons will have the ability to substantially influence all matters submitted to our stockholders for approval and to control our management and affairs, including extraordinary transactions such as mergers and other changes of corporate control, and going private transactions.

A large number of our common shares are issuable upon exercise of outstanding convertible securities which, if exercised or converted, would be dilutive to your holdings.

As of March 31, 2016, there are outstanding purchase options and warrants entitling the holders to purchase 2,602,639 common shares at a weighted average exercise price of $7.40 per share. This includes 26,105 warrants that are conditional upon the exercise of other warrants. As of March 31, 2016, there are 107,468 shares underlying promissory notes convertible into common stock at a weighted average exercise price of $5.60.

The exercise price for all of our outstanding options and warrants, or the conversion price of our convertible notes, may be less than your cost to acquire our common shares. In the event of the exercise or conversion of these securities, you could suffer substantial dilution of your investment in terms of your percentage ownership in us as well as the book value of your common shares. In addition, the holders of the convertible notes, common share purchase options or warrants may sell common shares in tandem with their exercise or conversion of those securities to finance that exercise or conversion, or may resell the shares purchased in order to cover any income tax liabilities that may arise from their exercise of the options or warrants or conversion of the notes.

Our issuance of additional common shares, or convertible securities, would be dilutive to your holdings.

We are entitled under our Articles of Incorporation to issue up to 30,000,000 shares of common stock. We have reserved for issuance 2,710,107 shares of common stock for existing options, warrants and convertible notes. As of March 31, 2016, we have issued and outstanding 7,622,393 shares of common stock. As a result, as of March 31, 2016 we had 19,667,500 common shares available for issuance to new investors or for use to satisfy indebtedness or pay service providers.

Our Board of Directors may generally issue shares of common stock, or options or warrants to purchase those shares, without further approval by our stockholders based upon such factors as our Board of Directors may deem relevant at that time. It is likely that we will be required to issue a large amount of additional securities to raise capital to further our development. It is also likely that we will be required to issue a large amount of additional securities to directors, officers, employees and consultants as compensatory grants in connection with their services, both in the form of stand-alone grants or under our stock plans. We cannot give you any assurance that we will not issue additional shares of common stock, or options or warrants to purchase those shares, under circumstances we may deem appropriate at the time.

Our issuance of additional shares of common stock in satisfaction of services, or to repay indebtedness, would be dilutive to your holdings.

Our Board of Directors may generally issue shares of common stock to pay for debt or services, without further approval by our stockholders based upon such factors that our Board of Directors may deem relevant at that time. For the past four fiscal years (ending March 31, 2016), we issued a total of 1,626,032 shares for debt to reduce our obligations. However, we did not issue any shares as payment for services in the fiscal year ended March 31, 2016. The average price discount of common stock issued for debt during the previous two fiscal years, weighted by the number of shares issued for debt in such period was 76% and 43% for the years ended March 31, 2015 and 2014, respectively.

For the past four fiscal years (ending March 31, 2016), we issued a total of 147,001 shares as payment for services. However, we did not issue any shares as payment for services in the fiscal year ended March 31, 2016. The average price discount (premium) of common stock issued for services during the previous two fiscal years, weighted by the number of shares issued was (6.6)% and 16.0% for the years ended March 31, 2015 and 2014, respectively. It is likely that we will issue additional securities to pay for services and reduce debt in the future, after we increase our authorized shares. We cannot give you any assurance that we will not issue additional shares of common stock at various discounts under circumstances we may deem appropriate at the time.

Our officers and directors are entitled to indemnification from us for liabilities under our articles of incorporation, which could be costly to us and may discourage the exercise of stockholder rights.

Our Articles of Incorporation contains provisions which eliminate the liability of our directors for monetary damages to our company and stockholders. Our by-laws also require us to indemnify our officers and directors. We may also have contractual indemnification obligations under our agreements with our directors, officers and employees. The foregoing indemnification obligations could result in our company incurring substantial expenditures to cover the cost of settlement or damage awards against directors, officers and employees that we may be unable to recoup. These provisions and resultant costs may also discourage our company from bringing a lawsuit against directors, officers and employees for breaches of their fiduciary duties, and may similarly discourage the filing of derivative litigation by our stockholders against our directors, officers and employees even though such actions, if successful, might otherwise benefit our company and stockholders.

Our by-laws and Nevada law may discourage, delay or prevent a change of control of our company or changes in our management, would have the result of depressing the trading price of our common stock.

Provisions of Nevada anti-takeover law (NRS 78.378 *et seq.*) could have the effect of delaying or preventing a third party from acquiring us, even if the acquisition arguably could benefit our stockholders. Various provisions of our by-laws may delay, defer or prevent a tender offer or takeover attempt of us that a stockholder might consider in his or her best interest. Our by-laws may be adopted, amended or repealed by the affirmative vote of the holders of at least a majority of our outstanding shares of capital stock entitled to vote for the election of directors, and except as provided by Nevada law, our Board of Directors shall have the power to adopt, amend or repeal the by-laws by a vote of not less than a majority of our directors. The interests of these stockholders and directors may not be consistent with your interests, and they may make changes to the by-laws that are not in line with your concerns.

Our authorized but unissued shares of common stock are available for our Board or Directors to issue without stockholder approval. We may use these additional shares for a variety of corporate purposes, however, faced with an attempt to obtain control of us by means of a proxy context, tender offer, merger or other transaction our Board of Directors acting alone and without approval of our stockholders can issue large amounts of capital stock as part of a defense to a take-over challenge.

The existence of the foregoing provisions and other potential anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

We incur substantial costs as a result of being a public company and our management expects to devote substantial time to public company compliance programs.

As a public company, we incur significant legal, insurance, accounting and other expenses, including costs associated with public company reporting. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from product development and commercialization activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. These laws and regulations could make it more difficult and costly for us to obtain director and officer liability insurance for our directors and officers, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified executive officers and qualified members of our Board of Directors, particularly to serve on our audit and compensation committees. In addition, if we are unable to continue to meet the legal, regulatory and other requirements related to being a public company, we may not be able to maintain the quotation of our common stock on the Nasdaq Capital Market or on any other senior market to which we may apply for listing, which would likely have a material adverse effect on the trading price of our common stock.

If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. Our research coverage by industry and financial analysts is currently limited. Even if our analyst coverage increases, if one or more of the analysts who cover us downgrade our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

ITEM 1B. UNRESOLVED STAFF COMMENTS

As a Smaller Reporting Company, we are not required to furnish information under this Item 1B.

ITEM 2. PROPERTIES

We currently lease approximately 2,576 square feet of executive office space at 9635 Granite Ridge Drive, Suite 100, San Diego, California 92123 under a 39-month gross plus utilities lease that commenced on December 1, 2014 with an initial rental rate of $6,054 per month. Such lease expires in March 2018. We believe this leased facility will be satisfactory for our office needs over the term of the lease.

We also lease approximately 1,700 square feet of laboratory space at 11585 Sorrento Valley Road, Suite 109, San Diego, California 92121 at the rate of $4,168 per month on a one-year lease that expires in November 2016. We believe this leased facility will be satisfactory for our laboratory needs over the term of the lease.

Our Exosome Sciences, Inc. subsidiary previously rented approximately 2,055 square feet of office and laboratory space at 11 Deer Park Drive, South Brunswick, New Jersey at the rate of $3,917 per month on a one-year lease that expired in October 2015. In October 2015, Exosome Sciences, Inc. relocated to a different suite at the same office complex. Exosome Sciences leased that suite, comprised of approximately 541 square feet of office and laboratory space located at 9 Deer Park Drive, South Brunswick, New Jersey, at the rate of $1,352 per month on a month-to-month lease basis. In January 2016, we exercised our 30-day notice to terminate the Exosome Sciences' lease in New Jersey prior to consolidating our laboratory operations in San Diego.

ITEM 3. LEGAL PROCEEDINGS

We may be involved from time to time in various claims, lawsuits, and/or disputes with third parties or breach of contract actions incidental to the normal course of our business operations. We are currently not involved in any litigation or any pending legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES

We have no disclosure applicable to this item.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

MARKET PRICE FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock is quoted on the Nasdaq Capital Market under the trading symbol "AEMD." Trading in our common stock historically has been volatile and often has been thin. On July 7, 2015, The NASDAQ Stock Market LLC approved our application for listing our common stock on the Nasdaq Capital Market under the symbol "AEMD," and we commenced trading on the Nasdaq Capital Market on July 13, 2015. Previously, our common stock was quoted on the OTCQB Marketplace under the trading symbol "AEMD."

The following table sets forth for the calendar periods indicated the quarterly high and low closing or bid, as applicable, prices for our common stock as reported by the Nasdaq Capital Market and/or the OTCQB Marketplace. The prices represent quotations between dealers, without adjustment for retail markup, mark down or commission, and do not necessarily represent actual transactions.

	CLOSING/BID PRICE	
PERIOD	HIGH	LOW
Calendar 2016:		
First Quarter	$7.01	$4.34
Calendar 2015:		
Fourth Quarter	8.20	6.17
Third Quarter	11.38	6.58
Second Quarter	14.00	6.51
First Quarter	19.50	8.50
Calendar 2014:		
Fourth Quarter	28.50	6.00
Third Quarter	9.00	5.00
Second Quarter	11.00	7.50
First Quarter	13.00	8.00

There were approximately 164 record holders of our common stock at June 28, 2016. The number of registered stockholders includes any beneficial owners of common shares held in street name.

The transfer agent and registrar for our common stock is Computershare Investor Services, located at 350 Indiana Street, Suite 800, Golden, Colorado 80401.

We have not paid any dividends on our common stock to date and do not anticipate that we will pay dividends in the foreseeable future. Any payment of cash dividends on our common stock in the future will be dependent upon the amount of funds legally available, our earnings, if any, our financial condition, our anticipated capital requirements and other factors that the board of directors may think are relevant. However, we currently intend for the foreseeable future to follow a policy of retaining all of our earnings, if any, to finance the development and expansion of our business and, therefore, do not expect to pay any dividends on our common stock in the foreseeable future.

Recent Sales of Unregistered Securities

We have sold or issued the following equity securities not registered under the Securities Act of 1933, or Securities Act, in reliance upon the exemption from registration pursuant to Section 4(a)(2) of the Securities Act or Regulation D of the Securities Act during the fiscal year ended March 31, 2016 and subsequent thereto through the date of filing this report. Except as stated below, no underwriting discounts or commissions were payable with respect to any of the following transactions.

Aethlon Medical, Inc. Equity Transactions in the Fiscal Year Ended March 31, 2016.

On June 25, 2015, we sold $6,000,000 of units, comprised of common stock and warrants, to 18 accredited investors at a price of $6.30 per unit. Each unit consisted of one share of common stock and 0.75 of a five-year warrant to purchase one share of common stock at an exercise price of $6.30 per share. Accordingly, we issued a total of 952,383 shares of unregistered common stock and warrants to purchase 714,285 shares of common stock. For its services as sole placement agent for the financing, we paid Roth Capital Partners, LLC (“Roth”) a cash fee of $285,512 and expense reimbursement of $75,000 and we issued them a five-year warrant to purchase 32,371 shares of common stock at an exercise price of $6.30 per share. We received $5,591,988 in net proceeds from this financing. As the warrants that were issued to the investors and to Roth were issued in connection with common stock for cash, they were considered issued in connection with the financing transaction and the warrant fair value, which was valued using a binomial lattice model, was recorded to additional paid-in-capital.

In connection with the financing, Mr. James Joyce, our Chief Executive Officer, Mr. James Frakes, our Chief Financial Officer and Dr. Chetan Shah, a director of our company, each agreed to waive their right to exercise certain stock options and warrants held by them representing the right to acquire 402,318 shares of common stock in the aggregate (the "Waivers"). The Waivers were required in order to make a sufficient number of shares of common stock available for issuance and the Waivers expired when we amended our Articles of Incorporation on March 31, 2016, to increase the number of authorized shares of our common stock from 10,000,000 to 30,000,000, following stockholder approval of such amendment at our annual stockholders' meeting on March 29, 2016.

During the three months ended September 30, 2015, we issued an aggregate of 5,292 shares of common stock to an accredited investor upon the exercise of previously issued warrants. The warrants were exercised on a cashless or "net" basis. Accordingly, we did not receive any proceeds from such exercises. The cashless exercise of such warrants resulted in the cancellation of previously issued warrants to purchase an aggregate of 1,744 shares of common stock.

During the three months ended December 31, 2015, we issued an aggregate of 6,757 unregistered shares of common stock to two investors upon the exercise of previously issued warrants. The warrants were exercised for cash and we received cash proceeds of $14,766 for an average purchase price of $2.19 per share per the terms of the warrants.

EQUITY COMPENSATION PLANS

SUMMARY EQUITY COMPENSATION PLAN DATA

Equity Compensation Plans

Summary equity compensation plan data

The following table sets forth information, as of March 31, 2016, about our equity compensation plans (including the potential effect of debt instruments convertible into common stock) in effect as of that date:

Plan category	(a) Number of securities	(b) Weighted-average exercise price of	(c) Number of securities

	to be issued upon exercise of outstanding options, warrants and rights (1)(2)	outstanding options, warrants and rights	remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	–	$ –	9,800
Equity compensation plans not approved by security holders (1)(3)	438,547	$ 10.94	3,028,845
Totals	438,547	$ 10.94	3,038,645

_____

(1) The description of the material terms of non-plan issuances of equity instruments is discussed in Note 5 to the accompanying consolidated financial statements.

(2) Net of equity instruments forfeited, exercised or expired.

(3) On March 31, 2016 we had 3,028,845 shares available under our 2010 Stock Incentive Plan.

2000 Stock Option Plan

Our 2000 Stock Option Plan provides for the grant of incentive stock options to our full-time employees (who may also be directors) and nonstatutory stock options to non-employee directors, consultants, customers, vendors or providers of significant services. The exercise price of any incentive stock option may not be less than the fair market value of the common stock on the date of grant or, in the case of an optionee who owns more than 10% of the total combined voting power of all classes of our outstanding stock, not be less than 110% of the fair market value on the date of grant. The exercise price, in the case of any nonstatutory stock option, must not be less than 75% of the fair market value of the common stock on the date of grant. The amount reserved under the 2000 Stock Option Plan is 10,000 options.

At March 31, 2016, all of the grants previously made under the 2000 Stock Option Plan had expired and 200 common shares had been issued under the plan, with 9,800 available for future issuance.

2010 Stock Incentive Plan

In August 2010, we adopted the 2010 Stock Incentive Plan, which provides incentives to attract, retain and motivate employees and directors whose present and potential contributions are important to our success by offering them an opportunity to participate in our future performance through awards of options, the right to purchase common stock, stock bonuses and stock appreciation rights and other awards. We initially reserved a total of 70,000 common shares for issuance under the 2010 Stock Incentive Plan.

In August 2010, we filed a registration statement on Form S-8 for the purpose of registering 70,000 common shares issuable under this plan under the Securities Act, and in July 2012, we filed a registration statement on Form S-8 for the purpose of registering 100,000 common shares issuable under this plan under the Securities Act.

On January 26, 2016, our Board of Directors approved an amendment to the 2010 Stock Incentive Plan to increase the total number of shares of common stock reserved for issuance under the plan to 3,170,000 shares, subject to amendment of our Articles of Incorporation to increase our authorized common stock. On March 29, 2016, we held an annual stockholders meeting, at which our stockholders approved the Amended 2010 Stock Incentive Plan and an amendment of our Articles of Incorporation to increase our authorized common stock to 30,000,000 shares. On March 31, 2016, we filed a Certificate of Amendment to our Articles of Incorporation to effect the increase in our authorized common stock. As a result of such amendment, the Amended 2010 Stock Incentive Plan became effective on March 31, 2016.

At March 31, 2016, we had 3,028,845 shares available under this plan.

2012 Directors Compensation Program

In July 2012, our Board of Directors approved a board compensation program that modifies and supersedes the 2005 Directors Compensation Program, which was previously in effect. Under the 2012 program, in which only non-employee directors may participate, an eligible director will receive a grant of $35,000 worth of ten-year options to acquire shares of common stock, with such grant being valued at the exercise price based on the average of the closing bid prices of the common stock for the five trading days preceding the first day of the fiscal year. In addition, under this program, eligible directors will receive cash compensation equal to $500 for each committee meeting attended and $1,000 for each formal board meeting attended.

In the fiscal year ended March 31, 2013, our Board of Directors granted ten-year options to acquire an aggregate of 33,342 shares of our common stock, all with an exercise price of $3.80 per share, to our four outside directors under the 2012 program.

In the fiscal year ended March 31, 2014, our Board of Directors granted ten-year options to acquire an aggregate of 31,911 shares of our common stock, all with an exercise price of $4.10 per share, to our five outside directors under the 2012 program.

In the fiscal year ended March 31, 2015, our Board of Directors granted ten-year options to acquire an aggregate of 11,053 shares of our common stock, all with an exercise price of $9.50 per share, to our three outside directors under the 2012 program. No stock option grants were issued to directors during the fiscal year ended March 31, 2016.

At March 31, 2016 we had issued 26,757 options under the old 2005 program to outside directors and 79,309 options to employee-directors, 21,756 outside directors' options had been forfeited, 5,000 outside directors' options had been exercised, 79,309 employee-directors' options had been forfeited and no options under the old 2005 program remained outstanding.

On June 6, 2014, our Board of Directors approved certain changes to the 2012 program. Under this modified program, a new eligible director will receive an initial grant of $50,000 worth of options to acquire shares of common stock, with such grant being valued at the exercise price based on the average of the closing bid prices of the common stock for the five trading days preceding the first day of the fiscal year. These options will have a term of ten years and will vest 1/3 upon grant and 1/3 upon each of the first two anniversaries of the date of grant. In addition, at the beginning of each fiscal year, each existing director eligible to participate in the modified 2012 program also will receive a grant of $35,000 worth of options valued at the exercise price based on the average of the closing bid prices of the common stock for the five trading days preceding the first day of the fiscal year. Such options will vest on the first anniversary of the date of grant. In lieu of per meeting fees, eligible directors will receive an annual board retainer fee of $30,000. The modified 2012 program also provides for the following annual retainer fees: Audit Committee Chair - $5,000, Compensation Committee chair - $5,000, Audit Committee member - $4,000, Compensation Committee member - $4,000 and lead independent director - $15,000.

Stand-alone grants

From time to time our Board of Directors grants common stock or common share purchase options or warrants to selected directors, officers, employees and consultants as equity compensation to such persons on a stand-alone basis outside of any of our formal stock plans. The terms of these grants are individually negotiated. There were no stock option grants to either employees or directors during the fiscal year ended March 31, 2016.

ITEM 6. SELECTED FINANCIAL DATA

As a Smaller Reporting Company, we are not required to furnish information under this Item 6.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with the consolidated Financial Statements and Notes thereto appearing elsewhere in this Annual Report.

Overview

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

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

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

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

Fiscal Years Ended March 31, 2016 and 2015

Results of Operations

Revenues

We recorded government contract revenue in the fiscal years ended March 31, 2016 and 2015. This revenue arose from work performed under our government contract with the Defense Advanced Research Projects Agency, or DARPA, and our subcontract with Battelle Memorial Institute, or Battelle, as follows:

	Fiscal Year Ended 3/31/16	Fiscal year Ended 3/31/15	Change in Dollars
DARPA contract	$863,011	$630,887	$232,124
Battelle subcontract	23,561	131,530	(107,969)
Total government contract revenue	$886,572	$762,417	$124,155

DARPA Contract

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

Originally, only the base year (year one of the contract) was effective for the parties; however, DARPA subsequently exercised the option on the second, third, fourth and fifth years of the contract. The milestones are comprised of planning, engineering and clinical targets, the achievement of which in some cases will require the participation and contribution of third party participants under the contract. We cannot assure you that we alone, or with third party participants, will meet such milestones to the satisfaction of the government and in compliance with the terms of the contract or that we will be paid the full amount of the contract revenues during any year of the contract term. We

commenced work under the contract in October 2011.

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

In the fiscal year ended March 31, 2016, we reported $863,011 in contract revenue for that fiscal year and in the fiscal year ended March 31, 2015, we reported $630,887 in contract revenue for that fiscal year.

As of March 31, 2016, we had invoiced DARPA for contract payments totaling $5,548,573 over the course of the contract.

Battelle Subcontract

We entered into a subcontract agreement with Battelle in March 2013. Battelle was chosen by DARPA to be the prime contractor on the systems integration portion of the original DARPA contract, and we are one of several subcontractors on that systems integration project. The Battelle subcontract is under a time and materials basis and we began generating revenues under the subcontract in the three months ended September 30, 2013. Our expected future revenue from the subcontract will be at the discretion of Battelle. The Battelle subcontract is our first cost-reimbursable contract.

Our revenue under this contract is a function of cost reimbursement plus an overhead mark-up for hours devoted to the project by specific employees (with specific hourly rates for those employees), for travel expenses related to the project, for any equipment purchased for the project and for the cost of any consultants hired by us to perform work on the project. Each payment will require approval by the program manager at Battelle.

Operating Expenses

Consolidated operating expenses were $5,271,406 for the fiscal year ended March 31, 2016 compared to $4,755,270 in the fiscal year ended March 31, 2015, an increase of $516,136. The net increase of $516,136 was due to increases in professional fees of $686,900 and to an increase in general and administrative expense of $21,898, which were partially offset by a decrease in payroll and related expenses of $192,662.

The $686,900 increase in our professional fees arose from a $815,125 increase in non-DARPA-related professional fees, which was partially offset by a decrease in DARPA-related professional fees of $36,446 and a decrease in Exosome's professional fees of $91,779.

The $815,125 increase in our non-DARPA-related professional fees was primarily due to $424,264 of credits and write-offs on accrued professional fees taken in the fiscal year ended March 31, 2015 as part of a negotiation of payoffs of those accrued fees. There was no comparable activity in the 2016 period. Without those write-offs in the 2015 period, our non-DARPA-related professional fees in the 2016 period were $390,861 over the pre write-off amount of non-DARPA-related professional fees in the 2015 period. That increase was due to a combination of an increase in our US clinical trial expenses of $84,212, an increase of scientific consulting expenses of $138,471, an increase in business development expense of $71,579 and an increase in our legal fees of $125,525, which largely related to work on financings and related registration statement filings.

The $21,898 increase in general and administrative expenses primarily arose from a $183,819 increase in our general and administrative expenses, which was partially offset by a $130,233 decrease in general and administrative expenses at Exosome and a $31,690 decrease in our DARPA-related general and administrative expenses. The $183,819 increase arose from a combination of $100,000 in Nasdaq listing fees and an increase of $70,161 in conference and trade show expenses.

The $192,662 decrease in payroll and related expenses was principally driven by a $258,240 decrease in the payroll and related expenses of Exosome due to headcount reductions and a $213,637 reduction in our stock-based compensation, which were partially offset by a $279,215 increase in payroll and related expenses of Aethlon Medical due primarily to salary increases and bonus payments.

Other Expense (Income)

In the fiscal year ended March 31, 2016, we recognized other expenses of $573,782 compared to $2,986,641 of other expense in the fiscal year ended March 31, 2015. The following table breaks out the various components of our other expense over the fiscal years ended March 31, 2016 and 2015:

	Components of Other Expense in Fiscal Year Ended		
	March 31, 2016	March 31, 2015	Change
Loss on debt conversion	$–	$2,753,989	$(2,753,989)
Interest and other debt expenses	573,782	452,276	121,506
Other (income)	–	(219,624)	219,624

Total other expense	$573,782	$2,986,641	$(2,412,859)

We recorded a loss on debt conversion of $2,753,989 in the fiscal year ended March 31, 2015, which arose from the conversion to equity of principal and accrued interest on certain notes payable. There was no comparable loss on debt conversion in the fiscal year ended March 31, 2016.

Other income for the fiscal year ended March 31, 2015 included a gain of $362,800 related to a reduction in our accrued damages due to various debt settlements over the fiscal year and a charge of $143,176 for the change in fair value related to the extension of the warrants of a note holder in exchange for a postponement in the agreed payment date of his notes.

Our interest and other debt expense increased by $121,506 from the fiscal year ended March 31, 2015 to the fiscal year ended March 31, 2016. The following table breaks out the various components of our interest expense over the fiscal years ended March 31, 2016 and 2015:

	Components of Interest Expense and Other Debt Expenses in Fiscal Year Ended		
	March 31, 2016	March 31, 2015	Change
Interest expense	$56,549	$166,899	$(110,350)
Amortization of deferred financing costs	144,683	118,147	26,536
Amortization of note discounts	372,550	155,230	217,320
Note restructuring expense	–	12,000	(12,000)
Total interest and other debt expenses	$573,782	$452,276	$121,506

As noted in the above table, the primary factor in the $121,506 overall increase in interest and other debt expenses was a $217,320 increase in the amortization of note discounts. That increase was due to a full year of amortization in the fiscal year ended March 31, 2016 compared to a partial year of amortization in the previous fiscal year since the related convertible notes that were assigned the note discount were funded in November 2014.

As a result of the above factors, our net loss before noncontrolling interests decreased from $6,979,494 for the fiscal year ended March 31, 2015 to $4,958,616 for the fiscal year ended March 31, 2016.

Liquidity and Capital Resources

At March 31, 2016, we had a cash balance of $2,123,737 and working capital of $1,877,532. This compares to a cash balance of $855,596 and working capital of $630,420 at March 31, 2015. Between April 1, 2016 and June 28, 2016, we billed $4,635 and collected $204,106 under our government contracts. Significant additional financing must be obtained in order to provide a sufficient source of operating capital and to allow us to continue to operate as a going concern. In addition, we will need to raise capital to complete the approved human clinical trial in the U.S. We anticipate the primary source of this additional financing will be from proceeds of the Company’s at-the-market offering program.

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

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

Going Concern

The accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the ordinary course of business. We have incurred continuing losses from operations and at March 31, 2016 had an accumulated deficit of approximately $86,502,000. These factors, among other matters, raise substantial doubt about our ability to continue as a going concern. A significant amount of additional capital will be necessary to advance the development of our products to the point at which they may become commercially viable. We intend to fund operations, working capital and other cash requirements for the fiscal year ending March 31, 2017 through debt and/or equity financing arrangements as well as through revenues and related cash receipts under our government contracts.

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

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

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

Cash Flows

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

	(In thousands)
	For the year ended
	March 31, 2016	March 31, 2015

Cash (used in) provided by:		
Operating activities	$(4,329)	$(5,049)
Investing activities	(9)	–
Financing activities	5,607	4,655
Net increase (decrease) in cash	$1,269	$(394)

Net Cash from Operating Activities.

We used cash in our operating activities due to our losses from operations. Net cash used in operating activities was approximately $4,329,000 in fiscal 2016 compared to net cash used in operating activities of approximately $5,049,000 in fiscal 2015, a decrease of approximately $720,000. The $720,000 decrease was primarily due to the combination of the use of approximately $1,802,000 in fiscal 2015 to pay down accounts payable, related party payables and other current liabilities and an increase in fiscal 2016 in the cash used in operations before changes in operating assets and liabilities of approximately $1,017,000.

Net Cash from Investing Activities.

During the fiscal year ended March 31, 2016, we purchased approximately $9,000 of equipment while in the fiscal year ended March 31, 2015 we did not use any cash for purchases of equipment.

Net Cash from Financing Activities.

Net cash generated from financing activities increased from approximately $4,655,000 in the fiscal year ended March 31, 2015 to approximately $5,607,000 in the fiscal year ended March 31, 2016. The net cash provided by financing activities in fiscal 2016 was all from the issuance of common stock, while the net cash provided by financing activities in fiscal 2015 arose from approximately $4,763,000 from the issuance of common stock and $415,000 from the issuance of notes payable, which was partially offset by approximately $523,000 in repayments of notes payable in cash.

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

Current Events

Common Stock Sales Agreement with H.C. Wainwright

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

Subject to the terms and conditions set forth in the Agreement, H.C. Wainwright will use its commercially reasonable efforts consistent with its normal trading and sales practices to sell the Shares from time to time, based upon our instructions. We have provided H.C. Wainwright with customary indemnification rights, and H.C. Wainwright will be entitled to a commission at a fixed rate equal to three percent (3.0%) of the gross proceeds per Share sold. In addition, we have agreed to pay certain expenses incurred by H.C. Wainwright in connection with the Agreement, including up

to $50,000 of the fees and disbursements of their counsel. The Agreement will terminate upon the sale of all of the Shares under the Agreement unless terminated earlier by either party as permitted under the Agreement.

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

Amendment of November 2014 Investment Documents

On June 27, 2016, we and certain investors (the "Investors") entered into Amendments (the "Amendments") to our November 2014 convertible notes in the original principal amount of $527,780 (the "Notes") and Class A Common Stock Purchase Warrants to purchase an aggregate of 47,125 shares of common stock (the "Existing Warrants") issued and sold by us to the Investors under a Subscription Agreement dated November 6, 2014. The Amendments provide that the Maturity Date (as defined in the Notes) is extended from June 1, 2016 to July 1, 2017 and that the Conversion Price (as defined in the Notes) is reduced from $5.60 per share of common stock to $5.00 per share of common stock. In addition, we reduced the purchase price (as defined in the Existing Warrants) from $8.40 per share to $5.00 per share. In connection with these modifications, each of the Investors signed a Consent and Waiver providing its consent under certain restrictive provisions, and waiving certain rights, including a right to participate in certain offerings made by us, under a Securities Purchase Agreement dated June 23, 2015, (the "2015 SPA") to which we, the Investors and certain other investors are parties, in order to facilitate the at-the-market equity program described above.

The Amendments also increase the principal amount of the Notes to $692,811.23 (in the aggregate) to (i) include accrued and unpaid interest through June 15, 2016, and (ii) increase the principal amount by $80,000 (in the aggregate) as an extension fee for the extended maturity date of the Notes set forth above. With respect to each Note, we entered into an Allonge to Convertible Promissory Note (each, an "Allonge") reflecting the changes in the principal amount, Maturity Date and Conversion Price of the Note.

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

Amendment of December 2014 Warrants

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

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

Critical Accounting Policies

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America ("GAAP") requires us to make a number of estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements. Such estimates and assumptions affect the reported amounts of expenses during the reporting period. On an ongoing basis, we evaluate estimates and assumptions based upon historical experience and various other factors and circumstances. We believe our estimates and assumptions are reasonable in the circumstances; however, actual results may differ from these estimates under different future conditions. We believe that the estimates and assumptions that are most important to the portrayal of our financial condition and results of operations, in that they require the most difficult, subjective or complex judgments, form the basis for the accounting policies deemed to be most critical to us. These critical accounting estimates relate to revenue recognition, stock purchase warrants issued with notes payable, beneficial conversion feature of convertible notes payable, impairment of intangible assets and long lived assets, stock compensation, deferred tax asset valuation allowance, and contingencies.

Fair Value Measurements

We measure the fair value of applicable financial and non-financial instruments based on the following fair value hierarchy:

- Level 1: Quoted market prices in active markets for identical assets or liabilities.
- Level 2: Observable market based inputs or unobservable inputs that are corroborated by market data.
- Level 3: Unobservable inputs that are not corroborated by market data.

The hierarchy noted above requires us to minimize the use of unobservable inputs and to use observable market data, if available, when determining fair value.

The fair value of derivative liabilities was determined based on unobservable inputs that are not corroborated by market data, which is a Level 3 classification. We recorded derivative liabilities on our balance sheet at fair value with changes in fair value recorded in our consolidated statements of operations. At March 31, 2016, we had no derivative liabilities.

Revenue Recognition

With respect to revenue recognition, we entered into a government contract with DARPA and have recognized revenue during the fiscal years ended March 31, 2016 and 2015 of $863,011 and $630,887, respectively, under such contract. We adopted the Milestone method of revenue recognition for the DARPA contract under Financial Accounting Standards Board's Accounting Standards Codification ("ASC") 605-28 "Revenue Recognition – Milestone Method" and we believe we meet the requirements under ASC 605-28 for reporting contract revenue under the Milestone Method for the fiscal years ended March 31, 2016 and 2015.

We also recognize revenue for a secondary smaller contract under a time and materials non-fixed price basis where we recognize revenue as the services are performed.

Stock Purchase Warrants

We grant warrants in connection with the issuance of certain notes payable and other financing transactions. When such warrants are classified as equity, we measure the relative estimated fair value of such warrants which represents a discount from the face amount of the notes payable. Such discounts are amortized to interest expense over the term of the notes. We analyze such warrants for classification as either equity or derivative liabilities and value them based on binomial lattice models.

Beneficial Conversion Feature of Notes Payable

The convertible feature of certain notes payable provides for a rate of conversion that is below market value. Such feature is normally characterized as a "beneficial conversion feature" of which we measure the estimated fair value in circumstances in which the conversion feature is not required to be separated from the host instrument and accounted for separately, and record that value in the consolidated financial statements as a discount from the face amount of the notes. Such discounts are amortized to interest expense over the term of the notes.

Share-based Compensation

We account for share-based compensation awards using the fair-value method and record such expense based on the grant date fair value in the consolidated financial statements over the requisite service period.

Derivative Instruments

We evaluate free-standing derivative instruments (or embedded derivatives) to properly classify such instruments within equity or as liabilities in our financial statements. Our policy is to settle instruments indexed to our common shares on a first-in-first-out basis.

The classification of a derivative instrument is reassessed at each reporting date. If the classification changes as a result of events during a reporting period, the instrument is reclassified as of the date of the event that caused the reclassification. There is no limit on the number of times a contract may be reclassified.

Instruments classified as derivative liabilities are remeasured each reporting period (or upon reclassification) and the change in fair value is recorded on our consolidated statement of operations in other expense (income). We had no derivative instruments at March 31, 2016 and at March 31, 2015.

Income Taxes

Deferred tax assets are recognized for the future tax consequences attributable to the difference between the consolidated financial statements and their respective tax basis. Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts reported for income tax purposes, and (b) tax credit carryforwards. We record a valuation allowance for deferred tax assets when, based on our best estimate of taxable income (if any) in the foreseeable future, it is more likely than not that some portion of the deferred tax assets may not be realized.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

41

Convertible Notes Payable and Warrants

NOVEMBER 2014 10% CONVERTIBLE NOTES

In November 2014, we entered into a subscription agreement with two accredited investors providing for the issuance and sale of (i) convertible promissory notes in the aggregate principal amount of $527,780 and (ii) five year warrants to purchase up to 47,123 shares of common stock at a fixed exercise price of $8.40 per share. These notes bear interest at the annual rate of 10% and mature on April 1, 2016.

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

The estimated relative fair value of warrants issued in connection with the November 2014 10% Convertible Notes was recorded as a debt discount and is amortized as additional interest expense over the term of the underlying debt. We recorded debt discount of $240,133 based on the relative fair value of these warrants. In addition, as the effective conversion price of the debt was less than market price of the underlying common stock on the date of issuance, we recorded an additional debt discount of $287,647 related to the beneficial conversion feature. As of December 31, 2015, the $527,780 principal amount outstanding under this agreement is presented net of unamortized debt discount of $93,137.

These notes are convertible at the option of the holders into shares of our common stock at a fixed price of $5.60 per share, for up to an aggregate of 94,246 shares of common stock for the principal balance and the accrued interest through March 31, 2016 is convertible into an additional 13,222 shares for a total amount of 107,468 shares. There are no registration requirements with respect to the shares of common stock underlying the notes or the warrants.

The pricing on both the conversion price and on the warrant exercise price reflected a negotiation that began in September 2014 and continued through funding in November 2014. During that period of time the price of our common stock rose significantly, which complicated the pricing negotiations. We ended up with pricing the notes and warrants at levels consistent with our prior equity unit issuances in October 2014.

Amendments of Convertible Promissory Note Terms

On November 12, 2015, we entered into an Amendment of Terms with the two investors that participated in the November 2014 10% Convertible Notes. The Amendment of Terms modifies the terms of the subscription agreement, notes and warrants to, among other things, extend the maturity date of the notes from April 1, 2016 to June 1, 2016, temporarily reduce the number of shares that we must reserve with respect to conversion of the notes, and temporarily suspend the time period during which one of the investors may exercise its warrants in order to provide us with additional authorized shares to issue as part of our ordinary business operations. In exchange for the investors' agreements in the Amendment of Terms, we paid one of the investors a cash fee of $90,000, which we recorded as deferred financing costs and will amortize over the remaining term of the notes. During the fiscal year ended March 31, 2016, $62,308 of amortization related to the amendment has been included in interest expense in the accompanying consolidated statements of operations.

On June 27, 2016, the maturity date of the November 2014 10% Convertible Notes was extended through July 1, 2017 (see Recent Developments above). Therefore, we classified the notes as non-current liabilities.

AMENDED AND RESTATED SERIES A 12% CONVERTIBLE NOTES

In June 2010, we entered into Amended and Restated Series A 12% Convertible Promissory Notes (the "Amended and Restated Notes") with the holders of certain promissory notes previously issued by us, extending the due date to December 31, 2010 on the aggregate principal balance of $900,000. During the fiscal year ended March 31, 2013, the holders of $15,000 of the Notes converted their principal and related accrued interest into common stock. During the fiscal year ended March 31, 2015, the holders of the remaining $885,000 of the Notes converted their principal and related accrued interest into common stock. There was no balance remaining at March 31, 2015.

The following transactions related to the Amended and Restated Notes impacted our consolidated statements of operations and statements of cash flows in the fiscal year ended March 31, 2015.

Weiner Note Conversion

On June 24, 2014, we entered into an agreement with the Ellen R. Weiner Family Revocable Trust (the "Trust"), a holder of a Series A 12% Convertible Note (the "Note"), which previously was classified as being in default. As per the agreement, the Trust converted past due principal of $660,000 and accrued interest balance of $343,200 into unregistered common stock, representing all amounts outstanding to the Trust.

42

Additionally, the Trust agreed to waive anti-dilution price protection underlying warrants previously issued to the Trust. On June 26, 2014, three other parties who held similar warrants also agreed to waive their anti-dilution price protection.

Under its agreement, the Trust converted the entire $1,003,200 past due principal and interest balance on the Note, which previously was in default, into an aggregate of 466,365 unregistered shares of our common stock and five-year warrants to acquire up to 136,190 shares of our common stock at an exercise price of $2.10 per share (which exercise price was the result of certain contractual price adjustments previously made during 2011) and up to 7,944 shares of our common stock at an exercise price of $5.40 per share (collectively, the "Conversion Securities"). Based on the fair value of the warrants and shares issued to the Trust for the accrued interest, we recorded a loss on settlement of notes of $1,791,421 during the fiscal year ended March 31, 2015.

In exchange for the Trust's conversion in full of the Note and accrued interest and for the waivers of anti-dilution price protection in the previously issued warrants, in addition to the Conversion Securities, we issued to the Trust 1,500 unregistered shares of common stock as a service fee, changed the exercise price of all of the previously issued warrants to $2.10 per share and extended the expiration date of all of the previously issued warrants to July 1, 2018. We valued the 1,500 share service fee at $12,000 based on our closing price on the date of the agreement and recorded that value as interest expense during the June 2014 period.

Bird Estate Extension

On July 8, 2014, we executed a written restructuring agreement (the "Agreement") with the Estate of Allan Bird (the "Estate"), a holder of a Series A 12% Convertible Note (the "Note"), which previously was classified as being in default. Since the negotiations for the Agreement were completed in the month of June, we recorded the impact of the Agreement as of June 30, 2014. In the Agreement, the Estate agreed to extend the expiration date of the Note to April 1, 2016, to convert approximately $116,970 of accrued interest to equity, and to waive anti-dilution price protection underlying the Note and warrants previously issued to the Estate.

Under the Agreement, the Estate converted the entire $116,970 past due interest balance on the Note, which previously was in default, into an aggregate of 51,837 unregistered shares of our common stock. The Estate received five-year warrants to acquire up to 46,429 shares of our common stock at an exercise price of $2.10 per share (which exercise price was the result of certain contractual price adjustments previously made during 2011). Based on our common stock prices during a period of negotiation with the Estate including during calendar year 2013, the Estate also received five-year warrants to acquire up to 2,708 shares of our common stock at an exercise price of $5.40 (collectively known as the "Conversion Securities"). Based on the fair value of the warrants and shares issued to the Estate for the accrued interest, we recorded a loss on settlement of notes of $663,209 during the fiscal year ended March 31, 2015.

In exchange for the Estate's extension of the Note, conversion of accrued interest and for the waivers of anti-dilution price protection in the previously issued warrants, in addition to the Conversion Securities, we also issued to the Estate 500 unregistered shares of common stock as an extension fee and extended the expiration date of all of the previously issued warrants to July 1, 2018. We valued the 500 share extension fee at $4,500 based on our closing price and recorded that value as a deferred financing cost, which we will amortize over the extended two year life of the Note.

Bird Estate Conversion

In November 18, 2014, we issued an aggregate of 112,500 shares of common stock to the Estate upon the conversion of an aggregate of $236,250 representing all $225,000 of unpaid principal and $11,250 of unpaid accrued interest due under the Note. The conversion price per share was $2.10.

Securities Issued for Services

Historically, we have issued securities in payment of services to reduce our obligations and to avoid using our cash resources. In the fiscal year ended March 31, 2016 we did not issue any securities in the payment of services. In the fiscal year ended March 31, 2015 we issued 27,654 common shares for services of which 8,587 were unregistered and were for investor relations services and corporate communications services. Included in the 27,654 common shares issued for services are 19,068 shares, registered under Form S-8 registration statements, which were issued as follows: 693 for financial consulting, 6,425 for scientific consulting and 11,950 for legal services. The average price (premium) discount of common shares issued for these services, weighted by the number of shares issued for services in this period, was approximately (6.6)%.

Securities Issued for Debt

Historically, we have also issued securities for debt to reduce our obligations to avoid using our cash resources. In the fiscal year ended March 31, 2016 we did not issue any securities for debt. In the fiscal year ended March 31, 2015 we issued 948,728 unregistered common shares for repayment in full of notes, including accrued interest, in the aggregate amount of $2,273,032. The average price discount of the common stock issued for debt was approximately 75.6%.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a Smaller Reporting Company, we are not required to furnish information under this Item 7A.

ITEM 8. FINANCIAL STATEMENTS

The consolidated financial statements listed in the accompanying Index to Financial Statements are attached hereto and filed as a part of this Report under Item 15.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)),, that are designed to ensure that information required to be

disclosed, in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate, to allow timely decisions regarding required disclosures.

In designing and evaluating the disclosure controls and procedures, we recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and we were required to apply our judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have carried out an evaluation as of the end of the period covered by this report under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures.

Based on our evaluation and subject to the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that there were no material weaknesses in our disclosure controls and procedures and that such disclosure controls and procedures were effective as of the end of the period covered by this report in providing reasonable assurance of achieving the desired control objectives, and therefore there were no corrective actions taken.

Internal Control over Financial Reporting

(a) Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of March 31, 2016. According to the guidelines established by Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, one or more material weaknesses renders a company's internal control over financial reporting ineffective. Based on this evaluation, we have concluded that our internal control over financial reporting was effective as of March 31, 2016.

(b) ***Changes in Internal Control Over Financial Reporting***

There was no change in our internal control over financial reporting during the quarter ended March 31, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

We have no disclosure applicable to this item.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires our officers, directors, and persons who own more than 10% of a registered class of our equity securities to file reports of ownership and changes in ownership with the Securities and Exchange Commission. Officers, directors, and greater than 10% beneficial owners are required by Securities and Exchange Commission regulation to furnish the Company with copies of all Section 16(a) forms they file. Based solely on our review of copies of the Section 16(a) reports filed for the fiscal year ended March 31, 2016, we believe that all filing requirements applicable to our officers, directors, and greater than 10% beneficial owners were complied with.

DIRECTORS AND EXECUTIVE OFFICERS

The names, ages and positions of our directors and executive officers as of June 28, 2016 are listed below:

NAMES	TITLE OR POSITION	AGE
James A. Joyce (1)	Chairman, Chief Executive Officer and Secretary	54
Rodney S. Kenley (2)	President and Director	66
James B. Frakes (3)	Chief Financial Officer and Senior Vice President - Finance	59
Franklyn S. Barry, Jr.	Director	76
Edward G. Broenniman	Director	79
Chetan S. Shah, MD	Director	47

(1) Effective June 1, 2001, Mr. Joyce was appointed our President and Chief Executive Officer, replacing Mr. Barry, who continues as a member of the Board of Directors. Mr. Joyce resigned from the position of President upon the appointment of Mr. Kenley to such position on October 27, 2010.

(2) Effective October 27, 2010, Mr. Kenley was appointed as our President.

(3) Effective September 27, 2010, Mr. Frakes was appointed as our Chief Financial Officer.

Certain additional information concerning the individuals named above is set forth below. This information is based on information furnished us by each individual noted.

James A. Joyce, Chairman, CEO and Secretary.

Mr. Joyce is the founder of Aethlon Medical, Inc. and has been the Chairman of the Board and Secretary since March 1999. On June 1, 2001, our Board of Directors appointed Mr. Joyce to the additional role of CEO. Mr. Joyce also serves as the Executive Chairman of Exosome Sciences, Inc. In 1992, Mr. Joyce founded and was the sole stockholder of James Joyce & Associates, an organization that provided management consulting and corporate finance advisory services to CEOs and CFOs of publicly traded companies. Previously, from 1989 to 1991, Mr. Joyce was Chairman and Chief Executive Officer of Mission Labs, Inc. Prior to that Mr. Joyce was a principal in charge of U.S. operations for London Zurich Securities, Inc. Mr. Joyce is a graduate of the University of Maryland. We believe that Mr. Joyce is qualified to serve as our director because of his role in founding our company and his prior experience, including his experience in the extracorporeal industry and in the financial markets.

Rodney S. Kenley, President and Director

Mr. Kenley has been President and a Director since October 2010. He has 38 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. 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 Medical, Inc. Mr. Kenley received his Bachelor of Arts degree in Biology and Chemistry from Wabash College, a Master's of Science degree in Molecular Biology from Northwestern University and a Masters of Management from the Kellogg School of Management, also at Northwestern University. We believe that Mr. Kenley is qualified to serve as our director as a result of his experience in developing extracorporeal blood purification products.

James B. Frakes, Chief Financial Officer and Senior Vice President – Finance

Mr. Frakes joined Aethlon Medical, Inc. 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. Mr. Frakes also serves as the Chief Financial Officer of Exosome Sciences, Inc. 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. Mr. Frakes received an MBA from the University of Southern California and completed his BA with Honors at Stanford University.

Franklyn S. Barry, Jr., Director

Mr. Barry was President and Chief Executive Officer of Hemex, Inc. from April 1997 through May 31, 2001 and our President and CEO from March 10, 1999 to May 31, 2001, when he returned to consulting until he retired in 2013. He became a director of Aethlon Medical, Inc. on March 10, 1999. From 1994 to April 1997, Mr. Barry was a private consultant. Included among his prior experiences are tenures as President of Fisher-Price and as co-founder and CEO of Software Distribution Services, which today operates as Ingram Micro-D, an international distributor of personal computer products. Mr. Barry serves on the Board of Directors of Merchants Mutual Insurance Company. We believe that Mr. Barry is qualified to serve as our director because of his extensive management experience.

Edward G. Broenniman, Director

Mr. Broenniman became a director of Aethlon Medical, Inc. in March 1999. He has been the Managing Director of The Piedmont Group, LLC, a venture advisory firm, since 1978. Mr. Broenniman recently served on the Board of Directors of publicly traded QuesTech (acquired by CACI International), and currently serves on the Boards of two privately held firms. His nonprofit Boards are the Dingman Center for Entrepreneurship's Board of Advisors at the University of Maryland, the National Association of Corporate Directors, National Capital Chapter and the Board of the Association for Corporate Growth, National Capital Chapter. We believe that Mr. Broenniman is qualified to serve as our director because of his extensive management experience.

Chetan S. Shah, MD, Director

Dr. Shah became a director of Aethlon Medical, Inc. in June 2013. Dr. Shah is a board certified Otolaryngologist. He is an Advisory Board Member at The Bank of Princeton, and a partner and Board member of the Surgery Center at Hamilton as well as Physician Management Systems and Princeton Eye & Ear, which he founded in 2009. Dr. Shah serves on the board of two other private companies. He holds teaching positions and serves on multiple hospital committees in the area and is on the Audiology and Speech Language Pathology Committee for the State of New Jersey. He also is a member of the Board of Medical Examiners for the State of New Jersey. Dr. Shah received his Bachelor’s degree and Medical Degree from Rutgers University and Robert Wood Johnson Medical School. We believe that Dr. Shah is qualified to serve as our director because of his medical background as both a board certified Otolaryngologist and a member of various medical boards and hospital committees in New Jersey.

Board of Directors

Our Board of Directors has the responsibility for establishing broad corporate policies and for overseeing our overall performance. Members of the Board of Directors are kept informed of our business activities through discussions with the CEO, President and other officers, by reviewing analyses and reports sent to them, and by participating in Board and committee meetings. Our bylaws provide that each of the directors serves for a term that extends to our next annual meeting of stockholders. Our Board of Directors presently has an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee, on each of which Messrs. Barry and Broenniman and Dr. Shah serve. Mr. Barry is Chairman of the Audit Committee, Mr. Broenniman is Chairman of the Nominating and Corporate Governance Committee, and Dr. Shah is Chairman of the Compensation Committee.

46

In July 2012, our Board of Directors approved a board compensation program that modifies and supersedes the 2005 Directors Compensation Program, which was previously in effect. Under the 2012 program, in which only non-employee directors may participate, an eligible director will receive a grant of $35,000 worth of ten-year options to acquire shares of common stock, with such grant being valued at the exercise price based on the average of the closing bid prices of the common stock for the five trading days preceding the first day of the fiscal year. In addition, under this program, eligible directors will receive cash compensation equal to $500 for each committee meeting attended and $1,000 for each formal board meeting attended.

In the fiscal year ended March 31, 2013, our Board of Directors granted ten-year options to acquire an aggregate of 33,342 shares of our common stock, all with an exercise price of $3.80 per share, to our four outside directors under the 2012 program.

In the fiscal year ended March 31, 2014, our Board of Directors granted ten-year options to acquire an aggregate of 31,911 shares of our common stock, all with an exercise price of $4.10 per share, to our five outside directors under the 2012 program.

In the fiscal year ended March 31, 2015, our Board of Directors granted ten-year options to acquire an aggregate of 11,053 shares of our common stock, all with an exercise price of $9.50 per share, to our three outside directors under the 2012 program.

There were no issuances of stock options to our outside directors in the fiscal year ended March 31, 2016.

At March 31, 2016 we had issued 26,757 options under the old 2005 program to outside directors and 79,309 options to employee-directors, 21,756 outside directors' options had been forfeited, 5,000 outside directors' options had been exercised, 79,309 employee-directors' options had been forfeited and no options under the old 2005 program remained outstanding.

On June 6, 2014, our Board of Directors approved certain changes to the 2012 program. Under this modified program, a new eligible director will receive an initial grant of $50,000 worth of options to acquire shares of common stock, with such grant being valued at the exercise price based on the average of the closing bid prices of the common stock for the five trading days preceding the first day of the fiscal year. These options will have a term of ten years and will vest 1/3 upon grant and 1/3 upon each of the first two anniversaries of the date of grant. In addition, at the beginning of each fiscal year, each existing director eligible to participate in the modified 2012 program also will receive a grant of $35,000 worth of options valued at the exercise price based on the average of the closing bid prices of the common stock for the five trading days preceding the first day of the fiscal year. Such options will vest on the first anniversary

of the date of grant. In lieu of per meeting fees, eligible directors will receive an annual board retainer fee of $30,000. The modified 2012 program also provides for the following annual retainer fees: Audit Committee Chair - $5,000, Compensation Committee chair - $5,000, Audit Committee member - $4,000, Compensation Committee member - $4,000 and lead independent director - $15,000.

Family Relationships

There are no family relationships between or among the directors, executive officers or persons nominated or chosen by us to become directors or executive officers.

There are no arrangements or understandings between any two or more of our directors or executive officers or between any of our directors or executive officers and any other person pursuant to which any director or officer was or is to be selected as a director or officer, and there is no arrangement, plan or understanding as to whether non-management stockholders will exercise their voting rights to continue to elect the current Board of Directors. There are also no arrangements, agreements or understandings between non-management stockholders that may directly or indirectly participate in or influence the management of our affairs.

Involvement in Legal Proceedings

To the best of our knowledge, during the past ten years, none of the following occurred with respect to a present or former director or executive officer of our company: (1) any bankruptcy petition filed by or against such person or any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time; (2) any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses); (3) being subject to any order, judgment or decree, not subsequently reversed, suspended or vacated, of any court of any competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities or banking activities; (4) being found by a court of competent jurisdiction (in a civil action), the Securities and Exchange Commission or the Commodities Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended or vacated; and (5) being the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree or finding, not subsequently reversed, suspended or vacated, relating to an alleged violation of any federal or state securities or commodities law or regulation, law or regulation respecting financial institutions or insurance companies or law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or (6) being the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Securities Exchange Act of 1934), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or associated persons.

47

Code of Ethics

On February 23, 2005, the Board of Directors approved a "Code of Business Conduct and Ethics," which applies to our principal executive officer, our principal financial officer, our principal accounting officer and persons performing similar tasks. Our Code of Business Conduct and Ethics is available on our company website at www.aethlonmedical.com.

Audit Committee and Audit Committee Financial Expert

Our Board of Directors formed an Audit Committee in May of 1999. Mr. Franklyn S. Barry, Jr. (the Chairman of the Audit Committee), Mr. Edward Broenniman and Dr. Chetan S. Shah serve as members of the Audit Committee. The Board of Directors has determined that each of Mr. Broenniman and Mr. Barry is an "audit committee financial expert" as that term is defined by Item 407 of Regulation S-K. Each of Mr. Broenniman, Mr. Barry and Dr. Shah meets the NASDAQ Stock Market's independence standards for members of such audit committees.

ITEM 11. EXECUTIVE COMPENSATION

EXECUTIVE COMPENSATION

The following executive compensation disclosure reflects all compensation awarded to, earned by or paid to the executive officers below for the fiscal years ended March 31, 2016 and March 31, 2015. The following table summarizes all compensation for fiscal years 2016 and 2015 received by our Chief Executive Officer, and our three most highly compensated executive officers who earned more than $100,000 in fiscal year 2016.

SUMMARY COMPENSATION TABLE FOR 2016 AND 2015 FISCAL YEARS

NAMED EXECUTIVE OFFICER AND PRINCIPAL POSITION	YEAR	SALARY ($)	BONUS ($)	STOCK AWARDS ($)	OPTION AWARDS ($)(5)	NON-EQUITY INCENTIVE PLAN COMPEN-	NON-QUALIFIED DEFERRED COMPEN-SATION	ALL OTHER COMP. ($)

						SATION ($)	EARNINGS ($)		
James A. Joyce (1)	2016	$370,417	$275,000	$–	$–	$–	$–	$–	$
CHIEF EXECUTIVE OFFICER	2015	$347,500	$95,000	$–	$246,000	$–	$–	$–	$
Richard H. Tullis, PhD (2)	2016	$188,000	$–	$–	$–	$–	$–	$–	$
VICE PRESIDENT AND CHIEF SCIENCE OFFICER	2015	$195,000	$5,000	$–	$8,200	$–	$–	$–	$
James B. Frakes (3)	2016	$226,429	$125,000	$–	$–	$–	$–	$–	$
CHIEF FINANCIAL OFFICER AND SVP-FINANCE	2015	$206,250	$31,500	$–	$41,000	$–	$–	$–	$
Rodney S. Kenley (4)	2016	$268,750	$50,000	$–	$–	$–	$–	$–	$
PRESIDENT	2015	$257,500	$15,000	$–	$41,000	$–	$–	$–	$

_____

(1) The aggregate number of stock awards and stock option awards issued to Mr. Joyce and outstanding as of March 31, 2016 is 68,000 and 210,000, respectively. Mr. Joyce received a $5,000 salary increase from $325,000 to $330,000 effective July 1, 2013. In June 2014, Mr. Joyce received a $20,000 salary increase from $330,000 to $350,000. In September 2015, Mr. Joyce received a $35,000 salary increase from $350,000 to $385,000.

(2) The aggregate number of stock awards and stock option awards issued to Dr. Tullis and outstanding as of March 31, 2016 is zero and 46,000, respectively. On November 7, 2014, we paid Dr. Tullis $5,000 for accrued expenses reimbursable to him. In January 2015, we paid Dr. Tullis $93,377 in payment of accrued salary. Dr. Tullis resigned as an employee effective February 9, 2016 and is now a consultant to the Company.

(3) Mr. Frakes was appointed as Chief Financial Officer on September 27, 2010 after previously serving as Senior Vice President-Finance on a part-time basis. The aggregate number of stock awards and stock option awards issued to Mr. Frakes and outstanding as of March 31, 2016 is zero and 25,000, respectively. In June 2014, Mr. Frakes received a $30,000 salary increase from $180,000 to $210,000. In September 2015, Mr. Frakes received a $25,000 salary increase from $210,000 to $235,000.

(4) Mr. Kenley was appointed President on October 27, 2011. The aggregate number of stock awards and stock option awards issued to Mr. Kenley and outstanding as of March 31, 2016 is zero and 35,000, respectively. In June 2014, Mr. Kenley received a $20,000 salary increase from $240,000 to $260,000. In September 2015, Mr. Kenley received a $15,000 salary increase from $260,000 to $275,000.

(5) See note 5 to our financial statements for the years ended March 31, 2016 and 2015 regarding the assumptions made in valuing the stock option awards in the above table.

Employment Agreements

We entered into an employment agreement with Mr. Joyce effective April 1, 1999. Effective June 1, 2001, Mr. Joyce was appointed President and Chief Executive Officer and his base annual salary was increased from $120,000 to $180,000. Effective January 1, 2005, Mr. Joyce's salary was increased from $180,000 to $205,000 per year. Under the terms of the agreement, his employment continues at a salary of $205,000 per year for successive one-year periods, unless given notice of termination 60 days prior to the anniversary of his employment agreement. Effective April 1, 2006. Mr. Joyce's salary was increased from $205,000 to $240,000. His salary was subsequently increased to $265,000 per year and effective May 1, 2008, his salary was increased from $265,000 to $290,000 per year. Effective April 1, 2010, his salary was increased from $290,000 to $325,000 per year. Effective July 2013, his salary was increased from $325,000 to $330,000 per year. In June 2014, his salary was increased from $330,000 to $350,000 per year. In September 2015, Mr. Joyce received a $35,000 salary increase from $350,000 to $385,000.

During the fiscal year ended March 31, 2016, Mr. Joyce earned bonuses totaling $100,000 from us, excluding a retention bonus (see below) and bonuses totaling $75,000 from Exosome Sciences, Inc. During the fiscal year ended March 31, 2015, Mr. Joyce earned bonuses totaling $50,000 from us and bonuses totaling $45,000 from Exosome

Sciences, Inc. All of those bonuses were based upon targets established by our compensation committee.

Mr. Joyce's employment agreement provides for medical insurance and disability benefits, and one year of severance pay if his employment is terminated by us without cause or due to change in our control before the expiration of the agreement, and allows for bonus compensation and stock option grants as determined by our Board of Directors. The agreement also contains restrictive covenants preventing competition with us and the use of confidential business information, except in connection with the performance of his duties for us, for a period of two years following the termination of his employment with us.

We entered into an employment agreement with Dr. Tullis effective January 10, 2000. Effective June 1, 2001, Dr. Tullis was appointed our Chief Science Officer (CSO). His compensation under the agreement was modified in June 2001 from $80,000 to $150,000 per year. Effective January 1, 2005, Dr. Tullis' salary was increased from $150,000 to $165,000 per year. Under the terms of the agreement, his employment continues at a salary of $165,000 per year for successive one-year periods, unless given notice of termination 60 days prior to the anniversary of his employment agreement. Dr. Tullis was granted 5,000 stock options to purchase our common stock in connection the completing certain milestones, such as the initiation and completion of certain clinical trials, the submission of proposals to the U.S. Food and Drug Administration, or FDA, and the filing of a patent application. Effective April 1, 2006, Dr. Tullis' salary was increased to $180,000 per year. Effective April 1, 2010, his salary was increased from $180,000 to $195,000 per year.

During the fiscal year ended March 31, 2015, Dr. Tullis earned a bonus of $5,000 from us. The bonus was based upon targets established by our compensation committee.

In February 2016, we entered into a part-time consulting agreement with Dr. Tullis. Under that agreement, Dr. Tullis will retain his title of CSO and will continue to provide services under the terms of a consulting agreement with us. In connection with the change in his employment, Dr. Tullis resigned as our Vice President. Under the consulting agreement, Tullis will render approximately twenty (20) hours per week of such services, for which we will pay him a consulting fee of $10,000 per month. The term of the consulting agreement is for an initial sixty-day period and, unless terminated earlier by either party, shall automatically extend for additional one-month periods. Either party to the consulting agreement may terminate it upon 30 days' prior written notice to the other party. Concurrently with the entry into the consulting agreement, Dr. Tullis and the Company mutually agreed to terminate his employment agreement with us.

On September 27, 2010, Mr. Frakes was appointed our Chief Financial Officer. We have not entered into a written employment agreement with Mr. Frakes. As Chief Financial Officer, Mr. Frakes received an annual salary initially set at $180,000 and medical insurance benefits. In June 2014, his salary was increased from $180,000 to $210,000 per year. In September 2015, Mr. Frakes received a $25,000 salary increase from $210,000 to $235,000.

During the fiscal year ended March 31, 2016, Mr. Frakes earned bonuses totaling $75,000 from us, excluding a retention bonus (see below) and during the fiscal year ended March 31, 2015, Mr. Frakes earned bonuses totaling $30,000 from us and a bonus of $1,500 from Exosome Sciences, Inc. All of those bonuses were based upon targets established by our compensation committee.

Mr. Kenley was appointed our President on October 27, 2010. Pursuant to a written offer of employment executed by us and Mr. Kenley, he received an annual salary initially set at $240,000 and medical insurance benefits. In June 2014, his salary was increased from $240,000 to $260,000 per year. In September 2015, Mr. Kenley received a $15,000 salary increase from $260,000 to $275,000.

During the fiscal year ended March 31, 2016, Mr. Kenley received a retention bonus (see below) and during the fiscal year ended March 31, 2015, Mr. Kenley earned bonuses totaling $15,000 from us. All of those bonuses were based upon targets established by our compensation committee.

Retention Agreements

On October 16, 2015, following a recommendation of our Compensation Committee, we approved retention bonus grants to three of our executive officers under a newly established Aethlon Senior Management Retention Program to maintain management stability going forward. The Board approved a $100,000 retention bonus for Mr. James A. Joyce, our Chief Executive Officer, a $50,000 retention bonus for Mr. Rodney S. Kenley, our President, and a $50,000 retention bonus for Mr. James B. Frakes, our Chief Financial Officer.

In connection with the bonus granted to Mr. Joyce, we entered into an amendment of Mr. Joyce’s Employment Agreement dated April 1, 1999. Pursuant to the amendment, if within two years of the effective date of the amendment, we terminate Mr. Joyce’s employment with us for “Cause” (as defined in his employment agreement) or Mr. Joyce terminates his employment with us other than for “Good Reason” (as defined in his employment agreement), Mr. Joyce must repay in full the amount of the bonus received from us. In the event of his death or disability or termination by us other than for “Cause” or termination by Mr. Joyce for “Good Reason,” Mr. Joyce will not be required to repay any portion of the bonus received by him.

In connection with the bonus granted to Mr. Kenley, we entered into an amendment of Mr. Kenley's Offer Letter dated October 27, 2010. Pursuant to the amendment, if within two years of the effective date of the amendment, we terminate Mr. Kenley's employment with us for "Cause" (as defined in the amendment) or Mr. Kenley terminates his employment with us other than for "Good Reason" (as defined in the amendment), Mr. Kenley must repay in full the amount of the bonus received from us. In the event of his death or disability or termination by us other than for "Cause" or termination by Mr. Kenley for "Good Reason," Mr. Kenley will not be required to repay any portion of the bonus received by him.

In connection with the bonus granted to Mr. Frakes, we entered into a Retention Bonus Agreement with Mr. Frakes. Pursuant to the agreement, if within two years of the effective date of the agreement, we terminate Mr. Frakes' employment with us for "Cause" (as defined in the agreement) or Mr. Frakes terminates his employment with us other than for "Good Reason" (as defined in the agreement), Mr. Frakes must repay in full the amount of the bonus received from us. In the event of his death or disability or termination by us other than for "Cause" or termination by Mr. Frakes for "Good Reason," Mr. Frakes will not be required to repay any portion of the bonus received by him.

Outstanding Equity Awards at 2016 Fiscal Year-End

The following table sets forth certain information concerning stock option awards granted to our named executive officers.

OUTSTANDING EQUITY AWARDS AT 2016 FISCAL YEAR END

OPTIONS AWARDS

NAME	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS EXERCISABLE (#)	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS UNEXERCISABLE (#)	EQUITY INCENTIVE PLAN AWARDS NUMBER OF SECURITIES UNDERLYING UNEXERCISED UNEARNED OPTIONS UNEXERCISABLE (#)	OPTION EXERCISE PRICE ($)	DATE OF OPTION EXPIRATION
James A. Joyce	50,000(1)	–	–	$18.00	09/21/17
	40,000(2)	–	–	$12.50	02/21/19
	50,000(3)	–	–	$12.50	09/27/20
	20,000(4)	20,000	–	$5.00	07/01/23
	20,000(7)	10,000		$9.50	06/06/24
Richard H. Tullis	15,000(5)	–	–	$20.50	06/14/18
	20,000(6)	–	–	$12.50	09/27/20
	5,000(4)	5,000	–	$5.00	07/01/23
	666(7)	334		$9.50	06/06/24
James B. Frakes	10,000(6)	–	–	$12.50	09/27/20
	5,000(4)	5,000	–	$5.00	07/01/23
	3,334(7)	1,666		$9.50	06/06/24
Rodney S. Kenley	20,000(6)	–	–	$12.50	10/27/20
	5,000(4)	5,000	–	$5.00	7/01/23
	3,334(7)	1,666		$9.50	06/06/24

Note: We have omitted the stock awards columns of the above table because we have no disclosure applicable to those columns.

(1) The option vested 20,000 shares at grant, with 10,000 shares vesting each annual anniversary date through June 13, 2010 and as a result of an Option Suspension Agreement with us, the expiration date was extended by 100 days.

(2) The option vested 20,000 at grant, with 10,000 shares vesting on December 31, 2009 and December 31, 2010 and as a result of an Option Suspension Agreement with us, the expiration date was extended by 100 days.

(3) The option was fully vested as of September 27, 2013.

(4) This option vests ratably on July 1, 2014, July 1, 2015 and July 1, 2016.

(5) This option was fully vested as of December 15, 2011.

(6) This option was fully vested as of October 27, 2014.

(7) This option vests ratably on June 6, 2014, June 6, 2015 and June 6, 2016.

Director Compensation for 2016 Fiscal Year

The following director compensation disclosure reflects all compensation awarded to, earned by or paid to the directors below for the fiscal year ended March 31, 2016.

	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
James A. Joyce (1)	$–	–	–	–	–	–	$–
Richard H. Tullis (2)	$–	–	–	–	–	–	$–
Rodney S. Kenley (3)	$–	–	–	–	–	–	$–
Edward G. Broenniman (4)	$38,000	–	–	–	–	–	$38,000
Franklyn S. Barry, Jr. (5)	$39,000	–	–	–	–	–	$39,000
Chetan S. Shah, MD (6)	$39,000	–	–	–	–	–	$39,000

(1) All compensation received by Mr. Joyce in fiscal year 2016 is disclosed in the Summary Compensation Table above. Mr. Joyce received no compensation as a director in fiscal year 2016.

(2) All compensation received by Dr. Tullis in fiscal year 2016 is disclosed in the Summary Compensation Table above. Dr. Tullis received no compensation as a director in fiscal year 2016. Dr. Tullis resigned from the Board of Directors effective June 5, 2015.

(3) All compensation received by Mr. Kenley in fiscal year 2016 is disclosed in the Summary Compensation Table above. Mr. Kenley received no compensation as a director in fiscal year 2016.

(4) The aggregate number of stock awards and options awards issued and outstanding as of March 31, 2016 are 0 and 43,431. Mr. Broenniman received stock option grants of 3,684 shares on June 6, 2014, 8,537 shares on March 14, 2014, and 9,211 shares on July 24, 2012 for his service as an outside director. The June 2014 option vested 3,684

shares on March 31, 2015, the March 2014 option vested all 8,537 shares at grant and the 2012 option vested 3,961 at grant, with 5,250 vesting in the June 2013 quarter. On October 21, 2014 and November 7, 2014, we paid Mr. Broenniman an aggregate of $10,063 for accrued Board of Directors fees and expenses reimbursable to him. In January 2015, we paid $84,500 to Mr. Broenniman in payment of accrued Board of Directors fees and amounts accrued for services rendered to us by him prior to the 1999 reorganization among Aethlon, Inc., Hemex, Inc. and us. In January 2016 we paid $39,000 to Mr. Broenniman in payment of accrued Board of Directors fees for the fiscal year ended March 31, 2015 and in April 2016 we paid $38,000 to Mr. Broenniman in payment of accrued Board of Directors fees for the fiscal year ended March 31, 2016.

(5) The aggregate number of stock awards and options awards issued and outstanding as of March 31, 2016 are 0 and 41,431. Mr. Barry received stock option grants of 3,684 shares on June 6, 2014, 8,537 shares on March 14, 2014 and 9,211 shares on July 24, 2012 for his service as an outside director. The June 2014 option vested 3,684 shares on March 31, 2015, the March 2014 option vested all 8,537 shares at grant and the 2012 option vested 3,961 at grant, with 5,250 vesting in the June 2013 quarter. On October 21, 2014 and November 7, 2014, we paid Mr. Barry an aggregate of $10,944 for accrued Board of Directors fees and expenses reimbursable to him. In January 2015, we paid $271,810 to Mr. Barry in payment of accrued director fees and amounts accrued for services rendered to us by him prior to the 1999 reorganization among Aethlon, Inc., Hemex, Inc. and us. In October 2015 we paid $39,000 to Mr. Barry in payment of accrued Board of Directors fees for the fiscal year ended March 31, 2015 and in April 2016 we paid $39,000 to Mr. Barry in payment of accrued Board of Directors fees for the fiscal year ended March 31, 2016.

(6) The aggregate number of stock awards and options awards issued and outstanding as of March 31, 2016 are 0 and 11,205. Dr. Shah received stock option grants of 3,684 on June 6, 2014 and 7,520 shares on July 24, 2012 for his service as an outside director. The June 2014 option vested 3,684 shares on March 31, 2015, and the 2014 option vested all 7,520 shares at grant. In January 2015, we paid $14,500 to Dr. Shah in payment of accrued director fees. In October 2015 we paid $39,000 to Dr. Shah in payment of accrued Board of Directors fees for the fiscal year ended March 31, 2015 and in April 2016 we paid $39,000 to Dr. Shah in payment of accrued Board of Directors fees for the fiscal year ended March 31, 2016.

Directors Compensation Program

We maintain a board compensation program, in which only non-employee directors may participate. Please see the “Equity Compensation Plans – 2012 Directors Compensation Program” section of this Report for more information on the program.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth information as of June 28, 2016, with respect to the ownership of our common stock, by (i) each person known by us to be the beneficial owner of more than five percent (5%) of the outstanding shares of each class of our capital stock, (ii) each of our directors and director nominees (if any), (iii) each of our named executive officers and (iv) all of our executive officers and directors as a group. The term "executive officer" is defined as the President/Chief Executive Officer, Secretary, Chief Financial Officer/Treasurer, any vice-president in charge of a principal business function (such as administration or finance), or any other person who performs similar policy making functions for us. We believe that each individual or entity named has sole investment and voting power with respect to shares of common stock indicated as beneficially owned by them, subject to community property laws where applicable, excepted where otherwise noted:

TITLE OF CLASS	NAME AND ADDRESS	AMOUNT AND NATURE OF BENEFICIAL OWNERSHIP (1)(2)	PERCENT OF BENEFICIAL OWNERSHIP
Common Stock	James A. Joyce, Chief Executive Officer and Director 9635 Granite Ridge Drive, Suite 100 San Diego, CA 92123	256,000 shares (3)	3.3%
Common Stock	Rodney S. Kenley, President and Director 9635 Granite Ridge Drive, Suite 100 San Diego, CA 92123	28,734 shares (4)	*
Common Stock	James B. Frakes, Chief Financial Officer 9635 Granite Ridge Drive, Suite 100 San Diego, CA 92123	18,534 shares (5)	*
Common Stock	Franklyn S. Barry, Jr., Director 9635 Granite Ridge Drive, Suite 100 San Diego, CA 92123	43,553 shares (6)	*
Common Stock	Edward G. Broenniman, Director 9635 Granite Ridge Drive, Suite 100 San Diego, CA 92123	49,075 shares (7)	*
Common Stock	Chetan Shah, MD, Director (11) 9635 Granite Ridge Drive, Suite 100 San Diego, CA 92123	387,828 shares (8)	5.0%
Common Stock	Ellen R Weiner Family Revocable Trust (11) 10300 W. Charleston Blvd. #13-222 Las Vegas, NV 89135	708,335 shares (9)	9.0%
Common Stock	Alpha Capital Anstalt	388,841 shares (10)	4.99%

	Lettstrasse 32, FL-9490 Vaduz, Furstentums, Liechtenstein		
Common Stock	Sachs Investment Group, LLC (11) 1346 S. Third St., Louisville, KY 40208	791,205 shares	10.4%
Common Stock	All Current Directors and Executive Officers as a Group (7 members)	783,724 shares	9.7%

* Less than 1%

(1) Based on 7,622,393 shares of common stock outstanding on our transfer records as of June 28, 2016.

(2) Calculated pursuant to Rule 13d-3(d)(1) of the Securities Exchange Act of 1934. Under Rule 13d-3(d)(1), shares not outstanding that are subject to options, warrants, rights or conversion privileges exercisable by a person within 60 days are deemed outstanding for the purpose of calculating the number and percentage owned by such person but not deemed outstanding for the purpose of calculating the percentage owned by each other person listed. Except where otherwise noted, we believe that each individual or entity named has sole investment and voting power with respect to the shares of common stock indicated as beneficially owned by such person, subject to community property laws, where applicable.

(3) Includes 50,000 stock options exercisable at $18.00 per share, 90,000 stock options exercisable at $12.50 per share, 20,000 stock options exercisable at $5.00 per share and 20,000 stock options exercisable at $9.50 per share.

(4) Includes 20,000 stock options exercisable at $12.50 per share, 5,000 stock options exercisable at $5.00 per share and 3,334 stock options exercisable at $9.50 per share.

(5) Includes 10,000 stock options exercisable at $12.50 per share, 5,000 stock options exercisable at $5.00 per share and 3,334 stock options exercisable at $9.50 per share.

(6) Includes 10,000 stock options exercisable at $20.50 per share, 10,000 stock options exercisable at $12.50 per share, 9,211 stock options exercisable at $3.80 per share, 8,537 stock options exercisable at $4.10 per share and 3,684 stock options exercisable at $9.50 per share.

(7) Includes 10,000 stock options exercisable at $20.50 per share, 12,000 stock options exercisable at $12.50 per share, 9,211 stock options exercisable at $3.80 per share, 8,537 stock options exercisable at $4.10 per share and 3,684 stock options exercisable at $9.50 per share.

(8) Includes warrants to purchase 109,322 shares of common stock at exercise prices ranging from $4.65 per share to $6.60 per share, and 11,205 stock options exercisable at $9.50 per share.

(9) Includes common stock issuable upon exercise of warrants held by the Ellen R. Weiner Family Revocable Trust. The trust owns 235,934 warrants to purchase common shares at prices ranging from $2.10 to $5.40 per share.

(10) Includes certain shares issuable upon the conversion of convertible notes and exercise of warrants held by Alpha Capital Anstalt (“Alpha”). Alpha owns a convertible note in the principal amount of $543,602.78 convertible into 108,721 shares of common stock at $5.00 and warrants to purchase 357,307 shares of common stock at an exercise price of $5.00 per share. Alpha’s beneficial ownership is limited contractually to the extent that exercise of such notes and warrants would cause the aggregate number of shares of common stock beneficially owned by Alpha to exceed 4.99% of our outstanding shares. Accordingly, beneficial ownership for Alpha does not reflect 296,000 shares underlying such notes and warrants that would cause the number of shares beneficially owned by Alpha to be 8.47% of our outstanding shares.

(11) More-than-5% stockholder.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The following describes all transactions since April 1, 2014, and all proposed transactions, in which we were or are to be a participant and the amount involved exceeds the lesser of $120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years, and in which any related person had or will have a direct or indirect material interest.

In July 2013, we borrowed $400,000 from Mr. Phillip Ward, one of our former directors, and Dr. Shah under 90-day notes bearing 10% interest. If we did not pay back those loans by October 9, 2013, then the notes would bear interest at a penalty rate of 12% and the noteholders would have the right at their discretion (i) to convert their principal and accrued interest into shares of common stock at $4.40 per share and (ii) to receive warrants to purchase common stock equal to 50% of the principal converted under the notes, with an exercise price of $6.60 per share. We subsequently repaid Mr. Ward’s note in cash. That repayment extinguished all potential common stock and warrant issuance provisions of Mr. Ward’s note. On July 24, 2014, we issued to Dr. Shah an aggregate of 50,079 shares of unregistered common stock and a seven-year warrant to purchase up to 25,040 shares of common stock at an exercise price of $6.60 per share upon the conversion of an aggregate of $220,349 of unpaid principal and accrued interest due under his note. The amount converted represented the entire amount outstanding under Dr. Shah’s note.

On June 6, 2014, our Board of Directors granted to our directors and our Chief Financial Officer ten-year options to acquire an aggregate of 52,053 shares of our common stock at an exercise price of $9.50 per share.

In July 2014, Exosome Sciences, Inc. paid a bonus of $15,000 to Mr. Joyce.

In October 2014, Exosome Sciences, Inc. paid bonuses of $15,000 to Mr. Joyce and $1,500 to Mr. Frakes.

On October 20, 2014, we issued to Dr. Shah 42,222 shares of common stock and three-year warrants to acquire up to 42,222 shares of common stock with exercise prices ranging from $4.65 to $5.50 per share. The common stock and warrants were issued to Dr. Shah upon his cash exercise, for an aggregate of $214,000, of previously issued warrants for 42,222 shares held by him.

On October 21, 2014 and November 7, 2014, we paid Mr. Franklyn Barry and Mr. Edward Broenniman, two of our outside directors, an aggregate of $10,944 and $10,063, respectively, for accrued Board of Directors fees and expenses

reimbursable to them. On November 7, 2014, we paid Dr. Tullis $5,000 for accrued expenses reimbursable to him.

In December 2014, we paid bonuses of $25,000 to Mr. Joyce, $15,000 to Mr. Kenley, $15,000 to Mr. Frakes and $5,000 to Dr. Tullis.

In December 2014, Exosome Sciences, Inc. paid Mr. Joyce a bonus of $15,000.

In January 2015, we made the following payments to certain of our officers and directors:

- bonuses of $25,000 to Mr. Joyce and $15,000 to Mr. Frakes;
- $93,377 to Dr. Tullis in payment of accrued salary;
- $14,500 to Dr. Shah in payment of accrued director fees;
- $84,500 to Mr. Broenniman in payment of accrued director fees and amounts accrued for services rendered to us prior to the 1999 reorganization among Aethlon, Inc., Hemex, Inc. and us; and
- $271,810 to Mr. Barry in payment of accrued director fees and amounts accrued for services rendered to us prior to the 1999 reorganization among Aethlon, Inc., Hemex, Inc. and us.

In June 2015, Mr. James Joyce, our Chief Executive Officer, Mr. James Frakes, our Chief Financial Officer and Dr. Chetan Shah, a director of our company, agreed to waive their rights to acquire an aggregate of 402,318 shares of common stock underlying certain stock options and warrants held by them. Those waivers were required in order to make a sufficient number of shares of common stock available for issuance upon the exercise of the warrants issued in our June 2015 financing. Those waivers expired when we amended our Articles of Incorporation on March 31, 2016, to increase sufficiently the number of authorized shares of common stock available for issuance following approval of that measure at our annual stockholders' meeting on March 29, 2016.

In September 2015, the Compensation Committee approved and we paid bonuses of $100,000 and $75,000 to Mr. Joyce and Mr. Frakes, respectively, for achieving an agreed milestone event of achieving a Nasdaq listing.

Retention Agreements

On October 16, 2015, following a recommendation of our Compensation Committee, we approved retention bonus grants to three of our executive officers under a newly established Aethlon Senior Management Retention Program to maintain management stability going forward. The Board approved a $100,000 retention bonus for Mr. James A. Joyce, our Chief Executive Officer, a $50,000 retention bonus for Mr. Rodney S. Kenley, our President, and a $50,000 retention bonus for Mr. James B. Frakes, our Chief Financial Officer.

In connection with the bonus granted to Mr. Joyce, we entered into an amendment of Mr. Joyce's Employment Agreement dated April 1, 1999. Pursuant to the amendment, if within two years of the effective date of the amendment, we terminate Mr. Joyce's employment with us for "Cause" (as defined in his employment agreement) or Mr. Joyce terminates his employment with us other than for "Good Reason" (as defined in his employment agreement), Mr. Joyce must repay in full the amount of the bonus received from us. In the event of his death or disability or termination by us other than for "Cause" or termination by Mr. Joyce for "Good Reason," Mr. Joyce will not be required to repay any portion of the bonus received by him.

In connection with the bonus granted to Mr. Kenley, we entered into an amendment of Mr. Kenley's Offer Letter dated October 27, 2010. Pursuant to the amendment, if within two years of the effective date of the amendment, we terminate Mr. Kenley's employment with us for "Cause" (as defined in the amendment) or Mr. Kenley terminates his employment with us other than for "Good Reason" (as defined in the amendment), Mr. Kenley must repay in full the amount of the bonus received from us. In the event of his death or disability or termination by us other than for "Cause" or termination by Mr. Kenley for "Good Reason," Mr. Kenley will not be required to repay any portion of the bonus received by him.

In connection with the bonus granted to Mr. Frakes, we entered into a Retention Bonus Agreement with Mr. Frakes. Pursuant to the agreement, if within two years of the effective date of the agreement, we terminate Mr. Frakes' employment with us for "Cause" (as defined in the agreement) or Mr. Frakes terminates his employment with us other than for "Good Reason" (as defined in the agreement), Mr. Frakes must repay in full the amount of the bonus received from us. In the event of his death or disability or termination by us other than for "Cause" or termination by Mr. Frakes for "Good Reason," Mr. Frakes will not be required to repay any portion of the bonus received by him.

Mr. Joyce received quarterly bonus payments of $15,000 from Exosome throughout the fiscal year ended March 31, 2016 per targets set by the Compensation Committee.

In October 2015, we paid accrued Board fees from the fiscal year ended March 31, 2015 of $39,000 each to Mr. Barry and Dr. Shah and paid Mr. Broenniman his accrued fiscal 2015 Board fees in January 2016.

In April 2016, we paid accrued Board fees from the fiscal year ended March 31, 2016 to Mr. Barry, Mr. Broenniman and Dr. Shah.

Director Independence

Each of Mr. Barry, Mr. Broenniman and Dr. Shah is an independent director as that term is defined by NASDAQ Stock Market Rule 5605(a)(2). We currently have a compensation committee, a nominating and corporate governance committee and an audit committee. Of the members of our Board of Directors, each of Mr. Barry, Mr. Broenniman and Dr. Shah meets the NASDAQ Stock Market's independence standards for members of such committees.

55

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table presents fees for professional services billed by Squar Milner LLP ("Squar Milner") for the fiscal years ended March 31, 2016 and 2015:

	Fiscal Year 2016	Fiscal Year 2015
Audit Fees (1)	$97,000	$97,000
Audit Related Fees (2)	21,000	72,840
Tax Fees (3)	6,325	3,380
All Other Fees (4)	–	–
	$124,325	$173,220

(1) Audit Fees include fees and expenses for professional services rendered in connection with the audit of our financial statements for fiscal 2016 and 2015 and for reviews of the financial statements included in each of our quarterly reports on Form 10-Q during fiscal 2016 and 2015.

(2) Audit Related Fees consist of fees billed for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements and are not reported under “Audit Fees.” Included in Audit Related Fees for fiscal 2016 and 2015 are fees and expenses related to reviews of registration statements and SEC filings other than Forms 10-K and 10-Q.

(3) Tax Fees include the aggregate fees billed during fiscal year 2016 and 2015 for professional services for preparation of income tax returns.

(4) All Other Fees consist of fees paid for products and services other than the services reported above. No such fees were billed by Squar Milner for fiscal 2016 or 2015.

Policy on Audit Committee Pre-approval of Audit and Permissible Non-audit Services of Independent Auditor

Our audit committee of the Board of Directors is responsible for pre-approving all audit, audit-related, tax and other permitted non-audit services to be performed for us by our independent auditor. The audit committee approved all of the services for which Squar Milner billed us as set forth in the above table.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENTS

The following documents are filed as part of this report on Form 10-K:

1. Consolidated Financial Statements for the years ended March 31, 2016 and 2015:

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets

Consolidated Statements of Operations

Consolidated Statements of Stockholders' Deficit

Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

2. Exhibits

2.1	Agreement and Plan of Reorganization Between Aethlon Medical, Inc. (formerly, Bishop Equities, Inc.) and Aethlon, Inc. dated March 10, 1999 (1)
2.2	Agreement and Plan of Reorganization Between Aethlon Medical, Inc. (formerly, Bishop Equities, Inc.) and Hemex, Inc. dated March 10, 1999 (1)
3.1	Articles of Incorporation of Aethlon Medical, Inc., as amended (2)
3.2	Bylaws of Aethlon Medical, Inc., as amended (35)
4.1	Form of Common Stock Certificate (3)
4.2	Form of Amended and Restated Warrant dated June 14, 2010 (12)

4.3 Form of Amended and Restated Warrant dated June 14, 2010 (QB) (12)

4.4 Form of Common Stock Purchase Warrant dated March 29, 2012 and April 15, 2012 (14)

4.5 Form of Common Stock Purchase Warrant dated June 19, 2012 (15)

4.6 Form of Common Stock Purchase Warrant dated August 29, 2012 (16)

4.7 Form of Common Stock Purchase Warrant dated October, November and December 2012 (17)

4.8 Form of Common Stock Purchase Warrant dated June 14, 2013 (18)

4.9 Form of Common Stock Purchase Warrant October 30, 2013 (19)

4.10 Form of Common Stock Purchase Warrant November 12, 2013 (20)

4.11 Form of Common Stock Purchase Warrant December 10, 2013 (21)

4.12 Form of Common Stock Purchase Warrant December 30, 2013 (22)

4.13 Form of Amendment to Notes and Warrants dated March 31, 2014 (23)

4.14 Form of Common Stock Purchase Warrant dated June 24, 2014 (24)

4.15 Form of Common Stock Purchase Warrant dated July 8, 2014 (25)

4.16 Form of Common Stock Purchase Warrant dated July 24, 2014 (26)

4.17 Form of Common Stock Purchase Warrant issued August and September 2014 (27)

4.18 Form of Class A Common Stock Purchase Warrant dated November 6, 2014 (27)

4.19 Form of Convertible Promissory Note dated November 6, 2014 (27)

4.20 Form of Common Stock Purchase Warrant issued December 2, 2014 (29)

4.21 Form of Purchase Agent Warrant dated December 2, 2014 (30)

4.22 Form of Warrant to Purchase Common Stock issued June 25, 2015 (32)

4.23 Form of Purchase Agent Warrant issued June 25, 2015 (33)

4.24 Form of Amendment to Notes and Warrants dated June 27, 2016 (40)

4.25 Form of Allonge to Convertible Promissory Note dated June 27, 2016 (40)

4.26 Form of Class A Common Stock Purchase Warrant issued June 27, 2016 (40)

4.27 Form of Consent and Waiver and Amendment dated June 27, 2016 (40)

10.1 2000 Stock Option Plan (34)++

10.2 Amended 2010 Stock Incentive Plan (4)

10.3 2005 Directors Compensation Program (34)++

10.4 2012 Directors Compensation Program, as amended on June 6, 2014 (34)++

10.5 Employment Agreement between Aethlon Medical, Inc. and James A. Joyce dated April 1, 1999 (5)++

10.6 Patent License Agreement by and amongst Aethlon Medical, Inc., Hemex, Inc., Dr. Julian L. Ambrus and Dr. David O. Scamurra (6)

10.7 Employment Agreement by and between Aethlon Medical, Inc. and Dr. Richard H. Tullis dated January 10, 2000 (6)++

10.8

	Stock Option Agreement by and between Aethlon Medical, Inc. and James A Joyce dated February 23, 2005 (7)++
10.9	Stock Option Agreement by and between Aethlon Medical, Inc. and Richard Tullis dated February 23, 2005 (7)++
10.10	Stock Option Agreement by and between Aethlon Medical, Inc. and Franklyn S. Barry, Jr. dated February 23, 2005 (7)++
10.11	Stock Option Agreement by and between Aethlon Medical, Inc. and Ed Broenniman dated February 23, 2005 (7)++
10.12	Stock Option Agreement by and between Aethlon Medical, Inc. and James A. Joyce dated September 9, 2005 (8)++
10.13	Stock Option Agreement by and between Aethlon Medical, Inc. and James A. Joyce dated June 13, 2007 (9)++
10.14	Stock Option Agreement by and between Aethlon Medical, Inc. and James A. Joyce dated December 15, 2008 (10)++
10.15	Stock Option Agreement by and between Aethlon Medical, Inc. and Franklyn S. Barry dated December 15, 2008 (10)++
10.16	Stock Option Agreement by and between Aethlon Medical, Inc. and Edward G. Broenniman dated December 15, 2008 (10)++
10.17	Stock Option Agreement by and between Aethlon Medical, Inc. and Richard H. Tullis dated December 15, 2008 (10)++

10.18	Standard Industrial Net Lease by and between Sorrento Business Complex and Aethlon Medical, Inc. dated September 28, 2009 (11)
10.19	Offer of Employment by and between Aethlon Medical, Inc. and Rodney S. Kenley dated October 27, 2010 (13)++
10.20	Stock Option Agreement of Rodney S. Kenley dated October 27, 2010 (13)++
10.21	Unit Subscription Agreement dated March 29, 2012 and April 5, 2012 (14)
10.22	Unit Subscription Agreement dated June 19, 2012 (15)
10.23	Unit Subscription Agreement dated August 29, 2012 (16)
10.24	Unit Subscription Agreement dated October, November and December 2012 (17)
10.25	Unit Subscription Agreement dated June 14, 2013 (18)
10.26	Form of Unit Purchase Agreement dated October 30, 2013 (19)
10.27	Form of Subscription Agreement October 30, 2013 (19)
10.28	Form of Unit Purchase Agreement dated November 12, 2013 (20)
10.29	Form of Subscription Agreement November 12, 2013 (20)
10.30	Form of Unit Purchase Agreement dated December 10, 2013 (21)
10.31	Form of Subscription Agreement December 10, 2013 (21)
10.32	Form of Unit Purchase Agreement dated December 30, 2013 (22)
10.33	Form of Subscription Agreement December 30, 2013 (22)
10.34	Form of Restructuring Agreement dated June 24, 2014 (24)
10.35	Form of Restructuring Agreement dated June 24, 2014 (24)
10.36	Form of Restructuring Agreement dated July 8, 2014 (25)
10.37	Second Amendment to Standard Industrial Net Lease by and between Sorrento Business Complex and Aethlon Medical, Inc. dated October 10, 2014 (3)
10.38	Form of Subscription Agreement dated November 6, 2014 (27)
10.39	Office Lease between T-C Stonecrest LLC and Aethlon Medical, Inc. dated November 13, 2014 (28)

10.40 Securities Purchase Agreement dated November 26, 2014 (29)

10.41 Registration Rights Agreement dated November 26, 2014 (29)

10.42 DARPA Contract dated September 30, 2011 (3) (Portions of this exhibit have been omitted pursuant to a request for confidential treatment.)

10.43 DARPA Contract Extension dated August 8, 2012 (3)

10.44 DARPA Contract Extension dated September 15, 2013 (3)

10.45 DARPA Contract Extension dated September 29, 2014 (3)

10.46 DARPA Contract Modification dated March 12, 2015 (34) (Portions of this exhibit have been omitted pursuant to a request for confidential treatment.)

10.47 UCI Clinical Trial Agreement signed April 9, 2015 (31)

10.48 Protocol for UCI Clinical Trial (31)

10.49 Budget for UCI Clinical Trial (31)

10.50 DaVita Master Services Agreement (35)

10.51 First Amendment to DaVita Master Services Agreement (35)

10.52 Work Order #1 under DaVita Master Services Agreement (35) (Portions of this exhibit have been omitted pursuant to a request for confidential treatment.)

10.53 Securities Purchase Agreement dated June 23, 2015 (32)

10.54 Registration Rights Agreement dated June 23, 2015 (32)

10.55 DARPA Contract Extension dated September 25, 2015 (36)

10.56 Amendment No. 1 to Joyce Employment Agreement dated October 16, 2015 (37)++

10.57 Amendment No. 1 to Kenley Offer Letter dated October 16, 2015 (37)++

10.58 Retention Bonus Agreement dated October 16, 2015 (37)++

10.59 Third Amendment to Standard Industrial Net Lease dated October 21, 2015 (38)

10.60 Amendment of Terms dated November 12, 2015 (38)

10.61 Consulting Agreement dated February 9, 2016 (39)

10.62 Stock Option Agreement by and between Aethlon Medical, Inc. and Richard Tullis dated September 27, 2010 *++

10.63 Stock Option Agreement by and between Aethlon Medical, Inc. and Richard Tullis dated July 1, 2013 *++

10.64 Stock Option Agreement by and between Aethlon Medical, Inc. and Richard Tullis dated June 6, 2014 *++

10.65 Amendment No. 1 to Stock Option Agreement by and between Aethlon Medical, Inc. and Richard Tullis dated December 15, 2008 *++

10.66 Amendment No. 1 to Stock Option Agreement by and between Aethlon Medical, Inc. and Richard Tullis dated September 27, 2010 *++

10.67 Amendment No. 1 to Stock Option Agreement by and between Aethlon Medical, Inc. and Richard Tullis dated July 1, 2013 *++

10.68	Amendment No. 1 to Stock Option Agreement by and between Aethlon Medical, Inc. and Richard Tullis dated June 6, 2014 *++
10.69	Common Stock Sales Agreement dated June 28, 2016 between Aethlon Medical, Inc. and H.C. Wainwright & Co., LLC (40)
10.70	Form of Consent and Waiver dated June 27, 2016 (40)
14	Code of Ethics (29)
21.1	List of subsidiaries (3)
23.1	Consent of Independent Registered Public Accounting Firm (Squar, Milner, Peterson, Miranda & Williamson, LLP) *
31.1	Certification of our Chief Executive Officer, pursuant to Securities Exchange Act rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes Oxley Act of 2002.*

31.2	Certification of our Chief Financial Officer, pursuant to Securities Exchange Act rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes Oxley Act of 2002.*
32.1	Statement of our Chief Executive Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350)*
32.3	Statement of our Chief Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350)*

101.INS	XBRL Instance Document*
101.SCH	XBRL Schema Document*
101.CAL	XBRL Calculation Linkbase Document*
101.DEF	XBRL Definition Linkbase Document*
101.LAB	XBRL Label Linkbase Document*
101.PRE	XBRL Presentation Linkbase Document*

* Filed herewith

++ Indicates a management contract or compensatory plan or arrangement

(1) Filed with the Company's Current Report on Form 8-K/A dated March 26, 1999 and incorporated by reference.

(2) Filed with the Company's Registration Statement on Form S-3 (File No. 333-211151) filed on May 5, 2016 and incorporated by reference.

(3) Filed with the Company’s Registration Statement on Form S-1 (File No. 333-201334) filed on December 31, 2014 and incorporated by reference.

(4) Filed with the Company’s Current Report on Form 8-K dated March 30, 2016 and incorporated by reference.

(5) Filed with the Company's Annual Report on Form 10-KSB filed on July 15, 1999 for the year ended March 31, 1999 and incorporated by reference.

(6) Filed with the Company's Annual Report on Form 10-KSB/A filed on September 10, 2004 for the year ended March 31, 2004 and incorporated by reference.

(7) Filed with the Company's Annual Report on Form 10-KSB filed on July 14, 2005 for the year ended March 31, 2005 and incorporated by reference.

(8) Filed with the Company's Current Report on Form 8-K filed on September 12, 2005 and incorporated by reference.

(9) Filed with the Company's Registration Statement on Form S-8 (File No. 333-168483) filed on August 2, 2010 and incorporated by reference.

(10) Filed with the Company's Current Report on Form 8-K dated December 19, 2008 and incorporated by reference.

(11) Filed with the Company's Quarterly Report on Form 10-Q filed on November 16, 2009 for the period ended September 30, 2009 and incorporated by reference.

(12) Filed with the Company's Annual Report on Form 10-K filed on July 2, 2010 for the year ended March 31, 2010 and incorporated by reference.

(13) Filed with the Company's Current Report on Form 8-K dated November 1, 2010 and incorporated by reference.

(14) Filed with the Company's Current Report on Form 8-K dated April 6, 2012 and incorporated by reference.

(15) Filed with the Company's Current Report on Form 8-K dated June 27, 2012 and incorporated by reference.

(16) Filed with the Company's Current Report on Form 8-K dated September 6, 2012 and incorporated by reference.

(17) Filed with the Company's Quarterly Report on Form 10-Q filed on February 12, 2013 for the period ended December 31, 2012 and incorporated by reference.

61

(18) Filed with the Company's Quarterly Report on Form 10-Q filed on August 13, 2013 for the period ended June 30, 2013 and incorporated by reference.

(19) Filed with the Company's Current Report on Form 8-K dated November 6, 2013 and incorporated by reference.

(20) Filed with the Company's Current Report on Form 8-K dated November 20, 2013 and incorporated by reference.

(21) Filed with the Company's Current Report on Form 8-K dated December 16, 2013 and incorporated by reference.

(22) Filed with the Company's Current Report on Form 8-K dated January 7, 2014 and incorporated by reference.

(23) Filed with the Company's Current Report on Form 8-K dated April 4, 2014 and incorporated by reference.

(24) Filed with the Company's Current Report on Form 8-K dated June 30, 2014 and incorporated by reference.

(25) Filed with the Company's Current Report on Form 8-K dated July 10, 2014 and incorporated by reference.

(26) Filed with the Company's Current Report on Form 8-K dated July 28, 2014 and incorporated by reference.

(27) Filed with the Company's Quarterly Report on Form 10-Q filed on November 10, 2014 for the period ended September 30, 2014 and incorporated by reference.

(28) Filed with the Company's Current Report on Form 8-K/A dated November 19, 2014 and incorporated by reference.

(29) Filed with the Company’s Current Report on Form 8-K dated November 28, 2014 and incorporated by reference.

(30) Filed with the Company’s Current Report on Form 8-K dated December 3, 2014 and incorporated by reference.

(31) Filed with the Company’s Current Report on Form 8-K dated April 15, 2015 and incorporated by reference.

(32) Filed with the Company’s Current Report on Form 8-K dated June 24, 2015 and incorporated by reference.

(33) Filed with the Company’s Current Report on Form 8-K dated June 26, 2015 and incorporated by reference.

(34) Filed with the Company's Registration Statement on Form S-1 (File No. 333-203487) filed on April 17, 2015 and incorporated by reference.

(35) Filed with the Company’s Annual Report on Form 10-K filed on June 26, 2015 for the year ended March 31, 2015 and incorporated by reference.

(36) Filed with the Company’s Current Report on Form 8-K dated September 28, 2015 and incorporated by reference.

(37) Filed with the Company’s Current Report on Form 8-K dated October 22, 2015 and incorporated by reference.

(38) Filed with the Company’s Quarterly Report on Form 10-Q filed on November 16, 2015 for the period ended September 30, 2015 and incorporated by reference.

(39) Filed with the Company’s Current Report on Form 8-K dated February 16, 2016 and incorporated by reference.

(40) Filed with the Company’s Current Report on Form 8-K dated June 28, 2016 and incorporated by reference.

62

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on the 29th day of June, 2016.

By: /s/ JAMES A. JOYCE
James A. Joyce
Chairman, Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ JAMES A. JOYCE James A. Joyce	Chairman of the Board, Chief Executive Officer and Principal Executive Officer	June 29, 2016
/s/ JAMES B. FRAKES James B. Frakes	Chief Financial Officer and Principal Accounting Officer	June 29, 2016
/s/ FRANKLYN S. BARRY, JR. Franklyn S. Barry, Jr.	Director	June 29, 2016
/s/ EDWARD G. BROENNIMAN Edward G. Broenniman	Director	June 29, 2016
/s/ RODNEY S. KENLEY Rodney S. Kenley	Director	June 29, 2016
/s/ CHETAN S. SHAH Chetan S. Shah	Director	June 29, 2016

63

AETHLON MEDICAL, INC. AND SUBSIDIARY

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

Aethlon Medical, Inc. and Subsidiary

We have audited the accompanying consolidated balance sheets of Aethlon Medical, Inc. and Subsidiary (the "Company") as of March 31, 2016 and 2015 and the related consolidated statements of operations, equity (deficit), and cash flows for each of the two years in the period ended March 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of March 31, 2016 and 2015, and the results of their operations and their cash flows for each of the two years in the period ended March 31, 2016, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, during 2015 the Company incurred a net loss and generated negative cash flows from operating activity and as of March 31, 2016 had an accumulated deficit of approximately $86,502,000. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

/s/ SQUAR MILNER LLP (formerly SQUAR, MILNER, PETERSON, MIRANDA & WILLIAMSON, LLP)

SAN DIEGO, CALIFORNIA

JUNE 29, 2016

AETHLON MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

	March 31, 2016	March 31, 2015
ASSETS		
CURRENT ASSETS		
Cash	$2,123,737	$855,596
Accounts receivable	199,471	193,341
Deferred financing costs	27,641	82,324
Prepaid expenses and other current assets	53,294	73,135
TOTAL CURRENT ASSETS	2,404,143	1,204,396
Property and equipment, net	36,038	56,091
Patents, net	94,161	103,325
Other assets	22,415	16,776
TOTAL ASSETS	$2,556,757	$1,380,588
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$244,804	$342,133
Due to related parties	145,112	146,112
Other current liabilities	136,695	85,731
TOTAL CURRENT LIABILITIES	526,611	573,976
Convertible notes payable, noncurrent portion	527,780	155,229
TOTAL LIABILITIES	1,054,391	729,205
COMMITMENTS AND CONTINGENCIES (Note 12)		
STOCKHOLDERS' EQUITY		
Common stock, $0.001 par value, 30,000,000 and 10,000,000 shares authorized at March 31, 2016 and 2015, respectively; 7,622,393 and 6,657,046 issued and outstanding at March 31, 2016 and 2015, respectively	7,621	6,657
Additional paid-in capital	88,047,142	82,238,507
Accumulated deficit	(86,502,043)	(81,629,714)
TOTAL AETHLON MEDICAL, INC STOCKHOLDERS' EQUITY BEFORE NONCONTROLLING INTERESTS	1,552,720	615,450

NONCONTROLLING INTERESTS	(50,354)	35,933
TOTAL STOCKHOLDERS' EQUITY	1,502,366	651,383
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$2,556,757	$1,380,588

See accompanying notes to the consolidated financial statements.

AETHLON MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended March 31,	
	2016	2015
REVENUES:		
Government contract revenue	$886,572	$762,417
Total revenues	886,572	762,417
OPERATING EXPENSES		
Professional fees	2,259,096	1,572,196
Payroll and related expenses	2,083,297	2,275,959
General and administrative	929,013	907,115
	5,271,406	4,755,270
OPERATING LOSS	(4,384,834)	(3,992,853)
OTHER (INCOME) EXPENSE		
Loss on debt conversion	–	2,753,989
Other income	–	(219,624)
Interest and other debt expenses	573,782	452,276
Total other expense	573,782	2,986,641
NET LOSS BEFORE NONCONTROLLING INTERESTS	(4,958,616)	(6,979,494)
LOSS ATTRIBUTABLE TO NONCONTROLLING INTERESTS	(86,287)	(182,337)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	$(4,872,329)	$(6,797,157)
Basic and diluted net loss per share available to common stockholders	$(0.66)	$(1.22)
Weighted average number of common shares outstanding - basic and diluted	7,393,695	5,594,447

See accompanying notes to the consolidated financial statements.

AETHLON MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF EQUITY (DEFICIT)

FOR THE YEARS ENDED MARCH 31, 2016 AND 2015

	ATTRIBUTABLE TO AETHLON MEDICAL, INC.				
	COMMON STOCK		ADDITIONAL PAID IN	ACCUMULATED	NON-CONTROLLING
	SHARES	AMOUNT	CAPITAL	DEFICIT	INTERESTS
BALANCE - MARCH 31, 2014	4,499,480	$ 4,497	$59,879,624	$(74,832,557)	$218,270
Issuances of common stock upon conversions of notes payable and convertible notes payable and related accrued interest	948,728	949	2,272,083	–	–

		February 27, 2009
/s/ John F. Levy	Director	February 27, 2009
John F. Levy		
/s/ Jerry McAleer	Director	February 27, 2009
Jerry McAleer		
/s/ John A. Quelch	Director	February 27, 2009
John A. Quelch		

/s/ David Scott David Scott	Director	February 27, 2009
/s/ Peter Townsend Peter Townsend	Director	February 27, 2009
/s/ James Roosevelt, Jr. James Roosevelt, Jr.	Director	February 27, 2009

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

Table of Contents

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of
Inverness Medical Innovations, Inc.:

We have audited the accompanying consolidated balance sheets of Inverness Medical Innovations, Inc. and Subsidiaries (the Company) as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders equity and comprehensive loss, and cash flows for each of the three years in the period ended December 31, 2008. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Inverness Medical Innovations, Inc. and Subsidiaries at December 31, 2008 and 2007, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2008, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company s internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated February 27, 2009, expressed an unqualified opinion thereon.

/s/ BDO Seidman, LLP

Boston, Massachusetts
February 27, 2009

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

	2008	2007	2006
Net product sales	$ 1,240,138	$ 800,915	$ 552,130
Services revenue	405,462	16,646	
Net product sales and services revenue	1,645,600	817,561	552,130
License and royalty revenue	25,826	21,979	17,324
Net revenue	1,671,426	839,540	569,454
Cost of net product sales	624,654	431,403	334,799
Cost of services revenue	177,098	5,261	
Cost of license and royalty revenue	9,115	9,149	5,432
Cost of net revenue	810,867	445,813	340,231
Gross profit	860,559	393,727	229,223
Operating expenses:			
Research and development	111,828	69,547	48,706
Purchase of in-process research and development		173,825	4,960
Sales and marketing	386,284	167,770	94,445
General and administrative	298,595	158,438	71,243
Loss on dispositions, net			3,498
Operating income (loss)	63,852	(175,853)	6,371
Interest expense, including amortization of original issue discounts and write-off of deferred financing costs	(101,144)	(83,025)	(26,570)
Other (expense) income, net	(2,212)	8,774	8,748
Loss before (benefit) provision for income taxes	(39,504)	(250,104)	(11,451)
(Benefit) provision for income taxes	(16,686)	(979)	5,727
Equity earnings of unconsolidated entities, net of tax	1,050	4,372	336
Net loss	(21,768)	(244,753)	(16,842)
Preferred stock dividends	(13,989)		
Net loss available to common stockholders	$ (35,757)	$ (244,753)	$ (16.842)
Net loss per common share basic and diluted	$ (0.46)	$ (4.75)	$ (0.49)
Weighted average shares basic and diluted	77,778	51,510	34,109

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands, except par value amounts)

	December 31, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 141,324	$ 414,732
Restricted cash	2,748	141,869
Marketable securities	1,763	2,551
Accounts receivable, net of allowances of $12,835 and $12,167 at December 31, 2008 and 2007, respectively	280,608	163,380
Inventories, net	199,131	148,231
Deferred tax assets	104,311	18,170
Income tax receivable	6,406	5,256
Receivable from joint venture, net	12,018	
Prepaid expenses and other current assets	74,234	58,785
Total current assets	822,543	952,974
Property, plant and equipment, net	284,483	267,880
Goodwill	3,046,083	2,148,850
Other intangible assets with indefinite lives	42,984	43,097
Core technology and patents, net	459,307	432,583
Other intangible assets, net	1,169,330	869,644
Deferred financing costs, net, and other non-current assets	46,884	51,747
Investments in unconsolidated entities	68,832	77,753
Marketable securities	591	20,432
Deferred tax assets	14,323	15,799
Total assets	$ 5,955,360	$ 4,880,759
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 19,058	$ 20,320
Current portion of capital lease obligations	451	776
Accounts payable	112,704	72,061
Accrued expenses and other current liabilities	233,132	174,935
Payable to joint venture, net		10,816
Total current liabilities	365,345	278,908
Long-term liabilities:		
Long-term debt, net of current portion	1,500,557	1,366,395
Capital lease obligations, net of current portion	468	358

Deferred tax liabilities	462,787	326,128
Deferred gain on joint venture	287,030	293,078
Other long-term liabilities	60,335	29,225
Total long-term liabilities	2,311,177	2,015,184
Commitments and contingencies (Notes 8, 9 and 11)		
Stockholders equity:		
Series B preferred stock, $0.001 par value (liquidation preference, $751,479) Authorized: 2,300 shares Issued and outstanding: 1,879 shares	671,501	
Common stock, $0.001 par value Authorized: 150,000 shares Issued and outstanding: 78,431 shares at December 31, 2008 and 76,789 shares at December 31, 2007	78	77
Additional paid-in capital	3,029,694	2,937,143
Accumulated deficit	(393,590)	(371,822)
Accumulated other comprehensive (loss) income	(28,845)	21,269
Total stockholders equity	3,278,838	2,586,667
Total liabilities and stockholders equity	$ 5,955,360	$ 4,880,759

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY AND COMPREHENSIVE LOSS

(in thousands, except par value amounts)

	Preferred Stock $0.001		Common Stock $0.001							
	Number of Shares	Par Value	Number of Shares	Par Value	Additional Paid-in Capital	Notes Receivable From Stockholders	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders Equity	Total Comprehensive Loss
BALANCE, DECEMBER 31, 2005		$	27,497	$ 27	$ 515,147	$ (14,691)	$ (110,227)	$ 7,052	$ 397,308	
Issuance of common stock in connection with acquisitions and equity offering, net of issuance costs of $9,617			10,893	11	295,488				295,499	
Exercise of common stock options and warrants and shares issued under employee stock purchase plan			825	1	10,330				10,331	
Stock-based compensation related to grants of common stock options					5,455				5,455	
Stock option income tax benefits					567				567	
Repayment of notes receivable from stockholder options						14,691			14,691	
Effect of adoption of SFAS No. 158								(3,738)	(3,738)	
Changes in cumulative								10,823	10,823	$ 10,823

translation adjustment								
Unrealized gain on available-for-sale securities					44	44		44
Net loss				(16,842)		(16,842)		(16,842)
Total comprehensive loss							$	(5,975)
BALANCE, DECEMBER 31, 2006	$ 39,215	$ 39	$ 826,987	$	$ (127,069)	$ 14,181	$ 714,138	

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY AND COMPREHENSIVE LOSS
(Continued)
(in thousands, except par value amounts)

	Preferred Stock $0.001		Common Stock $0.001				Accumulated Other	Total	Total
	Number of Shares	Par Value	Number of Shares	Par Value	Additional Paid-in Capital	Accumulated Deficit	Comprehensive Income	Stockholders Equity	Comprehensive Loss
BALANCE, DECEMBER 31, 2006		$	39,215	$ 39	$ 826,987	$ (127,069)	$ 14,181	$ 714,138	
Issuance of common stock in connection with acquisitions and equity offerings, net of issuance costs of $44,204			35,204	35	1,859,985			1,860,020	
Exercise of common stock options and warrants and shares issued under employee stock purchase plan			2,370	3	55,095			55,098	
Stock-based compensation related to grants of common stock options					57,480			57,480	
Fair value associated with options exchanged in acquisitions					135,022			135,022	
Stock option income tax benefits					2,574			2,574	
Minimum pension liability adjustment							341	341	$ 341

Changes in cumulative translation adjustment					12,758	12,758	12,758
Unrealized loss on interest rate swap (Note 10)					(9,518)	(9,518)	(9,518)
Unrealized gain on available-for-sale securities					3,507	3,507	3,507
Net loss				(244,753)		(244,753)	(244,753)
Total comprehensive loss							$ (237,665)
BALANCE, DECEMBER 31, 2007	$ 76,789	$ 77	$ 2,937,143	$ (371,822)	$ 21,269	$ 2,586,667	

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY AND COMPREHENSIVE LOSS
(Continued)
(in thousands, except par value amounts)

	Preferred Stock		Common Stock $0.001		Additional		Accumulated Other	Total	Total
	Number of Shares	Amount	Number of Shares	Par Value	Paid-in Capital	Accumulated Deficit	Comprehensive Income (Loss)	Stockholders Equity	Comprehens Loss
ALANCE, ECEMBER 31, 007		$	76,789	$ 77	$ 2,937,143	$ (371,822)	$ 21,269	$ 2,586,667	
suance of eries B preferred ock in onnection with cquisition of latria ealthcare, Inc., et of issuance osts of $350	1,788	657,573						657,573	
suance of ommon stock in onnection with cquisitions, net f issuance costs f $219			580		20,945			20,945	
xercise of ommon stock ptions and arrants and hares issued nder employee ock purchase lan			1,062	1	20,712			20,713	
referred stock vidends Note 16)	91	13,928			(14,026)			(98)	
air value ssociated with ptions xchanged in cquisitions					20,973			20,973	

tock-based ompensation lated to grants f common stock ptions				26,405			26,405		
tock option ncome tax enefits				17,542			17,542		
Minimum ension liability djustment						(562)	(562)	$	(562
hanges in umulative anslation djustment						(32,889)	(32,889)		(32,889
nrealized loss n interest rate wap (Note 10)						(11,614)	(11,614)		(11,614
nrealized loss n vailable-for-sale ecurities						(5,049)	(5,049)		(5,049
et loss					(21,768)		(21,768)		(21,768
otal omprehensive oss								$	(71,882
ALANCE, ECEMBER 31, 008	1,879	$ 671,501	78,431	$ 78	$ 3,029,694	$ (393,590)	$ (28,845)	$ 3,278,838	

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF CASH FLOWS

(in thousands)

	2008	2007	2006
Cash Flows from Operating Activities:			
Net loss	$ (21,768)	$ (244,753)	$ (16,842)
Adjustments to reconcile net loss to net cash provided by operating activities:			
Interest expense related to amortization of original issue discounts and write-off of deferred financing costs	5,930	10,963	4,158
Non-cash income related to currency hedge			(217)
Non-cash stock-based compensation expense	26,405	52,210	5,455
Charge for in-process research and development		173,825	4,960
Impairment of inventory	4,193		707
Impairment of long-lived assets	20,031	3,872	8,866
Loss (gain) on sale of fixed assets	777	59	(1,528)
Equity earnings of unconsolidated entities	(1,050)	(4,372)	(336)
Interest in minority investments	167	1,401	(299)
Depreciation and amortization	267,927	101,113	39,362
Deferred and other non-cash income taxes	(41,756)	(27,892)	(409)
Other non-cash items	4,378	197	714
Changes in assets and liabilities, net of acquisitions:			
Accounts receivable, net	(48,650)	47,018	(13,846)
Inventories, net	(49,226)	(1,463)	167
Prepaid expenses and other current assets	(7,373)	15,432	(86)
Accounts payable	16,467	(6,745)	210
Accrued expenses and other current liabilities	(32,008)	(33,893)	3,294
Other non-current liabilities	3,400	1,783	(60)
Net cash provided by operating activities	147,844	88,755	34,270
Cash Flows from Investing Activities:			
Purchases of property, plant and equipment	(66,061)	(36,398)	(19,717)
Proceeds from sale of property, plant and equipment	1,070	264	2,244
Cash paid for acquisitions and transactional costs, net of cash acquired	(649,899)	(2,036,116)	(131,465)
Cash received, net of cash paid, from formation of joint venture		324,170	
Cash received from (paid for) investments in minority interests and marketable securities	12,133	(10,177)	(25,817)
Increase in other assets	(10,575)	(28,273)	(4,077)
Net cash used in investing activities	(713,332)	(1,786,530)	(178,832)

Cash Flows from Financing Activities:			
Decrease (increase) in restricted cash	139,204	(141,869)	
Issuance costs associated with preferred stock	(350)		
Cash paid for financing costs	(1,401)	(40,675)	(2,787)
Dividends to preferred stockholders	(56)		
Proceeds from issuance of common stock, net of issuance costs	20,675	1,122,852	234,961
Net repayments on long-term debt	(13,787)	(22,326)	(20,000)
Net proceeds (repayments) from revolving lines-of-credit	137,242	1,114,171	(47,879)
Repayments of notes receivable			14,691
Tax benefit on exercised stock options	17,542	867	567
Principal payments of capital lease obligations	(1,300)	(636)	(546)
Net cash provided by financing activities	297,769	2,032,384	179,007
Foreign exchange effect on cash and cash equivalents	(5,689)	9,019	2,389
Net (decrease) increase in cash and cash equivalents	(273,408)	343,628	36,834
Cash and cash equivalents, beginning of period	414,732	71,104	34,270
Cash and cash equivalents, end of period	$ 141,324	$ 414,732	$ 71,104

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(1) Description of Business and Basis of Presentation

By developing new capabilities in near-patient diagnosis, monitoring and health management, Inverness Medical Innovations, Inc. and subsidiaries enable individuals to take charge of improving their health and quality of life at home. Our products and services, as well as our new product development efforts, focus on infectious disease, cardiology, oncology, drugs of abuse and women s health. In addition, we manufacture a variety of vitamins and nutritional supplements that we market under our brands and those of private label retailers in the consumer market primarily in the United States.

Our business is organized into four primary operating segments: (i) professional diagnostics, (ii) health management, (iii) consumer diagnostics and (iv) vitamins and nutritional supplements. The professional diagnostics segment includes an array of innovative rapid diagnostic test products and other in vitro diagnostic tests marketed to medical professionals and laboratories for detection of infectious diseases, cardiac conditions, oncology, drugs of abuse and pregnancy. The health management segment provides comprehensive, integrated programs and services focused on wellness, disease and condition management, productivity enhancement and informatics, all designed to reduce health-related costs and enhance the health and quality of life of the individuals we serve. The consumer diagnostics segment consists primarily of manufacturing operations related to our role as the exclusive manufacturer of products for SPD Swiss Precision Diagnostics, or SPD, our 50/50 joint venture with The Procter & Gamble Company, or P&G. SPD has significant operations in the worldwide over-the-counter pregnancy and fertility/ovulation test market. The vitamins and nutritional supplements segment includes branded and private label vitamins and nutritional supplements that are sold over-the-counter.

Acquisitions are an important part of our growth strategy. When we acquire businesses, we seek to complement existing products and services, enhance or expand our product lines and/or expand our customer base. We determine what we are willing to pay for each acquisition partially based on our expectation that we can cost effectively integrate the products and services of the acquired companies into our existing infrastructure. In addition, we utilize existing infrastructure of the acquired companies to cost effectively introduce our products to new geographic areas. All these factors contributed to the acquisition prices of acquired businesses that were in excess of the fair value of net assets acquired and the resultant goodwill (Note 4).

Following the completion of our 50/50 joint venture with P&G on May 17, 2007 (Note 13), we ceased to consolidate the operating results of our consumer diagnostics business, which represented $76.1 million of net product sales in 2007 (through the date the joint venture was formed) and $171.6 million of net product sales in 2006, and instead account for our 50% interest in the results of the joint venture under the equity method of accounting. In our capacity as the manufacturer of products for the joint venture, we supply product to the joint venture and record revenue on those sales. No gain on the proceeds that we received from P&G through the formation of our joint venture will be recognized in our financial statements until P&G s option to require us to purchase its interest in the joint venture at market value expires after the fourth anniversary of the closing.

The consolidated financial statements include the accounts of Inverness Medical Innovations, Inc. and its subsidiaries. Intercompany transactions and balances are eliminated and net earnings are reduced by the portion of the net earnings of subsidiaries applicable to minority interests. Equity investments in which we exercise significant influence but do not control and are not the primary beneficiary are accounted for using the equity method. Investments in which we are not able to exercise significant influence over the investee and which do not have readily determinable fair values

are accounted for under the cost method. Certain amounts for prior periods have been reclassified to conform to the current period classification.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(2) Summary of Significant Accounting Policies

(a) Use of Estimates

To prepare our financial statements in conformity with accounting principles generally accepted in the United States of America, our management must make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ significantly from such estimates.

(b) Foreign Currencies

We follow the provisions of Statement of Financial Accounting Standards (SFAS) No. 52, *Foreign Currency Translation.* In general, the functional currencies of our foreign subsidiaries are the local currencies. For purpose of consolidating the financial statements of our foreign subsidiaries, all assets and liabilities of the foreign subsidiaries are translated into U.S. dollars using the exchange rate at each balance sheet date while the stockholders equity accounts are translated at historical exchange rates. Translation gains and losses that result from the conversion of the balance sheets of the foreign subsidiaries into U.S. dollars are recorded to cumulative translation adjustment which is a component of accumulated other comprehensive income within stockholders equity (Note 18).

The revenue and expenses of our foreign subsidiaries are translated using the average rates of exchange in effect during each fiscal month during the year. Net realized and unrealized foreign currency exchange transaction losses of $0.9 million during 2008, losses of $1.6 million during 2007 and gains of $2.6 million during 2006, are included as a component of other income (expense), net in the accompanying consolidated statements of operations.

(c) Cash and Cash Equivalents

We consider all highly liquid investments purchased with original maturities of three months or less at the date of acquisition to be cash equivalents. Cash equivalents consisted of money market funds at December 31, 2008 and 2007.

(d) Restricted Cash

We have restricted cash of $2.7 million and $141.9 million as of December 31, 2008 and 2007, respectively. Of the $141.9 million, $139.7 million represented a cash escrow established in connection with our February 2008 acquisition of BBI Holdings Plc, or BBI (Note 4).

(e) Marketable Securities

We account for our investment in marketable securities in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. Securities classified as available-for-sale or trading are carried at estimated fair value, as determined by quoted market prices at the balance sheet date. Realized gains and losses on securities are included in earnings and are determined using the specific identification method. Unrealized holding gains and losses (except for other than temporary impairments) on securities classified as available for sale, are excluded from earnings

and are reported in accumulated other comprehensive income, net of related tax effects. Unrealized gains and losses on actively-traded securities are included in earnings. Marketable securities that are held indefinitely are classified in our accompanying balance sheet as long-term marketable securities.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(2) Summary of Significant Accounting Policies (Continued)

(f) Inventories

Inventories are stated at the lower of cost (first-in, first-out) or market and made up of raw material, work-in-process and finished goods. The cost elements of work-in-process and finished goods inventory consist of raw material, direct labor and manufacturing overhead. Where finished goods inventory is purchased from third-party manufacturers, the costs of such finished goods inventory represent the costs to acquire such inventory.

(g) Property, Plant and Equipment

We record property, plant and equipment at historical cost or, in the case of a business combination, at fair value on the date of the business combination. Depreciation and amortization are computed using the straight-line method based on the following estimated useful lives of the related assets: machinery, laboratory equipment and tooling, 2-21 years; buildings, 20-50 years; leasehold improvements, lesser of remaining term of lease or estimated useful life of asset; computer software and equipment, 1-6 years and furniture and fixtures, 2-15 years. Land is not depreciated. Depreciation and amortization expense related to property, plant and equipment amounted to $51.8 million, $28.3 million and $17.6 million in 2008, 2007 and 2006, respectively. Expenditures for repairs and maintenance are expensed as incurred.

(h) Goodwill and Other Intangible Assets with Indefinite Lives

We account for goodwill and other intangible assets with indefinite lives in accordance with SFAS No. 142, *Goodwill and Other Intangible Assets*, which establishes financial accounting and reporting standards for acquired goodwill and other intangible assets. Under the provisions of SFAS No. 142, goodwill and indefinite-lived intangible assets are required to be tested for impairment annually, in lieu of being amortized, using a fair value approach at the reporting unit level. Furthermore, testing for impairment is required on an interim basis if an event or circumstance indicates that it is more likely than not an impairment loss has been incurred. An impairment loss shall be recognized to the extent that the carrying amount of goodwill or any indefinite-lived intangible asset exceeds its implied fair value. Impairment losses shall be recognized in operating results.

Our valuation methodology for assessing impairment, using the discounted cash flows approach, requires management to make judgments and assumptions based on historical experience and projections of future operating performance. If these assumptions differ materially from future results, we may record impairment charges in the future. Our annual impairment review performed on September 30, 2008 did not indicate that goodwill or other indefinite-lived intangible assets related to our professional diagnostics, health management or our consumer diagnostics reporting units were impaired.

Despite current economic conditions and the fluctuation in our common stock price during the fourth quarter of 2008, we determined that, based on our 2008 financial performance, our unchanged expectations of future financial performance as used in our fair value analysis and the improvement in our common stock price subsequent to year end, a triggering event that would warrant further impairment testing had not occurred and therefore no updated testing was performed and no goodwill impairment was recorded during 2008. Should economic conditions deteriorate further or remain depressed for a prolonged period of time, estimates of future cash flows for each

reporting unit may be insufficient to support carrying value and the goodwill assigned to it, requiring us to test for impairment. Impairment charges, if any, may be material to our results of operations and financial position.

(i) Impairment of Other Long-Lived Tangible and Intangible Assets

In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, we evaluate long-lived tangible and intangible assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If indicators of impairment are present with respect to

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(2) Summary of Significant Accounting Policies (Continued)

long-lived tangible and intangible assets used in operations and undiscounted future cash flows are not expected to be sufficient to recover the assets carrying amount, additional analysis is performed as appropriate and the carrying value of the long-lived asset is reduced to the estimated fair value, if this is lower, and an impairment loss would be charged to expense in the period the impairment is identified. We believe that the carrying values of our other long-lived tangible and intangible assets were realizable as of December 31, 2008.

(j) Business Acquisitions

We account for acquired businesses using the purchase method of accounting as prescribed by SFAS No. 141, *Business Combinations.* Under the purchase method, the operating results of an acquired business are included in our consolidated financial statements starting from the consummation date of the acquisition. In addition, the assets acquired and liabilities assumed must be recorded at the date of acquisition at their respective estimated fair values, with any excess of the purchase price over the estimated fair values of the net assets acquired recorded as goodwill.

Significant judgment is required in estimating the fair value of intangible assets and in assigning their respective useful lives. The fair value estimates are based on available historical information and on future expectations and assumptions deemed reasonable by management, but are inherently uncertain.

We generally employ the income method to estimate the fair value of intangible assets, which is based on forecasts of the expected future cash flows attributable to the respective assets. Significant estimates and assumptions inherent in the valuations reflect a consideration of other marketplace participants, and include the amount and timing of future cash flows (including expected growth rates and profitability), the underlying product life cycles, economic barriers to entry, a brand s relative market position and the discount rate applied to the cash flows. Unanticipated market or macroeconomic events and circumstances may occur, which could affect the accuracy or validity of the estimates and assumptions.

Other significant estimates associated with the accounting for acquisitions include exit costs. We have undertaken certain restructurings of the acquired businesses to realize efficiencies and potential cost savings. Our restructuring activities include the elimination of duplicate facilities, reductions in staffing levels, and other costs associated with exiting certain activities of the businesses we acquire. Provided certain criteria are met, the estimated costs associated with these restructuring activities are treated as assumed liabilities, consistent with the guidance of Emerging Issue Task Force (EITF) Issue No. 95-3, *Recognition of Liabilities in Connection with a Purchase Business Combination.* Our estimates and assumptions associated with these restructuring activities may change as we execute approved plans. Decreases to the estimated costs are generally recorded as an adjustment to goodwill. Increases to the estimates are generally recorded as an adjustment to goodwill during the purchase price allocation period (generally within one year of the acquisition date) and as operating expenses thereafter.

Any common stock issued in connection with our acquisitions is determined based on the average market price of our common stock pursuant to EITF Issue No. 99-12, *Determination of the Measurement Date for the Market Price of Acquirer Securities Issued in a Purchase Business Combination.*

Some of our acquisitions have involved an exchange of employee stock options and restricted stock awards. Accordingly, we have accounted for these exchanges within a purchase business combination under the guidance of SFAS No. 123-R, *Share Based Payments*. In general, to the extent that the fair value of our awards approximate the fair value of the acquired-company awards, the fair value of the awards has been recognized as a component of the purchase price. The fair value of unvested or partially-vested awards is allocated between the vested and unvested portions of the awards. The fair value of the unvested portion is deducted from the purchase price and recognized as compensation cost as that portion vests.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(2) Summary of Significant Accounting Policies (Continued)

(k) Income Taxes

We follow the provisions of SFAS No. 109, *Accounting for Income Taxes,* under which deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities. Deferred tax assets and liabilities are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The provisions of SFAS No. 109 also require the recognition of future tax benefits such as net operating loss, or NOL, carryforwards, to the extent that the realization of such benefits is more likely than not. To the extent that it is not more likely than not that we will realize such benefits, we must establish a valuation allowance against the related deferred tax assets (Note 19).

We follow the provisions of Financial Accounting Standards Board (FASB) Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109*, (FIN 48). In accordance with FIN 48, we recognize some or all of the benefit of a tax position, if that position is more likely than not of being sustained on audit, based on the technical merits of the position (Note 19).

(l) Revenue Recognition

We primarily recognize revenue when the following four basic criteria have been met: (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services rendered, (3) the fee is fixed and determinable and (4) collection is reasonably assured.

The majority of our revenue is derived from product revenue. We recognize revenue upon title transfer of the products to third-party customers, less a reserve for estimated product returns and allowances. Determination of the reserve for estimated product returns and allowances is based on our management s analyses and judgments regarding certain conditions. Should future changes in conditions prove management s conclusions and judgments on previous analyses to be incorrect, revenue recognized for any reporting period could be adversely affected.

Additionally, we generate services revenue in connection with contracts with leading healthcare organizations whereby we distribute clinical expertise through fee-based arrangements. Revenue for fee-based arrangements is recognized over the period in which the services are provided. Some contracts provide that a portion of our fees are at risk if our customers do not achieve certain financial cost savings over a period of time, typically one year. Revenue subject to refund is not recognized if (i) sufficient information is not available to calculate performance measurements, or (ii) interim performance measurements indicate that we are not meeting performance targets. If either of these two conditions exists, we record the amounts as other current liabilities in the consolidated balance sheet, deferring recognition of the revenue until we establish that we have met the performance criteria. If we do not meet the performance targets at the end of the contractual period we are obligated under the contract to refund some or all of the at risk fees.

In connection with the acquisition of the Determine business in June 2005 from Abbott Laboratories, we entered into a transition services agreement with Abbott, whereby Abbott would continue to distribute the acquired products until both parties agreed the transition was completed. During the transition period, we recognized revenue on sales of the products when title transferred from Abbott to third party customers.

We also receive license and royalty revenue from agreements with third-party licensees. Revenue from fixed fee license and royalty agreements are recognized on a straight-line basis over the obligation period of the related license agreements. License and royalty fees that the licensees calculate based on their sales, which we have the right to audit under most of our agreements, are generally recognized upon receipt of the license or royalty payments unless we are able to reasonably estimate the fees as they are earned. License and royalty fees that are determinable prior to the receipt thereof are recognized in the period they are earned.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(2) Summary of Significant Accounting Policies (Continued)

(m) Employee Stock-Based Compensation Arrangements

Effective January 1, 2006, we began recording compensation expense associated with stock options and other forms of equity compensation in accordance with SFAS No. 123-R, *Share-Based Payment*, as interpreted by SEC Staff Accounting Bulletin (SAB) No. 107. We adopted the modified prospective transition method provided for under SFAS No. 123-R, and consequently have not retroactively adjusted results from prior periods. Under this transition method, compensation cost associated with stock options now includes: (i) amortization related to the remaining unvested portion of all stock option awards granted prior to January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123, and (ii) amortization related to all stock option awards granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123-R. In addition, we record expense over the offering period in connection with shares issued under our employee stock purchase plan. The compensation expense for stock-based compensation awards includes an estimate for forfeitures and is recognized over the expected term of the options using the straight-line method.

Our stock option plans provide for grants of options to employees to purchase common stock at the fair market value of such shares on the grant date of the award. The options generally vest over a four-year period, beginning on the date of grant, with a graded vesting schedule of 25% at the end of each of the four years. The fair value of each option grant is estimated on the date of grant using a Black-Scholes option-pricing method. We use historical data to estimate the expected price volatility and the expected forfeiture rate. The contractual term of our stock option awards is ten years. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant with a remaining term equal to the expected term of the option. We have not made any dividend payments nor do we have plans to pay dividends in the foreseeable future.

(n) Net (Loss) Income per Common Share

Net (loss) income per common share, computed in accordance with SFAS No. 128, *Earnings per Share*, is based upon the weighted average number of outstanding common shares and the dilutive effect of common share equivalents, such as options and warrants to purchase common stock, convertible preferred stock and convertible notes, if applicable, that are outstanding each year (Note 15).

(o) Other Operating Expenses

We expense advertising costs as incurred. In 2008, 2007 and 2006, advertising costs amounted to $15.7 million, $16.3 million and $23.0 million, respectively, and are included in sales and marketing expenses in the accompanying consolidated statements of operations.

Shipping and handling costs are included in cost of net revenue in the accompanying consolidated statements of operations. Additionally, to the extent that we charge our customers for shipping and handling costs, these costs are recorded as product revenues.

(p) Concentration of Credit Risk, Off-Balance Sheet Risks and Other Risks and Uncertainties

Financial instruments that potentially subject us to concentration of credit risk primarily consist of cash and cash equivalents and accounts receivable. We invest our excess cash primarily in high quality securities and limit the amount of our credit exposure to any one financial institution. We do not require collateral or other securities to support customer receivables; however, we perform on-going credit evaluations of our customers and maintain allowances for potential credit losses.

At December 31, 2008 and 2007, we had one individual customer account receivable balance outstanding that represented 14% and 12% of the gross account receivable balance, respectively. During 2008 and 2007,

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(2) Summary of Significant Accounting Policies (Continued)

we had one customer that represented 22% and 17% of our net revenue, respectively, and purchased our professional diagnostics products. During 2006, no customer represented greater than 10% of our net revenue.

We rely on a number of third parties to manufacture certain of our products. If any of our third-party manufacturers cannot, or will not, manufacture our products in the required volumes, on a cost-effective basis, in a timely manner, or at all, we will have to secure additional manufacturing capacity. Any interruption or delay in manufacturing could have a material adverse effect on our business and operating results.

(q) Financial Instruments and Fair Value of Financial Instruments

Our primary financial instruments at December 31, 2008 and 2007 consisted of cash equivalents, marketable securities, accounts receivable, accounts payable, debt and our interest rate swap contract. The estimated fair value of these financial instruments approximates their carrying values at December 31, 2008 and 2007. The estimated fair values have been determined through information obtained from market sources. We account for our derivative instruments in accordance with SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, and related amendments, including SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities.*

(r) Recent Accounting Pronouncements

Recently Issued Standards

In June 2008, the FASB ratified EITF Issue No. 07-05, *Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity s Own Stock*, which addresses the accounting for certain instruments as derivatives under SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities. Under this new pronouncement, specific guidance is provided regarding requirements for an entity to consider embedded features as indexed to the entity s own stock. This Issue is effective for fiscal years beginning after December 15, 2008. We are currently in the process of evaluating the impact of adopting this pronouncement.

In May 2008, the FASB issued FASB Staff Position (FSP) Accounting Principles Board (APB) 14-1, *Accounting for Convertible Debt Instruments That May Be Settled In Cash upon Conversion (Including Partial Cash Settlement)*. FSP APB 14-1 specifies that issuers of such instruments should separately account for the liability and equity components in a manner that will reflect the entity s nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. FSP APB 14-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years. This FSP should be applied retrospectively for all periods presented. We are currently in the process of evaluating the impact of adopting this pronouncement.

In April 2008, the FASB issued FSP 142-3, *Determination of the Useful Life of Intangible Assets*. FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, Goodwill and Other Intangible Assets. FSP 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008, as well as interim periods within those fiscal years. We are currently in the process of evaluating the impact of adopting this pronouncement.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities an Amendment of FASB Statement No. 133*. This statement requires entities that utilize derivative instruments to provide qualitative disclosures about their objectives and strategies for using such instruments, as well as any details of credit-risk-related contingent features contained within derivatives. It also requires entities to disclose additional information about the amounts and location of derivatives located within the

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(2) Summary of Significant Accounting Policies (Continued)

financial statements, how the provisions of SFAS No. 133 have been applied and the impact that hedges have on an entity s financial position, financial performance and cash flows. This statement is effective for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. We are currently in the process of evaluating the impact of adopting this pronouncement.

In December 2007, the FASB ratified the consensus reached by the EITF in EITF Issue No. 07-01, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*. The EITF concluded that a collaborative arrangement is one in which the participants are actively involved and are exposed to significant risks and rewards that depend on the ultimate commercial success of the endeavor. Revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF Issue No. 99-19, Reporting Revenue Gross as a Principal versus Net as an Agent, and other accounting literature. Payments to or from collaborators would be evaluated and presented based on the nature of the arrangement and its terms, the nature of the entity s business, and whether those payments are within the scope of other accounting literature. The nature and purpose of collaborative arrangements are to be disclosed along with the accounting policies and the classification and amounts of significant financial statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however required disclosure under EITF Issue No. 07-01 applies to the entire collaborative agreement. This Issue is effective for fiscal years beginning after December 15, 2008, and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. We are currently in the process of evaluating the impact of adopting this pronouncement.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an Amendment of Accounting Research Bulletin (ARB) No. 51*. This statement amends ARB No. 51 to establish accounting and reporting standards for the non-controlling interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a non-controlling interest in a subsidiary is an ownership interest in the consolidated entity and should therefore be reported as equity in the consolidated financial statements. The statement also establishes standards for presentation and disclosure of the non-controlling results on the consolidated income statement. SFAS No. 160 is effective for fiscal years beginning on or after December 15, 2008. We are currently in the process of evaluating the impact of adopting this pronouncement.

In December 2007, the FASB issued SFAS No. 141-R, *Business Combinations*. This statement replaces SFAS No. 141, but retains the fundamental requirements in SFAS No. 141 that the acquisition method of accounting be used for all business combinations. This statement requires an acquirer to recognize and measure the identifiable assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree at their fair values as of the acquisition date. The statement requires acquisition costs and any restructuring costs associated with the business combination to be recognized separately from the fair value of the business combination. SFAS No. 141-R establishes requirements for recognizing and measuring goodwill acquired in the business combination or a gain from a bargain purchase as well as disclosure requirements designed to enable users to better interpret the results of the business combination. SFAS No. 141-R is effective for fiscal years beginning on or after December 15, 2008. Given our history of acquisition activity, we anticipate the adoption of SFAS No. 141-R to have a significant impact on our consolidated financial statements. Early adoption of this statement is not permitted. As of December, 31, 2008 there were $3.8 million in capitalized acquisition costs classified in other non-current assets. The capitalized costs will be

written off in January 2009 when this statement becomes effective.

Recently Adopted Standards

Effective October 2008, we adopted FSP 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*. FSP 157-3 clarifies the application of SFAS No. 157 in an inactive

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(2) Summary of Significant Accounting Policies (Continued)

market. It demonstrated how the fair value of a financial asset is determined when the market for that financial asset is inactive. The adoption of these provisions did not have a material impact on our consolidated financial statements.

Effective January 1, 2008, we adopted EITF Issue No. 07-03, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*. EITF 07-03 concludes that non-refundable advance payments for future research and development activities should be deferred and capitalized until the goods have been delivered or the related services have been performed. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. The effect of applying this EITF is prospective for new contracts entered into on or after the date of adoption. The adoption of this EITF did not have a material impact on our consolidated financial statements.

Effective January 1, 2008, we adopted SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB No. 115*. This Statement provides companies with an option to measure, at specified election dates, many financial instruments and certain other items at fair value that are not currently measured at fair value. The standard also establishes presentation and disclosure requirements designed to facilitate comparison between entities that choose different measurement attributes for similar types of assets and liabilities. If the fair value option is elected, the effect of the first remeasurement to fair value is reported as a cumulative effect adjustment to the opening balance of retained earnings. The statement is to be applied prospectively upon adoption. The adoption of these provisions did not have a material impact on our consolidated financial statements.

Effective January 1, 2008, we adopted SFAS No. 157, *Fair Value Measurements*, for all financial instruments and non-financial instruments accounted for at fair value on a recurring basis. SFAS No. 157 establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. The standard applies whenever other standards require, (or permit), assets or liabilities to be measured at fair value. The standard does not expand the use of fair value in any new circumstances. The FASB has provided a one-year deferral for the implementation for other non-financial assets and liabilities. The adoption of these provisions did not have a material impact on our consolidated financial statements. For further information about the adoption of the required provisions of SFAS No. 157 see Note 7.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(3) Other Balance Sheet Information

Components of selected captions in the consolidated balance sheets consist of (in thousands):

	December 31, 2008	2007
Inventories, net:		
Raw materials	$ 45,161	$ 45,111
Work-in-process	41,651	40,184
Finished goods	112,319	62,936
	$ 199,131	$ 148,231
Property, plant and equipment, net:		
Machinery, laboratory equipment and tooling	$ 152,760	$ 134,776
Land and buildings	139,186	132,512
Leasehold improvements	22,158	29,032
Computer software and equipment	60,135	34,857
Furniture and fixtures	15,449	16,301
	389,688	347,478
Less: Accumulated depreciation and amortization	(105,205)	(79,598)
	$ 284,483	$ 267,880
Accrued expenses and other current liabilities:		
Compensation and compensation-related	$ 60,495	$ 55,397
Advertising and marketing	7,433	6,308
Professional fees	8,517	23,436
Interest payable	4,459	2,436
Royalty obligations	13,821	8,221
Deferred revenue	21,977	5,337
Taxes payable	47,658	39,778
Acquisition-related obligations	29,107	22,375
Other	39,665	11,647
	$ 233,132	$ 174,935

(4) Business Combinations

(a) Acquisitions in 2008

(i) Acquisition of Matria

On May 9, 2008, we acquired Matria Healthcare Inc., or Matria, a national provider of health improvement, disease management and high-risk pregnancy management programs and services. The preliminary aggregate purchase price was $834.6 million, which consisted of $141.3 million in cash, Series B convertible preferred stock with a fair value of approximately $657.9 million, $17.3 million of fair value associated with Matria employee stock options exchanged as part of the transaction and $18.0 million for direct acquisition costs. In addition, we assumed and immediately repaid debt totaling approximately $279.2 million. The operating results of Matria are included in our health management reporting unit and business segment.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(4) Business Combinations (Continued)

A summary of the preliminary purchase price allocation for this acquisition is as follows (in thousands):

Current assets	$ 109,106
Property, plant and equipment	24,460
Goodwill	836,178
Intangible assets	325,385
Other non-current assets	27,184
Total assets acquired	1,322,313
Current liabilities	358,270
Non-current liabilities	129,486
Total liabilities assumed	487,756
Net assets acquired	834,557
Less:	
Acquisition costs	17,961
Fair value of Series B convertible preferred stock issued (1,787,834 shares)	657,923
Fair value of stock options exchanged (1,490,655 options)	17,334
Cash consideration	$ 141,339

We expect that all of the amount allocated to goodwill will not be deductible for tax purposes.

Customer relationships are amortized based on patterns in which the economic benefits of customer relationships are expected to be utilized. Other finite-lived identifiable assets are amortized on a straight-line basis. The following are the intangible assets acquired and their respective amortizable lives (dollars in thousands):

	Amount	Amortizable Life
Core technology	$ 31,000	3 years
Database	25,000	10 years
Trade names	1,185	5 months
Customer relationships	253,000	13 years
Non-compete agreements	15,200	0.75-3 years
Total intangible assets with finite lives	$ 325,385	

(ii) Acquisition of BBI

On February 12, 2008, we acquired BBI Holdings Plc, or BBI, a publicly-traded company headquartered in the United Kingdom that specializes in the development and manufacture of non-invasive lateral flow tests and gold reagents. The preliminary aggregate purchase price was $163.2 million, which consisted of $138.6 million in cash, including $14.7 million of cash paid for shares of BBI common stock which we owned prior to the acquisition date, common stock with an aggregate fair value of $14.4 million, $6.6 million for direct acquisition costs and $3.6 million of fair value associated with BBI employee stock options exchanged as part of the transaction. The operating results of BBI are included in our professional and consumer diagnostics reporting units and business segments.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(4) Business Combinations (Continued)

A summary of the preliminary purchase price allocation for this acquisition is as follows (in thousands):

Current assets	$ 22,421
Property, plant and equipment	7,603
Goodwill	87,713
Intangible assets	90,201
Other non-current assets	3,001
Total assets acquired	210,939
Current liabilities	15,587
Non-current liabilities	32,141
Total liabilities assumed	47,728
Net assets acquired	163,211
Less:	
Acquisition costs	6,581
Fair value of common stock issued (251,085 shares)	14,397
Fair value of stock options/awards exchanged (329,612 options/25,626 awards)	3,639
Cash consideration	$ 138,594

We expect that all of the amount allocated to goodwill will not be deductible for tax purposes.

Customer relationships are amortized based on patterns in which the economic benefits of customer relationships are expected to be utilized. Other finite-lived identifiable assets are amortized on a straight-line basis. The following are the intangible assets acquired and their respective amortizable lives (dollars in thousands):

	Amount	Amortizable Life
Core technology	$ 28,043	15-20 years
Trade names and other intangible assets	16,180	10-25 years
Customer relationships	45,978	7-25 years
Total intangible assets with finite lives	$ 90,201	

(iii) Acquisition of Panbio

On January 7, 2008, we acquired Panbio Limited, or Panbio, an Australian publicly-traded company headquartered in Brisbane, Australia, that develops and manufactures diagnostic tests for use in the diagnosis of a broad range of infectious diseases. The preliminary aggregate purchase price was $36.5 million, which consisted of $35.9 million in cash and $0.6 million for direct acquisition costs. In June 2008, we sold certain assets totaling $1.8 million related to a particular product line. The sale of these assets, at their acquisition date fair values, is reflected in the preliminary purchase price allocation. The operating results of Panbio are included in our professional diagnostics reporting unit and business segment.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(4) Business Combinations (Continued)

A summary of the preliminary purchase price allocation for this acquisition is as follows (in thousands):

Current assets	$ 12,835
Property, plant and equipment	2,080
Goodwill	13,556
Intangible assets	17,717
Other non-current assets	246
Total assets acquired	46,434
Current liabilities	3,115
Non-current liabilities	6,810
Total liabilities assumed	9,925
Net assets acquired	36,509
Less:	
Acquisition costs	566
Cash consideration	$ 35,943

We expect that all of the amount allocated to goodwill will not be deductible for tax purposes.

Customer relationships are amortized based on patterns in which the economic benefits of customer relationships are expected to be utilized. Other finite-lived identifiable assets are amortized on a straight-line basis. The following are the intangible assets acquired and their respective amortizable lives (dollars in thousands):

	Amount	Amortizable Life
Core technology	$ 4,154	5-7 years
Trade name	2,382	10 years
Customer relationships	11,181	17-25 years
Total intangible assets with finite lives	$ 17,717	

(iv) Other acquisitions in 2008

During 2008, we acquired the following assets and businesses for an aggregate preliminary purchase price of $49.2 million, in which we paid $42.0 million in cash, $1.7 million in direct acquisition costs, and accrued contingent consideration and milestone payments totaling $5.5 million:

Certain assets from Mochida Pharmaceutical Co., Ltd, or Mochida. As part of the acquisition of certain assets, Mochida transferred the exclusive distribution rights in Japan for certain Osteomark products (Acquired April 2008)

Privately-owned provider of care and health management services (Acquired July 2008)

Vision Biotech Pty Ltd, or Vision, located in Cape Town, South Africa, a privately-owned distributor of rapid diagnostic products predominantly to the South African marketplace (Acquired September 2008)

Global Diagnostics CC, or Global, located in Johannesburg, South Africa, a privately-owned contract manufacturer and distributor of high quality rapid diagnostic tests predominantly to the South African marketplace (Acquired September 2008)

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(4) Business Combinations (Continued)

DiaTeam Diagnostika und Arzneimittel Großhandel GmbH, or DiaTeam, located in Linz, Austria, a privately-owned distributor of high quality rapid diagnostic tests predominantly to the Austrian marketplace (Acquired September 2008)

Prodimol Biotecnologia S.A., or Prodimol, located in Brazil, a privately-owned distributor of high quality rapid diagnostic tests predominantly to the Brazilian marketplace (Acquired October 2008)

Ameditech, Inc., or Ameditech, located in San Diego, California, a leading manufacturer of high quality drugs of abuse diagnostic tests (Acquired December 2008)

A summary of the preliminary purchase price allocation for these acquisitions is as follows (in thousands):

Current assets	$ 10,966
Property, plant and equipment	655
Goodwill	16,238
Other non-current assets	173
Intangible assets	36,938
Total assets acquired	64,970
Current liabilities	5,838
Non-current liabilities	9,955
Total liabilities assumed	15,793
Net assets acquired	49,177
Less:	
Acquisition costs	1,725
Accrued earned milestone and contingent consideration	5,466
Cash consideration	$ 41,986

Customer relationships are amortized based on patterns in which the economic benefits of customer relationships are expected to be utilized. Other finite-lived identifiable assets are amortized on a straight-line basis. The following are the intangible assets acquired and their respective amortizable lives (dollars in thousands):

	Amount	**Amortizable Life**

Core technology	$ 2,866	6-10 years
Trade names	2,690	10 years
Customer relationships	29,477	3.5-14 years
Non-compete agreements	1,063	2-5 years
Manufacturing know-how	842	5 years
Total intangible assets	$ 36,938	

Mochida, Vision, Global, DiaTeam, Prodimol and Ameditech are included in our professional diagnostics reporting unit and business segment; and the healthcare acquisition is included in our health management reporting unit and business segment. Goodwill has been recognized in the Vision, Global, DiaTeam, Prodimol and Ameditech transactions and amounted to approximately $16.2 million. Goodwill related to these acquisitions, excluding Ameditech, is not deductible for tax purposes.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(4) Business Combinations (Continued)

(b) Acquisitions in 2007

(i) Acquisition of ParadigmHealth

On December 21, 2007, we acquired ParadigmHealth, Inc., or ParadigmHealth, a privately-owned leading provider of precise medical management to provide optimal health outcomes for acutely ill and clinically complex patients. The aggregate purchase price was $236.8 million, which consisted of $236.0 million in cash and $0.8 million for direct acquisition costs. The operating results of ParadigmHealth are included in our health management reporting unit and business segment.

A summary of the purchase price allocation for this acquisition is as follows (in thousands):

Current assets	$ 34,498
Property, plant and equipment	2,163
Goodwill	168,172
Intangible assets	61,449
Total assets acquired	266,282
Current liabilities	1,094
Non-current liabilities	28,397
Total liabilities assumed	29,491
Net assets acquired	236,791
Less:	
Acquisition costs	844
Cash consideration	$ 235,947

We expect that substantially all of the amount allocated to goodwill will not be deductible for tax purposes.

Customer relationships are amortized based on patterns in which the economic benefits of customer relationships are expected to be utilized. Other finite-lived identifiable assets are amortized on a straight-line basis. The following are the intangible assets acquired and their respective amortizable lives (dollars in thousands):

	Amount	Amortizable Life
Core technology	$ 6,900	5-10 years

Trademarks	249	9 months
Software	5,100	8 years
Non-compete agreements	2,700	2 years
Customer relationships	46,500	6-21 years
Total intangible assets with finite lives	$ 61,449	

(ii) Acquisition of Redwood

On December 20, 2007, we acquired Redwood Toxicology Laboratories, Inc., or Redwood, a privately-owned drugs of abuse diagnostics and testing company. The aggregate purchase price was $53.8 million, which consisted of $53.3 million in cash and $0.5 million for direct acquisition costs. In addition, we assumed

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(4) Business Combinations (Continued)

and paid debt of $47.7 million. The operating results of Redwood are included in our professional diagnostics reporting unit and business segment.

A summary of the purchase price allocation for this acquisition is as follows (in thousands):

Current assets	$ 11,234
Property, plant and equipment	5,653
Goodwill	21,471
Intangible assets	66,020
Other non-current assets	84
Total assets acquired	104,462
Current liabilities	2,947
Non-current liabilities	47,708
Total liabilities assumed	50,655
Net assets acquired	53,807
Less:	
Acquisition costs	546
Cash consideration	$ 53,261

We expect that substantially all of the amount allocated to goodwill will not be deductible for tax purposes.

Customer relationships are amortized based on patterns in which the economic benefits of customer relationships are expected to be utilized. Other finite-lived identifiable assets are amortized on a straight-line basis. The following are the intangible assets acquired and their respective amortizable lives (dollars in thousands):

	Amount	Amortizable Life
Trademarks	$ 5,970	10 years
Non-compete agreements	2,800	2-5 years
Customer relationships	57,250	11-12.5 years
Total intangible assets with finite lives	$ 66,020	

(iii) Acquisition of Alere

On November 16, 2007, we acquired Alere Medical, Inc., or Alere Medical, a privately-held leading provider of care and health management services. The aggregate purchase price was $311.3 million, which consisted of $128.6 million in cash, common stock with an aggregate fair value of $161.1 million, $1.0 million for direct acquisition costs and $20.6 million of fair value associated with Alere Medical employee stock options which were exchanged as part of the transaction. The operating results of Alere Medical are included in our health management reporting unit and business segment.

With respect to Alere Medical, the terms of the acquisition agreement provided for contingent consideration payable to each Alere Medical stockholder who owned shares of our common stock or retained the option to purchase shares of our common stock on the six-month anniversary of the closing of the acquisition. The contingent consideration, payable in cash or stock at our election, was equal to the number of such shares of our common stock or options to purchase our common stock held on the six-month anniversary

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(4) Business Combinations (Continued)

multiplied by the amount that $58.31 exceeded the greater of the average price of our common stock for the ten business days preceding the six-month anniversary date, or 75% of $58.31. Accordingly, based on the price of our common stock for the ten business days preceding the six-month anniversary of the closing of the acquisition, we issued approximately 0.1 million shares of our common stock on May 30, 2008 to the Alere Medical stockholders based on the remaining outstanding shares at that time. Payment of this contingent consideration did not impact the purchase price for this acquisition.

A summary of the purchase price allocation for this acquisition is as follows (dollars in thousands):

Current assets	$ 13,332
Property, plant and equipment	8,897
Goodwill	262,565
Intangible assets	55,500
Other non-current assets	5,523
Total assets acquired	345,817
Current liabilities	10,651
Non-current liabilities	23,880
Total liabilities assumed	34,531
Net assets acquired	311,286
Less:	
Acquisition costs	959
Fair value of common stock issued (2,762,182 shares)	161,086
Fair value of stock options exchanged (380,894 options)	20,614
Cash consideration	$ 128,627

We expect that substantially all of the amount allocated to goodwill will not be deductible for tax purposes.

Customer relationships are amortized based on patterns in which the economic benefits of customer relationships are expected to be utilized. Other finite-lived identifiable assets are amortized on a straight-line basis. The following are the intangible assets acquired and their respective amortizable lives (dollars in thousands):

	Amount	Amortizable Life
Core technology	$ 6,100	3-6 years

Trademarks	1,500	10 years
Customer relationships	46,300	9 years
Non-compete agreements	1,600	0.5-1 year
Total intangible assets with finite lives	$ 55,500	

(iv) Acquisition of HemoSense

On November 6, 2007, we acquired HemoSense, Inc., or HemoSense, a publicly-traded developer and marketer of point-of-care testing products for therapeutic drug monitoring. The aggregate purchase price was $244.0 million, which consisted of common stock with an aggregate fair value of $226.4 million, $0.9 million for direct acquisition costs and $16.7 million of fair value associated with HemoSense employee stock options

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(4) Business Combinations (Continued)

which were exchanged as part of the transaction. The operating results of HemoSense are included in our professional diagnostics reporting unit and business segment.

A summary of the purchase price allocation for this acquisition is as follows (dollars in thousands):

Current assets	$ 23,399
Property, plant and equipment	1,936
Goodwill	137,791
Intangible assets	100,670
Other non-current assets	232
Total assets acquired	264,028
Current liabilities	15,232
Non-current liabilities	4,747
Total liabilities assumed	19,979
Net assets acquired	244,049
Less:	
Acquisition costs	939
Fair value of common stock issued (3,691,369 shares)	226,415
Fair value of stock options exchanged (380,732 options)	16,695
Cash consideration	$

We expect that substantially all of the amount allocated to goodwill will not be deductible for tax purposes.

Customer relationships are amortized based on patterns in which the economic benefits of customer relationships are expected to be utilized. Other finite-lived identifiable assets are amortized on a straight-line basis. The following are the intangible assets acquired and their respective amortizable lives (dollars in thousands):

	Amount	Amortizable Life
Core technology	$ 24,130	1-10 years
Trademarks	7,100	10 years
Customer relationships	69,100	20 years
Non-compete agreements	300	1 year
Internally-developed software	40	10 years

Total intangible assets with finite lives	$ 100,670

(v) Acquisition of Cholestech

On September 12, 2007, we acquired Cholestech Corporation, or Cholestech, a publicly-traded leading provider of diagnostic tools and information for immediate risk assessment and therapeutic monitoring of heart disease and inflammatory disorders. The aggregate purchase price was $354.7 million, which consisted of common stock with an aggregate fair value of $329.8 million, $4.6 million for direct acquisition costs and $20.3 million of fair value associated with the Cholestech employee stock options and restricted stock awards which were exchanged as part of the transaction. The operating results of Cholestech are included in our cardiology reporting unit of our professional diagnostics business segment.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(4) Business Combinations (Continued)

A summary of the purchase price allocation for this acquisition is as follows (dollars in thousands):

Current assets	$ 83,377
Property, plant and equipment	6,643
Goodwill	143,611
Intangible assets	209,078
Other non-current assets	669
Total assets acquired	443,378
Current liabilities	17,685
Non-current liabilities	71,032
Total liabilities assumed	88,717
Net assets acquired	354,661
Less:	
Acquisition costs	4,556
Fair value of common stock issued (6,840,361 shares)	329,774
Fair value of stock options/awards exchanged (733,077 options/awards)	20,331
Cash consideration	$

We expect that substantially all of the amount allocated to goodwill will not be deductible for tax purposes.

Customer relationships are amortized based on patterns in which the economic benefits of customer relationships are expected to be utilized. Other finite-lived identifiable assets are amortized on a straight-line basis. The following are the intangible assets acquired and their respective amortizable lives (dollars in thousands):

	Amount	Amortizable Life
Core technology	$ 83,833	13 years
Trademarks	20,590	10 years
Customer relationships	99,060	26 years
License agreement	355	7 years
Non-compete agreements	5,040	1.5-2 years
Internally-developed software	200	7 years
Total intangible assets with finite lives	$ 209,078	

(vi) Acquisition of Biosite

On June 29, 2007, we completed our acquisition of Biosite Incorporated, or Biosite, a publicly-traded global medical diagnostic company utilizing a biotechnology approach to create products for the diagnosis of critical diseases and conditions. The aggregate purchase price was $1.8 billion, which consisted of $1.6 billion in cash, $68.9 million in estimated direct acquisition costs and $77.4 million of fair value associated with Biosite employee stock options which were exchanged as part of the transaction. In connection with our acquisition of Biosite, we also recorded $45.2 million of compensation expense associated with unvested stock options. The operating results of Biosite are included in our cardiology reporting unit of our professional diagnostics business segment.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(4) Business Combinations (Continued)

A summary of the purchase price allocation for this acquisition is as follows (dollars in thousands):

Current assets	$ 325,804
Property, plant and equipment	145,144
Goodwill	778,734
Intangible assets	663,891
In-process research and development	169,000
Other non-current assets	102,343
Total assets acquired	2,184,916
Current liabilities	128,971
Non-current liabilities	266,621
Total liabilities assumed	395,592
Net assets acquired	1,789,324
Less:	
Acquisition costs	68,897
Cash settlement of vested stock options	51,503
Non-cash income tax benefits on stock options	2,574
Fair value of stock options exchanged (753,863 options)	25,879
Cash consideration	$ 1,640,471

As part of the purchase price allocation, IPR&D projects have been valued at $169.0 million. These are projects that have not yet achieved technological feasibility as of the date of our acquisition of Biosite.

We expect that substantially all of the amount allocated to goodwill will not be deductible for tax purposes.

Customer relationships are amortized based on patterns in which the economic benefits of customer relationships are expected to be utilized. Other finite-lived identifiable assets are amortized on a straight-line basis. The following are the intangible assets acquired and their and respective amortizable lives (dollars in thousands):

	Amount	Amortizable Life
Core technology	$ 237,691	5-19.5 years
Trademarks	78,100	10.5 years
Customer relationships	348,100	1.5-22.5 years

Total intangible assets with finite lives	$ 663,891

(vii) Acquisition of Instant

On March 12, 2007, we acquired 75% of the issued and outstanding capital stock of Instant Technologies, Inc., or Instant, a privately-owned distributor of rapid drugs of abuse diagnostic products used in the workplace, criminal justice and other testing markets. On December 28, 2007, we acquired the remaining 25% interest, bringing the aggregate purchase price to $60.8 million, which consisted of $38.9 million in cash, common stock with an aggregate fair value of $21.5 million and $0.3 million in direct acquisition costs. In addition, we assumed and paid debt of $4.9 million. The operating results of Instant are included in our professional diagnostics reporting unit and business segment.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(4) Business Combinations (Continued)

A summary of the purchase price allocation for this acquisition is as follows (dollars in thousands):

Current assets	$ 9,012
Property, plant and equipment	141
Goodwill	43,708
Intangible assets	28,520
Total assets acquired	81,381
Current liabilities	4,273
Non-current liabilities	16,334
Total liabilities assumed	20,607
Net assets acquired	60,774
Less:	
Acquisition costs	348
Fair value of common stock issued (463,399 shares)	21,530
Cash consideration	$ 38,896

We expect that the amount allocated to goodwill will not be deductible for tax purposes.

Customer relationships are amortized based on patterns in which the economic benefits of customer relationships are expected to be utilized. Other finite-lived identifiable assets are amortized on a straight-line basis. The following are the intangible assets acquired and their respective amortizable lives (dollars in thousands):

	Amount	Amortizable Life
Trademarks	$ 3,170	5 years
Customer relationships	25,350	12 years
Total intangible assets with finite lives	$ 28,520	

(viii) Other acquisitions in 2007

During the year ended December 31, 2007, we acquired the following businesses for an aggregate purchase price of $184.5 million, in which we paid $116.0 million in cash, issued 1.0 million shares of our common stock with an

aggregate fair value of $54.1 million, issued notes payable totaling $9.6 million, incurred $4.5 million in direct acquisition costs and accrued milestone payments totaling $0.3 million:

Matritech, Inc., or Matritech, located in Newton, Massachusetts and Freiburg, Germany, a biotechnology company principally engaged in the development, manufacturing, marketing, distribution and licensing of cancer diagnostic technologies and products (Acquired December 2007)

Aska Diagnostic, Inc., or Aska, located in Tokyo, Japan, a distributor of professional diagnostics in Japan (Acquired December 2007)

90.91% share in Biosystems S.A., or Biosystems, located in Cali and Bogota, Colombia, a distributor of diagnostics tests, instruments and reagents throughout Colombia (Acquired December 2007). In October 2008, we acquired the remaining 9.09% interest in Biosystems

the assets of Akubio, a research company located in Cambridge, England (Acquired October 2007)

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(4) Business Combinations (Continued)

Bio-Stat Healthcare Group, or Bio-Stat, located in Cheshire, United Kingdom, a privately-owned distributor of core laboratory and point-of-care diagnostic testing products to the U.K. marketplace (Acquired October 2007)

Spectral Diagnostics Private Limited and its affiliate Source Diagnostics (India) Private Limited, or Spectral/Source, located in New Delhi and Shimla, India, distributes professional diagnostics in India (Acquired July 2007)

52.45% share in Diamics, Inc., or Diamics, located in Novato, California, a developer of molecular-based cancer screening and diagnostic systems (Acquired July 2007)

Quality Assured Services, Inc., or QAS, located in Orlando, Florida, a privately-owned provider of diagnostic home tests and services in the U.S. marketplace (Acquired June 2007)

Orange Medical, or Orange, located in Tilburg, The Netherlands, a manufacturer and marketer of rapid diagnostic products to the Benelux marketplace (Acquired May 2007)

Promesan S.r.l., or Promesan, located in Milan, Italy, a distributor of point-of-care diagnostic testing products to the Italian marketplace (Acquired January 2007)

First Check Diagnostics LLC, or First Check, located in Lake Forrest, California, a privately-held diagnostics company in the field of home testing for drugs of abuse, including marijuana, cocaine, methamphetamines and opiates (Acquired January 2007)

the assets of Nihon Schering K.K., or NSKK, located in Japan, a diagnostic distribution business (Acquired January 2007)

Gabmed GmbH, or Gabmed, located in Nettetal, Germany, a distributor of point-of-care diagnostic testing products in the German marketplace (Acquired January 2007)

Med-Ox Chemicals Limited, or Med-Ox, located in Ottawa, Canada, a distributor of professional diagnostic testing products in the Canadian marketplace (Acquired January 2007)

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(4) Business Combinations (Continued)

A summary of the purchase price allocation for these acquisitions is as follows (in thousands):

Current assets	$ 38,518
Property, plant and equipment	4,145
Goodwill	110,255
Intangible assets	74,557
In-process research and development	4,826
Other non-current assets	838
Total assets acquired	233,139
Current liabilities	29,100
Non-current liabilities	19,584
Total liabilities assumed	48,684
Net assets acquired	184,455
Less:	
Acquisition costs	4,488
Notes payable	9,551
Accrued earned milestones	259
Fair value of common stock issued (1,017,244 shares)	54,111
Cash consideration	$ 116,046

NSKK and Promesan are included in our professional and consumer diagnostics reporting units and business segments; Matritech, Aska, Biosystems, Bio-Stat, Akubio, Spectral/Source, Orange, Gabmed and Med-Ox are included in our professional diagnostics reporting unit and business segment; QAS is included in our health management reporting unit and business segment; and First Check is included in our consumer diagnostics reporting unit and business segment. Diamics is consolidated and included in our professional diagnostics reporting unit and business segment. Goodwill has been recognized in the Matritech, Aska, Biosystems, Bio-Stat, Spectral/Source, Diamics, QAS, Orange, Gabmed, Promesan, First Check and Med-Ox transactions and amounted to approximately $110.3 million. Goodwill related to these acquisitions, with the exception of Matritech and First Check, is not deductible for tax purposes.

Customer relationships are amortized based on patterns in which the economic benefits of customer relationships are expected to be utilized. Other finite-lived identifiable assets are amortized on a straight-line

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(4) Business Combinations (Continued)

basis. The following are the intangible assets acquired and their respective amortizable lives (dollars in thousands):

	Amount	Amortizable Life
Core technology	$ 4,234	7.0-13.5 years
Supplier relationships	3,882	15 years
Trademarks	9,278	2-10 years
License agreements	920	15 years
Customer relationships	53,294	10-20 years
Non-compete agreements	801	3-4 years
Internally-developed software	1,910	7 years
Total intangible assets with finite lives	74,319	
Trademark	238	N/A
Total intangible assets with indefinite lives	238	
Total intangible assets	$ 74,557	

(c) Acquisitions in 2006

(i) Acquisition of the Innovacon business, including the ABON Facility

On March 31, 2006, we acquired the assets of ACON Laboratories business of researching, developing, manufacturing, marketing and selling lateral flow immunoassay and directly-related products in the United States, Canada, Europe (excluding Russia, the former Soviet Republics that are not part of the European Union and Turkey), Israel, Australia, Japan and New Zealand, or the Innovacon business. The preliminary aggregate purchase price was approximately $97.7 million which consisted of $55.1 million in cash, common stock with an aggregate fair value of $19.7 million, $12.9 million in estimated direct acquisition costs and an additional liability of $10.0 million which was paid in 2007, pursuant to the purchase agreement.

On May 15, 2006, as part of the Innovacon business we acquired a newly-constructed manufacturing facility in Hangzhou, China, pursuant to the terms of our acquisition agreement with ACON Laboratories, Inc. and its affiliates. In connection with the acquisition of the new facility, we acquired ABON BioPharm (Hangzhou) Co., Ltd, or ABON, the direct owner of the new factory and now our subsidiary. The preliminary aggregate purchase price was approximately $20.8 million which consisted of $8.8 million in cash and common stock with an aggregate fair value of $12.0 million. In addition, pursuant to the acquisition agreement, we made an additional payment of $4.1 million in cash as a result of the amount of cash acquired, net of indebtedness assumed, which increased the preliminary aggregate purchase price to $24.9 million.

This acquisition also had contingent payments due if the attainment of certain milestones were met. These milestones were achieved in 2008 resulting an an additional $6.0 million cash paid. We have made cash payments totaling $49.0 million and issued common stock with an aggregate fair value of $21.3 million as various milestones were achieved. This brings the aggregate purchase price for the Innovacon business, including the ABON facility to a total of $192.9 million. The operating results of the Innovacon business are included in our professional and consumer diagnostics reporting units and business segments.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(4) Business Combinations (Continued)

A summary of the purchase price allocation for this acquisition including the ABON facility discussed above is as follows (dollars in thousands):

Current assets	$ 25,914
Property, plant and equipment	10,274
Goodwill	120,920
Intangible assets	48,000
Total assets acquired	205,108
Current liabilities	4,081
Non-current liabilities	8,125
Total liabilities assumed	12,206
Net assets acquired	192,902
Less:	
Acquisition costs	12,962
Fair value of common stock issued (1,871,250 shares)	53,052
Cash consideration	$ 126,888

We expect that substantially all of the amount allocated to goodwill will not be deductible for tax purposes.

Customer relationships are amortized based on patterns in which the economic benefits of customer relationships are expected to be utilized. Other finite-lived identifiable assets are amortized on a straight-line basis. The following are the intangible assets acquired and their respective amortizable lives (dollars in thousands):

	Amount	Amortizable Life
Core technology	$ 16,200	7 years
Supplier relationships	3,300	1.8 years
Trademarks	800	10 years
Customer relationships	27,700	16.8-17.8 years
Total intangible assets with finite lives	$ 48,000	

Additionally, in connection with the acquisition of the Innovacon business, we entered into an agreement for the purchase of ACON Laboratories lateral flow immunoassay sales and distribution business in all territories not included within the territories acquired in connection with our March 31, 2006 acquisition described above. Under the terms of this agreement, in the event that this business achieves a specified level of profitability, we will acquire this business in 2009 for a formulaic price based on the revenues and earnings of the business. Alternatively, we may elect not to complete the acquisition of the business in exchange for a payment equal to 15% of the purchase price that would have been due had we elected to complete the acquisition.

(ii) Acquisition of Clondiag

On February 28, 2006, we acquired 67.45% of CLONDIAG chip technologies GmbH, or Clondiag, a privately-held company located in Jena in Germany which is developing a multiplexing technology for nucleic acid and immunoassay-based diagnostics. Pursuant to the acquisition agreement, we purchased the remaining

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(4) Business Combinations (Continued)

32.55% on August 31, 2006. The aggregate purchase price was $23.1 million, which consisted of an initial cash payment of $11.9 million, common stock with an aggregate fair value of $5.8 million, a $5.3 million cash payment to acquire the remaining 32.55% stock ownership and $0.1 million in direct acquisition costs. Additionally, pursuant to the terms of the acquisition agreement, we have an obligation to settle existing employee bonus arrangements with the Clondiag employees totaling 1.1 million ($1.3 million). In connection with this obligation, we issued common stock with a fair value of $0.7 million to the employees of Clondiag and a cash payment of $0.5 million. As of December 31, 2008, our remaining obligation was $0.1 million. This obligation increased our aggregate purchase price to $24.4 million as of December 31, 2006 and resulted in additional goodwill.

In addition, the terms of the acquisition agreement provided for contingent consideration in the event that four specified products were developed on Clondiag s platform technology during the three years following the acquisition date. This contingent consideration has been accounted for as an increase in the aggregate purchase price when the milestones are achieved. During 2007, we paid cash of $0.9 million and issued 56,079 shares of our common stock with a fair value of $1.5 million, in conjunction with Clondiag meeting one of the milestones mentioned above. During 2008, we paid cash of $2.6 million and issued 0.2 million shares of our common stock with a fair value of $4.5 million in conjunction with Clondiag meeting the final three milestones. Upon settlement of the third and fourth milestones, we recognized a $0.2 million foreign currency exchange gain which was included in the aggregate purchase price. The payments of the contingent consideration have increased our aggregate purchase price to $34.1 million. The operating expenses of Clondiag, which consist principally of research and development activities, have been included in our corporate and other business segment in 2006 and in our professional diagnostics segment in 2008 and 2007.

A summary of the purchase price allocation for this acquisition is as follows (dollars in thousands):

Current assets	$ 1,191
Property, plant and equipment	1,783
Goodwill	16,937
Intangible assets	11,310
In-process research and development	4,960
Other non-current assets	20
Total assets acquired	36,201
Current liabilities	1,296
Non-current liabilities	850
Total liabilities assumed	2,146
Net assets acquired	34,055
Less:	
Acquisition costs	92

Realized foreign currency exchange gain	221
Accrued obligation cost	55
Fair value of common stock issued (467,415 shares)	12,457
Cash consideration	$ 21,230

We also evaluated certain in-process research and development projects and have expensed, as in-process research and development, those projects that have not yet attained technical feasibility. The amount expensed during the year ended December 31, 2006 was $5.0 million.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(4) Business Combinations (Continued)

We expect that substantially all of the amount allocated to goodwill will not be deductible for tax purposes.

Other finite-lived identifiable assets are amortized on a straight-line basis. The following are the intangible assets acquired and their respective amortizable lives (dollars in thousands):

	Amount	Amortizable Life
Core technology	$ 11,310	20 years
Total intangible assets with finite lives	$ 11,310	

(d) Restructuring Plans Related to Business Combinations

In connection with several of our acquisitions, we initiated integration plans to consolidate and restructure certain functions and operations, including the relocation and termination of certain personnel of these acquired entities and the closure of certain of the acquired entities leased facilities. These costs have been recognized as liabilities assumed, in connection with the acquisition of these entities in accordance with EITF Issue No. 95-3, and are subject to potential adjustments as certain exit activities are confirmed or refined. The following table summarizes the liabilities established for exit activities related to these acquisitions (in thousands):

	Severance Related	Facility And Other	Total Exit Activities
Balance at December 31, 2005	$ 1,489	$ 939	$ 2,428
Payments	(172)	(150)	(322)
Currency adjustments	177		177
Balance at December 31, 2006	1,494	789	2,283
Acquisitions	19,823	1,327	21,150
Payments	(6,763)	(218)	(6,981)
Currency adjustments	25		25
Balance at December 31, 2007	14,579	1,898	16,477
Acquisitions	19,561	3,897	23,458
Payments	(23,407)	(854)	(24,261)
Currency adjustments	(385)	(15)	(400)
Balance at December 31, 2008	$ 10,348	$ 4,926	$ 15,274

(i) 2008 Acquisitions

In connection with our acquisition of Matria, we implemented an integration plan to improve operating efficiencies and eliminate redundant costs resulting from the acquisition. The restructuring plan impacted all cost centers within the Matria organization, as activities were combined with our existing business operations. We recorded $15.2 million in exit costs, all of which relates to change in control and severance costs to involuntarily terminate employees. As of December 31, 2008, $4.0 million in severance costs remain unpaid.

In conjunction with our acquisition of Panbio, we formulated a restructuring plan to realize efficiencies and cost savings. In February 2008, we agreed upon a plan to close Panbio s facility located in Columbia, Maryland. The manufacturing operation at the Maryland-based facility has been transferred to a third-party manufacturer and the sales and distribution of the products at this facility has been transferred to our newly-formed shared services center in Orlando, Florida. We recorded $0.6 million in exit costs, including

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(4) Business Combinations (Continued)

$0.4 million related to facility and other exit costs and $0.2 million related to severance costs. As of December 31, 2008, $0.3 million in exit costs remain unpaid. See Note 23 for additional restructuring charges related to the Panbio facility closure and integration.

Although we believe our plan and estimated exit costs for our 2008 acquisitions are reasonable, actual spending for exit activities may differ from current estimated exit costs.

(ii) 2007 Acquisitions

In conjunction with our acquisition of Biosite, we implemented an integration plan to improve efficiencies and eliminate redundant costs resulting from the acquisition. The restructuring plan impacted all cost centers within the Biosite organization, as activities were combined with our existing business operations. Since the inception of the plan, we recorded $15.4 million in exit costs, of which $15.1 million relates to change in control and severance costs to involuntarily terminate employees and $0.3 million relates to facility and other exit costs. As of December 31, 2008, $1.3 million in exit costs remain unpaid.

During 2007, we formulated restructuring plans in connection with our acquisition of Cholestech, consistent with our acquisition strategy to realize operating efficiencies and cost savings. Additionally, in March 2008, we announced plans to close the Cholestech facility in Hayward, California. We are transitioning the manufacturing of the related products to our Biosite facility in San Diego, California and have transitioned the sales and distribution of the products to our newly-formed shared services center in Orlando, Florida. Since inception of the plans, we recorded $9.2 million in exit costs, of which $6.5 million relates to executive change in control agreements and severance costs to involuntarily terminate employees and $2.7 million relates to facility exit costs. As of December 31, 2008, $6.7 million in exit costs remain unpaid.

In conjunction with our acquisition of HemoSense, we formulated restructuring plans during 2007 to realize operating efficiencies and cost savings. Additionally, in March 2008, we announced plans to close the HemoSense facility in San Jose, California. We are transitioning the manufacturing of the related products to our Biosite facility in San Diego, California and have transitioned the sales and distribution of the products to our newly-formed shared services center in Orlando, Florida. Since inception of the plans, we recorded $1.5 million in exit costs, of which $1.3 million relates to severance costs to terminate employees and $0.2 million relates to facility and other exit costs. As of December 31, 2008, $0.5 million in exit costs remain unpaid.

See Note 23 for additional restructuring charges related to the Cholestech and HemoSense facility closures and integration.

In conjunction with our acquisition of Matritech, we formulated a plan to exit the leased facility of Matritech in Newton, Massachusetts and recorded $1.5 million in facility exit costs. As of December 31, 2008, $1.1 million of the facility exit costs remain unpaid.

In conjunction with our acquisition of Alere Medical and ParadigmHealth, we recorded $2.2 million related to executive change in control agreements and severance costs to involuntarily terminate employees. As of December 31,

2008, $0.9 million remains unpaid.

Although we believe our plans and estimated exit costs for our 2007 acquisitions are reasonable, actual spending for exit activities may differ from current estimated exit costs.

(iii) Other Acquisitions

As a result of our acquisition of Ostex in 2003, we established a restructuring plan whereby we exited the facilities of Ostex in Seattle, Washington, and combined the activities of Ostex with our existing manufacturing and distribution facilities. Total severance costs associated with involuntarily terminated

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(4) Business Combinations (Continued)

employees were $1.6 million, all of which has been paid as of December 31, 2006. Facility exit costs, including costs to vacate the Ostex facilities and lease commitments, were $2.4 million, of which $0.4 million remains unpaid as of December 31, 2008.

(e) Pro Forma Financial Information

The following table presents selected unaudited financial information, including the assets of Instant, Biosite, Cholestech and Matria, as if the acquisitions of these entities had occurred on January 1, 2007. Pro forma results also reflect the impact of the formation of our consumer diagnostics business joint venture with P&G (Note 13(a)(i)) as if the joint venture had been formed on January 1, 2007. Pro forma results exclude adjustments for various other less significant acquisitions completed since January 1, 2007, as these acquisitions did not materially affect our results of operations.

The pro forma results are derived from the historical financial results of the acquired businesses for all periods presented and are not necessarily indicative of the results that would have occurred had the acquisitions been consummated on January 1, 2007 (in thousands, except pet share amount).

	2008	2007
	(unaudited)	
Pro forma net revenue	$ 1,783,801	$ 1,362,196
Pro forma net loss available to common shareholders	$ (47,793)	$ (131,732)
Pro forma net loss per common share basic and diluted(1)	$ (0.61)	$ (2.34)

(1) Net loss per common share amounts are computed as described in Note 15.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(5) Goodwill and Other Intangible Assets

The following is a summary of goodwill and other intangible assets as of December 31, 2008 (in thousands, except useful life):

	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value	Useful Life
Amortized intangible assets:				
Core technology and patents	$ 547,816	$ 88,509	$ 459,307	1-20 years
Other intangible assets:				
Supplier relationships	17,167	10,477	6,690	1.8-15 years
Trademarks and trade names	151,245	27,612	123,633	2-25 years
License agreements	10,445	9,655	790	5-8.5 years
Customer relationships	1,151,893	175,150	976,743	1.5-26 years
Manufacturing know-how	7,208	3,825	3,383	5-15 years
Other	78,469	20,378	58,091	0.5-11 years
Total other intangible assets	1,416,427	247,097	1,169,330	
Total intangible assets with finite lives	$ 1,964,243	$ 335,606	$ 1,628,637	
Intangible assets with indefinite lives:				
Goodwill	$ 3,046,083	$	$ 3,046,083	
Other intangible assets	42,984		42,984	
Total intangible assets with indefinite lives	$ 3,089,067	$	$ 3,089,067	

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(5) Goodwill and Other Intangible Assets (Continued)

The following is a summary of goodwill and other intangible assets as of December 31, 2007 (in thousands, except useful life):

	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value	Useful Life
Amortized intangible assets:				
Core technology and patents	$ 476,609	$ 44,026	$ 432,583	1-20 years
Other intangible assets:				
Supplier relationships	18,307	9,101	9,206	1.8-15 years
Trademarks and trade names	137,352	11,964	125,388	5-25 years
License agreements	10,105	8,167	1,938	5-8.5 years
Customer relationships	770,230	46,516	723,714	1.5-26 years
Manufacturing know-how	3,616	3,558	58	1-15 years
Other	10,938	1,598	9,340	0.5-10 years
Total other intangible assets	950,548	80,904	869,644	
Total intangible assets with finite lives	$ 1,427,157	$ 124,930	$ 1,302,227	
Intangible assets with indefinite lives:				
Goodwill	$ 2,148,850	$	$ 2,148,850	
Other intangible assets	43,097		43,097	
Total intangible assets with indefinite lives	$ 2,191,947	$	$ 2,191,947	

We amortize intangible assets with finite lives using primarily the straight-line method over the above estimated useful lives of the respective intangible asset. We believe that the straight-line method is appropriate, as it approximates the pattern in which economic benefits are consumed in circumstances where such patterns can be reliably determined. In certain circumstances, such as certain customer relationship assets, accelerated amortization is recognized which reflect estimate of the cash flows. Amortization expense of intangible assets, which in the aggregate amounted to $214.1 million, $64.6 million and $21.8 million in 2008, 2007 and 2006, respectively, is included in cost of net revenue, research and development, sales and marketing and general and administrative in the accompanying consolidated statements of operations. During 2006, there was no amortization expense included in general and administrative on the accompanying consolidated statement of operations. The allocation of amortization expense to the expense categories is based on the intended usage and the expected benefits of the intangible assets in relation to the expense categories.

The following is a summary of estimated aggregate amortization expense of intangible assets for each of the five succeeding fiscal years as of December 31, 2008 (in thousands):

2009	$ 233,399
2010	$ 207,012
2011	$ 182,741
2012	$ 159,117
2013	$ 139,607

In accordance with SFAS No. 142, we perform annual impairment tests of the carrying value of our goodwill by reporting unit. Our annual impairment review on September 30, 2008 did not indicate that

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(5) Goodwill and Other Intangible Assets (Continued)

goodwill related to our professional diagnostics, health management and consumer diagnostics reporting units were impaired. For further discussion see Note 2(h).

We allocate goodwill by reporting unit based on the relative percentage of estimated future revenues generated for the respective reporting unit as of the acquisition date. Goodwill amounts allocated to our professional diagnostics, health management and consumer diagnostics reporting units are summarized as follows (in thousands):

	Professional Diagnostics	Health Management	Consumer Diagnostics	Total
Goodwill at December 31, 2006	$ 353,361	$	$ 86,008	$ 439,369
Acquisitions(1)	1,267,985	463,066	8,940	1,739,991
Other(2)(3)	13,254		(43,764)	(30,510)
Goodwill at December 31, 2007	1,634,600	463,066	51,184	2,148,850
Acquisitions(1)	93,473	817,113	1,497	912,083
Other(2)	(14,850)			(14,850)
Goodwill at December 31, 2008	$ 1,713,223	$ 1,280,179	$ 52,681	$ 3,046,083

(1) Includes purchase accounting adjustments recorded to the acquired entities opening balance sheet and additional payments made for earn-outs and milestones achieved.

(2) These amounts relate primarily to adjustments resulting from fluctuations in foreign currency exchange rates.

(3) Includes amounts written off in connection with the formation of our 50/50 joint venture with P&G.

We generally expense costs incurred to internally-develop intangible assets, except for costs that are incurred to establish patents and trademarks, such as legal fees for initiating, filing and obtaining the patents and trademarks. As of December 31, 2008, we had approximately $7.8 million of costs capitalized, net of amortization, in connection with establishing patents and trademarks which are included in other intangible assets, net, in the accompanying consolidated balance sheets. Upon the successful registration of the patents and trademarks, we commence amortization of such intangible assets over their estimated useful lives. Costs incurred to maintain the patents and trademarks are expensed as incurred.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(6) Long-term Debt

We had the following long-term debt balances outstanding (in thousands):

	December 31, 2008	December 31, 2007
First Lien Credit Agreement Term loan	$ 960,750	$ 970,500
First Lien Credit Agreement Revolving line-of-credit	142,000	
Second Lien Credit Agreement	250,000	250,000
3% Senior subordinated convertible notes	150,000	150,000
Lines-of-credit	3,503	3,730
Other	13,362	12,485
	1,519,615	1,386,715
Less: Current portion	(19,058)	(20,320)
	$ 1,500,557	$ 1,366,395

The following describes each of the above listed debt instruments:

(a) First Lien Credit Agreement and Second Lien Credit Agreement

On June 26, 2007, in conjunction with our acquisition of Biosite, we entered into a First Lien Credit Agreement, or senior secured credit facility, and a Second Lien Credit Agreement, or junior secured credit facility, collectively, secured credit facility, with certain lenders, General Electric Capital Corporation as administrative agent and collateral agent, and certain other agents and arrangers, and certain related guaranty and security agreements. The senior secured credit facility initially provided for term loans in the aggregate amount of $900.0 million and, subject to our continued compliance with the senior secured credit facility, a $150.0 million revolving line-of-credit. The junior secured credit facility provides for term loans in the aggregate amount of $250.0 million. We may repay any future borrowings under the senior secured credit facility revolving line-of-credit at any time, but in no event later than June 26, 2013. We must repay the entire junior facility term loan on June 26, 2015. As of December 31, 2008, the term loans and the revolving line-of-credit under the senior secured credit facility bore interest at 3.89% and 3.64%, respectively. The term loan under the junior secured credit facility bore interest at 6.14%.

On November 15, 2007, we amended the senior secured credit facility, increasing the total amount of credit available to us to $1,125,000,000 resulting from the increase in the term loans to the aggregate amount of $975.0 million. Additionally, under the amendment, we must repay the senior secured credit facility term loans as follows: (a) in two initial installments in the amount of $2,250,000 each on September 30, 2007 and December 31, 2007 (each of which installment payment has been made), (b) in twenty-five consecutive quarterly installments, beginning on March 31, 2008 and continuing through March 31, 2014, in the amount of $2,437,500 each and (c) in a final installment on June 26, 2014 in an amount equal to the then outstanding principal balance of the senior secured credit facility term

loans.

As of December 31, 2008, aggregate borrowings amounted to $142.0 million under the senior secured credit facility revolving line-of-credit and $1.2 billion under the term loans. Interest expense related to the secured credit facility for the year ended December 31, 2008, including amortized deferred financing costs, was $85.2 million. As of December 31, 2008, accrued interest related to the credit facilities amounted to $3.4 million. As of December 31, 2008, we were in compliance with all debt covenants related to the above debt, which consisted principally of maximum consolidated leverage and minimum interest coverage requirements.

In August 2007, we entered into interest rate swap contracts, with an effective date of September 28, 2007, that have a total notional value of $350.0 million and have a maturity date of September 28, 2010.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(6) Long-term Debt (Continued)

These interest rate swap contracts pay us variable interest at the three-month LIBOR rate, and we pay the counterparties a fixed rate of 4.85%. These interest rate swap contracts were entered into to convert $350.0 million of the $1.2 billion variable rate term loan under the senior credit facility into fixed rate debt. Based on the terms of the interest rate swap contracts and the underlying debt, these interest rate swap contracts were determined to be effective, and thus qualify as a cash flow hedge under SFAS No. 133. As such, any changes in the fair market value of these interest rate swaps are recorded in accumulated other comprehensive income on the accompanying consolidated balance sheet until earnings are affected by the variability of cash flows. As of December 31, 2008 and 2007, we recorded cumulative changes of $21.1 million and $9.5 million, respectively, in accumulated other comprehensive income on the accompanying balance sheets.

In January 2009, we entered into interest rate swap contracts, with an effective date of January 14, 2009, that have a total notional value of $500.0 million and have a maturity date of January 5, 2011. These interest rate swap contracts pay us variable interest at the one-month LIBOR rate, and we pay the counterparties a fixed rate of 1.195%. These interest rate swap contracts were entered into to convert $500.0 million of the $1.2 billion variable rate term loan under the secured credit facility into fixed rate debt.

(b) 3% Senior Subordinated Convertible Notes, Principal Amount $150.0 million

On May 14, 2007, we sold $150.0 million principal amount of 3% senior subordinated convertible notes due 2016 (the Convertible Notes) in a private placement to qualified institutional buyers. At the initial conversion price of $52.30, the Convertible Notes were convertible into an aggregate 2,868,120 shares of our common stock. The conversion price was subject to adjustment one year from the date of sale. Based upon the daily volume-weighted price per share of our common stock for the thirty consecutive trading days ending May 9, 2008, the conversion price decreased from $52.30 to $43.98 in May 2008. The decrease in conversion price resulted in additional shares of our common stock becoming issuable upon conversion of our senior subordinated convertible notes. The senior subordinated convertible notes are now convertible into 3.4 million shares of our common stock at a conversion price of $43.98. Interest accrues at 3% per annum, compounded daily, on the outstanding principal amount and is payable in arrears on May 15th and November 15th, which started on November 15, 2007. Interest expense for the year ended December 31, 2008 and 2007, including amortized deferred costs, was $5.0 million and $3.1 million, respectively.

We evaluated the Convertible Notes agreement for potential embedded derivatives under SFAS No. 133 and related applicable accounting literature, including EITF Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock* , and EITF Issue No. 05-4, *The Effect of a Liquidated Damages Clause on a Freestanding Financial Instrument Subject to Issue No. 00-19*. The conversion feature and the make-whole provision were determined to not meet the embedded derivative criteria as set forth by SFAS No. 133. Therefore, no fair value has been recorded for these items.

(c) Prior Senior Credit Facility

As of December 31, 2006, $44.8 million of borrowings were outstanding under our then senior credit facility dated June 30, 2005. On February 1, 2007, using a portion of the proceeds from our January 2007 sale of 6.9 million shares of common stock (Note 16), we paid the remaining principal balance outstanding and accrued interest under the June

2005 senior credit facility. We terminated our June 2005 senior credit facility in conjunction with our refinancing activities discussed above. We had no outstanding loans under the June 2005 senior credit facility at the time it was terminated.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(6) Long-term Debt (Continued)

Borrowings under the revolving lines-of-credit and term loan bore interest at either (i) the London Interbank Offered Rate (LIBOR), as defined in the agreement, plus applicable margins or, at our option or (ii) a floating Index Rate, as defined in the agreement, plus applicable margins. For the year ended December 31, 2007, interest expense, including amortization of deferred financing costs, under this senior credit facility was $4.7 million. Included in interest expense is the write-off of $2.6 million, in unamortized deferred financing costs.

For the year ended December 31, 2006, we recorded interest expense, including amortization of deferred financing costs, under these senior credit facilities in the aggregate amount of $8.9 million.

(d) Senior Subordinated Notes, 8.75%, Principal Amount $150.0 million

On June 26, 2007, we fully repaid our 8.75% senior subordinated notes due 2012 (the Notes). The total amount repaid, including principal of $150.0 million and a prepayment premium of $9.3 million, was $159.3 million. Accrued interest of $4.8 million was also paid as part of the final settlement of these Notes and unamortized deferred financing costs of $3.7 million were written off as a result of the repayment.

(e) Lines-of-credit

Some of our subsidiaries maintain a local line-of-credit for short-term advances. At December 31, 2008, a total of $3.5 million was borrowed against these local lines-of-credit.

(f) Other Debt

Included in other above, for the year ended December 31, 2008, are borrowings by certain of our subsidiaries from various financial institutions. The borrowed funds are used to fund capital expenditure and working capital requirements. Interest expense on these borrowings was $1.4 million for the year ended December 31, 2008.

(g) Maturities of Long-term Debt

The following is a summary of the maturities of long-term debt outstanding on December 31, 2008 (in thousands):

2009	$ 19,058
2010	15,372
2011	11,158
2012	10,177
2013	9,850
Thereafter	1,454,000
	$ 1,519,615

(7) Fair Value Measurements

Effective January 1, 2008, we implemented SFAS No. 157, *Fair Value Measurement*, for our financial assets and liabilities that are re-measured and reported at fair value at each reporting period-end date, and non-financial assets and liabilities that are re-measured and reported at fair value at least annually. In accordance with the provisions of FASB Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157,* we have elected to defer implementation of SFAS No. 157 as it relates to our non-financial assets and non-financial liabilities that are recognized and disclosed at fair value in the financial statements on a non-

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(7) Fair Value Measurements (Continued)

recurring basis until January 1, 2009. We are evaluating the impact, if any, this Standard will have on our non-financial assets and liabilities. The adoption of SFAS No. 157 to our financial assets and liabilities and non-financial assets and liabilities that are re-measured and reported at fair value at least annually did not have an impact on our financial results.

Financial assets and liabilities recorded on the accompanying condensed consolidated balance sheets are categorized based on the inputs to the valuation techniques as follows:

Level 1 - Financial assets and liabilities whose values are based on unadjusted quoted prices for identical assets or liabilities in an active market that the company has the ability to access at the measurement date (examples include active exchange-traded equity securities, listed derivatives and most U.S. Government and agency securities).

Level 2 - Financial assets and liabilities whose values are based on quoted prices in markets where trading occurs infrequently or whose values are based on quoted prices of instruments with similar attributes in active markets. Level 2 inputs include the following:

Quoted prices for identical or similar assets or liabilities in non-active markets (examples include corporate and municipal bonds which trade infrequently);

Inputs other than quoted prices that are observable for substantially the full term of the asset or liability (examples include interest rate and currency swaps); and

Inputs that are derived principally from or corroborated by observable market data for substantially the full term of the asset or liability (examples include certain securities and derivatives).

Level 3 - Financial assets and liabilities whose values are based on prices or valuation techniques that require inputs that are both unobservable and significant to the overall fair value measurement. These inputs reflect management s own assumptions about the assumptions a market participant would use in pricing the asset or liability. We currently do not have any Level 3 financial assets or liabilities.

The following table presents information about our assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2008, and indicates the fair value hierarchy of the valuation techniques we utilized to determine such fair value (in thousands):

Description	December 31, 2008	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)
Assets:			

Marketable securities	$	2,354	$	2,354	$	
Strategic investments(1)		229		229		
Total assets	$	2,583	$	2,583	$	
Liabilities:						
Interest rate swap liability(2)	$	21,132	$		$	21,132
Total liabilities	$	21,132	$		$	21,132

(1) Represents our investment in StatSure which is included in investments in unconsolidated entities on our accompanying consolidated balance sheets.

(2) Included in other long-term liabilities in our accompanying consolidated balances sheets.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(8) Capital Leases

The following is a schedule of the future minimum lease payments under the capital leases, together with the present value of such payments as of December 31, 2008 (in thousands):

2009	$ 495
2010	362
2011	84
2012	10
2013	22
Total future minimum lease payments	973
Less: Imputed interest	(54)
Present value of future minimum lease payments	919
Less: Current portion	(451)
	$ 468

At December 31, 2008, the capitalized amounts of the building, machinery and equipment and computer equipment under capital leases were as follows (in thousands):

Machinery, laboratory equipment and tooling	$ 1,077
Computer equipment	269
Furniture and fixtures	141
	1,487
Less: Accumulated amortization	(514)
	$ 973

The amortization expense of assets recorded under capital leases is included in depreciation and amortization expense of property, plant and equipment.

(9) Postretirement Benefit Plans

(a) Employee Savings Plans

Our company and several of our U.S.-based subsidiaries sponsor various 401(k) savings plans, to which eligible domestic employees may voluntarily contribute a portion of their income, subject to statutory limitations. In addition

to the participants own contributions to these 401(k) savings plans, we match such contributions up to a designated level. Total matching contributions related to employee savings plans were $4.6 million, $1.5 million and $0.8 million in 2008, 2007 and 2006, respectively.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(9) Postretirement Benefit Plans (Continued)

(b) U.K. Pension Plans

Changes in benefit obligations, plan assets, funded status and amounts recognized on the balance sheet as of and for the years ended December 31, 2008 and 2007, for our Defined Benefit Plan, were as follows (in thousands):

	2008	2007
Change in projected benefit obligation		
Benefit obligation at beginning of year	$ 12,627	$ 12,370
Interest cost	677	660
Actuarial loss (gain)	534	(470)
Benefits paid	(182)	(140)
Curtailment gain	(1,113)	
Foreign exchange impact	(3,465)	207
Benefit obligation at end of year	$ 9,078	$ 12,627
Change in accumulated benefit obligation		
Benefit obligation at beginning of year	$ 9,159	$ 8,959
Interest cost	677	660
Actuarial loss (gain)	534	(470)
Benefits paid	(182)	(140)
Curtailment gain	(1,113)	
Foreign exchange impact	(2,508)	150
Benefit obligation at end of year	$ 6,567	$ 9,159
Change in plan assets		
Fair value of plan assets at beginning of year	$ 9,143	$ 8,189
Actual return on plan assets	(1,543)	220
Employer contribution	835	750
Benefits paid	(182)	(150)
Foreign exchange impact	(2,325)	134
Fair value of plan assets at end of year	$ 5,928	$ 9,143
Funded status at end of year	$ (3,150)	$ (3,484)

The net amounts recognized in the accompanying consolidated balance sheets are as follows (in thousands):

	2008	2007
Accrued benefit asset (liability)	$ (603)	$ 34
Long-term benefit liability	(5,498)	(4,594)
Intangible asset	2,951	1,076
Net amount recognized	$ (3,150)	$ (3,484)

The measurement date used to determine plan assets and benefit obligations for the Defined Benefit Plan was December 31, 2008 and 2007.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(9) Postretirement Benefit Plans (Continued)

The following table provides the weighted-average actuarial assumptions:

	2008	2007
Assumptions used to determine benefit obligations:		
Discount rate	6.10%	5.80%
Rate of compensation increase	3.85%	4.15%
Assumptions used to determine net periodic benefit cost:		
Discount rate	5.80%	5.25%
Expected return on plan assets	7.20%	7.30%
Rate of compensation increase	4.15%	3.80%

The actuarial assumptions are reviewed on an annual basis. The overall expected long-term rate of return on plan assets assumption was determined based on historical investment return rates on portfolios with a high proportion of equity securities.

The annual cost of the Defined Benefit Plan is as follows (in thousands):

	2008	2007	2006
Interest cost	$ 677	$ 660	$ 586
Expected return on plan assets	(634)	(620)	(461)
Amortization of net loss	(80)	(90)	(26)
Curtailment gain	(1,113)		
Net periodic benefit cost (benefit)	$ (1,150)	$ (50)	$ 99

The plan assets of the Defined Benefit Plan comprise of a mix of stocks and fixed income securities and other investments. At December 31, 2008, these stocks and fixed income securities represented 63% and 37%, respectively, of the market value of the pension assets. We expect to contribute approximately 0.5 million British Pounds Sterling (or $0.6 million at December 31, 2008) to the Defined Benefit Plan in 2009. We expect benefits to be paid to plan participants of approximately $0.2 million per year for each of the next five years and for benefits totaling $0.2 million to be paid annually for the five years thereafter.

Unipath Limited, or Unipath contributed $1.0 million in 2008 and $1.2 million in 2007 and 2006 to a Defined Contribution Plan, which was recognized as an expense in the accompanying consolidated statement of operations.

(10) Derivative Financial Instruments

We use derivative financial instruments (interest rate swap contracts) in the management of our interest rate exposure related to our senior credit facilities. We do not hold or issue derivative financial instruments for speculative purposes.

In August 2007, we entered into interest rate swap contracts, with an effective date of September 28, 2007, that have a total notional value of $350.0 million and have a maturity date of September 28, 2010. These interest rate swap contracts pay us variable interest at the three-month LIBOR rate, and we pay the counterparties a fixed rate of 4.85%. These interest rate swap contracts were entered into to convert $350.0 million of the $1.2 billion variable rate term loan under the senior credit facility into fixed rate debt. Based on the terms of the interest rate swap contracts and the underlying debt, these interest rate swap contracts were determined to be effective, and thus qualify as a cash flow hedge under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. As such, any changes in the fair value of these

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(10) Derivative Financial Instruments (Continued)

interest rate swaps are recorded in other comprehensive income on the accompanying consolidated balance sheet until earnings are affected by the variability of cash flows. As of December 31, 2008 and 2007, we recorded cumulative changes of $21.1 million and $9.5 million, respectively, in accumulated other comprehensive income on the accompanying balance sheets in connection with our interest rate swap contracts.

See Note 13(b) regarding our Chembio Diagnostics, Inc., or Chembio, warrants and Note 13(d) regarding StatSure Diagnostic Systems, Inc., or StatSure, warrants which are accounted for as derivative instruments.

(11) Commitments and Contingencies

(a) Operating Leases

We have operating lease commitments for certain of our facilities and equipment that expire on various dates through 2021. The following schedule outlines future minimum annual rental payments under these leases at December 31, 2008 (in thousands):

2009	$ 25,377
2010	19,159
2011	15,380
2012	11,011
2013	9,985
Thereafter	13,470
	$ 94,382

Rent expense relating to operating leases was approximately $35.4 million, $17.4 million and $11.8 million during 2008, 2007 and 2006, respectively.

(b) Capital Expenditure Commitments

At December 31, 2008, we had total outstanding non-cancelable equipment purchase commitments of $17.5 million.

(c) Contingent Consideration Obligations

We have contingent consideration contractual terms related to our acquisitions of Alere Medical, Ameditech, Binax, Inc., or Binax, Bio-Stat, Clondiag, Diamics, First Check, Gabmed, Global, Matritech, Promesan, Spectral/Source, Vision and our most recently acquired healthcare business. With the exception of Alere Medical, the contingent considerations will be accounted for as increases in the aggregate purchase prices if and when the contingencies occur.

With respect to Alere Medical, the terms of the acquisition agreement provided for contingent consideration payable to each Alere Medical stockholder who owned shares of our common stock or retained the option to purchase shares of our common stock on the six-month anniversary of the closing of the acquisition. The contingent consideration, payable in cash or stock at our election, was equal to the number of such shares of our common stock or options to purchase our common stock held on the six-month anniversary multiplied by the amount that $58.31 exceeded the greater of the average price of our common stock for the ten business days preceding the six-month anniversary date, or 75% of $58.31. Accordingly, based on the price of our common stock for the ten business days preceding the six-month anniversary of the closing of the acquisition, we issued approximately 0.1 million shares of our common stock on May 30, 2008 to the Alere

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(11) Commitments and Contingencies (Continued)

Medical stockholders based on the remaining outstanding shares at that time. Payment of this contingent consideration did not impact the purchase price for this acquisition.

With respect to Ameditech, the terms of the acquisition agreement require us to pay an earn-out upon successfully meeting certain revenue targets for the one year period ending on the first anniversary of the acquisition date and the one year period ending on the second anniversary of the acquisition date. The maximum amount of incremental consideration payable is $4.0 million.

With respect to Binax, the terms of the acquisition agreement provide for $11.0 million of contingent cash consideration payable to the Binax shareholders upon the successful completion of certain new product developments during the five years following the acquisition. As of December 31, 2008, the remaining contingent consideration to be earned is approximately $7.3 million.

With respect to Bio-Stat, the terms of the acquisition provided for contingent consideration payable in the form of loan notes to the Bio-Stat shareholders, if certain EBITDA (earnings before interest, taxes, depreciation and amortization) milestones were met for 2007. The EBITDA milestones were met in 2007 and loan notes totaling £3.4 million ($6.2 million) were issued during the third quarter of 2008. As of December 31, 2008, the loan notes remain outstanding with an approximate value of $4.9 million.

With respect to Clondiag, the terms of the acquisition agreement provided for $8.9 million of contingent consideration, consisting of approximately 0.2 million shares of our common stock and approximately $3.0 million of cash or stock in the event that four specified products were developed on Clondiag s platform technology during the three years following the acquisition date. Successful completion of the second milestone occurred during the first quarter of 2008 for which we made a payment for $0.9 million and issued 56,080 shares of our common stock during the first quarter of 2008. Successful completion of the third and fourth milestones occurred during the third quarter of 2008 for which we made payment for $1.6 million and issued 0.1 million shares of our common stock during the fourth quarter of 2008. No further milestones exist.

With respect to Diamics, the terms of the acquisition agreement provide for contingent consideration payable upon the successful completion of certain milestones, including development of business plans and marketable products. As of December 31, 2008, the remaining contingent consideration to be earned is approximately $2.3 million.

With respect to First Check, the terms of the acquisition agreement required us to pay an earn-out to First Check equal to the incremental revenue growth of the acquired products for 2007 and for the first nine months of 2008, as compared to the immediately preceding comparable periods. The 2007 milestone, totaling $2.2 million, was met and accrued as of December 31, 2007 and was paid during the first quarter of 2008. The 2008 milestone, totaling $0.3 million, was met and accrued during the third quarter of 2008 and was paid in the fourth quarter of 2008. No further milestones exist.

With respect to Gabmed, the terms of the acquisition agreement provide for contingent consideration totaling up to 750,000 payable in up to five annual amounts beginning in 2007, upon successfully meeting certain revenue and EBIT (earnings before interest and taxes) milestones in each of the respective annual periods. The 2007 milestone, totaling

0.1 million ($0.2 million), was met and accrued as of June 30, 2008 and was paid during the third quarter of 2008.

With respect to Global, the terms of the acquisition agreement provided for contingent consideration payable upon successfully meeting certain revenue targets in 2008. As of December 31, 2008, the 2008 revenue targets were met resulting in accrued contingent consideration totaling $0.2 million. No further milestones exist.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(11) Commitments and Contingencies (Continued)

With respect to Matritech, the terms of the acquisition agreement required us to pay an earn-out to the former Matritech shareholders upon successfully meeting certain revenue targets in 2008. As of December 31, 2008, the milestones were not achieved. No further milestones exits.

With respect to Promesan, the terms of the acquisition agreement provide for contingent consideration payable upon successfully meeting certain annual revenue targets. Total contingent consideration of up to 0.6 million is payable in three equal annual amounts of 0.2 million beginning in 2007 and ending in 2009. The 2007 milestone, totaling 0.2 million ($0.3 million), was met and accrued as of December 31, 2007 and was paid during the first quarter of 2008. The 2008 milestone, totaling 0.2 million ($0.3 million), was met and accrued as of December 31, 2008.

With respect to Spectral/Source, the terms of the acquisition agreement required us to pay an earn-out equal to two times the consolidated revenue of Spectral/Source less $4.0 million, if the consolidated profits before tax of Spectral/Source was at least $0.9 million on the one year anniversary (milestone period) following the acquisition date. If consolidated profits before tax of Spectral/Source for the milestone period were less than $0.9 million, then the amount of the payment would be equal to seven times Spectral/Source s consolidated profits before tax less $4.0 million. The contingent consideration was payable 60% in cash and 40% in stock. The revenue and profit milestones were met and accrued during the fourth quarter of 2008 for which we made payment for $1.6 million and issued 53,372 shares of our common stock during the fourth quarter of 2008. No further milestones exist.

With respect to Vision, the terms of the acquisition agreement provide for incremental consideration payable to the former Vision shareholders. The maximum amount of incremental consideration payable is approximately $3.2 million, of which $1.0 million is guaranteed and accrued as of December 31, 2008. The remaining contingent consideration is payable upon the completion of certain milestones and successfully maintaining certain production levels and product costs during each of the two years following the acquisition date. As of December 31, 2008, no milestones have been met.

With respect to our most recently-acquired healthcare business, the terms of the acquisition agreement provide for contingent consideration payable upon successfully meeting certain revenue and EBITDA targets for the twelve months ending June 30, 2009 and December 31, 2010, respectively. We accrued a liability in the amount of $3.8 million to avoid recognition of negative goodwill, as a result of not recognizing additional purchase price consideration that is contingent on future events. As of December 31, 2008, the $3.8 million liability remains accrued.

(d) Legal Proceedings

Estate of Melissa Prince Quisenberry v. Alere Medical, Inc., TA Associates, Inc., Covington Associates, et al.

On September 19, 2008, the Estate of Melissa Prince Quisenberry filed a class action complaint in the Superior Court of California on behalf of herself and others similarly situated against Alere Medical Inc., or Alere Medical, and Agora Parent, Inc., both of which are wholly owned subsidiaries; Ronald D. Geraty, MD, chief executive officer of Alere Medical and certain other individuals who were executive officers, directors and/or significant shareholders of Alere Medical; as well as certain other unaffiliated entities. Plaintiff and class owned common and/or preferred stock in Alere Medical and allege that the defendants forced them to tender their stock in connection with the March 14,

2007 sale of Alere Medical to an unaffiliated entity at a price which was substantially lower than the price at which we bought Alere Medical on October 24, 2007. Plaintiff also alleges that the individual defendants breached fiduciary duties of good faith, fair dealing, loyalty and candor; and that Alere Medical and certain unaffiliated entities aided, abetted and substantially participated in the breach of fiduciary duty. We believe that we have strong defenses to all of the allegations

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(11) Commitments and Contingencies (Continued)

made by the class and we intend to defend the claims vigorously. However, an outcome against Alere Medical could potentially have a material adverse impact on our sales, operations or financial performance.

Healthways, Inc. and Robert Bosch North America Corp, v. Alere Medical, Inc.

Healthways, Inc. and Robert Bosch North America Corp. filed a complaint in U.S. District Court in the Northern District of Illinois on November 5, 2008 against Alere Medical, Inc. alleging infringement of 11 patents, licensed by Bosch from Healthways. Alere Medical answered the complaint and filed counterclaims seeking declarations that the patents are invalid and not infringed. The plaintiffs subsequently filed an amended complaint substituting Alere LLC, or Alere, our consolidated health management subsidiary, as the defendant in place of Alere Medical. We believe that we have strong defenses to Healthways allegations and we intend to defend them vigorously. However, a ruling against Alere could potentially have a material adverse impact on our sales, operations or financial performance or could limit our current or future business opportunities.

Claims in the Ordinary Course and Other Matters

We are not a party to any other pending legal proceedings that we currently believe could have a material adverse impact on our sales, operations or financial performance. However, because of the nature of our business, we may be subject at any particular time to commercial disputes, consumer product claims, negligence claims or various other lawsuits arising in the ordinary course of our business, including infringement, employment or investor matters, and we expect that this will continue to be the case in the future. Such lawsuits generally seek damages, sometimes in substantial amounts.

As an example, as we have previously reported, in April 2008, Pyramid Holdings Inc., a purchaser in our November 2007 public offering of our common stock, filed a putative securities class action against us, Ron Zwanziger, our chairman, chief executive officer and president, and David Teitel, our chief financial officer, in the United States District Court for the District of Massachusetts, alleging that the prospectus supplement and registration statement with respect to the November 2007 public offering were inaccurate and misleading and omitted to state material facts. The plaintiffs have subsequently filed their amended class action complaint, adding as defendants each of our then current directors, a former director, and a former chief financial officer. We believe that the allegations are baseless, and we intend to defend against them vigorously.

Also, our subsidiary Alere Medical continues to defend infringement claims brought by Health Hero Network, Inc., which alleges to have patented certain processes related to home monitoring of patients.

While we believe that we have strong defenses to the claims brought by Pyramid Holdings and Health Hero and we intend to defend them vigorously, these, or other claims, could potentially have a negative impact on our sales, operations or financial performance or could limit our existing or future business opportunities.

In addition, we aggressively defend our patent and other intellectual property rights. This often involves bringing infringement or other commercial claims against third parties. These suits can be expensive and result in counterclaims challenging the validity of our patents and other rights.

(12) Co-development Agreement with ITI Scotland Limited

On February 25, 2005, we entered into a co-development agreement with ITI Scotland Limited, or ITI, whereby ITI agreed to provide us with £30.0 million over three years to partially fund research and development programs focused on identifying novel biomarkers and near-patient and home-use tests for cardiovascular and other diseases (the programs). We agreed to invest £37.5 million in the programs over three years from the date of the agreement. Through our subsidiary, Stirling Medical Innovations Limited, or Stirling, we established a new research center in Stirling, Scotland, where we consolidated many of our

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(12) Co-development Agreement with ITI Scotland Limited (Continued)

existing cardiology programs and will ultimately commercialize products arising from the programs. ITI and Stirling will have exclusive rights to the developed technology in their respective fields of use. As qualified expenditures were made under the co-development arrangement, we recognized the fee earned during the period as a reduction of our related expenses, subject to certain limitations. As of December 31, 2007, we had earned full funding under this arrangement in the amount of £30.0 million ($56.0 million) and as such, no funding was earned in 2008. For the fiscal years ended December 31, 2007 and 2006, we recognized $20.0 million and $18.4 million of reimbursements, respectively, of which $18.5 million and $16.6 million, respectively, offset our research and development spending and $1.5 million and $1.8 million, respectively, reduced our general, administrative and marketing spending incurred by Stirling. Though the funding arrangement has completed, Stirling continues to support ITI in exploiting the developed technology into their fields of interest.

(13) Investment in Unconsolidated Entities and Marketable Securities

(a) Equity Method Investments

(i) Joint Venture with P&G

In May 2007, we completed our 50/50 joint venture with P&G for the development, manufacturing, marketing and sale of existing and to-be-developed consumer diagnostics, outside the cardiology, diabetes and oral care fields. At the closing, we transferred our related consumer diagnostics assets totaling $63.6 million, other than our manufacturing and core intellectual property assets, to the joint venture, and P&G acquired its interest in the joint venture for a cash payment of approximately $325.0 million.

We also entered into an option agreement with P&G, pursuant to which P&G has the right, for a period of 60 days commencing on the fourth anniversary date of the agreement, to require us to acquire all of P&G s interest in the joint venture at fair market value, and P&G has the right, upon certain material breaches by us of our obligations to the joint venture, to acquire all of our interest in the joint venture at fair market value. No gain on the proceeds that we received from P&G through the formation of the joint venture will be recognized in our financial statements until P&G s option to require us to purchase its interest in the joint venture expires. The deferred gain recorded on our accompanying consolidated balance sheets as of December 31, 2008 and 2007 was $287.0 million and $293.1 million, respectively.

We also entered into a manufacturing agreement with P&G, whereby we will manufacture consumer diagnostics and sell these products to the joint venture entity. In our capacity as the manufacturer of products for the joint venture, we recorded $103.0 million and $65.0 million in manufacturing revenue for the year ended December 31, 2008 and 2007, respectively, which is included in net product sales in our accompanying consolidated statements of operations.

Furthermore, we entered into certain transition and long-term services agreements with the joint venture, pursuant to which we will provide certain operational support services to the joint venture. Revenue related to these service agreements for the year ended December 31, 2008 and 2007 was $2.4 million and $2.5 million, respectively, and is included in our services revenue on our consolidated statements of operations. Customer receivables associated with this revenue has been classified as other receivables within prepaid and other current assets on our accompanying

consolidated balance sheets in the amount of $16.2 million and $29.5 million as of December 31, 2008 and 2007, respectively. In connection with the joint venture arrangement, the joint venture bears the collection risk associated with these receivables.

Upon completion of the arrangement to form the joint venture, we ceased to consolidate the operating results of our consumer diagnostics business related to the joint venture and instead account for our 50% interest in the results of the joint venture under the equity method of accounting in accordance with APB

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(13) Investment in Unconsolidated Entities and Marketable Securities (Continued)

Opinion No. 18, *The Equity Method of Accounting for Investments in Common Stock.* For the year ended December 31, 2008 and 2007, we recorded a loss of $0.9 million and earnings of $3.0 million, respectively, in equity earnings of unconsolidated entities, net of tax, in our accompanying consolidated statements of operations, which represented our share of the joint venture s net income for the respective periods including restructuring related expenses. During 2008, the joint venture paid $11.2 million in cash to both of the parent companies, equally reducing the respective investments in the joint venture.

(ii) Vedalab S.A.

In November 2006, we acquired 40% of Vedalab S.A., or Vedalab, a French manufacturer and supplier of rapid diagnostic tests in the professional markets. The aggregate purchase price was $9.7 million which consisted of $7.6 million in cash, 49,787 shares of our common stock with an aggregate fair value of $2.0 million and $0.1 million in estimated direct acquisition costs. On the same date, we settled an on-going patent infringement claim with Vedalab. Under the terms of the settlement, Vedalab paid us $5.1 million and agreed to pay us royalties on future sales ranging from 5% to 10%, depending on the products being sold in exchange for a license under certain patents to manufacture its current products at its facility in Alencon, France. The payment of $5.1 million has been included as income in our financial results for the year ended December 31, 2006, of which $4.6 million relates to periods prior to 2006 and has been included in other income (expense), net and the remaining $0.5 million has been recorded as license and royalty revenue. We account for our 40% investment in Vedalab under the equity method of accounting in accordance with APB Opinion No. 18, *The Equity Method of Accounting for Investments in Common Stock*. In January 2007, we received $0.7 million from Vedalab in the form of a dividend distribution. This was accounted for as a reduction in the value of our investment in accordance with APB Opinion No. 18. For the year ended December 31, 2008 and 2007, we recorded $0.5 million and $0.3 million, respectively, in equity earnings of unconsolidated entities, net of tax, in our accompanying consolidated statement of operations, which represented our minority share of Vedalab s net income for the respective period.

(iii) TechLab, Inc.

In May 2006, we acquired 49% of TechLab, Inc., or TechLab, a privately-held developer, manufacturer and distributor of rapid non-invasive intestinal diagnostics tests in the areas of intestinal inflammation, antibiotic associated diarrhea and parasitology. The aggregate purchase price was $8.8 million which consisted of 303,417 shares of our common stock with an aggregate fair value of $8.6 million and $0.2 million in estimated direct acquisition costs. We account for our 49% investment in TechLab under the equity method of accounting, in accordance with APB Opinion No. 18. In 2008 and 2007, we received $1.4 million and $0.6 million, respectively, from TechLab in the form of dividend distributions. These were accounted for as a reduction in the value of our investment in accordance with APB Opinion No. 18. For the year ended December 31, 2008, 2007 and 2006, we recorded $1.5 million, $1.1 million and $0.6 million, respectively, in equity earnings of unconsolidated entities, net of tax, in our accompanying consolidated statement of operations, which represented our minority share of TechLab s net income for the respective period.

(b) Investment in Chembio

In September 2006, we acquired 5% of Chembio, a developer and manufacturer of rapid diagnostic tests for infectious diseases, through the purchase of 40 shares of their preferred stock. The preferred stock pays a dividend of 7%, payable in cash or common stock. The aggregate purchase price of $2.0 million was paid in cash. In addition to the preferred stock, we received a warrant to purchase 625,000 shares of Chembio s common stock at $0.80 per share. Chembio s stock is publicly-traded. The warrant, accounted for as a derivative instrument, had a fair value of approximately $0.4 million at the date of issuance. The fair value of this warrant was estimated at the time of issuance using the Black-Scholes pricing model and assuming no

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(13) Investment in Unconsolidated Entities and Marketable Securities (Continued)

dividend yield, expected volatility of 116%, risk-free rate of 4.9% and a contractual term of five years. In December 2007, we exercised our warrant and purchased 625,000 shares of Chembio s common stock and recorded a $0.3 million loss in connection with our mark-to- market of this warrant, which we have included in other income (expense), net in our accompanying consolidated statement of operations for the year ended December 31, 2007. Furthermore, we converted our 40 shares of their preferred stock into common stock. At December 31, 2008 and 2007, we owned 5.4 million shares of common stock in Chembio with a fair market value of approximately $0.6 million and $1.3 million, respectively, and which are classified as marketable securities, non-current on our accompanying consolidated balance sheets. We recorded an unrealized holding loss of approximately $1.4 million and $0.6 million in accumulated other comprehensive income within stockholders equity on our accompanying consolidated balance sheets as of December 31, 2008 and 2007, respectively.

(c) Investment in BBI

Our investment in BBI consisted of marketable equity securities purchased in May 2007. On receipt, the shares were recorded at their market value. At December 31, 2007, the fair market value of these securities, which have been included in marketable securities, long-term, on our accompanying consolidated balance sheet, was approximately $19.0 million, representing an unrealized holding gain of approximately $4.3 million which was recorded in accumulated other comprehensive income within stockholders equity on our accompanying consolidated balance sheets as of December 31, 2007. We acquired BBI in February 2008, at which time we recorded the original cost of this investment as part of our preliminary purchase price and reversed the $4.3 million unrealized holding gain from accumulated other comprehensive income.

(d) Investment in StatSure

In October 2007, we acquired 5% of StatSure, a developer and marketer of oral fluid collection devices for the drugs of abuse market, through the purchase of 1.4 million shares of their common stock. The aggregate purchase price of $0.5 million was paid in cash. In addition to the common stock, we received a warrant to purchase 1.1 million shares of StatSure s common stock at $0.35 per share. StatSure s stock is publicly-traded. The warrant, accounted for as a derivative instrument, in accordance with SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, had a fair value of approximately $0.3 million at the date of issuance. The fair value of this warrant was estimated at the time of issuance using the Black-Scholes pricing model and assuming no dividend yield, expected volatility of 150%, a risk-free rate of 3.9% and a contractual term of five years. We marked-to-market the warrant over the contractual term and recorded an unrealized loss of $0.3 million and an unrealized gain of $0.1 million in other income (expense), net in our accompanying consolidated statement of operations for the year ended December 31, 2008 and 2007, respectively. As of December 31, 2008, the warrant was valued at approximately $25,000.

(14) In-Process Research and Development

In connection with three of our acquisitions since 2006, we have acquired various IPR&D projects. Substantial additional research and development will be required prior to any of our acquired IPR&D programs and technology platforms reaching technological feasibility. In addition, once research is completed, each product candidate acquired

will need to complete a series of clinical trials and receive FDA or other regulatory approvals prior to commercialization. Our current estimates of the time and investment required to develop these products and technologies may change depending on the different applications that we may choose to pursue. We cannot give assurances that these programs will ever reach technological feasibility or develop into products that can be marketed profitably. For example, we have discontinued funding certain of

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(14) In-Process Research and Development (Continued)

the programs listed below. In addition, we cannot guarantee that we will be able to develop and commercialize products before our competitors develop and commercialize products for the same indications.

The following table sets forth IPR&D projects for companies and certain assets we have acquired since 2006 (in thousands):

Company/ Year Assets Acquired	Purchase Price	IPR&D(1)	Programs Acquired	Discount Rate Used in Estimating Cash Flows(1)	Year of Expected Launch
Diamics/2007	$ 4,000	$ 682	PapMap (Pap Screening Methods)	63%	2009-2010
		1,049	C-Map (Automated Pap Screening)	63%	2009-2010
		3,094	POC (Point of Care Systems)	63%	2009-2010
		$ 4,825			
Biosite/2007	$ 1,800,000	$ 13,000	Triage Sepsis Panel	15%	2008-2010
		156,000	Triage NGAL	15%	2008-2010
		$ 169,000			
Clondiag/2006	$ 24,000	$ 1,800	CHF (Congestive Heart Failure)	37%	2008-2009
		2,500	ACS (Acute Coronary Syndrome)	37%	2009-2010
		660	HIV (Human Immuno-deficiency Virus)	37%	2008-2009
		$ 4,960			

(1) Management assumes responsibility for determining the valuation of the acquired IPR&D projects. The fair value assigned to IPR&D for each acquisition is estimated by discounting, to present value, the cash flows expected

once the acquired projects have reached technological feasibility. The cash flows are probability adjusted to reflect the risks of advancement through the product approval process. In estimating the future cash flows, we also considered the tangible and intangible assets required for successful exploitation of the technology resulting from the purchased IPR&D projects and adjusted future cash flows for a charge reflecting the contribution to value of these assets.

(15) Net Loss Per Common Share

The following table sets forth the computation of basic and diluted net loss per common share (in thousands, except per share amounts):

	2008	2007	2006
Net loss per common share basic and diluted:			
Numerator:			
Net loss	$ (21,768)	$ (244,753)	$ (16,842)
Less: Preferred stock dividends	(13,989)		
Net loss available to common stockholders	$ (35,757)	$ (244,753)	$ (16,842)
Denominator:			
Weighted average shares outstanding	77,778	51,510	34,109
Net loss per common share basic and diluted	$ (0.46)	$ (4.75)	$ (0.49)

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(15) Net Loss Per Common Share (Continued)

We had the following potential dilutive securities outstanding on December 31, 2008: (a) options and warrants to purchase an aggregate of 10.6 million shares of our common stock at a weighted average exercise price of $32.15 per share, (b) 3.4 million shares related to the issuance of our $150.0 million, 3% senior subordinated convertible notes and (c) 1.9 million shares of our Series B convertible preferred stock, convertible under certain circumstances at $69.32 per share into 10.8 million shares of our common stock. Potential dilutive securities were not included in the computation of diluted net loss per common share in 2008 because the inclusion thereof would be antidilutive.

We had the following potential dilutive securities outstanding on December 31, 2007: (a) options and warrants to purchase an aggregate of 8.3 million shares of our common stock at a weighted average exercise price of $30.82 per share and (b) 1.8 million shares related to the issuance of our $150.0 million, 3% senior subordinated convertible notes. Potential dilutive securities were not included in the computation of diluted loss per common share in 2007 because the inclusion thereof would be antidilutive.

We had the following potential dilutive securities outstanding on December 31, 2006: options and warrants to purchase an aggregate of 4.1 million shares of our common stock at a weighted average exercise price of $20.75 per share. Potential dilutive securities were not included in the computation of diluted loss per common share in 2006 because the inclusion thereof would be antidilutive.

(16) Stockholders Equity

(a) Common Stock

As of December 31, 2008, we had 150.0 million shares of common stock, $0.001 par value, authorized, of which approximately 78.4 million shares were issued and outstanding, 11.1 million shares were reserved for issuance upon grant and exercise of stock options under current stock option plans, 0.5 million shares were reserved for issuance under our employee stock purchase plan and 0.5 million shares were reserved for issuance upon exercise of outstanding warrants. In addition, we have potential dilutive securities consisting of our $150 million, 3% senior subordinated convertible notes, convertible into 3.4 million shares of our common stock (Note 6(b)) and 1.9 million shares of our Seried B convertible preferred stock, convertible under certain circumstances at $69.32 per share into 10.8 million shares of our common stock (Note 16(b)).

In November 2007, we sold an aggregate 13.6 million shares of our common stock at $61.49 per share through an underwritten public offering. Certain of our officers also sold a total of 165,698 shares of common stock in the offering. Proceeds to us from the offering were approximately $806.9 million, net of issuance costs of $31.8 million, which includes deductions for underwriting discounts and commissions and takes into effect the reimbursement by the underwriters of a portion of our offering expenses. The net proceeds were used to fund certain acquisitions with the remainder of the net proceeds retained for working capital and other general corporate purposes.

In January 2007, we sold an aggregate 6.9 million shares of our common stock at $39.65 per share through an underwritten public offering, inclusive of 0.9 million shares associated with the exercise of our underwriter option to purchase additional shares to cover over-allotments. Proceeds from the offering were approximately $261.3 million, net of issuance costs of $12.3 million, which included deductions for underwriting discounts and commissions and

takes into effect the reimbursement by the underwriters of a portion of our offering expenses. Of this amount, we used $44.9 million to repay principal outstanding and accrued interest on our term loan under our senior credit facility, with the remainder of the net proceeds retained for working capital and other general corporate purposes.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(16) Stockholders Equity (Continued)

(b) Preferred Stock

As of December 31, 2008, we had 5.0 million shares of preferred stock, $0.001 par value, authorized, of which 2.3 million shares were designated as Series B Convertible Perpetual Preferred Stock, or Series B preferred stock. On May 8, 2008, in connection with our acquisition of Matria we issued 1.8 million shares of the Series B preferred stock with a fair value of approximately $657.9 million (Note 4(a)(i)).

Each share of Series B preferred stock, which has a liquidation preference of $400.00 per share, is convertible, at the option of the holder and only upon certain circumstances, into 5.7703 shares of our common stock, plus cash in lieu of fractional shares. The initial conversion price is $69.32 per share, subject to adjustment upon the occurrence of certain events, but will not be adjusted for accumulated and unpaid dividends. Upon a conversion of shares of the Series B preferred stock, we may, at our option, satisfy the entire conversion obligation in cash or through a combination of cash and common stock. There were no conversions as of December 31, 2008.

Generally, the shares of Series B preferred stock are convertible, at the option of the holder, if during any calendar quarter beginning with the second calendar quarter after the issuance date of the Series B preferred stock, if the closing sale price of our common stock for each of 20 or more trading days within any period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter exceeds 130% of the conversion price per share of common stock in effect on the last trading day of the immediately preceding calendar quarter. In addition, the shares of Series B preferred stock are convertible, at the option of the holder, in certain other circumstances, including those relating to the trading price of the Series B preferred stock and upon the occurrence of certain fundamental changes or major corporate transactions. We also have the right, under certain circumstances relating to the trading price of our common stock, to force conversion of the Series B preferred stock. Depending on the timing of any such forced conversion, we may have to make certain payments relating to foregone dividends, which payments we can make, at our option, in the form of cash, shares of our common stock, or a combination of cash and shares of our common stock.

Each share of Series B preferred stock accrues dividends at $12.00, or 3%, per annum, payable quarterly on January 15, April 15, July 15 and October 15 of each year, commencing following the first full calendar quarter after the issuance date. Dividends on the Series B preferred stock are cumulative from the date of issuance. For the year ended December 31, 2008, Series B preferred stock dividends amounted to $14.0 million, which reduced earnings available to common stockholders for purposes of calculating net loss per common share in 2008 (Note 15). Accrued dividends are payable only if declared by our board of directors and, upon conversion by the Series B preferred stockholder, holders will not receive any cash payment representing accumulated dividends. If our board of directors declares a dividend payable, we have the right to pay the dividends in cash, shares of common stock, additional shares of Series B preferred stock or a similar convertible preferred stock or any combination thereof.

On September 15, 2008, the board of directors declared a dividend of $4.77 per share on the Series B preferred stock. The dividend was paid in shares of Series B preferred stock in an amount per share of Series B preferred stock equal to the quotient of (a) $4.77 divided by (b) 97% of the average of the volume-weighted average price per share of the Series B preferred stock on the American Stock Exchange for each of the five consecutive trading days ending on the second trading day immediately prior to the record date of the dividend. We paid cash in lieu of any fractional shares

resulting from the dividend. The dividend totaling $8.5 million was paid on October 15, 2008 to holders of record of Series B preferred stock at the close of business on October 1, 2008. This was the first dividend declared and paid on the Series B preferred stock, and such payment covered the amount of all dividends accrued from May 9, 2008, the original issuance date of the Series B preferred stock, through September 30, 2008.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(16) Stockholders Equity (Continued)

On December 10, 2008, the board of directors declared a dividend of $3.00 per share on the Series B preferred stock. The dividend was paid in shares of Series B preferred stock in an amount per share of Series B preferred stock equal to the quotient of (a) $3.00 divided by (b) 97% of the average of the volume-weighted average price per share of the Series B preferred stock on the American Stock Exchange for each of the five consecutive trading days ending on the second trading day immediately prior to the record date of the dividend. We paid cash in lieu of any fractional shares resulting from the dividend. The dividend totaling $5.5 million was paid on January 15, 2009 to holders of record of Series B preferred stock at the close of business on January 2, 2009. Such payment covered the amount of all dividends accrued from October 1, 2008 through December 31, 2008. As of December 31, 2008, 1.9 million shares of Series B preferred stock are issued and outstanding.

The holders of Series B preferred stock have liquidation preferences over the holders of the Company s common stock and other classes of stock, if any, outstanding at the time of liquidation. Upon liquidation, the holders of outstanding Series B preferred stock would receive an amount equal to $400.00 per share of Series B preferred stock, plus any accumulated and unpaid dividends. As of December 31, 2008, the liquidation preference of the outstanding Series B preferred stock was $751.5 million. The holders of the Series B preferred stock have no voting rights, except with respect to matters affecting the Series B preferred stock (including the creation of a senior preferred stock).

We evaluated the terms and provisions of our Series B preferred stock to determine if it qualified for derivative accounting treatment under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. Based on our evaluation, these securities do not qualify for derivative accounting under SFAS No. 133.

(c) Stock Options and Awards

In 2001, we adopted the 2001 Stock Option and Incentive Plan (as amended, the 2001 Plan) which currently allows for the issuance of up to 11.1 million shares of common stock and other awards. The 2001 Plan is administered by the Compensation Committee of the Board of Directors in order to select the individuals eligible to receive awards, determine or modify the terms and conditions of the awards granted, accelerate the vesting schedule of any award and generally administer and interpret the 2001 Plan. The key terms of the 2001 Plan permit the granting of incentive or nonqualified stock options with a term of up to ten years and the granting of stock appreciation rights, restricted stock awards, unrestricted stock awards, performance share awards and dividend equivalent rights. The 2001 Plan also provides for option grants to non-employee directors and automatic vesting acceleration of all options and stock appreciation rights upon a change in control, as defined by the 2001 Plan. As of December 31, 2008 and 2007, there were 0.8 million and 2.3 million, respectively, shares available for future grant under the 2001 plan.

In August 2001, we sold to our chief executive officer 1.2 million shares of restricted common stock at a price of $9.13 per share. Two-thirds of the restricted stock, or 0.8 million shares, vested ratably over 36 months; the remaining one-third, or 0.4 million shares, vested ratably over 48 months. Except for the par value of the common stock, which was paid in cash, the chief executive officer purchased the restricted stock with a five-year promissory note, which, for accounting purposes, was treated as a non-recourse note. The total interest under the promissory note was fully recourse to our chief executive officer. The note was due and payable on August 16, 2006 and bore interest at an annual rate of 4.99%. Interest income recorded under this note amounted to $0.3 million for the year ended December 31, 2006. In August, 2006 the note and accrued interest were paid in full (Note 21).

In August 2001, we granted two non-qualified stock options to purchase an aggregate of 0.8 million shares of common stock at an exercise price of $6.20 per share to two other key executive officers. These

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(16) Stockholders Equity (Continued)

options were set to expire on January 31, 2002. In December 2001, the executive officers exercised these options (one fully; one partially) by paying cash in the amount of par value and delivering promissory notes for the difference, as permitted pursuant to the terms of the original grant. For accounting purposes, the promissory notes were treated as non-recourse notes. The notes were due and payable in December 2006 and bore interest at an annual rate of 3.97%, the applicable federal rate for a five-year note in effect during the month of exercise. The notes and accrued interest were paid in full in December 2006 (Note 21). Interest income recorded under these notes amounted to $0.2 million for the year ended December 31, 2006.

The following summarizes all stock option activity during the year ended December 31 (in thousands, except exercise price):

	2008		2007		2006	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding at January 1	7,836	$ 31.42	3,775	$ 21.11	3,902	$ 18.82
Exchanged	1,820	$ 30.52	3,606	$ 23.48		$
Granted	1,787	$ 34.13	2,807	$ 49.53	666	$ 31.88
Exercised	(836)	$ 16.84	(2,204)	$ 23.70	(510)	$ 17.30
Canceled/expired/forfeited	(452)	$ 37.75	(148)	$ 33.33	(283)	$ 21.81
Outstanding at December 31	10,155	$ 32.65	7,836	$ 31.42	3,775	$ 21.11
Exercisable at December 31	5,866	$ 27.08	3,887	$ 20.03	2,408	$ 17.16

The aggregate intrinsic value of the options outstanding at December 31, 2008 was $9.7 million. The aggregate intrinsic value of the options exercisable at December 31, 2008 was $9.6 million. The aggregate intrinsic value of stock options exercised during 2008, 2007 and 2006 was $18.2 million, $62.5 million and $7.4 million, respectively. Based on equity awards outstanding as of December 31, 2008, there was $62.6 million of unrecognized compensation costs related to unvested share-based compensation arrangements that are expected to vest. Such costs are expected to be recognized over a weighted average period of 1.5 years.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(16) Stockholders Equity (Continued)

(d) Warrants

The following is a summary of all warrant activity during the three years ended December 31:

	Number of Shares (in thousands)	Exercise Price	Weighted Average Exercise Price
Warrants outstanding and exercisable, December 31, 2005	758	$ 3.81-$24.00	$ 16.47
Exercised	(452)	$ 3.88-$18.12	$ 16.51
Warrants outstanding and exercisable, December 31, 2006	306	$ 3.81-$24.00	$ 16.42
Exchanged	285	$ 14.52-$29.78	$ 28.98
Exercised	(122)	$ 13.54-$29.78	$ 19.31
Warrants outstanding and exercisable, December 31, 2007	469	$ 3.81-$29.78	$ 20.80
Exercised	(12)	$ 13.54-$20.06	$ 19.64
Warrants outstanding and exercisable, December 31, 2008	457	$ 3.81-$29.78	$ 20.83

The following represents additional information related to warrants outstanding and exercisable at December 31, 2008:

	Outstanding and Exercisable		
Exercise Price	Number of Shares (in thousands)	Weighted Average Remaining Contract Life (in years)	Weighted Average Exercise Price
$3.81-$3.93	4	1.48	$ 3.87
$4.48-$4.57	1	1.54	$ 4.54
$5.44-$5.57	4	1.58	$ 5.53

$7.37-$7.55	2	1.66	$	7.48
$13.54-$18.12	219	2.97-3.72	$	14.41
$20.06-$29.78	152	6.78	$	29.66
$24.00	75	6.25	$	24.00
	457	5.03	$	20.83

The majority of the warrants included in the table above were issued in connection with debt and equity financings, or amendments thereto, of which warrants to purchase an aggregate of 0.3 million shares of our common stock were issued to officers and directors of our company or entities controlled by these officers and directors and were outstanding at December 31, 2008. The value of warrants issued in connection with debt financings yielded original issue discounts and additional interest expense of $0.5 million in 2006. No such expense was incurred during 2008 and 2007. All outstanding warrants have been classified in equity, pursuant to provision EITF No. 00-19.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(16) Stockholders Equity (Continued)

(e) Employee Stock Purchase Plan

In 2001, we adopted the 2001 Employee Stock Purchase Plan under which eligible employees are allowed to purchase shares of our common stock at a discount through periodic payroll deductions. Purchases may occur at the end of every six month offering period at a purchase price equal to 85% of the market value of our common stock at either the beginning or end of the offering period, whichever is lower. We may issue up to 1.0 million shares of common stock under this plan. At December 31, 2008, 0.5 million shares had been issued under this plan.

(17) Stock-based Compensation

In accordance with SFAS No. 123-R, our results of operations for the year ended December 31, 2008, 2007 and 2006 reflected compensation expense for new stock options granted since January 1, 2006, and vested under our stock incentive plan and employee stock purchase plan and the unvested portion of previous stock option grants which vested during the years ended December 31, 2008, 2007 and 2006. Stock-based compensation expense in the amount of $26.4 million ($20.7 million, net of tax), $57.5 million ($52.7 million, net of tax) and $5.5 million ($4.9 million, net of tax), was reflected in our consolidated statements of operations for the year ended December 31, 2008, 2007 and 2006, respectively, as follows (in thousands):

	2008	2007	2006
Cost of net revenue	$ 1,504	$ 608	$ 391
Research and development	4,627	2,215	1,390
Sales and marketing	4,264	1,699	682
General and administrative	16,010	52,958	2,992
	$ 26,405	$ 57,480	$ 5,455

Included in the amount above for general and administrative expense for the year ended December 31, 2007, is $45.2 million related to our assumption of Biosite options. The expense relates to the acceleration of unvested Biosite employee options. See Note 4(b) regarding our acquisition of Biosite.

In accordance with SFAS No. 123-R, for the year ended December 31, 2008, 2007 and 2006, the presentation of our cash flows reports the excess tax benefits from the exercise of stock options as financing cash flows. For the year ended December 31, 2008, 2007 and 2006, excess tax benefits generated from option exercises amounted to $17.5 million, $0.9 million and $0.6 million, respectively.

The following assumptions were used to estimate the fair value of options granted during the year ended December 31, 2008, 2007 and 2006 using the Black-Scholes option-pricing model:

	2008	2007	2006
Risk-free interest rate	2.39-3.14%	3.15-5.00%	4.00-4.67%
Expected dividend yield			
Expected life	5.19 years	6.25 years	6.25 years
Expected volatility	37-43%	44%	41%

The weighted average fair value under the Black-Scholes option pricing model of options granted to employees during 2008, 2007 and 2006 was $10.66, $24.05 and $15.29, respectively. All options granted during these periods were granted at fair market value on date of grants.

For the year ended December 31, 2008, in accordance with SFAS 123-R, we recorded compensation expense of $2.8 million related to our Employee Stock Purchase Plan. The fair value of the option component

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(17) Stock-based Compensation (Continued)

of the Employee Stock Purchase Plan shares was estimated at the date of grant using the Black-Scholes pricing model and assumed an expected volatility of 43.31% to 53.87%, a risk-free interest rate range of 2.13% to 3.32% and an expected life of 181 and 184 days. The charge is included in general and administrative in the table above.

For the year ended December 31, 2007, in accordance with SFAS 123-R, we recorded compensation expense of $1.5 million related to our Employee Stock Purchase Plan. The fair value of the option component of the Employee Stock Purchase Plan shares was estimated at the date of grant using the Black-Scholes pricing model and assumed an expected volatility of 32.64% to 69.49%, a risk-free interest rate range of 4.17% to 4.94% and an expected life of 181 and 184 days. The charge is included in general and administrative in the table above.

For the year ended December 31, 2006, in accordance with SFAS 123-R, we recorded compensation expense of $0.3 million related to our Employee Stock Purchase Plan. The fair value of the option component of the Employee Stock Purchase Plan shares were estimated at the date of grant using the Black-Scholes pricing model and assumed an expected volatility of 33%, a risk-free interest rate range of 4.55% to 4.99% and an expected life of 0.5 years. The charge is included in general and administrative in the table above.

(18) Other Comprehensive Income

SFAS No. 130, *Reporting Comprehensive Income*, establishes standards for the reporting and display of comprehensive income. In general, comprehensive income combines net income and other changes in equity during the year from non-owner sources. Accumulated other comprehensive income is recorded as a component of stockholders equity. The following is a summary of the components of and changes in accumulated other comprehensive income as of December 31, 2008 and in each of the three years then ended (in thousands):

	Cumulative Translation Adjustment (Note 2(b))	Pension Liability Adjustment (Note 9(b))	Other(1)	Accumulated Other Comprehensive Income (loss)(2)
Balance at December 31, 2005	$ 7,052	$	$	$ 7,052
Period change	10,823	(3,738)	44	7,129
Balance at December 31, 2006	17,875	(3,738)	44	14,181
Period change	12,758	341	(6,011)	7,088
Balance at December 31, 2007	30,633	(3,397)	(5,967)	21,269
Period change	(32,889)	(562)	(16,663)	(50,114)
Balance at December 31, 2008	$ (2,256)	$ (3,959)	$ (22,630)	$ (28,845)

(1) Other represents (realization of) unrealized gains on available-for-sale securities and interest rate swap.

(2) All of the components of accumulated other comprehensive income relate to our foreign subsidiaries, except item (1) above. No adjustments for income taxes were recorded against other comprehensive income, as we intend to permanently invest in our foreign subsidiaries in the foreseeable future.

(19) Income Taxes

Our income tax (benefit) provision in 2008, 2007 and 2006 mainly represents those recorded by us and certain of our U.S. subsidiaries and by our foreign subsidiaries Unipath in the United Kingdom, Inverness

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(19) Income Taxes (Continued)

Medical France, and Inverness Medical Switzerland. Loss before (benefit) provision for income taxes consists of the following (in thousands):

	2008	2007	2006
United States	$ (52,935)	$ (235,862)	$ (5,089)
Foreign	13,431	(14,242)	(6,362)
	$ (39,504)	$ (250,104)	$ (11,451)

Our primary temporary differences that give rise to the deferred tax asset and liability are NOL carryforwards, nondeductible reserves, accruals and differences in bases of the tangible and intangible assets, and the gain on the joint venture transaction. The income tax effects of these temporary differences are as follows (in thousands):

	2008	2007
NOL and capital loss carryforwards	$ 102,484	$ 141,620
Tax credit carryforwards	15,884	18,236
Nondeductible reserves	9,488	5,327
Nondeductible accruals	67,142	41,318
Difference between book and tax bases of tangible assets	3,133	2,328
Difference between book and tax bases of intangible assets	35,986	35,042
Gain on joint venture	33,264	37,300
All other	1,162	26
Gross deferred tax asset	268,543	281,197
Less: Valuation allowance	(12,740)	(18,899)
Total deferred tax assets	255,803	262,298
Deferred tax liabilities:		
Difference between book and tax bases of tangible assets	10,824	6,249
Difference between book and tax bases of intangible assets	588,766	524,603
Other	366	23,973
Total deferred tax liability	599,956	554,825
Net deferred tax liability	$ 344,153	$ 292,527

Reported as:		
Deferred tax assets, current portion	$ 104,311	$ 18,170
Deferred tax assets, long-term	14,323	15,799
Deferred tax liabilities, current portion		(368)
Deferred tax liabilities, long-term	(462,787)	(326,128)
Net deferred tax liability	$ (344,153)	$ (292,527)

As of December 31, 2008, we had approximately $256.6 million of domestic NOL carryforwards and $15.9 million of foreign NOL and foreign capital loss carryforwards, which either expire on various dates through 2027 or can be carried forward indefinitely. These loss carryforwards are available to reduce future federal and foreign taxable income, if any. These loss carryforwards are subject to review and possible adjustment by the appropriate taxing authorities. The domestic NOL carryforwards include approximately

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(19) Income Taxes (Continued)

$199.2 million of pre-acquisition losses at Matria, Alere Medical, ParadigmHealth, Biosite, Cholestech, Diamics, HemoSense, IMN, Ischemia and Ostex. Also included in our domestic NOL carryforwards at December 31, 2008 was approximately $17.5 million resulting from the exercise of employee stock options, the tax benefit of which was recognized as a credit to additional paid-in capital rather than a reduction of income tax. Our domestic NOL s are subject to the Internal Revenue Service Code Section 382 limitation. Section 382 imposes an annual limitation on the use of these losses to an amount equal to the value of the company at the time of the ownership change multiplied by the long-term tax exempt rate. The Section 382 limited amount for 2009 is approximately $167.0 million.

We have recorded a valuation allowance of $12.7 million as of December 31, 2008 due to uncertainties related to the future benefits, if any, from our deferred tax assets related primarily to our foreign businesses and certain U.S. net operating losses and tax credits. This is a reduction of $6.2 million from the valuation allowance of $18.9 million as of December 31, 2007. The decrease is primarily related to the recognition of foreign NOLs. The valuation allowance is based on our estimates of taxable income by jurisdiction in which we operate and the period over which our deferred tax assets will be recoverable. In the event that actual results differ from these estimates or we adjust these estimates in future periods, we may need to establish an additional valuation allowance or reduce our current valuation allowance which could materially impact our tax provision.

In accordance with SFAS No. 109, the accounting for the tax benefits of acquired deductible temporary differences and NOL carryforwards, which are not recognized at the acquisition date because a valuation allowance is established and which are recognized subsequent to the acquisitions, will be applied first to reduce to zero any goodwill and other non-current intangible assets related to the acquisitions. Any remaining benefits would be recognized as a reduction of income tax expense. As of December 31, 2008, $3.7 million of deferred tax assets with a valuation allowance pertains to acquired companies, the future benefits of which will be applied to reduce our income tax expense as required under SFAS No. 141-R, *Business Combinations*, adopted January 1, 2009.

Our China-based manufacturing subsidiaries qualify for a reduced income tax rate in 2008 and an income tax holiday for 2007. The general income tax rate is 25%. The income tax rate for ABON is 12.5% for 2008, 2009 and 2010, and for IM Shanghai it is 9% for 2008, 10% for 2009, 11% for 2010 and 24% for 2011. The reduced rates for 2008, 2009, 2010 and 2011 are grandfathered in the China Tax Reform Act. A tax rate of 15% or 25% will apply to 2011 and future years. The tax rate of 15% applies to companies with high technology status. We are in the process of applying for high technology status. The reduced tax rate produced a tax expense of approximately $1.0 million. In the absence of the reduced tax rate for 2008 a tax rate of 25% would apply which would have resulted in a tax expense of approximately $2.0 million in 2008. The earnings per common share effect of the reduced tax rate is $0.01 for 2008. The tax holiday provided an income tax rate of 0% in 2007. In the absence of the tax holiday, a tax rate of 33% would apply, which would have resulted in a tax expense of approximately $3.8 million in 2007. The earnings per share common effect of the tax holiday is $0.07 for 2007.

The estimated amount of undistributed earnings of our foreign subsidiaries is $86.1 million at December 31, 2008. No amount for U.S. income tax has been provided on undistributed earnings of our foreign subsidiaries because we consider such earnings to be indefinitely reinvested. In the event of distribution of those earnings in the form of dividends or otherwise, we would be subject to both U.S. income taxes, subject to an adjustment, if any, for foreign tax credits, and foreign withholding taxes payable to certain foreign tax authorities. Determination of the amount of

U.S. income tax liability that would be incurred is not practicable because of the complexities associated with this hypothetical calculation, however, unrecognized foreign tax credit carryforwards may be available to reduce some portion of the U.S. tax liability, if any.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(19) Income Taxes (Continued)

The following table presents the components of our (benefit) provision for income taxes (in thousands):

	2008	2007	2006
Current:			
Federal	$ 7,433	$ 2,434	$
State	7,250	2,073	423
Foreign	10,387	22,406	5,315
	25,070	26,913	5,738
Deferred:			
Federal	(5,897)	(4,961)	3,152
State	(4,237)	(1,523)	289
Foreign	(31,622)	(21,408)	(3,452)
	(41,756)	(27,892)	(11)
Total tax (benefit) provision	$ (16,686)	$ (979)	$ 5,727

The following table presents a reconciliation from the U.S. statutory tax rate to our effective tax rate:

	2008	2007	2006
Statutory rate	35%	35%	35%
Effect of Biosite in-process R&D write-off		(24)	
Effect of Diamics in-process R&D write-off		(1)	
Effect of Biosite compensation charges and other non-cash compensation		(6)	
Effect of losses and expenses not benefited			(28)
Stock-based compensation	(10)		
Rate differential on foreign earnings	3		(2)
Research and development benefit	6	1	14
State income taxes, net of federal benefit	2	(1)	(4)
Deferred tax on indefinite-lived assets			(31)
Accrual to return reconciliation			(9)
Other permanent items and FIN 48	(4)	1	
Change in valuation allowance	11	(4)	(27)
Effective tax rate	43%	1%	(52)%

We adopted FIN 48, *Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement 109* on January 1, 2007. During the year ended December 31, 2008, we increased the liability for income taxes associated with uncertain tax positions by $2.4 million for a total of $11.1 million at December 31, 2008. The primary reason for the increase is due to our acquisitions of Clondiag and Matria, where we increased the liability for income taxes associated with uncertain tax positions by $1.8 million. Any future recognition of the Clondiag or Matria tax benefit is generally recorded to income due to the adoption of SFAS No. 141-R, *Business Combinations*, effective January 1, 2009. In addition, consistent with the provisions of FIN 48, we classified $11.1 million of income tax liabilities as non-current income tax liabilities because a payment of cash is not anticipated within one year of the balance sheet date. These non-current income tax liabilities are recorded in other long-term liabilities in our consolidated balance sheet at December 31, 2008.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(19) Income Taxes (Continued)

We anticipate an increase every quarter to the total amount of unrecognized tax benefits. We do not anticipate a significant increase or decrease of the total amount of unrecognized tax benefits within twelve months of the reporting date.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	Amount
Balances as of January 1, 2007	$ 2,248
Additions for tax positions taken during prior years	53
Additions for tax positions in current year acquisitions	6,229
Additions for tax positions taken during current year	235
Expiration of statutes of limitations or closure of tax audits	
Balances as of December 31, 2007	8,765
Additions for tax positions taken during prior years	63
Additions for tax positions in current and prior year acquisitions	2,296
Additions for tax positions taken during current year	143
Expiration of statutes of limitations or closure of tax audits	(134)
Balance as of December 31, 2008	$ 11,133

Interest and penalties related to income tax liabilities are included in income tax expense. The interest and penalties recorded in 2008 amounted to $0.4 million. The balance of accrued interest and penalties recorded on the consolidated balance sheet at December 31, 2008 was $0.8 million.

With limited exceptions, we are subject to U.S. federal, state and local or non-U.S. income tax audits by tax authorities for 2002 through 2007. We are currently under income tax examination by the IRS and a number of state and foreign tax authorities and anticipate these audits will be completed by the end of 2009. We cannot currently estimate the impact of these audits due to the uncertainties associated with tax examinations.

(20) Financial Information by Segment

Under SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*, operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. Our chief operating decision-making group is composed of the chief executive officer and members of senior management. Our reportable operating segments are Professional Diagnostics, Health Management, Consumer Diagnostics, Vitamins and Nutritional Supplements, and Corporate and Other. Our operating results include license and royalty revenue which are allocated to Professional Diagnostics and Consumer Diagnostics

on the basis of the original license or royalty agreement.

Included in the operating results of Professional Diagnostics in 2008 are expenses related to our research and development activities in the area of cardiology, as a result of our recent cardiology-related acquisitions, which amounted to $37.0 million.

Included in the operating results of Professional Diagnostics in 2007 are expenses related to our research and development activities in the area of cardiology, as a result of our 2007 cardiology-related acquisitions, which amounted to $26.5 million, net of $18.5 million of reimbursements received from ITI as part of the co-development arrangement that we entered into in February 2005.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(20) Financial Information by Segment (Continued)

Included in the operating results of Corporate and Other in 2006 are expenses related to our research and development activities in the area of cardiology, which amounted to $30.2 million, net of $16.6 million of reimbursements received from ITI as part of the co-development arrangement mentioned above.

Operating loss of $250.7 million for the year ended December 31, 2007 in our Corporate and Other segment includes the write-off of $173.8 million of IPR&D incurred in connection with our acquisitions of Biosite and Diamics and $45.2 million of stock-based compensation related to employee stock options assumed in the acquisition of Biosite. Total assets related to our cardiology research operations in Scotland and Germany, which are included in Professional Diagnostics in 2008 and 2007 and included in Corporate and Other in 2006 in the tables below, amounted to $37.9 million at December 31, 2008, $39.4 million at December 31, 2007 and $18.4 million at December 31, 2006.

The accounting policies of the segments are the same as those described in the summary of significant accounting policies. We evaluate performance of our operating segments based on revenue and operating income (loss). Revenues are attributed to geographic areas based on where the customer is located. Segment information for 2008, 2007 and 2006 are as follows (in thousands):

2008	Professional Diagnostics	Health Management	Consumer Diagnostics	Vitamins and Nutritional Supplements	Corporate and Other	Total
Net revenue to external customers	$ 1,051,301	$ 392,399	$ 138,853	$ 88,873	$	$ 1,671,426
Operating income (loss)	$ 97,994	$ 11,241	$ 9,505	$ (840)	$ (54,048)	$ 63,852
Depreciation and amortization	$ 171,980	$ 85,990	$ 6,809	$ 2,286	$ 862	$ 267,927
Restructuring charge	$ 36,196	$	$ 238	$	$	$ 36,434
Stock-based compensation	$	$	$	$	$ 26,405	$ 26,405
Assets	$ 3,687,685	$ 1,850,236	$ 223,383	$ 65.263	$ 128,793	$ 5,955,360
Expenditures for property, plant and equipment	$ 46,859	$ 7,935	$ 1,917	$ 362	$ 8,988	$ 66,061

2007	Professional Diagnostics	Health Management	Consumer Diagnostics	Vitamins and Nutritional Supplements	Corporate and Other	Total
Net revenue to external customers	$ 582,250	$ 23,374	$ 161,092	$ 72,824	$	$ 839,540
Operating income (loss)	$ 61,067	$ (498)	$ 15,332	$ (1,061)	$ (250,693)	$ (175,853)

Depreciation and amortization	$	82,797	$	4,487	$	9,106	$	2,917	$	1,806	$	101,113
Restructuring charge	$	3,965	$		$	2,737	$		$		$	6,702
Stock-based compensation	$		$		$		$		$	57,480	$	57,480
Assets	$	3,748,931	$	635,415	$	309,175	$	49,655	$	137,583	$	4,880,759
Expenditures for property, plant and equipment	$	30,581	$	2,257	$	1,366	$	872	$	1,559	$	36,635

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(20) Financial Information by Segment (Continued)

2006	Professional Diagnostics	Health Management	Consumer Diagnostics	Vitamins and Nutritional Supplements	Corporate and Other	Total
Net revenue to external customers	$ 310,632	$	$ 176,771	$ 82,051	$	$ 569,454
Operating income (loss)	$ 42,554	$	$ 26,975	$ (3,013)	$ (60,145)	$ 6,371
Depreciation and amortization	$ 27,030	$	$ 5,062	$ 3,270	$ 4,000	$ 39,362
Restructuring charge	$ 7,625	$	$ 2,921	$	$ 2,587	$ 13,133
Stock-based compensation	$	$	$	$	$ 5,455	$ 5,455
Assets	$ 625,560	$	$ 314,815	$ 49,896	$ 95,500	$ 1,085,771
Expenditures for property, plant and equipment	$ 9,905	$	$ 1,807	$ 475	$ 7,530	$ 19,717

	2008	2007	2006
Revenue by Geographic Area:			
United States	$ 1,209,166	$ 529,870	$ 335,405
Europe	285,696	198,525	136,971
Other	176,564	111,145	97,078
	$ 1,671,426	$ 839,540	$ 569,454

	2008	2007
Long-lived Tangible Assets by Geographic Area:		
United States	$ 222,450	$ 198,225
United Kingdom	12,113	36,204
China	19,491	17,975
Other	30,429	15,476
	$ 284,483	$ 267,880

(21) Related Party Transactions

In November 2008, the Zwanziger Family Trust, a trust established for the benefit of the children of Ron Zwanziger, our Chairman, Chief Executive Officer and President, and the trustee of which is Mr. Zwanziger s sister, purchased certain of our securities from third parties in market transactions. The purchase consisted of approximately $1.0 million of each of the following securities: our common stock, our Series B Preferred Stock, our Convertible Notes, interests in our First Lien Credit Agreement and interests in our Second Lien Credit Agreement. To the extent we make principal and interest payments under the Convertible Notes and the credit facilities in accordance with their terms, the Zwanziger Family Trust, as a holder of Convertible Notes and as a lender under the credit facilities, will receive its proportionate share. In connection with its purchases of interests under our First Lien Credit Agreement and Second Lien Credit Agreement, the Trust agreed that, whenever the consent or vote of the lenders is required under the credit facilities, it will vote the outstanding principal amount of its holdings in the same proportion as the votes cast by the other lenders under these credit facilities.

In May 2007, we completed our 50/50 joint venture with P&G for the development, manufacturing, marketing and sale of existing and to-be-developed consumer diagnostics, outside the cardiology, diabetes and

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(21) Related Party Transactions (Continued)

oral care fields. At December 31, 2008 and 2007, we had a net receivable from the joint venture of $12.0 million and a net payable to the joint venture of $10.8 million, respectively. Additionally, customer receivables associated with revenue earned after the joint venture was completed have been classified as other receivables within prepaid and other current assets on our accompanying consolidated balance sheets in the amount of $16.2 million and $29.5 million as of December 31, 2008 and 2007, respectively. In connection with the joint venture arrangement, the joint venture bears the collection risk associated with these receivables. Sales to the joint venture under our manufacturing agreement totaled $103.0 million and $65.0 million during the year ended December 31, 2008 and 2007, respectively, and are included in net product sales in our accompanying statements of operations. Under the terms of our product supply agreement, SPD purchases products from our manufacturing facilities in the U.K. and China. SPD in turn sells a portion of those tests back to Inverness for final assembly and packaging. Once packaged, the tests are sold to P&G for distribution to third party customers in North America. As a result of these related transactions we have recorded $15.6 million of trade receivables which are included in accounts receivable on our consolidated balance sheet as of December 31, 2008 and $18.9 million of trade accounts payable which are included in accounts payable on our consolidated balance sheet as of December 31, 2008. During 2008, the joint venture paid $11.2 million in cash to both of the parent companies, equally reducing the respective investments in the joint venture.

On March 22, 2007, we entered into a convertible loan agreement with BBI whereby we loaned them £7.5 million ($14.7 million as of the transaction date). Under the terms of the agreement, the loan amount would simultaneously convert into shares of BBI common stock per the prescribed conversion formula defined in the loan agreement, in the event the BBI consummated a specific target acquisition on or before September 30, 2007. On May 15, 2007, BBI consummated a specific target acquisition and the loan converted into 5,208,333 shares of BBI s common stock which is included in investments in unconsolidated entities on our accompanying consolidated balance sheet at December 31, 2007. In February 2008, we acquired the remaining outstanding shares of BBI common stock in connection with our acquisition of BBI (Note 4).

In December 2006, one of our key executive officers, paid us $1,606,831 in full satisfaction of his obligations to us, including principal and accrued interest, under a previously disclosed, five-year promissory note dated August 16, 2001. The promissory note was provided to us in connection with his purchase of 250,000 shares of our common stock in August, 2001 (Note 16).

In December 2006, one of our key executive officers, paid us $2,571,320 in full satisfaction of his obligations to us, including principal and accrued interest, under a previously disclosed, five-year promissory note dated August 16, 2001. The promissory note was provided to us in connection with his purchase of 399,381 shares of our common stock in August, 2001 (Note 16).

In August 2006, our Chairman, Chief Executive Officer and President, paid us $11,197,096 in full satisfaction of his obligations to us, including principal and accrued interest, under a previously disclosed, five-year promissory note dated August 16, 2001. The promissory note was provided to us in connection with his purchase of 1,168,191 shares of our common stock in August, 2001 (Note 16).

In June 2006, we issued 25,000 shares of our common stock as consideration for the acquisition of all of the capital stock of Innovative Medical Devices BVBA. The seller of the capital stock of Innovative Medical Devices BVBA is

the spouse of the Chief Executive Officer, SPD Swiss Precision Diagnostics, our 50/50 joint venture with P&G.

(22) Valuation and Qualifying Accounts

We have established reserves against accounts receivable for doubtful accounts, product returns, discounts and other allowances. The activity in the table below includes all accounts receivable reserves. Provisions for doubtful accounts are recorded as a component of general and administrative expenses. Provisions for returns,

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(22) Valuation and Qualifying Accounts (Continued)

discounts and other allowances are charged against net product sales. The following table sets forth activities in our accounts receivable reserve accounts (in thousands):

	Balance at Beginning of Period	Provision	Amounts Charged Against Reserves	Balance at End of Period
Year ended December 31, 2006	$ 9,748	$ 22,914	$ (24,261)	$ 8,401
Year ended December 31, 2007	$ 8,401	$ 28,352	$ (24,586)	$ 12,167
Year ended December 31, 2008	$ 12,167	$ 20,810	$ (20,142)	$ 12,835

We have established reserves against obsolete and slow-moving inventories. The activity in the table below includes all inventory reserves. Provisions for obsolete and slow-moving inventories are recorded as a component of cost of net product sales. The following table sets forth activities in our inventory reserve accounts (in thousands):

	Balance at Beginning of Period	Provision	Amounts Charged Against Reserves	Balance at End of Period
Year ended December 31, 2006	$ 7,742	$ 6,661	$ (6,184)	$ 8,219
Year ended December 31, 2007	$ 8,219	$ 8,067	$ (8,164)	$ 8,122
Year ended December 31, 2008	$ 8,122	$ 9,194	$ (6,478)	$ 10,838

(23) Restructuring Activities

The following table sets forth the aggregate charges associated with restructuring plans recorded in operating income (loss) for the years ended December 31, (in thousands):

	2008	2007	2006
Fixed asset and inventory write-off	$ 18,837	$ 3,870	$ 6,989
Severance	8,357	1,989	2,886
Intangible asset write-off	5,103		2,722
Facility and other exit costs	4,137	843	536
	$ 36,434	$ 6,702	$ 13,133

(a) 2008 Restructuring Plans

In May 2008, we decided to close our facility located in Bedford, England, and initiated steps to cease operations at this facility and transition the manufacturing operations principally to our manufacturing facilities in Shanghai and Hangzhou, China. Based upon this decision, we recorded $12.6 million in restructuring charges during the year ended December 31, 2008, including $6.9 million related to the acceleration of facility restoration costs, $4.8 million of fixed asset impairments, $1.1 million in severance costs, $0.7 million in early termination lease penalties and $0.9 million related to a pension plan curtailment gain associated with the Bedford employees being terminated. Of these restructuring charges, $5.7 million was charged to our professional diagnostics business segment as follows: $3.5 million to cost of net product sales, $0.2 million to research and development expense, $0.2 million to sales and marketing expense and $1.8 million to general and administrative expense. We also recorded $6.7 million related to the accelerated present value accretion of our lease restoration costs due to the early termination of our facility lease to interest expense.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(23) Restructuring Activities (Continued)

In addition to the restructuring charges discussed above, $14.5 million of charges associated with the Bedford facility closure were borne by SPD our consumer diagnostics joint venture with P&G, during the year ended December 31, 2008. Included in these charges were $8.4 million of fixed asset impairments, $3.2 million in early termination lease penalties, $2.6 million in severance and retention costs, $0.2 million facility exit costs and $0.1 million related to the acceleration of facility restoration costs. Of these restructuring charges, 50%, or $7.2 million, has been included in equity earnings of unconsolidated entities, net of tax, in our consolidated statements of operations for the year ended December 31, 2008. Of the total exit costs incurred by SPD and us under this plan, including severance related costs, lease penalties and restoration costs, $10.1 million remains unpaid as of December 31, 2008. We anticipate incurring additional costs of approximately $17.2 million related to the closure of this facility, including, but not limited to, severance and retention costs, rent obligations and incremental interest expense associated with our lease obligations which will terminate the end of 2011. Of these additional anticipated costs, approximately $20.5 million will be borne by SPD and $9.6 million will be borne by us. We expect the majority of these costs to be incurred by the end of 2009, which is our anticipated facility closure date.

In February 2008, we decided to cease research and development activities for one of the products in development at our Bedford, England facility, based upon comparison of the product under development with existing products acquired in the HemoSense acquisition. During the year ended December 31, 2008, we recorded restructuring charges of $9.4 million, of which $6.8 million related to the impairment of fixed assets, $1.9 million related to the write-off of inventory, $0.5 million related to contractual obligations with suppliers and $0.2 million related to severance costs to involuntarily terminate employees working on the development of this product. The $9.4 million was included in our professional diagnostics business segment and included $6.0 million charged to cost of net product sales, $3.3 million charged to research and development expense and $0.1 million charged to sales and marketing expense. Of the $0.7 million in contractual obligations and severance costs, all has been paid as of December 31, 2008. We do not expect to incur significant additional charges under this plan.

In April 2008, we initiated cost reduction efforts at our facilities in Stirling, Scotland, consolidating our business activities into one facility and with our Biosite operations. As a result of these efforts, we recorded $3.3 million in restructuring charges for the year ended December 31, 2008, consisting of $2.0 million in fixed asset impairments, $1.0 million in severance costs and $0.3 million in facility exit costs. These charges are included in our professional diagnostics business segment as follows: $3.2 million to research and development expense and $0.1 million to general and administrative expense. Of the $1.3 million in severance and facility exit costs, $0.1 million remains unpaid at December 31, 2008. We do not expect to incur significant additional charges under this plan.

On March 18, 2008, we announced our plans to close our BioStar Inc., or BioStar, facility in Louisville, Colorado, and exit production of the BioStar OIA product line, along with our plans to close two of our newly-acquired facilities in the San Francisco, California area, relating to Cholestech and HemoSense and one of our newly-acquired facility in Columbia, Maryland, relating to Panbio. The Cholestech operation, which was acquired in September 2007 and manufactures and distributes the Cholestech LDX system, a point-of-care monitor of blood cholesterol and related lipids used to test patients at risk of, or suffering from, heart disease and related conditions, will move to our Biosite facility in San Diego, California by the middle of 2009. The HemoSense operation, which was acquired in November 2007 and manufactures and distributes the INRatio System, an easy-to-use, hand-held blood coagulation monitoring system for use by patients and healthcare professionals in the management of warfarin, a commonly prescribed

medication used to prevent blood clots, has substantially moved to our Biosite facility as of December 31, 2008. The Panbio distribution facility, which was acquired in January 2008, has been transferred to our distribution center in Freehold, New Jersey as of December 31, 2008.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(23) Restructuring Activities (Continued)

BioStar manufacturing ceased at the end of June 2008, with BioStar OIA products available for purchase through the end of the first quarter of 2009. During the year ended December 31, 2008, we incurred $10.6 million in restructuring charges related to this plan, which consisted of $5.1 million of intangible assets impairment, $1.4 million in severance-related costs, $0.6 million in fixed asset impairments, $1.2 million in facility exit costs and $2.3 million related to the write-off of inventory. Of the $10.6 million, which is included in our professional diagnostics business segment, $7.1 million was charged to cost of net product sales, $2.0 million was charged to sales and marketing expense and $1.5 million was charged to general and administrative. We expect to incur an additional $0.1 million in charges under this plan during the first half of 2009, primarily related to severance and facility exit costs. As of December 31, 2008, $0.4 million in severance and facility exit costs remain unpaid.

As a result of our plans to transition the businesses of Cholestech and HemoSense to Biosite and Panbio to Orlando, Florida and close these facilities, we incurred $3.8 million in restructuring charges during the year ended December 31, 2008, of which $2.7 million relates to severance and retention costs, $0.4 million in fixed asset impairments, $0.5 million in transition costs and $0.2 million in present value accretion of facility lease costs related to these plans. Of the $3.8 million included in our professional diagnostics business segment, $1.2 million was charged to cost of net product sales, $0.5 million was charged to research and development expense, $0.3 million was charged to sales and marketing expense and $1.6 million was charged to general and administrative expense. We also recorded $0.2 million related to the present value accretion of our facility lease costs due to the early termination of our facility lease to interest expense. Of the $3.4 million in exit costs, $2.5 million remains unpaid as of December 31, 2008.

We anticipate incurring an additional $2.3 million in restructuring charges under our Cholestech and HemoSense plans, primarily related to severance, retention and outplacement benefits, along with other costs to transition the Cholestech and HemoSense operations to our Biosite facility. See Note 4(d) for further information and costs related to these plans.

In addition to transitioning the businesses of Cholestech and HemoSense to Biosite, we also made the decision to close our Innovacon facility in San Diego, California and move the operating activities to Biosite; the Innovacon business is the rapid diagnostics business that we acquired from ACON Laboratories, Inc. During the year ended December 31, 2008, we recorded $0.6 million in restructuring charges, of which $0.5 million relates to facility lease and exit costs and $0.1 million relates to impairment of fixed assets. These charges are included in our professional diagnostics business segment and were charged to general and administrative. As of December 31, 2008, $0.2 million in restructuring costs remain unpaid. We vacated the facility in August 2008 and do not anticipate incurring additional costs under this plan.

(b) 2007 Restructuring Plans

During 2007, we committed to several plans to restructure and integrate our world-wide sales, marketing, order management and fulfillment operations, as well as evaluate certain research and development projects. The objectives of the plans were to eliminate redundant costs, improve customer responsiveness and improve efficiencies in operations. As a result of these restructuring plans, we recorded $3.0 million in restructuring charges during the year ended December 31, 2008. The $3.0 million charge included $2.6 million related to severance charges and

outplacement services and $0.4 million related to facility exit costs. These restructuring charges consisted of $0.1 million charged to cost of net revenue, $1.6 million charged to sales and marketing expenses and $1.3 million charged to general and administrative expenses, all of which were included in our professional diagnostics business segments. Since inception of the plan we have recorded $8.2 million in restructuring charges, including $3.8 million related to severance charges and outplacement services, $0.4 million related to facility exit costs and $4.0 million related to impairment charges on fixed assets. Of the $8.2 million recorded, $1.8 million and $6.4 million were included in our consumer diagnostics and

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(23) Restructuring Activities (Continued)

professional diagnostics business segment, respectively. As of December 31, 2008, $1.2 million of severance-related charges and facility exit costs remain unpaid. We do not anticipate incurring additional charges related to this plan.

In addition, we recorded restructuring charges associated with the formation of our joint venture with P&G. In connection with the joint venture, we committed to a plan to close one of our sales offices in Germany and in Sweden, as well as evaluate redundancies in all departments of the consumer diagnostics business segment that are impacted by the formation of the joint venture. For the year ended December 31, 2008, we recorded $0.2 million in severance costs related to this plan, which was primarily charged to general and administrative expenses. We have recorded $1.4 million in restructuring charges since inception of the plan, of which $1.0 million relates to severance costs and $0.4 million relates to facility and other exit costs. Of the total $1.4 million in severance and exit costs, $0.1 million remains unpaid as of December 31, 2008. We do not anticipate incurring additional charges related to this plan.

(c) 2006 Restructuring Plans

In May 2006, we committed to a plan to cease operations at our ABI manufacturing facility in San Diego, California and to write off certain excess manufacturing equipment at other impacted facilities. Additionally, in June 2006, we committed to a plan to reorganize the sales and marketing and customer service functions in certain of our U.S. professional diagnostics companies. For the year ended December 31, 2007, we recorded $0.4 million in net restructuring charges under these plans, which primarily relates to $0.6 million in facility exit costs, offset by a $0.2 million adjustment due to the finalization of fixed asset write-offs. Of the $0.4 million net charge, the $0.2 million adjustment was recorded to cost of net revenue, and was included in our consumer diagnostics segment, and $0.6 million was charged to general and administrative expense, and was included in our professional diagnostics business segment.

Net restructuring charges since the commitment date consist of $6.7 million related to impairment of fixed assets and inventory, $2.7 million related to an impairment charge on an intangible asset, $2.5 million related to severance, and $0.6 million related to facility closing costs. Of the $12.5 million recorded in operating income, $8.2 million, $1.7 million and $2.6 million were included in our professional diagnostics, consumer diagnostics, and corporate and other business segments, respectively. As of December 31, 2008, $0.1 million of the severance related charges remains unpaid.

(d) 2005 Restructuring Plan

In May 2005, we committed to a plan to cease operations at our facility in Galway, Ireland. During the year ended December 31, 2006, we recorded a net restructuring gain of $3.2 million, of which $0.4 million related to charges for severance, early retirement and outplacement services, $0.1 million related to an impairment charge of fixed assets, $0.6 million related to facility closing costs and $4.3 million related to foreign exchange gains as a result of recording a cumulative translation adjustment to other income relating primarily to this plan of termination. The charges for the year ended December 31, 2006 consisted of $0.7 million charged to cost of goods sold, $0.4 million charged to general and administrative and $4.3 million in gains recorded to other expense. Of the net restructuring gain of $3.2 million included in our net loss for the year ended December 31, 2006, the $1.1 million loss and the $4.3 million gain were included in our consumer diagnostics and corporate and other business segments, respectively.

Additionally, during the year ended December 31, 2006, we recorded a $1.4 million gain on the sale of our CDIL facility in Ireland which has been recorded in loss on dispositions, net in our consolidated statements of operations and was included in our corporate and other business segment for these periods (Note 25).

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(23) Restructuring Activities (Continued)

Net restructuring charges since the commitment date consist of $2.6 million related to severance, early retirement and outplacement services, $2.4 million related to impairment of fixed assets and inventory and $1.2 million related to facility closing costs, offset by $4.3 million related to net foreign exchange gains relating primarily to this plan of termination and a $1.4 million gain on the sale of the manufacturing facility. Of the total $6.2 million restructuring charges recorded in operating income, $0.3 million and $5.9 million were included in our professional diagnostics and consumer diagnostics business segments, respectively. The $4.3 million and $1.4 million gains were included in our corporate and other business segment. The plan of termination was substantially complete as of December 31, 2006 and all costs related to severance, early retirement, outplacement services and facility closing costs have been paid as of December 31, 2006.

(e) Restructuring Reserves

The following table summarizes our liabilities related to the restructuring activities associated with the plans discussed above (in thousands):

	Balance at Beginning of Period	Additions to the Reserve	Amounts Paid	Other (1)	Balance at End of Period
Year ended December 31, 2006	$ 949	$ 3,422	$ (2,820)	$ 14	$ 1,565
Year ended December 31, 2007	$ 1,565	$ 2,828	$ (3,264)	$ (6)	$ 1,123
Year ended December 31, 2008	$ 1,123	$ 25,642	$ (9,148)	$ (2,823)	$ 14,794

(1) Represents foreign currency translation adjustment.

(24) Supplemental Cash Flow Information

Cash Paid for Interest and Income Taxes:

During fiscal 2008, 2007 and 2006, we made cash payments for interest totaling $88.6 million, $65.0 million and $22.7 million, respectively.

During fiscal 2008, 2007 and 2006, total net cash paid (received) for income taxes was $5.5 million, $(31.5) million and $8.8 million, respectively.

Table of Contents

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(24) Supplemental Cash Flow Information (Continued)

Non-cash Investing Activities:

During fiscal 2008, 2007 and 2006, we issued shares of our common stock and exchanged employee stock options in connection with several of our acquisitions (dollars in thousands):

		Common Stock Issued		Employee Stock Options/ Restricted Stock Awards Exchanged	
Company Acquired	Date of Acquisition	Number of Shares	Fair Value of Shares	Number of Shares	Fair Value of Shares
Matria Healthcare, Inc.	May 9, 2008		$	1,490,655	$ 17,334
BBI Holdings Plc	February 12, 2008	251,085	$ 14,397	355,238	$ 3,639
Matritech, Inc.	December 12, 2007	616,671	$ 35,592		$
Biosystems S.A.	December 11, 2007	33,373	$ 1,948		$
Alere Medical, Inc.	November 16, 2007	2,762,182	$ 161,086	380,894	$ 20,614
HemoSense, Inc.	November 6, 2007	3,691,369	$ 226,415	380,732	$ 16,695
Cholestech Corporation	September 12, 2007	6,840,361	$ 329,774	733,077	$ 20,331
Spectral Diagnostics Private Limited(1)	July 27, 2007	93,558	$ 3,737		$
Biosite Incorporated(2)	June 29, 2007		$	753,863	$ 28,453
Quality Assured Services, Inc.	June 7, 2007	273,642	$ 12,834		$
Instant Technologies, Inc.	December 28, 2007	463,399	$ 21,530		$
ABON BioPharm (Hangzhou) Co. Ltd. and ACON Laboratories	May 15, 2006	1,871,250	$ 53,052		$
CLONDIAG chip technologies GmbH	February 28, 2006	467,715	$ 12,457		$

(1) The acquisition of Spectral Diagnostics Private Limited also included its affiliate Source Diagnostics (India) Private Limited.

(2) The value includes $2.6 million associated with net operating loss, or NOL, carryforwards related to stock options issued to Biosite Incorporated employees.

Non-cash Financing Activities:

During 2008 and 2007, we recorded non-cash charges to accumulated other comprehensive income of $11.6 million and $9.5 million, respectively, representing the change in fair market value of our interest rate swap agreement.

(25) Loss on Dispositions, Net

During 2006, we recorded a net loss on dispositions of $3.5 million. Included in this net loss is a $4.9 million charge associated with management s decision to dispose of our Scandinavian Micro Biodevices ApS, or SMB, research operation, which was part of our professional diagnostics and corporate and other business segments, of which $2.0 million is related to impaired assets, primarily goodwill associated with SMB, and a $2.9 million loss on the sale of SMB. The sale of this operation was completed in the fourth quarter of 2006. The net loss on dispositions also includes an offsetting $1.4 million gain on the sale of an idle manufacturing facility in Galway, Ireland, as a result of our 2005 restructuring plan. This facility was associated with our consumer diagnostics business segment.